UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL **'O'**

Case No.	2:15-cv-07102-CAS-KS	Date	November 19, 2015
Title	KRISTIN BIORN V. WRIGHT MEDICAL TECHNOLOGY, INC. ET AL.		

Present: The Honorable	CHRISTINA A. SNYDER, U.S. DISTRICT JUDGE	
CONNIE LEE	Not Present	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: DEFENDANTS' MOTION TO DISMISS Counts I, VI, VII, and VIII (Docket #18, filed October 21, 2015)

The Court finds this motion appropriate for decision without oral argument. See Fed. R. Civ. P. 78; C.D. Cal. Local Rule 7-15. Accordingly, the matter is hereby taken under submission.

I. INTRODUCTION

On September 9, 2015, plaintiff Kristin Biorn filed the instant action against defendants Wright Medical Technology, Inc. ("WMT" or "defendant") and Wright Medical Group, Inc. ("WMG") (collectively, "defendants"). See Compl. Plaintiff asserts eights claims against defendants: (1) strict products liability—manufacturing defect, (2) strict products liability—failure to warn, (3) negligence, (4) negligence—failure to recall/retrofit, (5) breach of implied warranty, (6) fraudulent misrepresentation, (7) fraudulent concealment, and (8) negligent misrepresentation. Id.

On October 20, 2015, the parties stipulated to dismiss WMG from this action and plaintiff's fifth claim for breach of implied warranty. Dkt. 17. The Court dismissed defendant WMG and plaintiff's claim for breach of implied warranty without prejudice on October 21, 2015. Id. at 2.

On October 21, 2015, defendant WMT filed a motion to dismiss plaintiff's first, sixth, seventh, and eighth claims pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. 18. On November 2, 2015, plaintiff filed an opposition, Dkt. 20, and on November

6, 2015, WMT filed a reply, Dkt. 21. Having carefully considered the parties' arguments, the Court finds and concludes as follows.

II. BACKGROUND

Plaintiff's complaint alleges the following facts: Plaintiff underwent a total surgical replacement of her left hip on August 20, 2013. Compl. ¶ 3. During the procedure, Dr. Jason Snibbe ("Dr. Snibbe") implanted into plaintiff a hip system called the Profemur Total Hip System ("Profemur"). Id. ¶¶ 3, 59. On or about April 5, 2015, while "[plaintiff] was performing a normal and expected activity of daily living," the Profemur device suffered a "catastrophic failure" and broke into two pieces. Id. ¶ 62-63. Plaintiff was subsequently taken to St. John's Hospital emergency room and from there transferred to Cedars-Sinai Medical Center of Los Angeles where Dr. Snibbe surgically removed the Profemur on April 6, 2015. Id. ¶¶ 64–65.

The Profemur is an artificial hip system that consists of two components: a modular neck and a femoral stem. Id. ¶ 13. The complaint alleges that defendants are corporations engaged in the business of "designing, licensing, manufacturing, distributing, selling, [and] marketing . . . numerous prosthetic orthopedic products, including the [Profemur]." Id. ¶¶ 4–5, 7. Defendants began manufacturing and selling the Profemur after December 13, 2000, when defendants received permission from the United States Food and Drug Administration ("FDA") to distribute the Profemur within the United States. Id. ¶¶ 13, 16. The device the FDA approved contains a modular neck that was designed and had previously been distributed in Europe by a company called Cremascoli. Id. ¶ 14. The complaint alleges that the "FDA never considered and approved the safety of the [Profemur], but instead concluded only that [it] was substantially equivalent to an already legally marketed device, i.e., the Cremascoli modular neck device." Id. ¶ 15.

The complaint further alleges that defendants made "representations, statements, claims, and guarantees about its Profemur modular necks" in "various marketing and promotional material published and distributed by [defendants] from approximately [2002 to 2005]." Id. ¶ 20. Specifically, plaintiff alleges that WMT made the following representations:

> The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception.
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> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:
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> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion

Id. (emphasis in original).

Despite these representations, plaintiff alleges that defendants had in fact received notice of fractures of the Profemur necks that had been implanted in patients in Europe prior to 2001. Id. ¶ 24. However, defendants allegedly failed to disclose this history of fractures in European patients to the FDA. Id. ¶¶ 24–25. Plaintiff further claims that defendants did not inform surgeons known to have implanted the Profemur of any fractures until December 1, 2008, when they issued a safety alert to medical professionals. Id. ¶ 36. This safety alert provided that defendants had "received reports of 43 modular neck failures as of November 21, 2008" and that "initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports." Id. Despite their investigations into these fractures, defendants allegedly never issued any warning that the Profemur should not be used in heavier patients or in patients who engage in heavy lifting or impact sports. Id. ¶¶ 39–42. Plaintiff claims that defendants failed to inform patients with Profemur or their surgeons that: (1) Profemur has a "higher than expected" rate of fracture, (2) Profemur was "known to be failing from fatigue fractures in high activity or

heavier weight patients at higher than expected rates," and (3) Profemur was known to fail during normal activities of daily living. Id. ¶¶ 80–82.

III. LEGAL STANDARD

A. Rule 12(b)(6)

A motion pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the claims asserted in a complaint. Under this Rule, a district court properly dismisses a claim if "there is a 'lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory.' " Conservation Force v. Salazar, 646 F.3d 1240, 1242 (9th Cir. 2011) (quoting Balisteri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1988)). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). "[F]actual allegations must be enough to raise a right to relief above the speculative level." Id.

In considering a motion pursuant to Rule 12(b)(6), a court must accept as true all material allegations in the complaint, as well as all reasonable inferences to be drawn from them. Pareto v. FDIC, 139 F.3d 696, 699 (9th Cir. 1998). The complaint must be read in the light most favorable to the nonmoving party. Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001). However, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009); see Moss v. United States Secret Service, 572 F.3d 962, 969 (9th Cir. 2009) ("[F]or a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief."). Ultimately, "[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Iqbal, 556 U.S. at 679.

Unless a court converts a Rule 12(b)(6) motion into a motion for summary judgment, a court cannot consider material outside of the complaint (e.g., facts presented in briefs, affidavits, or discovery materials). In re American Cont'l Corp./Lincoln Sav. & Loan Sec. Litig., 102 F.3d 1524, 1537 (9th Cir. 1996), rev'd on other grounds sub nom Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26 (1998). A court may, however, consider exhibits submitted with or alleged in the complaint and matters that may be judicially noticed pursuant to Federal Rule of Evidence 201. In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 986 (9th Cir. 1999); see Lee v. City of Los Angeles, 250 F.3d 668, 689 (9th Cir. 2001).

As a general rule, leave to amend a complaint which has been dismissed should be freely granted. Fed. R. Civ. P. 15(a). However, leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986).

B. Rule 9(b)

Federal Rule of Civil Procedure 9(b) requires that the circumstances constituting a claim for fraud be pled with particularity. Federal Rule of Civil Procedure 9(b) applies not just where a complaint specifically alleges fraud as an essential element of a claim, but also where the claim is "grounded in fraud" or "[sounds] in fraud." Vess v. Ciba-Geigy Corp. U.S.A., 317 F.3d 1097, 1103–04 (9th Cir. 2003). A claim is said to be "grounded in fraud" or "'sounds in fraud'" where a plaintiff alleges that defendant engaged in fraudulent conduct and relies on solely on that conduct to prove a claim. Id. "In that event, . . . the pleading of that claim as a whole must satisfy the particularity requirement of [Fed. R. Civ. P.] 9(b)." Id. However, where a plaintiff alleges claims grounded in fraudulent and non fraudulent conduct, only the allegations of fraud are subject to heightened pleading requirements. Id. at 1104.

A pleading is sufficient under Fed. R. Civ. P. 9(b) if it "[identifies] the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations." Walling v. Beverly Enters., 476 F.2d 393, 397 (9th Cir. 1973). This requires that a false statement must be alleged, and that "circumstances indicating

falseness" must be set forth. In re GlenFed Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994). Thus, Rule 9(b) requires a plaintiff to "identify the 'who, what, when, where and how of the misconduct charged,' as well as 'what is false or misleading about [the purportedly fraudulent conduct], and why it is false." Cafasso, ex rel. United States v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)).

IV. ANALYSIS

A. Plaintiff's First Claim

WMT moves to dismiss plaintiff's first claim for strict products liability—manufacturing defect. "A product has a manufacturing defect if it 'differs from the manufacturer's intended result or from other ostensibly identical units of the same product line.' " Johnson v. United States Steel Corp., 240 Cal. App. 4th 22, 32 (2015) (quoting Barker v. Lull Engineering Co., 20 Cal. 3d 413, 429 (1978)). Alternatively, "[a] manufacturing defect exists when an item is produced in a substandard condition." McCabe v. Am. Honda Motor Co., 100 Cal. App. 4th 1111, 1120 (2002). To state a manufacturing defect claim, a plaintiff must allege "*how* the [product] either deviated from [the manufacturer's] intended result/design or *how* the [product] deviated from other seemingly identical [] models." Lucas v. City of Visalia, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010) (emphasis in original). "A bare allegation that the [product] had 'a manufacturing defect' is an insufficient legal conclusion." Id. (citing Iqbal, 556 U.S. 662, 677 (2009)).

WMT argues that plaintiff's first claim should be dismissed because she fails to allege sufficient facts to support a manufacturing defect claim. Mot., at 3. Specifically, WMT contends that plaintiff has failed to identify either how the Profemur deviated from the manufacturer's intended design or result, or how the product deviated from seemingly identical models. Mot., at 4. However, in plaintiff's complaint, she alleges that the hip device she received "was dangerous, unsafe, and defective in manufacture" because it contained defects including "an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery." Compl. ¶ 90.

Accordingly, plaintiff has alleged both how the product she received differed from WMT's intended result and how it differed from other identical models—it suffered a "catastrophic failure" when the modular neck fractured into two separate pieces. The fact that the product suffered such a significant, and potentially dangerous, failure strongly suggests that it was produced in a "substandard condition" or at least in a manner different from WMT's "intended result." And it appears that, unlike the product plaintiff received, many consumers have never suffered similar failures in their Profemurs. See Compl. ¶¶ 32-35. Similarly, plaintiff has alleged that, unlike the intended design, and unlike identical models, the Profemur she received had "an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use." Id. ¶ 90.

Taken together, plaintiff has alleged sufficient facts regarding a potential manufacturing defect in the Profemur that was implanted in her hip to "nudge[] [her] claims across the line from conceivable to plausible." Twombly, 550 U.S. at 570. Accordingly, WMT's motion to dismiss plaintiff's first claim is DENIED.

B. Plaintiff's Sixth, Seventh, and Eighth Claims

WMT seeks dismissal of plaintiffs' sixth claim for fraudulent misrepresentation, seventh claim for fraudulent concealment, and eighth claim for negligent misrepresentation. The principal basis for WMT's motion is that plaintiffs' claims, which sound in fraud, are not pled with particularity as required by Federal Rule of Civil Procedure 9(b).[1]

[1] The parties dispute whether plaintiff's claim for negligent misrepresentation should be evaluated under Rule 8, or the more stringent standard for claims sounding in fraud under Rule 9(b). There is some disagreement amongst courts regarding whether claims for negligent misrepresentation must satisfy Rule 9(b). See Valencia v. Wells Fargo Home Mortgage Inc., 2014 WL 5812578 (N.D. Cal. 2014) ("The Ninth Circuit has not yet decided whether Rule 9(b)'s heightened pleading standard applies to a claim for negligent misrepresentation, but most district courts in California hold that it does.") (quoting Villegas v. Wells Fargo Bank, N.A., 2012 WL 4097747, at *7 (N.D. Cal. 2014)). Some courts have held that where a negligent misrepresentation claim is

Here, plaintiff's claims are predicated on defendant's alleged misrepresentations and omissions regarding the safety and effectiveness of the Profemur. Opp'n at 4. Plaintiff alleges that defendants made the following representations in their marketing materials:

> The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception.
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> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:
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> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion

Compl. ¶ 20 (emphasis in original). Plaintiff quotes this representation from a specific marketing material identified as "Wright Medical Technical Monograph MH688-102"

"grounded in fraud," Rule 9(b) applies. See,e.g., Vess v. Ciba-Geigy Corp., 317 F.3d 1097, 1103–04 (9th Cir. 2003) ("The rule does not require that allegations supporting a claim be stated with particularity when those allegations describe non-fraudulent conduct."); but see Petersen v. Allstate Indem. Co., 281 F.R.D. 413, 418 (C.D. Cal. 2012) ("[B]ecause an allegation of negligent misrepresentation suggests only that the defendant failed to use reasonable care—an objective standard—it does not result in the kind of 'harm' that Rule 9(b) was designed to prevent.") (emphasis in original). However, as stated infra, the Court finds that, even applying the more stringent standards of Rule 9(b) plaintiff has adequately alleged a claim for negligent misrepresentation.

and copyrighted in 2004. Id.

Further, plaintiff alleges that patient testimonials that appeared in defendant's marketing materials "represented that patients who received [defendants'] artificial hips have already returned to or are about to return to such activities as running, jogging, snow skiing, water skiing, marathon running, tennis, racquetball, golf, horseback riding, work that involves lifting and moving heavy objects, active military duty, karate, competitive wrestling and competitive motocross racing, among other activities." Id. ¶ 53. These testimonials were allegedly available to defendants' "representatives/distributors, physicians, patients, and the public" and appeared in materials published by Wright from 2005 to present. Id. ¶ 53. Moreover, plaintiff alleges that "plaintiff's healthcare providers were unaware of the falsity of said representations," which led her to rely on them. Id. ¶¶ 127-28.

Next, plaintiff alleges that prior to her implant, defendant failed to inform its patients or surgeons about certain facts including: (1) reports of fractures of Profemur, Id. ¶ 36; (2) Profemur's higher than anticipated rates of failure due to fracture, Id. ¶ 80; (3) that Profemur is known to fail in high activity or heavier patients, Id. ¶¶ 81–83; and (4) that Profemur is known to fail from fractures during normal activities of daily living, Id. ¶ 82.

Plaintiff argues that her allegations that WMT failed to disclose this information, together with the alleged affirmative misrepresentations quoted above, satisfy the pleading requirements of Rule 9(b). The Court agrees. Rule 9(b) requires that plaintiffs' allegations of fraud must be pled with enough particularity to enable WMT to "prepare an adequate answer from the allegations." Walling v. Beverly Enterprises, 476 F.2d 393, 397 (9th Cir. 1973). After reviewing the allegations set forth above, the Court concludes that the complaint is sufficiently specific to permit WMT to answer. Plaintiff identifies specific statements, made at specific times, and in specific marketing materials. This is sufficient to satisfy Rule 9(b).

Nonetheless, WMT argues that the complaint does not sufficiently allege that plaintiff relied on the statements she identifies. See Reply at 3. To adequately plead reliance, a plaintiff must "establish a complete causal relationship between the alleged

misrepresentations and the harm claimed to have resulted." Mirkin v. Wasserman, 5 Cal. 4th 1082, 1092 (1993). "Actual reliance occurs when the defendant's misrepresentation is an immediate cause of the plaintiff's conduct, altering his legal relations, and when, absent such representation, the plaintiff would not, in all reasonable probability, have entered into the transaction." Cadlo v. Owens-Illinois, Inc., 125 Cal. App. 4th 513, 519 (2004) (citing Engalla v. Permanente Medical Group, Inc., 15 Cal. 4th 651, 976 (1997)).

Here, plaintiff alleges that defendant failed to inform its Profemur patients of certain risks by omitting material facts. See Opp'n at 5. Specifically, the complaint alleges that "plaintiff and plaintiff's healthcare providers relied on Defendants' incomplete and inaccurate representations as to the safety and performance of the [Profemur] when selecting, recommending, and implanting the [Profemur]." Compl. ¶ 136. Stated differently, absent the misrepresentations, plaintiff and her surgeon would not have selected the Profemur. Thus, because plaintiff has established a causal relationship, the Court finds that plaintiff has sufficiently pled reliance on WMT's statements. Mirkin, 5 Cal. 4th at 1092; see Romero v. Countrywide Bank, N.A., 740 F.Supp. 2d 1129, 1146 (N.D. Cal. 2010) ("Plaintiffs can demonstrate reliance by showing that 'had the omitted information been disclosed, [they] would have been aware of it and behaved differently.'") (citations omitted).

Defendant resists this conclusion and argues that plaintiff "does not allege she ever saw this so-called marketing material, when she saw it, or that she relied upon it in choosing to obtain the hip system at issue." Reply at 4. In support of its argument, defendant relies on Rice v. Sunbeam Products, Inc., 2013 WL 146270 (C.D. Cal. 2013) (Snyder, J.). In Rice, this Court found that the plaintiff had failed to sufficiently allege claims for fraudulent misrepresentation and omission in connection with her purchase of an allegedly defective Crock-Pot. Id. at *6. However, in that case, while plaintiff alleged that defendants had misrepresented that their Crock-Pot's were "safe for household use" she "[did] not allege if these statements appear in the Crock–Pot Owner's Manual, packaging, advertisements, or elsewhere." Id. Here, by contrast, plaintiff alleges that defendant's misrepresentations appeared in "marketing and promotional material published and distributed by [defendants] from approximately the year 2002, and into the year 2005, and available to [defendant's] sales representatives and distributors, surgeons, patients, and the general public." Compl. ¶ 20. Plaintiff additionally provides a citation

to the Wright Medical Technical Monograph MH688-102, copyright 2004, as the source containing these alleged misrepresentations. Id. Accordingly, this case is factually distinct from Rice.

Defendant further asserts that the allegations in support of plaintiff's fraudulent concealment claim sound more in the nature of a failure to warn claim. See Reply at 6. However, defendant cites no authority for the proposition that factual allegations in support of a failure to warn claim cannot also support fraud claims. Moreover, because many of plaintiff's claims rest on omission of facts, the level of specificity required is relaxed. Falk v. General Motors Corp., 496 F. Supp. 2d 1088, 1099 (N.D. Cal. 2007) ("[A] fraud by omission claim can succeed without the same level of specificity required by a normal fraud claim."). Thus, the Court finds that plaintiff has pled her claims with the requisite particularity to satisfy Rule 9(b). Accordingly, the Court DENIES defendant's motion to dismiss plaintiff's fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims.[2]

[2] Finally, WMT asserts that plaintiff's fraud claims are not cognizable because they are in effect allegations of fraud on the FDA. See Mot., at 11. According to defendant, because there is no recognized private cause of action under the Food, Drug, and Cosmetics Act ("FDCA"), plaintiff's fraud claims are precluded as preempted under federal law. Id. However, as written, the complaint does not allege fraud on the FDA, but rather fraud on the plaintiff and her healthcare providers. Should the factual basis for plaintiff's fraud claims turn out to be fraudulent representations made to the FDA, WMT is free to address that issue on summary judgment.

V. CONCLUSION

In accordance with the foregoing, defendant's motion to dismiss plaintiff's first, sixth, seventh, and eighth claims pursuant to Federal Rule of Civil Procedure 12(b)(6) is **DENIED**.

The hearing date of November 23, 2015 at 10:00 AM, is **VACATED.**

IT IS SO ORDERED.

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