UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

MELBA JOHNSON,

Plaintiff,

v.

HOLOGIC, INC.,

Defendant.

No. 2:14-cv-0794-JAM-KJN-PS

FINDINGS AND RECOMMENDATIONS

Plaintiff Melba Johnson ("plaintiff"), proceeding without the assistance of counsel, originally filed this products liability action in the Sacramento County Superior Court on February 10, 2014.[1] (ECF No. 1-1 (Sacramento County Superior Court Summons and Complaint).) Defendant Hologic, Inc. ("defendant") subsequently removed the case to this court pursuant to the court's diversity jurisdiction and filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). (ECF Nos. 1, 7.) On June 9, 2014, the court issued an order granting defendant's motion for judgment on the pleadings, but granted plaintiff leave to amend her complaint. (ECF No. 14.) On July 7, 2014, plaintiff filed a first amended complaint. (ECF No. 15.) Defendant subsequently filed a motion for judgment on the pleadings

[1] This action proceeds before this court pursuant to Eastern District of California Local Rule 302(c)(21) and 28 U.S.C. § 636(b)(1).

pursuant to Rule 12(c) with respect to plaintiff's first amended complaint, which is presently before the court. (ECF No. 16.) Plaintiff filed an opposition to the motion and defendant filed a reply. (ECF Nos. 20, 22.)

On the court's own motion, this matter was taken under submission without a hearing. The undersigned has fully considered the parties' briefs and appropriate portions of the record. For the reasons that follow, the court recommends that defendant's motion for judgment on the pleadings be granted, and plaintiff's claims be dismissed with prejudice.

I. Background

Plaintiff filed this action in the Sacramento County Superior Court on February 10, 2014, asserting claims for strict products liability and negligence based on allegations that she was injured while using a mammography machine designed and manufactured by defendant. (ECF No. 1-1.) Defendant subsequently removed the case to this court on the basis of this court's diversity jurisdiction and filed an answer to the complaint. (ECF Nos. 1, 3.) On May 2, 2014, defendant filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). (ECF No. 7.) On June 9, 2014, the court issued an order granting defendant's motion for judgment on the pleadings on the basis that both of plaintiff's claims were preempted by the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, 360c *et seq.*, but granted plaintiff leave to amend her complaint due to the possibility that plaintiff might be able to allege a state-law tort claim that "parallels" the requirements set forth in the FDCA. (ECF No. 14.) On July 7, 2014, plaintiff filed the operative first amended complaint.

Plaintiff alleges in the first amended complaint that on or about March 13, 2012, she was injured when using the "Selenia Dimensions 3D system Class III" ("Selenia System"), a mammography machine designed and manufactured by defendant, Hologic, Inc. (ECF No. 15 at 1.) Plaintiff alleges that her use of the machine resulted in her suffering from "broken glands, severe itching and two scars." (Id.) Plaintiff alleges that these injuries were "caused by the magnitude of the radiation [produced by the machine] and any relation to 'Tomosynthesis' [sic] and any formula used to make the 3d images and also the weight of the [machine's] compressors

that held down [her] breast." (Id.) Plaintiff further alleges that defendant failed to follow the Food and Drug Administration's ("FDA") regulations regarding defendant's duty to report adverse events, namely the requirements set forth in 21 C.F.R. § 803.50 and 21 C.F.R. § 803.52. Plaintiff alleges that her claims are based on strict liability and negligence.

Defendant now moves to for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) with respect to all claims asserted in plaintiff's first amended complaint.

II. Legal Standards

Rule 12(c) of the Federal Rules of Civil Procedure permits a party to seek judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial." "A motion for judgment on the pleadings should be granted where it appears the moving party is entitled to judgment as a matter of law." Geraci v. Homestreet Bank, 347 F.3d 749, 751 (9th Cir. 2003); Westlands Water Dist. v. Firebaugh Canal, 10 F.3d 667, 670 (9th Cir. 1993) ("[J]udgment on the pleadings is appropriate when, even if all allegations in the complaint are true, the moving party is entitled to judgment as a matter of law.").

"A judgment on the pleadings is a decision on the merits." 3550 Stevens Creek Associates v. Barclays Bank of California, 915 F.2d 1355, 1356 (9th Cir. 1990). In addition to considering the allegations of the complaint, the court may also take into account materials to which it can take judicial notice. Heliotrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981, n.18 (9th Cir. 1999). The central issue in considering a Rule 12(c) motion is whether the complaint states a valid claim for relief when considered in a light most favorable to the plaintiff. Hughes v. Tobacco Inst., Inc., 278 F.3d 417, 420 (5th Cir. 2001). "[A]ll allegations of fact of the opposing party are accepted as true." Austad v. United States, 386 F.2d 147, 149 (9th Cir. 1967). A motion for judgment on the pleadings may be granted if, after assessing the complaint and matters for which judicial notice is proper, it appears "beyond doubt that the [non-moving party] cannot prove any facts that would support his claim for relief." Morgan v. County of Yolo, 436 F.Supp.2d 1152, 1155 (E.D. Cal. 2006), aff'd, 277 F. App'x 734 (9th Cir. 2008); R.J. Corman Derailment Services, LLC v. Int'l Union of Operating Engineers, Local 150, AFL-CIO, 335 F.3d 643, 647 (7th Cir. 2003).

"A Rule 12(c) motion challenges the legal sufficiency of the opposing party's pleadings and operates in much the same manner as a motion to dismiss under Rule 12(b)(6)." Morgan v. County of Yolo, 436 F.Supp.2d 1152, 1154-55 (E.D. Cal. 2006). Analysis under Rule 12(c) is "substantially identical" to analysis under Rule 12(b)(6) because, under both rules a court determines whether the facts alleged in the complaint, taken as true, entitle the plaintiff to a legal remedy. Chavez v. U.S., 683 F.3d 1102, 1108 (9th Cir. 2012). Similar to a Rule 12(b)(6) motion to dismiss, when addressing a motion on the pleadings, a court must assess whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "[A] court considering a motion to dismiss can 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." Iqbal, 556 U.S. at 679.

Mere conclusory statements in a complaint and "formulaic recitation[s] of the elements of a cause of action" are insufficient. Twombly, 550 U.S. at 555. Thus, a court discounts conclusory statements, which are not entitled to the presumption of truth, before determining whether a claim is plausible. Iqbal, 556 U.S. at 678. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Determining 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." Id. at 679.

Courts have discretion to grant leave to amend in conjunction with motions made pursuant to Rule 12(c). Moran v. Peralta Cmty. Coll. Dist., 825 F.Supp. 891, 893 (N.D. Cal. 1993) (citing Amersbach v. City of Cleveland, 598 F.2d 1033, 1038 (6th Cir. 1979). Generally, leave to amend a complaint is denied only if it is clear that the deficiencies of the complaint cannot be cured by amendment. DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992).

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III. Defendant's Motion for Judgment on the Pleadings

Defendant argues that it should be entitled to judgment on the pleadings in this matter because plaintiff's allegations in the first amended complaint demonstrate that there is no causal connection between the alleged violation of FDA regulations and the injuries plaintiff alleges she sustained when using the Selenia System. Defendant's argument is well-taken.

As noted in the court's earlier order granting defendant's motion for judgment on the pleadings with respect to plaintiff's original complaint, the judicially-noticed documents provided by defendants in connection with its previous motion for judgment on the pleadings demonstrate that the Selenia System is a Class III Medical Device that was evaluated under the FDA's premarket approval process. Accordingly, this device falls within the MDA regulatory regime, including the MDA's preemption provision.

The MDA's preemption provision provides:

> 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—
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> (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). Section 360(k) expressly preempts a state-law claim where specific federal requirements apply to the particular medical device that is the subject of claim, and the state-law claim imposes a standard of care or behavior that is "different from, or in addition to" the specific federal requirements relating to the safety and effectiveness of the device. Riegel v. Medtronic, 552 U.S. 312, 322 (2008). Furthermore, a claim may be subject to implied preemption under the MDA when it "seek[s] to enforce an exclusively federal requirement not grounded in traditional state tort law." Kashani-Matts v. Medtronic, Inc., 2014 WL 819392, at *2 (C.D. Cal. Feb. 14, 2014) (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352-53 (2001)). "Together, express preemption and implied preemption leave only a 'narrow gap' through which the plaintiff's claims must fit in order to survive." Id. (citing Perez v. Nidek Co., 711 F.3d 1109,

1120 (9th Cir. 2013)).

"[T]he MDA does not preempt state-law causes of action for damages in which the state-law duty 'parallels' the federal-law duty under the MDA." Stengel v. Medtronic Inc., 704 F.3d 1224, 1231 (9th Cir. 2013) cert. denied, 134 S. Ct. 2839 (U.S. 2014); Riegel, 552 U.S. at 330 ("[Section] 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."). "In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under [Section] 360k(a), the plaintiff must show that the requirements are genuinely equivalent. State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011) (internal quotations omitted). Accordingly, in order to properly plead "parallel" claims that survive preemption, the plaintiff "must demonstrate facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." Cohen v. Guidant Corp., 2011 WL 637472, at *1 (C.D. Cal. 2011).

Here, plaintiff bases her state-law products liability claims on the allegation that defendant failed to report the adverse event causing plaintiff's injuries to the FDA in violation of 21 C.F.R. § 803.50 and 21 C.F.R. § 803.52. "Manufacturers are required by the FDCA to report to the FDA adverse events where an approved device may have caused or contributed to a death or serious injury, or where a recurring malfunction would likely cause or contribute to a death or serious injury." Hawkins v. Medtronic, Inc., 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014) (citing Stengel, 704 F.3d at 1226-27); 21 C.F.R. § 803.50(a); see 21 U.S.C. § 360i(a). Furthermore, the regulations also require manufacturers to include certain information in such reports. 21 C.F.R. § 803.52 (listing the information a manufacturer must include in a report submitted to the FDA pursuant to 21 C.F.R. § 803.50). Because plaintiff alleges that defendant completely failed to report her injuries caused by the Selenia System to the FDA, she properly alleges violations of 21 C.F.R. § 803.50 and 21 C.F.R. § 803.52. Therefore, the first amended complaint satisfies the first

pleading requirement for a "parallel" claim.

However, plaintiff does not plead facts sufficient to show the existence of a causal connection between defendant's alleged failure to report in conformance with FDA regulations and plaintiff's injuries. Plaintiff generally alleges that defendant failed to report the adverse event giving rise to her injuries to the FDA and that she suffered injuries in the form of "broken glands, severe itching and two scars." (ECF No. 15 at 1.) Plaintiff's allegations clearly show that plaintiff's injuries were caused by her use of the Selenia Dimensions 3D System, not defendant's failure to report to the FDA that this device caused those injuries. Any failure to report this particular adverse event to the FDA could not have caused the injuries alleged in the first amended complaint because it was necessary for plaintiff's injuries to have occurred before defendant's duty to report that event could arise. Accordingly, when the allegations of plaintiff's first amended complaint are taken as true, plaintiff cannot show the existence of "a causal nexus between the alleged injury and the violation." Cohen, 2011 WL 637472, at *1.

Furthermore, while allegations of a violation of the FDA's regulations concerning a failure to report to the FDA adverse events that occurred prior to the plaintiff's alleged injury-causing event involving the medical device at issue may support a "parallel" state-law claim based on a failure-to-warn or negligence theory under certain circumstances, see Stengel, 704 F.3d at 1226-27 (holding that the plaintiff's state-law negligence claim based on allegations that the defendant failed to report to the FDA adverse incidents involving the use of its device despite defendant's knowledge of those incidents and duty to report under the FDA's regulations was a "parallel" claim and, therefore, not preempted by the MDA); Martin v. Medtronic, Inc., 2014 WL 3635292, at *12 (D. Ariz. July 23, 2014) ("Courts have held that failure-to-warn claims based on failure to report adverse events to the FDA escape[ ] both express and implied preemption." (internal quotations omitted)); Houston v. Medtronic, Inc. (Houston II), 2014 WL 1364455, at *8 (C.D. Cal. Apr. 2, 2014), plaintiff's first amended complaint contains no allegations indicating that plaintiff premises her products liability claims on the existence of such previous violations. To the contrary, plaintiff makes it clear in both the allegations of the first amended complaint and in the arguments she asserts in her opposition to defendant's present motion that she bases her

claims solely on the allegation that defendant failed to report her injuries caused by her use of the Selenia System *after* the injury-causing event had already occurred. There is no mention by plaintiff in the first amended complaint that defendant failed to report to the FDA the occurrence of similar adverse incidents that occurred prior to her use of the machine, that her claims are based on a failure-to-warn theory of products liability, or that her negligence claim is premised on defendant's failure to report adverse events other than the one that caused her alleged injuries.

Because plaintiff's first amended complaint fails to allege state-law claims that parallel the federal requirements under the MDA, those claims are preempted. Accordingly, defendant's motion for judgment on the pleadings should be granted. Furthermore, defendant's motion should be granted without leave to further amend the complaint because plaintiff has previously been given the opportunity to amend and her amended pleading contains the same defects as the prior complaint and no additional facts that could possibly support a cognizable "parallel" state-law claim that could escape preemption by the MDA.

IV. Conclusion

Based on the foregoing, IT IS HEREBY RECOMMENDED that:

1. Defendant's motion for judgment on the pleadings (ECF No. 16) be granted;

2. Plaintiff's claims asserted in the first amended complaint be dismissed with prejudice; and

3. The Clerk of Court be directed to close this case and vacate all dates.

These findings and recommendations are submitted to the United States District Judge assigned to the case, pursuant to the provisions of 28 U.S.C. § 636(b)(l). Within fourteen (14) days after being served with these findings and recommendations, any party may file written objections with the court and serve a copy on all parties. Such a document should be captioned "Objections to Magistrate Judge's Findings and Recommendations." Any reply to the objections shall be served on all parties and filed with the court within fourteen (14) days after service of the objections. The parties are advised that failure to file objections within the specified time may

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waive the right to appeal the District Court's order. Turner v. Duncan, 158 F.3d 449, 455 (9th Cir. 1998); Martinez v. Ylst, 951 F.2d 1153, 1156-57 (9th Cir. 1991).

IT IS SO RECOMMENDED.

Dated: January 5, 2015

KENDALL J. NEWMAN
UNITED STATES MAGISTRATE JUDGE