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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

MELBA JOHNSON,
Plaintiff,
v.
HOLOGIC, INC.,
Defendant.

No. 2:14-cv-0794-LKK-KJN (PS)

ORDER

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. (ECF No. 1.) Presently before the court is defendant’s Motion for Judgment on the Pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure seeking to dismiss plaintiff’s complaint in its entirety on the basis that plaintiff’s claims are preempted by federal law. (ECF No. 8.) Plaintiff filed an opposition to defendant’s motion. (ECF No. 10.) Defendant filed a reply. (ECF No. 12.)

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).

1 The court heard this matter on its June 5, 2014 law and motion calendar. Plaintiff Melba
2 Johnson appeared on her own behalf. Attorney Sharon Mayo appeared on behalf of defendant
3 Hologic, Inc. The undersigned has fully considered the parties' briefs, the parties' oral
4 arguments, and appropriate portions of the record. For the reasons that follow, defendant's
5 motion for judgment on the pleadings is granted, but with leave to amend.

6 I. Background

7 Plaintiff's state court complaint consists of a four-page "personal injury" form complaint
8 along with an additional form page specifically tailored to causes of action based on products
9 liability. (ECF No. 1-1 at 7-11.) Based on the boxes plaintiff has checked off on the form
10 complaint, it appears that plaintiff alleges two causes of action against defendant based on
11 products liability, one claim based on strict liability, and the other based on negligence. (Id. at
12 11.) More specifically, plaintiff alleges that "[o]n or about . . . March 13, 2012 plaintiff was
13 injured by the following product: Hologic, Inc. manufactured Selenia brand digital 3-D
14 mamography [sic] machine" and that "plaintiff was a patient treated with the device." (Id.)
15 Plaintiff further alleges that "defendant[] knew the product would be purchased and used without
16 inspection for defects," that "[t]he product was defective when it left the control of . . . defendant[
17]," and that "[t]he product at the time of [plaintiff's] injury was being used in a manner intended
18 by defendant[]." (Id.) Plaintiff also alleges that her "injury was the legal (proximate) result of . .
19 . [defendant's] manufacture[] or assembl[y of] the product," the "design[] and manufacture[]
20 [of] component parts supplied to the manufacturer," and "[sale of] the product to the public."
21 (Id.) Finally, plaintiff alleges that defendant owed a duty to her and that her injury was the
22 proximate result of defendant's negligence.² (Id.) Plaintiff requests relief in the form of
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24 ² Plaintiff makes a number of additional factual allegations in her opposition to defendant's
25 motion regarding her alleged injury and the specific circumstances leading to this injury. (ECF
26 No. 10.) However, the court cannot consider these additional factual allegations because the
27 court may only consider the allegations within the complaint itself as well as materials to which it
28 can take judicial notice when assessing a motion for judgment on the pleadings pursuant to
Federal Rule of Civil Procedure 12(c). See Heliotrope Gen., Inc. v. Ford Motor Co., 189 F.3d
971, 981 (9th Cir. 1999).

1 compensatory damages, including hospital and other medical expenses. (Id. at 10.)

2 II. Requests for Judicial Notice

3 In support of its Motion for Judgment on the Pleadings, defendant requests that the court
4 take judicial notice of the following three documents: (1) a February 11, 2011 Premarket
5 Approval letter for the Selenia Dimensions 3D System (ECF No. 8-3, Exhibit B); (2) a Food and
6 Drug Administration (“FDA”) Summary of Safety and Effectiveness Data for the Selenia
7 Dimensions 3D System” available through the FDA’s website³; and (3) a product classification
8 listing for the digital breast tomosynthesis mammography system from the FDA’s medical device
9 classification database webpage.⁴ Plaintiff does not oppose defendant’s requests for judicial
10 notice.

11 Under Federal Rule of Evidence 201, “[t]he court may judicially notice a fact that is not
12 subject to reasonable dispute because it: (1) is generally known within the trial court’s territorial
13 jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot
14 reasonably be questioned.” Fed. R. Evid. 201(b). Courts may take judicial notice of “*undisputed*
15 matters of public record,” but generally may not take judicial notice of “*disputed* facts stated in
16 public records.” Lee v. City of Los Angeles, 250 F.3d 668, 690 (9th Cir. 2001) (emphasis in
17 original). Facts subject to judicial notice may be considered on a Rule 12(c) motion. McCain v.
18 Stockton Police Dept., 2011 WL 4710696 at *2 (C.D. Cal. Oct. 4, 2011) (citing Mullis v. U.S.
19 Bankr. Ct., 828 F.2d 1385, 1388 (9th Cir. 1987)).

20 The Court finds that the documents here meet the requirements of Federal Rule of
21 Evidence 201. The court may take judicial notice of information in government documents or
22 from a government website when the fact “is not subject to reasonable dispute because it can
23 accurately and readily be determined from sources whose accuracy cannot reasonably be
24 questioned.” Fed. R. Evid. 201; Daniels-Hall v. Nat’l Educ. Ass’n, 629 F.3d 992, 998-99 (9th
25 Cir. 2010); United States v. Head, 2013 WL 5739095 at *1, n.1 (E.D. Cal. Oct. 22, 2013);

26 ³ This document is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080003b.pdf.

27 ⁴ This webpage is available at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=OTE)
28 [classification.cfm?ID=OTE](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=OTE).

1 Clifford v. Regents of Univ. of California, 2012 WL 1565702 at *5 (E.D. Cal. Apr. 30, 2012); see
2 Erickson v. Boston Scientific Corp., 846 F. Supp. 2d 1085, 1089 (C.D. Cal. 2011) (granting
3 request for judicial notice of FDA’s Premarket Approval documents for defendants’ pacemaker
4 product); In re Amgen Inc. Sec. Litig., 544 F. Supp. 2d 1009, 1023 (C.D. Cal. 2008) (granting
5 requests for judicial notice of information posted on the FDA’s website). Accordingly,
6 defendant’s requests for judicial notice are granted.

7 III. Legal Standard

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

15 “A judgment on the pleadings is a decision on the merits.” 3550 Stevens Creek
16 Associates v. Barclays Bank of California, 915 F.2d 1355, 1356 (9th Cir. 1990). In addition to
17 considering the allegations of the complaint, the court may also take into account materials to
18 which it can take judicial notice. Heliotrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981,
19 n.18 (9th Cir. 1999). “[T]he central issue is whether, in light most favorable to the plaintiff, the
20 complaint states a valid claim for relief.” Hughes v. Tobacco Inst., Inc., 278 F.3d 417, 420 (5th
21 Cir. 2001). “[A]ll allegations of fact of the opposing party are accepted as true.” Austad v.
22 United States, 386 F.2d 147, 149 (9th Cir. 1967). A motion for judgment on the pleadings may
23 be granted if, after assessing the complaint and matters for which judicial notice is proper, it
24 appears “beyond doubt that the [non-moving party] cannot prove any facts that would support his
25 claim for relief.” Morgan v. County of Yolo, 436 F.Supp.2d 1152, 1155 (E.D. Cal. 2006), aff’d,
26 277 F. App’x 734 (9th Cir. 2008); R.J. Corman Derailment Services, LLC v. Int’l Union of
27 Operating Engineers, Local 150, AFL-CIO, 335 F.3d 643, 647 (7th Cir. 2003).

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1 “A Rule 12(c) motion challenges the legal sufficiency of the opposing party’s pleadings
2 and operates in much the same manner as a motion to dismiss under Rule 12(b)(6).” Morgan v.
3 County of Yolo, 436 F.Supp.2d 1152, 1154-55 (E.D. Cal. 2006). Analysis under Rule 12(c) is
4 “substantially identical” to analysis under Rule 12(b)(6) because, under both rules a court
5 determines whether the facts alleged in the complaint, taken as true, entitle the plaintiff to a legal
6 remedy. Chavez v. U.S., 683 F.3d 1102, 1108 (9th Cir. 2012). Similar to a Rule 12(b)(6) motion
7 to dismiss, when addressing a motion on the pleadings, a court must assess whether the complaint
8 “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on
9 its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550
10 U.S. 544, 570 (2007)). “[A] court considering a motion to dismiss can begin by identifying
11 pleadings that, because they are no more than conclusions, are not entitled to the assumption of
12 truth. While legal conclusions can provide the framework of a complaint, they must be supported
13 by factual allegations.” Iqbal, 556 U.S. at 679.

14 Mere conclusory statements in a complaint and “formulaic recitation[s] of the elements of
15 a cause of action” are insufficient. Twombly, 550 U.S. at 555. Thus, a court discounts
16 conclusory statements, which are not entitled to the presumption of truth, before determining
17 whether a claim is plausible. Iqbal, 556 U.S. at 678. “A claim has facial plausibility when the
18 plaintiff pleads factual content that allows the court to draw the reasonable inference that the
19 defendant is liable for the misconduct alleged.” Id. “Determining whether a complaint states a
20 plausible claim for relief will . . . be a context-specific task that requires the reviewing court to
21 draw on its judicial experience and common sense.” Id. at 679.

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

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1 IV. Defendant’s Motion for Judgment on the Pleadings

2 Defendant argues that both of plaintiff’s claims are preempted by the Medical Device
3 Amendments of 1976 (“MDA”) to the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§
4 301 *et seq.*, 360c *et seq.*, which contains an express preemption clause.

5 The MDA’s preemption provision states that:

6 [N]o State or political subdivision of a State may establish or
7 continue in effect with respect to a device intended for human use
any requirement—

8 (1) which is different from, or in addition to, any requirement
9 applicable under this chapter to the device, and

10 (2) which relates to the safety or effectiveness of the device or to
11 any other matter included in a requirement applicable to the device
under this chapter.

12 21 U.S.C. § 360k(a). The MDA regulatory regime established three classes of medical devices
13 based on the level of risk they present. Riegel v. Medtronic, 552 U.S. 312, 316 (2008). Class I
14 devices, such as bandages and latex gloves, are subject to the lowest level of regulation, Class II
15 devices, such as powered wheelchairs, receive closer FDA scrutiny, and Class III devices, such as
16 replacement heart valves, receive the most intensive federal oversight. Id. at 316-17. The FDA
17 has exclusive authority to regulate and assess the safety and effectiveness of medical devices
18 through the premarket approval or an equivalent process. Id. at 316-320 (describing the
19 “rigorous” premarket approval process medical devices falling into one of the three MDA classes
20 must undergo).

21 Here, the judicially-noticed documents demonstrate that defendant manufactured the
22 Selenia Dimensions 3D System, which forms the basis for plaintiff’s products liability claims,
23 and that this machine is a Class III Medical Device that was evaluated under the FDA’s
24 premarket approval process. Accordingly, this device falls within the MDA regulatory regime,
25 including the MDA’s preemption provision.

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1 In Riegel v. Medtronic, the United States Supreme Court held that the MDA expressly
2 preempts state law claims if “specific federal requirements apply to the particular medical device
3 that is the subject of the state law claim,” and “the state-law tort claim imposes a standard of care
4 or behavior that is ‘different from, or in addition to’ the specific federal requirements.” 552 U.S.
5 at 322 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 498-99 (1996) (holding that MDA
6 preemption applies to common law claims such as “strict products liability, breach of implied
7 warranty, and negligence”)). District courts in the Ninth Circuit have applied Riegel to preempt a
8 broad range of state law claims brought against FDA-approved Class III medical devices,
9 including products liability claims under California state law. See, e.g., Norton v. Indep. Tech.,
10 LLC, 2011 WL 3584491 (E.D. Cal. Aug. 15, 2011) (granting defendant’s Rule 12(c) motion
11 because plaintiff’s products liability and negligence claims concerning a Class III motorized
12 wheelchair were preempted by the MDA); Cohen v. Guidant Corp., 2011 WL 637472, at *1 (C.D.
13 Cal. Feb. 15, 2011) (holding that plaintiff’s “state law claims are preempted by federal law
14 because the pacemaker at issue in this action . . . is a Class III Medical Device that was evaluated
15 under the equivalent of the FDA’s premarket approval process”).

16 Plaintiff’s claims as pled are preempted by federal law because they are each premised on
17 the impropriety of a design, manufacturing or labeling process specifically approved by the FDA
18 through its premarket approval procedures, and they thus constitute state law claims imposing
19 requirements that are “different from, or in addition to” federal requirements. Riegel, 552 U.S. at
20 322; see also Medtronic, Inc., 518 U.S. at 498-99; Norton, 2011 WL 3584491.

21 Nevertheless, the MDA “does not prevent a State from providing a damages remedy for
22 claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather
23 than add to, federal requirements.” Riegel, 552 U.S. at 322. In order to properly plead “parallel”
24 claims that survive preemption, however, a plaintiff “must demonstrate facts (1) showing an
25 alleged violation of FDA regulations or requirements related to [the device], and (2) establishing
26 a causal nexus between the alleged injury and the violation.” Cohen v. Guidant Corp., 2011 WL
27 637472 at *1 (C.D. Cal. 2011). However, plaintiff does not allege in her complaint that defendant
28 violated FDA requirements in the design, manufacture or labeling of the Selenia Dimensions 3D

1 System. Accordingly, defendant’s motion for judgment on the pleadings is granted, but with
2 leave to amend because plaintiff could conceivably allege facts supporting the existence of viable
3 “parallel claims” based on defendant’s failure to comply with the FDA-approved standards.⁵

4 If plaintiff elects to file an amended complaint, it shall be captioned “First Amended
5 Complaint” and shall not exceed 20 pages. Furthermore, the first amended complaint shall be
6 limited to asserting “parallel” claims against defendant, meaning that plaintiff must be able to
7 make good faith factual allegations showing that defendant violated FDA regulations or
8 requirements related to the Selenia Dimensions 3D System and that there was a causal
9 relationship between plaintiff’s alleged injury and defendant’s violation.⁶ See Cohen, 2011 WL
10 637472 at *1.

11 Plaintiff is informed that the court cannot refer to a prior complaint, brief, exhibits, or
12 other filing to make plaintiff’s first amended complaint complete. Local Rule 220 requires that
13 an amended complaint be complete in itself without reference to any prior pleading. Thus, once
14 the first amended complaint is filed, it supersedes the original complaint, which no longer serves
15 any function in the case.

16 Importantly, nothing in this order requires plaintiff to file a first amended complaint. If
17 plaintiff determines that she does not wish to pursue the action at this juncture, she may instead
18 file a request for voluntary dismissal of the action without prejudice pursuant to Federal Rule of
19 Civil Procedure 41(a)(1)(A)(i).

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23 ⁵ Defendant also argues that plaintiff’s allegations are not adequately pled under the Federal Rule
24 of Civil Procedure 8(a) standards announced in Bell Atl. Corp. v. Twombly, 550 U.S. 544, 545
25 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009). While the court agrees that plaintiff’s form
26 complaint lacks the factual support necessary to undergird a plausible claim under this standard,
the court declines to address this argument at this time because defendant’s motion for judgment
on the pleadings is granted with leave to amend on the basis of preemption.

27 ⁶ Plaintiff is cautioned that if she chooses to file an amended complaint, she must have a good
28 faith factual basis for the allegations asserted in that pleading. Failure to make allegations in
good faith could result in the imposition of sanctions. See Fed. R. Civ. P. 11(b), (c).

1 V. Conclusion

2 For the foregoing reasons, IT IS HEREBY ORDERED THAT:

3 1. Defendant's motion for judgment on the pleadings (ECF No. 8) is granted with
4 leave to amend.


5 2. Within 30 days of this order, plaintiff shall file either (a) a first amended complaint
6 in compliance with this order or (b) a request for voluntary dismissal of the action without
7 prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i).

8 3. Defendants shall file a response to any first amended complaint within 30 days of
9 service with that pleading.

10 4. Failure to file either a first amended complaint or a request for voluntary dismissal
11 by the required deadline may result in the imposition of any appropriate sanctions, including
12 monetary sanctions and/or potential dismissal of the action with prejudice pursuant to Federal
13 Rule of Civil Procedure 41(b).

14 IT IS SO ORDERED.

15 Dated: June 6, 2014

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18 KENDALL J. NEWMAN
19 UNITED STATES MAGISTRATE JUDGE
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