UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CIVIL MINUTES—GENERAL

Case No.	**CV 16-7316-DMG (KSx)**	Date	December 27, 2018
Title	***Sara Ebrahimi v. Mentor Worldwide LLC***	Page	1 of 4

Present: The Honorable DOLLY M. GEE, UNITED STATES DISTRICT JUDGE

KANE TIEN	NOT REPORTED
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiff(s)	Attorneys Present for Defendant(s)
None Present	None Present

Proceedings: IN CHAMBERS - ORDER RE DEFENDANT'S MOTION TO DISMISS THIRD AMENDED COMPLAINT [42]

On June 12, 2018, Plaintiff Sara Ebrahimi filed the Third Amended Complaint ("TAC") against Defendant Mentor Worldwide LLC. [Doc. # 41.] The TAC alleges a single cause of action for strict product liability arising out of a manufacturing defect in Mentor's silicone gel breast implants ("Implants"). *Id.* at 11–12.[1] On July 3, 2018, Mentor filed a motion to dismiss the TAC. [Doc. # 42.] The motion has since been fully briefed. [Doc. ## 43, 44.] Having duly considered the parties' written submissions, the Court **GRANTS** Mentor's motion **without further leave to amend**.

I.
FACTUAL BACKGROUND

In its Order dismissing Ebrahimi's original Complaint, the Court provided a factual summary of the case that need not be repeated here. *See* Order re Def's Mot. to Dismiss at 2–3 ("September 15, 2017 Order") [Doc. # 23]. To the extent that the TAC raises any new allegations that are relevant to the instant motion, the Court addresses them *infra* Part III.

II.
LEGAL STANDARD

The Court set forth the applicable legal standard for motions to dismiss in its September 15, 2017 Order, which applies to the pending motion as well. *See* Sept. 15, 2017 Order at 4.

[1] All page references herein are to page numbers inserted by the CM/ECF system.

III.
DISCUSSION

Mentor argues that Ebrahimi's manufacturing defect claim is expressly preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). *See* Mot. at 9–12. For a manufacturing defect claim to survive MDA preemption, it must include "specific allegations that the manufacturing of the device both fell short of the [Food and Drug Administration's ('FDA's')] requirements for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1092 (N.D. Cal. 2016) (quoting *Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1028 (C.D. Cal. 2015)) (internal quotation marks omitted) (collecting cases). In particular, "a plaintiff must allege 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.'" *See Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (quoting *Cohen v. Guidant Corp.*, No. CV–05–8070–R, 2011 WL 637472, at *1 (C.D. Cal. 2011)) (alteration in original). *Erickson* held that a plaintiff cannot simply allege that a defendant violated FDA regulations to avoid express preemption. *See Erickson*, 846 F. Supp. 2d at 1092. Instead, "a plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue, or identify specific [Premarket Approval ('PMA')] requirements that have been violated." *Id.* (citation omitted) (internal quotation marks omitted) (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

Ebrahimi alleges that "[t]he shell [on the Implants placed in her body] was too thin or porous to contain the gel within the levels established by FDA guidelines, to wit: minimal bleed at low levels of insignificant clinical consequence." *See* TAC at ¶ 31. This assertion relies on a passage from Mentor's Product Insert Data Sheet. *See id.* at ¶¶ 34–37. The Sheet provides in pertinent part that "[s]mall quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state) have been found to diffuse ('bleed') through an intact implant shell." *See* Product Insert Data Sheet: Mentor MemoryGel Breast Implants at 20, *available at* https://www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/breastimplants/ucm245623.pdf [*hereinafter* Sheet].[2] The Sheet further provides that "Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact [I]mplants into the body. . . . Over

[2] The Court judicially notices the Sheet as it is available on the FDA's website. *See Gerritsen v. Warner Bros. Entm't Inc.*, 112 F. Supp. 3d 1011, 1033 (C.D. Cal. 2015) (holding that a court may judicially notice information on websites belonging to government agencies).

99% of the LMW silicones and platinum stayed in the [I]mplant. The overall body of available evidence supposes that the extremely low level of gel bleed is of no clinical consequence." *See id.*

The Court rejects Ebrahimi's assertion that the Sheet announces an FDA manufacturing requirement for the Implants. The Sheet simply indicates that Mentor conducted a laboratory test on one of its Implants, and that Mentor found that 99% of the LMW silicones and platinum remained within that Implant. *See* Sheet at 20. The Sheet does not state that the FDA required Mentor to manufacture a shell that retains 99% of the LMW silicones and platinum contained therein. *See id.* In fact, the Sheet does not purport to announce the FDA's manufacturing specifications. Rather, it is a "physician labeling document [that] is intended to provide an overview of essential information about Mentor's MemoryGel Silicone Gel-Filled Breast Implants, including [(*inter alia*)] . . . a summary of clinical study results . . . ." *See id.* at 1. Thus, Ebrahimi's allegation constitutes an "unwarranted deduction[] of fact" that is not entitled to the presumption of truth. *See In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (quoting *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001)); *see also De La Paz*, 159 F. Supp. 3d at 1092 (quoting *Funke*, 147 F. Supp. 3d at 1028 (holding that a complaint must include "*specific allegations* that the manufacturing of the device . . . fell short of *the FDA's requirements for manufacturing*" (emphasis added)).

The remainder of the TAC fails to adequately allege that the Implants violated the FDA's manufacturing requirements. Ebrahimi repeats the averments regarding Dr. Blais' findings that she included in the Second Amended Complaint ("SAC"), *compare* SAC at ¶ 25 [Doc. # 28], *with* TAC at ¶ 29, which the Court found to be insufficient to survive a motion to dismiss, *see* Order re Def.'s Mot. to Dismiss at 6–7 ("May 25, 2018 Order") [Doc. # 40]. Further, the Court previously concluded that Ebrahimi's resort to generalized FDA regulations governing the manufacture of the Implants (*e.g.*, the quality system requirements imposed by 21 C.F.R. section 820.20 *et seq.*) fell short of satisfying her pleading burden. *See* May 25, 2018 at 6; TAC at ¶¶ 32.a–i, 33 (vaguely alleging that the Implants deviated from these general regulations). Accordingly, the Court once again concludes that Ebrahimi's manufacturing defect claim is preempted by the MDA.

On two prior occasions, the Court concluded that Ebrahimi did not adequately allege a manufacturing defect cause of action. *See* Sept. 15, 2017 Order at 9; May 25, 2018 Order at 5–7. As Ebrahimi has once again failed to allege such a claim, the Court shall not grant her leave to file yet another amended complaint. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) ("In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, *repeated failure to cure deficiencies by amendments previously allowed*, undue prejudice to the opposing party by virtue of allowance of the amendment, *futility of*

amendment, etc.—the leave [to amend] sought should, as the rules require, be 'freely given.'" (emphasis added)).

IV.
CONCLUSION

For the foregoing reasons, the Court **DISMISSES** the TAC **with prejudice**. A Judgment in favor of Mentor shall be entered forthwith.