UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

SANDRA BROGE,

Plaintiff,

v.

ALN INTERNATIONAL, INC.,

Defendant.

Case No. 17-cv-07131-BLF

ORDER RE MOTION TO DISMISS CLAIMS 1 AND 2 OF SECOND AMENDED COMPLAINT; DENYING MOTION AS TO CLAIM 1; AND GRANTING MOTION AS TO CLAIM 2 WITHOUT LEAVE TO AMEND

[RE: ECF 61]

Defendant ALN International, Inc. moves to dismiss Claims 1 and 2 of Plaintiff Sandra Broge's second amended complaint ("SAC") under Federal Rule of Civil Procedure 12(b)(6). The Court has vacated the hearing that was scheduled for April 17, 2019, and taken the motion under submission without oral argument. *See* Order Submitting Motion, ECF 69.

For the reasons discussed below, the motion is DENIED as to Claim 1 and GRANTED WITHOUT LEAVE TO AMEND as to Claim 2.

I. BACKGROUND

Plaintiff alleges that she was implanted with a medical device designed, manufactured, and marketed by Defendant ALN International, Inc. ("ALN International"). The device – the ALN Optional Vena Cava Filter ("IVC Filter") – was implanted on June 15, 2014 to treat deep vein thrombosis and pulmonary embolism. SAC ¶ 8. Those conditions can occur when blood clots travel from the blood vessels in the legs and pelvis through the inferior vena cava, or IVC, which is the vein that returns blood to the heart from the lower extremities. SAC ¶ 25. The IVC Filter is designed to trap and filter such blood clots. SAC ¶ 28.

Defendant marketed the IVC Filter as safe and easy to remove after implantation. SAC ¶ 66. However, when Plaintiff's physician attempted to remove the IVC Filter on November 9,

2015, removal was impossible because the IVC Filter had perforated, and become embedded in, the vena cava wall. SAC ¶ 9. Plaintiff underwent a second surgery on March 6, 2016, at which time the IVC Filter was successfully removed. SAC ¶ 10. Plaintiff alleges that as a result of these events, she suffered permanent and lift-threatening injuries and incurred significant medical expenses. SAC ¶ 11.

Plaintiff filed the original complaint, containing twelve claims, in the Santa Clara County Superior Court. Compl., Exh. A to Notice of Removal, ECF 1. Defendant removed the action to federal district court and filed a Rule 12(b)(6) motion. Through two rounds of motion practice and corresponding amendments, Plaintiffs' claims have been whittled down to four claims set forth in the operative SAC: (1) strict products liability – inadequate warning; (2) strict products liability – manufacturing defect; (3) negligence; and (4) unjust enrichment. SAC, ECF 54.

Defendant seeks dismissal of Claims 1 and 2, arguing that Plaintiff has failed to cure the defects in those claims described in the Court's prior dismissal orders and that further amendment would be futile.

II. LEGAL STANDARD

"A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted 'tests the legal sufficiency of a claim.'" *Conservation Force v. Salazar*, 646 F.3d 1240, 1241-42 (9th Cir. 2011) (quoting *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)). While a complaint need not contain detailed factual allegations, it "must contain 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 claim is facially plausible when it "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

III. DISCUSSION

A. Strict Products Liability – Inadequate Warning (Claim 1)

Claim 1 of the SAC alleges strict products liability based on inadequate warning. "California law places a duty on manufacturers to warn of a particular risk if it is known or knowable in light of the generally recognized and prevailing best scientific and medical

knowledge available at the time of manufacture and distribution." *Rosa v. Taser Int'l, Inc.*, 684 F.3d 941, 946 (9th Cir. 2012) (internal quotation marks, citation, and emphasis omitted). Under this standard, "the manufacturer is held to the knowledge and skill of an expert in the field; it is obliged to keep abreast of any scientific discoveries and is presumed to know the results of all such advances." *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1113 n.3 (1996). "A manufacturer cannot defeat liability because it did not review the relevant scientific literature." *Rosa*, 684 F.3d at 946. However, "a manufacturer is not under a duty to warn of every report of a possible risk, no matter how speculative, conjectural, or tentative, because inundating the public indiscriminately with notice of any and every hint of danger would inevitably dilute the force of any specific warning given." *Id*. (internal quotation marks, citation, and brackets omitted).

"In cases involving medical devices, California applies the 'learned intermediary' doctrine which provides that the duty to warn runs to the physician, not the patient." *Hammarlund v. C.R. Bard, Inc.*, No. 2:15-CV-05506-SVW-JEM, 2015 WL 5826780, at *4 (C.D. Cal. Oct. 2, 2015). Thus a plaintiff alleging failure to warn regarding a medical device must allege that an adequate warning would have changed the physician's decision to prescribe the product. *Id*.

The Court previously dismissed this claim because Plaintiff focused on Defendant's knowledge at the time she was implanted with the IVC Filter rather than the relevant time period when the IVC Filter was manufactured or distributed; Plaintiff's allegations regarding Defendant's knowledge were not supported by any facts showing that Defendants knew or should have known about the alleged risks in implanting the IVC Filter; and Plaintiff's allegation that a warning would have altered her physician's decision to prescribe the IVC Filter was wholly conclusory. Order Granting Motion to Dismiss FAC at 4, ECF 51. Defendant contends that SAC does not cure these deficiencies. The Court concludes that Plaintiff has added facts which are sufficient to state a claim for relief.

Plaintiff now focuses on the correct time frame, when the IVC Filter was manufactured and distributed, rather than when it was implanted. SAC ¶ 86. Additionally, she now alleges factual bases for her assertion that Defendant knew or should have known that the IVC Filter posed a significant risk of failure. SAC ¶¶ 86-88. Specifically, she alleges that Defendant knew

or should have known of risks posed by their product based on a July 9, 2009 "incident event report" and a 2013 case report published in The Journal of Vascular Medicine and Surgery. SAC ¶¶ 86-87. The 2009 incident event report described "an injury where the ALN filter had malfunctioned, requiring multiple snares to be used in attempts to retrieve the filter. Due to the defective design of the device, the specially designed hooks were not able to retrieve the device, and it was deemed unremovable after an exhaustive surgical attempt to do so." SAC ¶ 88. The 2013 case report described an incident in which an IVC Filter implanted in a Japanese man migrated to the right ventricle, causing new thrombi that were potentially fatal. SAC ¶ 87. Plaintiff's allegations that an adequate warning would have altered her physician's decision to prescribe the IVC Filter are still conclusory, but given Plaintiff's other amendments to the claim and her allegation that she herself would not have consented to implantation of the device had her physician passed on a warning from Defendant, the Court is satisfied that the claim is adequately pled.

Defendant argues that Plaintiff's amendments are inadequate to show that Defendant knew or should have known that the IVC Filter put patients at risk, because the 2009 incident involved a design defect and the Court previously dismissed Plaintiff's claim for design defect, and the 2013 article described migration of the IVC Filter rather than the embedding of the IVC Filter in the vena cava wall, as happened to Plaintiff. The Court is not prepared to draw the distinctions argued by Defendant at the Rule 12(b)(6) stage. It may be that Defendant can show in appropriate motion or at trial that Defendant did not have actual or constructive knowledge of a risk sufficient to trigger a duty to warn. Those are questions for another day. At this stage, the Court concludes that Plaintiff's factual allegations give rise to a reasonable inference that Defendant knew or should have known of risks created by its product which triggered a duty to warn.

The motion to dismiss Claim 1 is DENIED.

B. Strict Products Liability – Manufacturing Defect (Claim 2)

Claim 2 of the SAC alleges strict products liability based on manufacturing defect. "Under a strict products liability claim based on manufacturing defect, a plaintiff must allege that while a 'suitable design is in place, [ ] the manufacturing process has in some way deviated from that

design' resulting in a defective product." *Hammarlund*, 2015 WL 5826780, at *4 (citing *In re Coordinated Latex*, 99 Cal. App 4th 594, 613 (2002)). "Under the manufacturing defect theory, generally a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1154 (E.D. Cal. 2010) (internal quotation marks and citation omitted). In order to state a claim, the plaintiff must explain how the product deviated from the manufacturer's intended design or how it deviated from other seemingly identical products. *Id.* at 1155. "A bare allegation that the [product] had 'a manufacturing defect' is an insufficient legal conclusion." *Id.*

The Court previously dismissed this claim because Plaintiff had failed to allege facts from which it could be inferred that the IVC Filter was suitably designed, and that her unit deviated from such design. Order Granting Motion to Dismiss FAC at 5, ECF 51. Plaintiff still has not alleged facts indicating that the IVC Filter was suitably designed. To the contrary, she alleges facts giving rise to a reasonable inference that the IVC Filter was *not* suitably designed and that the medical issues she suffered were due to the design rather than her particular unit's deviation from the design.

Specifically, Plaintiff alleges that "[t]he ALN Optional Vena Cava Filter is designed with legs (or struts) if differing lengths to avoid intertwining in the introduction catheter, however this feature makes the device more susceptible to post-implantation perforation, penetration, or intertwining with other veins and/or tissue." SAC ¶ 48, ECF 54. Moreover, the anchoring barbs located on the IVC Filter's struts "are particularly susceptible to perforation." SAC ¶ 52. "Additionally, the ALN Optional Vena Cava Filter and Extraction Kit is intended as a removable filter with a special tool for ease of retrieval, however the device must remain in perfect placement, or the retrieval hook will be unable to latch properly, rending removal difficult, if not impossible." *Id*. The IVC Filter was "designed in such way that when exposed to expected and reasonably foreseeable in-vivo conditions the devices will fracture, migrate, tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism." SAC ¶ 53. "The anchoring mechanism of the ALN Optional Vena Cava Filter is also insufficient

to prevent tilting and migration post-placement." SAC ¶ 54. "The configuration of the Inferior vena cava ('IVC') filters also renders them prothrombotic. This means that the ALN Optional Vena Cava Filter actually lead to the formation of thromboembolism and pulmonary emboli – the exact condition that these devices are meant to prevent." SAC ¶ 55.

Plaintiff alleges that "[t]he ALN Vena Cava Filter implanted in plaintiff suffered a manufacturing defect because it did not conform to the suitable design mentioned above." SAC ¶ 100. As discussed, no "suitable design" is identified in the SAC. Plaintiff alleges that Defendant "manufactured the hardware used in the device implanted in the Plaintiff, such that it failed to meet specifications as to the appropriate metal content, strength, and number of inclusions, which substantially increased the risk of fatigue failure, perforation, and migration in each device." SAC ¶ 102. However, Plaintiff provides absolutely no information regarding such specifications.

While the Court recognizes that it can be difficult for a plaintiff to allege details regarding the manner in which a particular device deviated from the design, Plaintiff has not come close to alleging that the IVC Filter was suitably designed or how the unit implanted in her deviated from such design. To the contrary, all of her allegations suggest that her medical issues derived from the design itself. Accordingly, Claim 2 is subject to dismissal.

Having made that determination, the Court must decide whether leave to amend is warranted. Leave ordinarily must be granted unless one or more of the following factors is present: (1) undue delay, (2) bad faith or dilatory motive, (3) repeated failure to cure deficiencies by amendment, (4) undue prejudice to the opposing party, and (5) futility of amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (discussing *Foman* factors). The Court finds no undue delay (factor 1) or bad faith (factor 2). However, despite the Court's prior orders dismissing the original complaint and the FAC with guidance regarding amendment, Plaintiff still has not alleged a viable claims for manufacturing defect (factor 3). Granting further opportunity to amend would impose undue prejudice on Defendant (factor 4) where it appears that amendment would be futile (factor 5). The Court thus concludes that further leave to amend is not warranted.

Claim 2 is DISMISSED WITHOUT LEAVE TO AMEND.

IV. ORDER

Defendant's motion to dismiss is DENIED as to Claim 1 for strict products liability based on inadequate warning, and GRANTED WITHOUT LEAVE TO AMEND as to Claim 2 for strict products liability based on manufacturing defect.

Dated: May 13, 2019

BETH LABSON FREEMAN
United States District Judge