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**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 GRANTING MOTION TO
DISMISS FIRST AMENDED
COMPLAINT WITH LEAVE TO
AMEND**

[RE: ECF 38]

On October 25, 2018, the Court heard oral argument regarding Defendant ALN International, Inc.’s motion to dismiss Plaintiff Sandra Broge’s first amended complaint (“FAC”) under Federal Rule of Civil Procedure 12(b)(6). For the reasons stated on the record and discussed below, the motion is GRANTED WITH LEAVE TO AMEND.

I. BACKGROUND¹

This action arises from medical issues suffered by Broge after implantation of a medical device allegedly designed, manufactured, and marketed by Defendant ALN International, Inc. (“ALN International”). FAC ¶ 12, ECF 35. The device – the ALN Optional Vena Cava Filter (“IVC Filter”) – was implanted in Broge to treat deep vein thrombosis and pulmonary embolism. *Id.* ¶¶ 1, 8. The IVC Filter was designed for easy removal once it was no longer medically necessary, but the first attempt to remove it failed because it had become embedded in Broge’s vena cava wall. *Id.* ¶ 9. Broge needed an additional surgery to remove the IVC Filter. *Id.* ¶ 10.

¹ Broge’s well-pled factual allegations are accepted as true for purposes of the motion to dismiss. *See Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 690 (9th Cir. 2011).

1 Broge filed this suit against ALN International in the Santa Clara County Superior Court,
2 alleging that she suffered unspecified “permanent and life-threatening injuries, requiring extensive
3 medical care and treatment,” as a result of a malfunction of the IVC Filter. Compl. ¶¶ 11-12, Exh.
4 A to Notice of Removal, ECF 1. She asserted numerous claims against ALN International under
5 California law. No other defendants were named in the suit.

6 ALN International removed the complaint to federal district court on the basis of diversity
7 of citizenship and, shortly thereafter, filed a motion to dismiss under Federal Rule of Civil
8 Procedure 12(b)(6) for failure to state a claim. Notice of Removal, ECF 1; Motion to Dismiss,
9 ECF 16. The Court granted the motion in part and denied it in part, with leave to amend in part
10 and without leave to amend in part. Order, ECF 30. The Court noted that although Broge had
11 sued only ALN International, her complaint referred to the conduct and knowledge of other
12 entities, including “ALN Implants Chirurgicaux” and “ALN Implants.” *Id.* at 3. The Court also
13 identified deficiencies in most of Broge’s claims. *Id.* at 3-8.

14 Broge thereafter filed the operative FAC, asserting claims for: (1) strict products liability –
15 inadequate warning; (2) strict products liability – manufacturing defect; (3) negligence;
16 (4) negligent misrepresentation; (6) breach of express warranty²; (7) fraudulent misrepresentation;
17 (8) fraudulent concealment; (9) unjust enrichment; (10) violation of California Business &
18 Professions Code § 17200; and (11) violation of California Business & Professions Code § 17500.
19 FAC, ECF 35.

20 ALN International moves to dismiss a number of the claims asserted in the FAC under
21 Rule 12(b)(6), asserting that Broge has not cured the pleading deficiencies identified by the Court
22 in its prior order.

23 **II. LEGAL STANDARD**

24 “A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a
25 claim upon which relief can be granted ‘tests the legal sufficiency of a claim.’” *Conservation*
26 *Force v. Salazar*, 646 F.3d 1240, 1241-42 (9th Cir. 2011) (quoting *Navarro v. Block*, 250 F.3d
27

28 ² Due to what appears to be a clerical error, no Claim 5 is alleged in the FAC.

1 729, 732 (9th Cir. 2001)). While a complaint need not contain detailed factual allegations, it
2 “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible
3 on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*,
4 550 U.S. 544, 570 (2007)). A claim is facially plausible when it “allows the court to draw the
5 reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

6 **III. DISCUSSION**

7 ALN International seeks dismissal of Claim 1 for strict products liability based on
8 inadequate warning, Claim 2 for strict products liability based on manufacturing defect, Claim 4
9 for negligent misrepresentation, Claim 6 for breach of express warranty, Claim 7 for fraudulent
10 misrepresentation, Claim 8 for fraudulent concealment, Claim 10 for violation of California
11 Business & Professions Code § 17200, Claim 11 for violation of California Business &
12 Professions Code § 17500, and the claim for punitive damages. The Court previously dismissed
13 all of these claims with leave to amend. In large part, it appears that Broge simply disregarded the
14 Court’s guidance in the prior dismissal order. Several claims of the FAC are virtually identical to
15 those previously dismissed from the original complaint, and other claims have been amended in
16 only minor ways. When the Court raised this issue at the hearing, Broge’s counsel requested
17 further leave to amend. The Court indicated that it would grant Broge one final opportunity to
18 amend her pleading.

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

20 Claim 1 of the FAC alleges strict products liability based on inadequate warning.
21 Manufacturers are strictly liable for injuries caused by their failure to warn of risks that were
22 “known to the scientific community” or “reasonably scientifically knowable” at the time of
23 manufacture or distribution. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1108-09 (1996). “In
24 cases involving medical devices, California applies the ‘learned intermediary’ doctrine which
25 provides that the duty to warn runs to the physician, not the patient.” *Hammarlund v. C.R. Bard,*
26 *Inc.*, No. 2:15-CV-05506-SVW-JEM, 2015 WL 5826780, at *4 (C.D. Cal. Oct. 2, 2015).
27 Consequently, to plead a strict liability claim based on inadequate warning, the plaintiff must
28 allege both that the defendant failed to warn of dangers known or reasonably scientifically

1 knowable at the time of manufacture or distribution, and that the plaintiff’s physician would have
2 altered the decision to use the medical device had an adequate warning been given. *Id.* at *4-5.

3 The Court previously dismissed this claim because it was based on allegations that a third
4 party, “ALN Implants,” knew or could have discovered the alleged defects in the IVC Filter.
5 Order at 4, ECF 30. There were no allegations as to what the defendant in this case, ALN
6 International, knew or could have discovered. *Id.* Moreover, Broge focused on what was known
7 or knowable when the product was implanted, not what was known or knowable at the time of
8 manufacture or distribution. *Id.* Finally, the Court found inadequate Broge’s conclusory
9 allegation that her physician would not have prescribed the IVC Filter had adequate warnings been
10 given.

11 It does not appear that Broge amended this claim at all. *Compare* Compl. ¶¶ 94-101 with
12 FAC ¶¶ 85-92. She still alleges that “ALN Implants” knew or could have discovered the alleged
13 defects in the IVC Filter, still focuses on the time of implantation rather than the time of
14 manufacture or distribution, and still alleges only in conclusory fashion that warnings would have
15 altered her physician’s decision to prescribe the IVC Filter. FAC ¶¶ 85-92.

16 Claim 1 for strict products liability based on inadequate warning is DISMISSED WITH
17 LEAVE TO AMEND.

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

19 Claim 2 of the FAC alleges strict products liability based on manufacturing defect. The
20 manufacturing defect theory “presuppose[s] that a suitable design is in place, but that the
21 manufacturing process has in some way deviated from that design.” *In re Coordinated Latex*
22 *Glove Litig.*, 99 Cal. App. 4th 594, 613 (2002), *as modified on denial of reh’g* (July 15, 2002).
23 “Under the manufacturing defect theory, generally a manufacturing or production defect is readily
24 identifiable because a defective product is one that differs from the manufacturer’s intended result
25 or from other ostensibly identical units of the same product line.” *Lucas v. City of Visalia*, 726 F.
26 Supp. 2d 1149, 1154 (E.D. Cal. 2010) (internal quotation marks and citation omitted). In order to
27 state a claim, the plaintiff must explain how the product deviated from the manufacturer’s
28 intended design or how it deviated from other seemingly identical products. *Id.* at 1155. “A bare

1 allegation that the [product] had ‘a manufacturing defect’ is an insufficient legal conclusion.” *Id.*

2 The Court previously dismissed this claim because Broge’s bare allegations that the IVC
3 Filter “contained manufacturing defects” and that it “differed from Defendant’s design or
4 specifications, or from other typical units in of the same product line” were insufficient to state a
5 claim. Order at 5, ECF 30. The Court also noted that Broge’s allegations centered on the conduct
6 of third party “ALN Implants” rather than the conduct of Defendant ALN International. *Id.*

7 Broge has added new allegations that the IVC Filter was “designed with a hook so it can be
8 removed only by the Jugular Approach using one of the ALN Removal Kits or using a snare,” and
9 that the IVC Filter implanted in her “did not conform to the suitable design” because it “could not
10 be removed by the Jugular Approach using one of the ALN Removal Kits or using a snare.” FAC
11 ¶¶ 95-96. The difficulty retrieving Broge’s IVC Filter, standing alone, is insufficient to plausibly
12 allege the existence of a manufacturing defect. *See Victorino v. FCA US LLC*, No. 16cv1617-
13 GPC(JLB), 2016 WL 6441518, at *4 (S.D. Cal. Nov. 1, 2016) (allegations that vehicle stopped
14 working and experienced electrical failure were insufficient to state a claim for manufacturing
15 defect; claim was allowed to go forward only after addition of specific facts regarding vehicle’s
16 performance that raised an inference of a defect in the transmission). Broge must allege some
17 facts from which it could be inferred that that IVC Filter was suitably designed but that the unit
18 implanted in Broge deviated from the design. *See id.* Moreover, Broge again alleges the conduct
19 of third party “ALN Implants” in the manufacturing process rather than the conduct of Defendant
20 ALN International.

21 Broge argues that her allegations of manufacturing defect are adequate under *Waldo v. Eli*
22 *Lilly & Co.*, No. CIV. S-13-0789 LKK/EFB, 2013 WL 5554623, at *3 (E.D. Cal. Oct. 8, 2013). In
23 *Waldo*, the plaintiff claimed that her child was born with heart defects as a result of the plaintiff’s
24 ingestion of Prozac during pregnancy. The plaintiff’s claim for strict liability based on
25 manufacturing defect was allowed to proceed even though she had alleged only that “[t]he subject
26 product was not made in accordance with Defendant[‘s] specifications or performance standards.”
27 *Id.* (alterations in original). The district court held that to “require Waldo to identify, at the
28 pleadings stage, the defect in a pharmaceutical she ingested more than a decade ago would be to

1 effectively absolve Eli Lilly of any potential liability at the pleadings stage.” *Id.* Reasoning that
2 “[y]ears-old pharmaceuticals are quite different from products, such as lawnmowers or
3 automobiles, which are both durable and readily compared to other instances of the product line,”
4 the district court denied Eli Lilly’s motion to dismiss. *Id.* That reasoning does not apply in the
5 present case, which does not involve a pill that ceased to exist a decade ago but rather a physical
6 product more akin to a lawnmower or automobile.

7 Claim 2 for strict products liability based on manufacturing defect is DISMISSED WITH
8 LEAVE TO AMEND.

9 **C. Negligent Misrepresentation (Claim 4)**

10 Claim 4 of the FAC is for negligent misrepresentation. “The elements of negligent
11 misrepresentation are (1) the misrepresentation of a past or existing material fact, (2) without
12 reasonable ground for believing it to be true, (3) with intent to induce another’s reliance on the fact
13 misrepresented, (4) justifiable reliance on the misrepresentation, and (5) resulting damage.” *Nat’l*
14 *Union Fire Ins. Co. of Pittsburgh, PA v. Cambridge Integrated Servs. Grp., Inc.*, 171 Cal. App.
15 4th 35, 50 (2009) (internal quotation marks and citation omitted).

16 When addressing this claim in its prior order, the Court noted that there is a split among
17 district courts in the Ninth Circuit as to whether the heightened pleading requirements of Federal
18 Rule of Civil Procedure 9(b) apply to claims of negligent misrepresentation. Order at 6, ECF 30.
19 The Court concluded that it did not need to determine Rule 9(b)’s applicability because Broge’s
20 allegations failed to satisfy even the more lenient standards set forth in *Iqbal* and *Twombly*. *Id.*
21 Broge had alleged that ALN International “negligently and carelessly represented” the safety of
22 the IVC Filter, but she had not provided any factual basis for inferring that ALN International
23 lacked reasonable grounds to believe that its representations were true. Order at 6, ECF 30.
24 Moreover, Broge had alleged that the representations were in many different forms, including
25 press releases, advertising campaigns, labeling materials, print advertisements, commercial media
26 containing material representations, and instructions for use. *Id.* The Court held that “the general
27 reference to every conceivable form of communication is insufficient to give rise to a plausible
28 claim of negligent misrepresentation.” *Id.*

1 Broge has repeated the general allegations described above, but she also has added some
2 new allegations describing ALN International’s representations with more particularity. FAC ¶¶
3 108-16, ECF 35. For example, she now alleges that ALN International’s webpage includes a PDF
4 brochure and technical sheet available for download which state that the IVC Filter has a “High
5 performance design” and “Proven clinical effectiveness,” and that “Devices intended to be
6 retrievable at any time.” FAC ¶¶ 115-16. However, Broge still has not alleged any facts showing
7 that ALN International lacked reasonable grounds for believing those representations to be true.

8 Claim 4 for negligent misrepresentation is DISMISSED WITH LEAVE TO AMEND.

9 **D. Breach of Express Warranty (Claim 6)**

10 Claim 6 of the FAC alleges breach of express warranty. In order to state a claim for breach
11 of express warranty, the plaintiff must allege the exact terms of the warranty. *See Williams v.*
12 *Beechnut Nutrition Corp.*, 185 Cal. App. 3d 135, 142 (Cal. Ct. App. 1986). The Court previously
13 dismissed this claim for failure to allege the exact terms of the warranty. Order at 7, ECF 30.

14 Broge has reiterated her previous vague statements regarding warranties made on
15 “packaging inserts and media advertisements.” FAC ¶ 131. She has added two paragraphs which
16 are more specific:

17 Defendant’s brochure for its ALN Vena Cava Filter promised “The ALN Vena
18 Cava Filter with hook “can be removed only by Jugular approach using one of the
ALN Removal Kits or using a snare.”

19 FAC ¶ 132, ECF 35.

20 Defendant’s brochure also stated “The filter could be easily inserted and
21 successfully removed up to 1 year after insertion. Its safety and efficacy in
22 preventing pulmonary embolism should be properly assessed in a randomized
study.” (CHEST 2007; 131:223-229).

23 FAC ¶ 133.

24 As an initial matter, the statements set forth in paragraph 133 quote from “CHEST” – a
25 source other than ALN International – and therefore it does not appear that they would constitute
26 an express warranty of ALN International. Moreover, even assuming that the statements
27 regarding safe removal of the IVC Filter within one year do constitute a warranty by ALN
28 International, Broge does not allege facts showing that the warranty was breached. It appears from

1 Broge’s own allegations that her physician did not attempt to remove the filter until nearly
2 seventeen months after it was implanted, well beyond the alleged one-year warranty term. *See*
3 FAC ¶¶ 8-9.

4 Claim 6 for breach of express warranty is DISMISSED WITH LEAVE TO AMEND.

5 **E. Fraudulent Misrepresentations and Fraudulent Concealment (Claims 7 and 8)**

6 Claims 7 and 8 of the FAC allege fraudulent misrepresentation and fraudulent
7 concealment, respectively. “To establish a claim for fraudulent misrepresentation, the plaintiff
8 must prove: (1) the defendant represented to the plaintiff that an important fact was true; (2) that
9 representation was false; (3) the defendant knew that the representation was false when the
10 defendant made it, or the defendant made the representation recklessly and without regard for its
11 truth; (4) the defendant intended that the plaintiff rely on the representation; (5) the plaintiff
12 reasonably relied on the representation; (6) the plaintiff was harmed; and (7) the plaintiff’s reliance
13 on the defendant’s representation was a substantial factor in causing that harm to the plaintiff.”
14 *Graham v. Bank of Am., N.A.*, 226 Cal. App. 4th 594, 605-06 (2014) (internal quotation marks and
15 citation omitted). “The required elements for fraudulent concealment are: (1) concealment or
16 suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the plaintiff;
17 (3) the defendant intended to defraud the plaintiff by intentionally concealing or suppressing the
18 fact; (4) the plaintiff was unaware of the fact and would not have acted as he or she did if he or she
19 had known of the concealed or suppressed fact; and (5) plaintiff sustained damage as a result of
20 the concealment or suppression of the fact.” *Id.* at 606.

21 Federal Rule of Civil Procedure 9(b) requires that “[i]n alleging fraud or mistake, a party
22 must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P.
23 9(b). In order to satisfy this heightened pleading standard, a plaintiff must provide “an account of
24 the time, place, and specific content of the false representations as well as the identities of the
25 parties to the misrepresentations.” *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007)
26 (internal quotation marks and citation omitted); *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097,
27 1106 (9th Cir. 2003) (“Averments of fraud must be accompanied by the who, what, when, where,
28 and how of the misconduct charged.” (internal quotation marks and citation omitted)). Rule 9(b)

1 applies to claims of fraudulent misrepresentation and claims of fraudulent concealment. *See Vess*,
2 317 F.3d at 1105 (allegations of misrepresentation did not satisfy Rule 9(b)); *389 Orange St.*
3 *Partners v. Arnold*, 179 F.3d 656, 662 (9th Cir. 1999) (applying Rule 9(b) to fraudulent
4 concealment claim).

5 The Court previously dismissed Broge’s claims for fraudulent misrepresentation and
6 fraudulent concealment because they lacked any factual basis for inferring that ALN International
7 knew that its representations regarding the IVC Filter were untrue or concealed material facts
8 regarding the IVC Filter. Order at 7, ECF 30. The claims also lacked any details regarding the
9 “the who, what, when, where, and how” of the alleged misconduct. *See Vess*, 317 F.3d at 1106.
10 Broge has failed to cure these pleading deficiencies. For example, she alleges that “Defendant
11 failed to state the full extent of ways in which the product was not safe and had numerous serious
12 side effects, of which Defendants had full knowledge and did not accurately or adequately warn.”
13 FAC ¶ 147. However, she does not identify the ways in which the product was not safe, the side
14 effects, or any facts showing that ALN International knew this information when it published the
15 brochures and technical sheet on its website.

16 Claims 7 and 8 for fraudulent misrepresentation and fraudulent concealment are
17 DISMISSED WITH LEAVE TO AMEND.

18 **F. §§ 17200 and 17500 (Claims 10 and 11)**

19 Claims 10 and 11 allege violations of California Business & Professions Code §§ 17200
20 and 17500, respectively. The Court previously dismissed these claims because they are grounded
21 in Broge’s allegations of fraud, which the Court found to be inadequate. Order at 8, ECF 30.
22 Broge has not amended her §§ 17200 and § 17500 claims to allege any other basis for liability. As
23 noted above, Broge’s fraud claims are still inadequate.

24 Claims 10 and 11 for violations of §§ 17200 and 17500 are DISMISSED WITH LEAVE
25 TO AMEND.

26 **G. Punitive Damages**

27 In the original complaint, Broge’s sought punitive damages based on her allegations of
28 fraud. Compl. ¶¶ 249-50. The Court dismissed the claim for punitive damages on the basis that

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Broge had failed to allege fraud with adequate specificity. Order at 8, ECF 30.

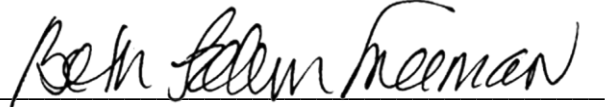
In the FAC, Broge has deleted her allegations as to the basis for punitive damages. Due to what appears to be a clerical error, the “Prayer for Punitive Damages” simply requests special damages, costs of suit, pre-judgment interest, post-judgment interest, restitution, and attorneys’ fees. FAC ¶¶ 197-98.

The claim for punitive damages is DISMISSED WITH LEAVE TO AMEND.

IV. ORDER

- (1) The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claims 1, 2, 4, 6, 7, 8, 10, and 11, and as to the prayer for punitive damages.
- (2) Pursuant to the request of Broge’s counsel at the hearing, any amended complaint shall be filed on or before January 16, 2019.
- (3) Leave to amend is limited to the claims addressed in this order. Broge may not add new claims or parties without obtaining prior leave of the Court.

Dated: December 3, 2018


BETH LABSON FREEMAN
United States District Judge