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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 IN PART AND  
DENYING IN PART MOTION TO  
DISMISS COMPLAINT, WITH LEAVE  
TO AMEND IN PART AND WITHOUT  
LEAVE TO AMEND IN PART**

[RE: ECF 16]

On May 3, 2018, the Court heard oral argument regarding Defendant ALN International, Inc.'s motion to dismiss Plaintiff Sandra Broge's complaint under Federal Rule of Civil Procedure 12(b)(6). The Court stated its intention to grant in part and deny in part the motion to dismiss, with leave to amend; highlighted the complaint's deficiencies; and set a deadline of July 2, 2018 for amendment. The Court indicated that it would issue a brief written order memorializing its ruling. Accordingly, for the reasons stated on the record and discussed below, the motion to dismiss is GRANTED IN PART AN DENIED IN PART, WITH LEAVE TO AMEND IN PART AND WITHOUT LEAVE TO AMEND IN PART.

**I. BACKGROUND<sup>1</sup>**

Plaintiff filed this action in the Santa Clara County Superior Court in November 2017, following medical issues arising from implantation of a device manufactured by Defendant ALN

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<sup>1</sup> Plaintiff'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 International, Inc. Compl. ¶ 12, Exh. A to Notice of Removal, ECF 1. Plaintiff was implanted  
2 with the ALN Optional Vena Cava Filter (“IVC Filter”) to treat deep vein thrombosis and  
3 pulmonary embolism. *Id.* ¶ 8. The IVC Filter was designed for easy removal once it was no  
4 longer medically necessary, but the first attempt to remove it from Plaintiff failed because it had  
5 become embedded in the vena cava wall. *Id.* ¶ 9. Plaintiff had to undergo an additional surgery to  
6 remove the IVC Filter. *Id.* ¶ 10.

7 The complaint alleges that Plaintiff suffered unspecified “permanent and life-threatening  
8 injuries, requiring extensive medical care and treatment,” as a result of a malfunction of the IVC  
9 Filter. Compl. ¶ 11. The claims asserted in the complaint include: (1) strict products liability –  
10 defective design; (2) strict products liability – inadequate warning; (3) strict products liability –  
11 manufacturing defect; (4) negligence; (5) negligent misrepresentation; (6) fraudulent  
12 misrepresentation; (7) fraudulent concealment; (8) breach of express warranty; (9) breach of  
13 implied warranty of merchantability; (10) unjust enrichment; (11) violation of California Business  
14 & Professions Code § 17200; and (12) violation of California Business & Professions Code  
15 § 17500.

16 Defendant removed the complaint to federal district court on the basis of diversity of  
17 citizenship. Notice of Removal, ECF 1. Shortly thereafter, Defendant filed the present motion to  
18 dismiss.

19 **II. LEGAL STANDARD**

20 “A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a  
21 claim upon which relief can be granted ‘tests the legal sufficiency of a claim.’” *Conservation*  
22 *Force v. Salazar*, 646 F.3d 1240, 1241-42 (9th Cir. 2011) (quoting *Navarro v. Block*, 250 F.3d  
23 729, 732 (9th Cir. 2001)). While a complaint need not contain detailed factual allegations, it  
24 “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible  
25 on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*,  
26 550 U.S. 544, 570 (2007)). A claim is facially plausible when it “allows the court to draw the  
27 reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

28

1       **III. DISCUSSION**

2           Defendant seeks dismissal of all claims asserted in the complaint other than the fourth  
3 claim for negligence, and it also seeks dismissal of Plaintiff’s prayer for punitive damages. Before  
4 turning to the parties’ arguments, the Court makes a general observation that the complaint lacks  
5 clarity as a whole because of Plaintiff’s multiple references to conduct and knowledge of entities  
6 which are not named as defendants. For example, Plaintiff alleges that “ALN Implants  
7 Chirugicaux” is the entity which obtained clearance to market the IVC Filter, that “ALN Implants”  
8 received reports of tilting, perforation, and other defects, and that “ALN Implants knew or could  
9 have discovered” that the IVC Filter posed a significant risk of failure. Compl. ¶¶ 45, 63, 95. It is  
10 unclear what relationship, if any, exists between these entities and the only named defendant in  
11 this action, ALN International, Inc. To the extent Plaintiff is attempting to impute the conduct or  
12 knowledge of these other ALN entities to Defendant ALN International, Inc., she has not alleged  
13 sufficient facts.

14           **A. Strict Products Liability – Defective Design (Claim 1)**

15           Plaintiff concedes that Claim 1, alleging strict products liability based on design defect, is  
16 precluded by California law. *See Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173,  
17 184 (2013) (recognizing “an exemption from design defect strict products liability for all  
18 implanted medical devices that are available only through the services of a physician”).

19           The motion to dismiss is GRANTED WITHOUT LEAVE TO AMEND as to Claim 1.

20           **B. Strict Products Liability – Inadequate Warning (Claim 2)**

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

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

4 Plaintiff alleges that “[a]t the time that the ALN Optional Vena Cava Filter was implanted  
5 in Plaintiff, *ALN Implants* knew or could have discovered that the ALN Optional Vena Cava  
6 Filters posed a significant and higher risk of failure than other similar IVC filters, including for  
7 fracture, migration, tilting, thrombosis, migration, tilt, inability to retrieve and pulmonary  
8 embolism.” Compl. ¶ 95 (emphasis added). This allegation fails to meet the standards set forth  
9 above in several respects. First, it alleges that ALN Implants – not Defendant ALN International,  
10 Inc. – knew or could have discovered the alleged defects. Second, the allegation as to what was  
11 known or knowable when Plaintiff was *implanted* is irrelevant, as liability turns on what was  
12 known or knowable when Defendant manufactured or distributed the product. Plaintiff also  
13 alleges in only conclusory fashion that her physician would not have prescribed the IVC Filter had  
14 an adequate warning been given. *Id.* ¶ 101. Similar allegations were rejected as inadequate in  
15 *Hammarlund*.

16 The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claim 2.

17 **C. Strict Products Liability – Manufacturing Defect (Claim 3)**

18 Claim 3 alleges strict products liability based on manufacturing defect. The manufacturing  
19 defect theory “presuppose[s] that a suitable design is in place, but that the manufacturing process  
20 has in some way deviated from that design.” *In re Coordinated Latex Glove Litig.*, 99 Cal. App.  
21 4th 594, 613 (2002), *as modified on denial of reh’g* (July 15, 2002). “Under the manufacturing  
22 defect theory, generally a manufacturing or production defect is readily identifiable because a  
23 defective product is one that differs from the manufacturer’s intended result or from other  
24 ostensibly identical units of the same product line.” *Lucas v. City of Visalia*, 726 F. Supp. 2d  
25 1149, 1154 (E.D. Cal. 2010) (internal quotation marks and citation omitted). In order to state a  
26 claim, the plaintiff must explain how the product deviated from the manufacturer’s intended  
27 design or how it deviated from other seemingly identical products. *Id.* at 1155. “A bare allegation  
28 that the [product] had ‘a manufacturing defect’ is an insufficient legal conclusion.” *Id.*

1 Plaintiff alleges that the IVC Filter “contained manufacturing defects” and that it “differed  
2 from Defendant’s design or specifications, or from other typical units in of the same product line.”  
3 Compl. ¶ 105. Those bare allegations of defect are insufficient to state a claim. Plaintiff also  
4 alleges that “*ALN Implants* also manufactured the hardware used in the device implanted in the  
5 Plaintiff, such that it failed to meet specifications as to the appropriate metal content, strength, and  
6 number of inclusions, which substantially increased the risk of fatigue failure, perforation, and  
7 migration in each device.” *Id.* ¶ 106 (emphasis added). As discussed above, ALN Implants is not  
8 a named defendant in this case. Moreover, Plaintiff does not allege what metal content the IVC  
9 Filter should have had pursuant to the product’s design, what metal content it actually had, or how  
10 any discrepancy caused her injury. Without some information regarding the “specifications” that  
11 the IVC Filter allegedly failed to meet, Defendant cannot fairly be expected to respond to this  
12 claim.

13 The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claim 3.

14 **D. Negligent Misrepresentation (Claim 5)**

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

21 Defendant argues that Plaintiff has not alleged these elements with the specificity required  
22 by Federal Rule of Civil Procedure 9(b), which requires that “[i]n alleging fraud or mistake, a  
23 party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ.  
24 P. 9(b). In order to satisfy this heightened pleading standard, a plaintiff must provide “an account  
25 of the time, place, and specific content of the false representations as well as the identities of the  
26 parties to the misrepresentations.” *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007)  
27 (internal quotation marks and citation omitted); *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097,  
28 1106 (9th Cir. 2003) (“Averments of fraud must be accompanied by the who, what, when, where,

1 and how of the misconduct charged.” (internal quotation marks and citation omitted)). In  
2 response, Plaintiff argues that her claim for negligent misrepresentation sounds in negligence  
3 rather than fraud, and therefore is not subject to the requirements of Rule 9(b).

4 “[T]here is a split among Ninth Circuit district courts over whether Rule 9(b)’s pleading  
5 requirements apply to negligent misrepresentation,” and [t]he Ninth Circuit has not directly  
6 addressed the question.” *Atkins v. Calypso Sys. Inc.*, No. CV-14-02706-PHX-NVW, 2016 WL  
7 10650809, at \*8 n. 2 (D. Ariz. Nov. 16, 2016) (collecting cases). This Court need not determine  
8 Rule 9(b)’s applicability here, because even absent that heightened pleading standard Plaintiff has  
9 failed to state a claim. Although it indicated at the hearing that it was not inclined to apply Rule  
10 9(b) to the claim for negligent misrepresentation, the Court concludes on further review of the  
11 complaint that Plaintiff’s allegations fail to satisfy even the more lenient standards set forth in  
12 *Iqbal* and *Twombly*. Plaintiff alleges that “Defendant negligently and carelessly represented to  
13 the Plaintiff, her health care providers, and the public that certain material facts were true.”  
14 Compl. ¶ 117. Those facts included among others that the IVC Filter was safe, eliminated the risk  
15 of perforation of the vena cava, and was easy to remove. *Id.* This information “was in the form of  
16 reports, press releases, advertising campaigns, labeling materials, print advertisements,  
17 commercial media containing material representations, and instructions for use.” *Id.* ¶ 118.  
18 Information also was distributed through Defendant’s “officers, directors, agents, and  
19 representatives.” *Id.* These allegations do not provide any factual basis for inferring that  
20 Defendant lacked reasonable grounds to believe that the representations were true. Moreover, the  
21 general reference to every conceivable form of communication is insufficient to give rise to a  
22 plausible claim of negligent misrepresentation.

23 The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claim 5.

24 **E. Fraudulent Misrepresentations and Fraudulent Concealment (Claims 6 and 7)**

25 Claims 6 and 7 are for fraudulent misrepresentation and fraudulent concealment,  
26 respectively. “To establish a claim for fraudulent misrepresentation, the plaintiff must prove:  
27 (1) the defendant represented to the plaintiff that an important fact was true; (2) that representation  
28 was false; (3) the defendant knew that the representation was false when the defendant made it, or

1 the defendant made the representation recklessly and without regard for its truth; (4) the defendant  
2 intended that the plaintiff rely on the representation; (5) the plaintiff reasonably relied on the  
3 representation; (6) the plaintiff was harmed; and (7) the plaintiff's reliance on the defendant's  
4 representation was a substantial factor in causing that harm to the plaintiff." *Graham v. Bank of*  
5 *Am., N.A.*, 226 Cal. App. 4th 594, 605-06 (2014) (internal quotation marks and citation omitted).  
6 "The required elements for fraudulent concealment are: (1) concealment or suppression of a  
7 material fact; (2) by a defendant with a duty to disclose the fact to the plaintiff; (3) the defendant  
8 intended to defraud the plaintiff by intentionally concealing or suppressing the fact; (4) the  
9 plaintiff was unaware of the fact and would not have acted as he or she did if he or she had known  
10 of the concealed or suppressed fact; and (5) plaintiff sustained damage as a result of the  
11 concealment or suppression of the fact." *Id.* at 606.

12 Rule 9(b) clearly applies to these claims. *See Vess*, 317 F.3d at 1105 (allegations of  
13 misrepresentation did not satisfy Rule 9(b)); *389 Orange St. Partners v. Arnold*, 179 F.3d 656, 662  
14 (9th Cir. 1999) (applying Rule 9(b) to fraudulent concealment claim). Like her claim for negligent  
15 misrepresentation, Plaintiff's claims for fraudulent misrepresentation and fraudulent concealment  
16 lack any factual basis for inferring that Defendant knew that its representations regarding the IVC  
17 Filter were untrue. The claims also lack any details regarding the "the who, what, when, where,  
18 and how" of the alleged misconduct. *See Vess*, 317 F.3d at 1106.

19 The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claims 6 and 7.

20 **F. Breach of Express Warranty (Claim 8)**

21 Claim 8, for breach of express warranty, requires Plaintiff to allege: "the exact terms of  
22 the warranty, plaintiff's reasonable reliance thereon, and a breach of that warranty which  
23 proximately causes plaintiff injury." *Williams v. Beechnut Nutrition Corp.*, 185 Cal. App. 3d 135,  
24 142 (Cal. Ct. App. 1986). Plaintiff has not alleged the exact terms of the warranty.

25 The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claim 8.

26 **G. Breach of Implied Warranty of Merchantability (Claim 9)**

27 Plaintiff concedes that Claim 9, asserting breach of implied warranty of merchantability,  
28 fails for lack of privity. *See Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058

1 (2008) (“Privity of contract is a prerequisite in California for recovery on a theory of breach of  
2 implied warranties of fitness and merchantability.” (internal quotation marks and citation  
3 omitted)).

4 The motion to dismiss is GRANTED WITHOUT LEAVE TO AMEND as to Claim 9.

5 **H. Unjust Enrichment (Claim 10)**

6 Defendant seeks dismissal of Claim 10 on the basis that California does not recognize  
7 unjust enrichment as an independent cause of action. Relying on *Astiana v. Hain Celestial Group,*  
8 *Inc.*, 783 F.3d 753, 762 (9th Cir. 2015), this Court has held that a claim for unjust enrichment may  
9 be asserted under California law. *See Romero v. Flowers Bakeries, LLC*, No. 14-CV-05189-BLF,  
10 2015 WL 2125004, at \*9 (N.D. Cal. May 6, 2015); *see also ESG Capital Partners, LP v. Stratos*,  
11 828 F.3d 1023, 1038 (9th Cir. 2016) (“While California case law appears unsettled on the  
12 availability of such a cause of action, this Circuit has construed the common law to allow an  
13 unjust enrichment cause of action through quasi-contract.”). This Court also has rejected the  
14 notion that unjust enrichment claims should be dismissed at the pleadings stage even if they are  
15 duplicative of other claims. *See Romero*, 2015 WL 2125004, at \*9 (citing Fed. R. Civ. P. 8(d)(2)).

16 The motion to dismiss is DENIED as to Claim 10.

17 **I. §§ 17200 and 17500 (Claims 11 and 12) and Punitive Damages**

18 Plaintiff’s claims for unfair competition under California Business & Professions Code §§  
19 17200 and 17500, and her prayer for punitive damages, are grounded in allegations of fraud.  
20 Compl. ¶¶ 170 (§ 17200 claim based on “acts of untrue and misleading advertising); 176 (§ 17500  
21 claim based on “untrue or misleading statements); 249-50 (prayer for punitive damages based on  
22 Defendant’s misrepresentations and concealment of material information regarding the IVC  
23 Filter). However, Plaintiff does not allege “the who, what, when, where, and how” of the alleged  
24 misconduct with the specificity required by Rule 9(b). *See Vess*, 317 F.3d at 1106.

25 The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claims 11 and 12,  
26 and as to the prayer for punitive damages.

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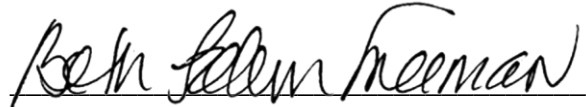


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**IV. ORDER**

- (1) The motion to dismiss is GRANTED WITH LEAVE TO AMEND as to Claims 2, 3, 5, 6, 7, 8, 11, and 12, and as to the prayer for punitive damages;
- (2) The motion to dismiss is GRANTED WITHOUT LEAVE TO AMEND as to Claims 1 and 9;
- (3) The motion to dismiss is DENIED as to Claim 10; and
- (4) Any amended complaint shall be filed on or before July 2, 2018.

Dated: May 14, 2018

  
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BETH LABSON FREEMAN  
United States District Judge