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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

DINA ANDREN and SIDNEY
BLUDMAN, individually and on
behalf of other members of the general
public similarly situated,

Plaintiffs,

CASE NO. 16cv1255-GPC(NLS)

**ORDER GRANTING
DEFENDANTS’ MOTION TO
DISMISS WITH LEAVE TO
AMEND**

[Dkt. No. 11.]

v.

ALERE, INC., a Delaware corporation
ALERE HOME MONITORING,
INC., a Delaware Corporation;
ALERE SAN DIEGO, INC., a
Delaware corporation,

Defendants.

Before the Court is Defendants’ motion to dismiss the complaint. (Dkt. No. 11.)
An opposition and reply were filed. (Dkt. Nos. 16, 17.) Based on the reasoning below,
the Court GRANTS Defendants’ motion to dismiss with leave to amend.

Background

On May 26, 2016, Plaintiffs Dina Andren (“Andren”) and Sidney Bludman

1 (“Bludman”) filed a purported class action complaint alleging that Defendants Alere,
2 Inc., Alere Home Monitoring, Inc. and Alere San Diego, Inc. (“Defendants”)
3 unlawfully, deceptively and misleadingly engaged in the manufacturing, marketing and
4 sales of the INRatio products which include “INRatio PT/INR Monitors,” “INRatio
5 PT/INR Test Strips,” “INRatio2 PT/INR Monitors” and “INRatio2 PT/INR Test Strips”
6 (collectively, the “INRatio products”). (Dkt. No. 1, Compl.)

7 In the late 1990's Defendants' predecessor, HomoSense, Inc.¹, developed and
8 manufactured the “INRatio products” which are electronic testing devices designed to
9 assist patients who have been prescribed blood-thinners, such as warfarin, to monitor
10 their blood clotting time at home. (Id. ¶¶ 2, 14, 20.) The INRatio monitor, paired with
11 the INRatio test strips are known as the “INRatio testing kit” (Id. ¶ 21.) The ability to
12 monitor and test their blood-clotting times and adjust patients' blood-thinner dosages
13 is critical as an inappropriate amount of blood-thinners can result in serious bodily
14 injury and death. (Id. ¶ 2.)

15 The International Normalized Ratio (“INR”) is a standardized metric used to
16 determine the relative speed at which blood clots in a patient's body. (Id. ¶ 17.) “A
17 patient's INR is calculated by comparing a patient's prothrombin time (the speed at
18 which the patient's blood clots) against the normal mean prothrombin time (the average
19 speed for bloodclotting in the general population). The resulting contrast between a
20 patient's prothrombin time and the normal mean prothrombin time is the patient's
21 INR.” (Id.) Doctors and patients use the INR to monitor the blood-clotting speed for
22 patients who have been prescribed blood thinners to determine whether a patient should
23 increase or decrease his/her dosage of blood thinners. (Id. ¶ 18.)

24 In October 2002, the FDA approved the INRatio testing kit for home use and
25 sales began in 2003. (Id. ¶ 22.) The “INRatio2” testing kit was later developed and

26
27 ¹In August 2007, Alere, Inc. (then known as Inverness Medical Innovation,
28 Inc.) purchased HomoSense, Inc. (Dkt. No. 1, Compl. ¶ 14.) In 2008, HomoSense,
Inc. transferred its operations to Alere, Inc.'s facility in San Diego, California. (Id.) In
2013, HomoSense, Inc.'s operations were merged into the Alere San Diego corporate
entity. (Id.)

1 operated similarly to the INRatio testing kit. (Id. ¶ 23.)

2 Sometime immediately after the INRatio products became available to the
3 public, Defendants received numerous complaints about the INRatio products' efficacy
4 and accuracy. (Id. ¶ 26.) For example, some consumers found that the INR results they
5 were getting when using the INRatio products differed from the results they obtained
6 when they sent blood from the same samples to independent labs for testing. (Id.) The
7 deviations between the INRatio products' test results and those of independent labs
8 were "clinically significant." (Id.) Between 2002 and 2014, Defendants received over
9 18,000 complaints concerning malfunctions with the INRatio products, no less than 3
10 of which resulted in deaths. (Id. ¶ 28.)

11 In May 2005, after receiving numerous complaints about the INRatio products,
12 the FDA conducted an inspection of Defendants' San Jose operations facility and
13 following the inspection, the FDA sent a warning letter admonishing them for their
14 failure to file Medical Device Reporting ("MDR") reports based on failing to report
15 complaints about "discrepant lab results" and "generating clinically significant
16 erroneous values." (Id. ¶¶ 29-33.) From May 15, 2006 through July 13, 2006, the FDA
17 conducted another inspection of the San Jose facility and on November 29, 2006, the
18 FDA sent Defendants another warning letter for numerous failure to comply with
19 statutory regulations. (Id. ¶¶ 34, 35.)

20 On April 16, 2014, Defendants issued a voluntary "Class 1" recall notice for the
21 INRatio2 test strips, citing the disparity between INR results obtained with the
22 INRatio2 system versus significantly higher INR results when re-testing was performed
23 by an independent laboratory. (Id. ¶ 38.) Defendants' recall notice requested that
24 customers immediately cease using the INRatio2 PT/INR test strips and instead use
25 alternate methods to perform INR testing. (Id.) Despite the recall, Defendants did not
26 reimburse consumers for the purchase of these dangerous devices. (Id.) On December
27 5, 2014, Defendants issued a voluntary recall letter for the INRatio PT/INR Monitor
28 and INRatio2 PT/INR Monitor, as well as the INRatio PT/INR Test Strips. The letter

1 stated, “[i]n certain cases an INRatio PT/INR Testing kit may provide an INR result
2 that is significantly lower than a result obtained using a laboratory INR system.” (Id.
3 ¶ 40.) The letter also instructed customers, inter alia, to discuss the contents of the
4 letter with their doctors and “arrange with your doctor to have your INR measured
5 using a laboratory method.” (Id.)

6 Despite receiving numerous complaints from users and multiple warning letters
7 from the FDA, notifying them that the results produced by the INRatio products
8 differed from those produced by independent laboratories, Defendants continued
9 selling the INRatio products and marketed and advertised them as “accurate,”
10 “convenient,” “effective,” “reliable,” “optimal” and “safe. (Id. ¶ 3.) As a result, due
11 to the erroneous results produced by the products, patients have been misled and have
12 caused them to improperly adjust their blood-thinner dosages increasing the risk and
13 likelihood of serious bodily injury or death. (Id. ¶ 4.)

14 Plaintiffs allege that Defendants misrepresented in its marketing advertising and
15 promotional materials that the INRatio products were “accurate” “convenient,”
16 “effective,” “reliable,” “optimal,” and “safe” and Defendants made further
17 misrepresentations to consumers by omitting material information, particularly by
18 failing to disclose that the INRatio products produce false and misleading results, from
19 the packaging and marketing materials of the INRatio testing kit. (Id. ¶ 21.)

20 Plaintiff Dina Andren suffers from a medical condition that requires her to
21 regularly take warfarin. (Id. ¶ 53.) As a result, Andren closely monitors her INR with
22 an INRatio2 PT/INR testing kit she bought from a pharmacy on April 30, 2015 for
23 \$375 and which requires her to buy numerous boxes of replacement INRatio test strips,
24 that range in price from \$240-285 per box, to continue monitoring the INR. (Id. ¶¶ 53-
25 55.) “When purchasing her INRatio products, she relied on Alere’s representations that
26 the products were accurate, convenient, effective, reliable, optimal and safe.” (Id. ¶
27 56.) Were it not for these representations or had she known that Alere was omitting that
28 it knew its products produced erroneous INR results, Andren would not have purchased

1 or used the INRatio products. (Id.)

2 On the morning of May 24, 2015, Andren tested her INR using her INRatio2
3 testing kit. (Id. ¶ 57.) The test results indicated an INR of 2.7 and believing her INR
4 was above 2.5, Plaintiff Andren did not take Lovenox. (Id.) Later that day, Plaintiff
5 Andren was rushed to the hospital where doctors determined she had suffered a stroke.
6 (Id. ¶ 58.) Following her stroke, Andren continued using her INRatio2 and
7 accompanying test strips to closely monitor her INR and adjust her warfarin dosage
8 accordingly. (Id. ¶ 59.) In July of 2015, after having carefully monitored and regulated
9 her INR with the INRatio 2 testing kit for over a month following her stroke, Andren
10 suffered a Transient Ischemic Attack (“TIA”), otherwise known as a “mini-stroke.”
11 (Id. ¶ 60.) When Andren returned home, she continued to use her INRatio2 testing kit
12 to monitor her INR and had another TIA in March 2016. (Id. ¶¶ 61, 62.) While at the
13 hospital, Andren was informed, for the first time, that her INRatio2 testing kit had been
14 the subject of a Class 1 recall. (Id. ¶ 63)

15 Plaintiff Sidney Bludman has suffered from a medical condition that requires
16 him to regularly take warfarin for 28 years. (Id. ¶ 65.) For approximately 26 years,
17 Bludman would have his INR tested once a month in a laboratory. (Id. ¶ 66.) For all
18 26 years, his INR remained fairly consistent and required very infrequent minor
19 adjustments of his warfarin dosage. (Id.)

20 Bludman began using an INRatio2 PT/INR testing kit to regularly monitor his
21 INR at home in 2013 and he was required to purchase boxes of replacement INRatio2
22 test strips in order to continue with his periodic INR testing and each contained 24
23 replacement test strips that costs about \$120. (Id. ¶¶ 67, 68.) “In using the INRatio
24 products, Bludman relied on Alere’s representations that the products were accurate,
25 convenient, effective, reliable, optimal and safe.” (Id. ¶ 69.) Were it not for these
26 representations, and the omission of material information that INRatio products
27 produced erroneous results, Bludman would not have purchased or used the INRatio
28 products. (Id.)

1 In February of 2016, his INR, tested on his INRatio2 testing kit, became
2 exceedingly high and based on the high INR, Bludman reduced his warfarin dosage
3 which caused him to suffer a TIA on February 10, 2016. (Id. ¶¶ 70, 71.) Upon
4 returning home from the hospital, Bludman began monitoring his INR with his
5 INRatio2 testing kit and compared those results with the results of blood tests
6 conducted by a laboratory at his hospital. (Id. ¶ 72.) He found that his INR, as
7 indicated by his INRatio2 testing kit, was consistently .4-.6 higher than his INR, as
8 indicated by the results of the lab tests. (Id.) As a result of his TIA, Bludman is now
9 at a higher risk for future ischemic attacks. (Id. ¶ 73.)

10 Plaintiff alleges four causes of action for violations of California’s Consumers
11 Legal Remedies Act (“CLRA”), California’s Unfair Competition Law pursuant to
12 California Business & Professions Code section 17200 *et seq.* (“UCL”), fraud and
13 unjust enrichment. (Dkt. No. 1. Compl.) Defendants move to dismiss all four causes
14 of action based on Plaintiffs’ failure to satisfy the pleading requirements of Federal
15 Rule of Civil Procedure 9(b) for their allegations of material misrepresentations and
16 fraudulent omissions.

17 **A. Defendants’ Request for Judicial Notice**

18 In their opposition, Defendants request judicial notice of numerous documents
19 arguing that either they are referenced in the Complaint or they are matters of public
20 record and not subject to reasonable dispute. (Dkt. No. 11-1.) In response, Plaintiffs
21 object as to Exhibit B, “Alere INRatio2 Self-Test User Guide”, and Exhibit A, “FDA
22 501(k) Substantial Equivalence Determination Decision Summary” (“501(k)
23 Summary”). (Dkt. No. 17.) Plaintiffs object because Defendants are not using the
24 existence of these documents to attack the Complaint on its face but are relying on the
25 contents of the documents to assert merits-based defenses to Plaintiffs’ allegations.
26 They also object because the User Guide is not authenticated. In reply, Defendants
27 argue that these documents are proper for judicial notice.

28 As a general rule, “a district court may not consider any material beyond the

1 pleadings in ruling on a Rule 12(b)(6) motion.” Lee v. City of Los Angeles, 250 F.3d
2 668, 688 (9th Cir. 2001). However, two exceptions exist where a district court may
3 take consider “material which is properly submitted as part of the complaint” or if the
4 documents are not attached to the complaint, they may be considered if the documents’
5 “authenticity . . . is not contested” and “the plaintiff’s complaint necessarily relies” on
6 them. Id. (citations omitted). In addition, a court may take judicial notice of “matters
7 of public record” under Federal Rule of Civil Procedure (“Rule”) 201. Id. at 688-89.
8 Under Rule 201, a court may not take judicial notice of a fact that is “subject to
9 reasonable dispute.” Fed. R. Evid. 201(b). If the contents of a matter of public record
10 are in dispute, the court may take notice of the fact of the document at issue but not of
11 the disputed information contained within. See Lee, 250 F.3d at 689-90.

12 Here, as to Exhibit B, the Complaint does not cite to or rely on the User Guide,
13 the User Guide is not a matter of public record and Plaintiffs challenge its authenticity.
14 Therefore, judicial notice of the User Guide is not proper and the Court DENIES
15 Defendants’ request for judicial notice as to Exhibit B. Furthermore, as Plaintiffs note
16 and the Court agrees, Defendants ask the Court to consider documents outside the
17 complaint and to rule on a factual issue not proper on a motion to dismiss. In their
18 motion, Defendants seek dismissal of the complaint arguing that the User Guide
19 provides sufficient disclosures concerning the INRatio products and that they did not
20 omit material information. While Defendants argue that their disclosures were
21 sufficient, such a ruling is not proper at the motion to dismiss stage.

22 As to Exhibit A, Plaintiffs argue that Defendants improperly cite to the contents
23 of the 510(k) Summary asserting in their motion that “Patients can obtain these devices
24 only with a prescription.” (Dkt. No. 11, Ds’ Mot. at 8.) Plaintiffs dispute that Alere
25 INRatio2 PT/INR can be only be obtained with a prescription and state they allege, in
26 their complaint, that Andren purchased the product from a pharmacy absent a
27 prescription. (Dkt. No. 17 at 4.) Contrary to Plaintiffs’ argument, the Complaint does
28 not allege Andren purchased the INRatio2 PT/INR “absent a prescription.” Despite

1 Plaintiffs’ failure to assert that Andren purchased the product without a prescription,
2 because Plaintiffs dispute their contents, the Court can only take judicial notice of the
3 fact of the document and not the contents contained in the document. See Lee, 250
4 F.3d at 689-90. Accordingly, the Court DENIES Defendants’ request for judicial
5 notice of Exhibits A & B. The Court GRANTS Defendants’ request for judicial notice
6 of Exhibits C through G as they are matters of public record and are unopposed.

7 **B. Legal Standard on Federal Rule of Civil Procedure 12(b)(6)**

8 Federal Rule of Civil Procedure (“Rule”) 12(b)(6) permits dismissal for “failure
9 to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). Dismissal
10 under Rule 12(b)(6) is appropriate where the complaint lacks a cognizable legal theory
11 or sufficient facts to support a cognizable legal theory. See Balistreri v. Pacifica Police
12 Dep’t., 901 F.2d 696, 699 (9th Cir. 1990). Under Rule 8(a)(2), the plaintiff is required
13 only to set forth a “short and plain statement of the claim showing that the pleader is
14 entitled to relief,” and “give the defendant fair notice of what the . . . claim is and the
15 grounds upon which it rests.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555
16 (2007).

17 A complaint may survive a motion to dismiss only if, taking all well-pleaded
18 factual allegations as true, it contains enough facts to “state a claim to relief that is
19 plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly,
20 550 U.S. at 570). “A claim has facial plausibility when the plaintiff pleads factual
21 content that allows the court to draw the reasonable inference that the defendant is
22 liable for the misconduct alleged.” Id. “Threadbare recitals of the elements of a cause
23 of action, supported by mere conclusory statements, do not suffice.” Id. “In sum, for
24 a complaint to survive a motion to dismiss, the non-conclusory factual content, and
25 reasonable inferences from that content, must be plausibly suggestive of a claim
26 entitling the plaintiff to relief.” Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir.
27 2009) (quotations omitted). In reviewing a Rule 12(b)(6) motion, the Court accepts as
28 true all facts alleged in the complaint, and draws all reasonable inferences in favor of

1 the plaintiff. al-Kidd v. Ashcroft, 580 F.3d 949, 956 (9th Cir. 2009).

2 Where a motion to dismiss is granted, “leave to amend should be granted ‘unless
3 the court determines that the allegation of other facts consistent with the challenged
4 pleading could not possibly cure the deficiency.’” DeSoto v. Yellow Freight Sys., Inc.,
5 957 F.2d 655, 658 (9th Cir. 1992) (quoting Schreiber Distrib. Co. v. Serv-Well
6 Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986)). In other words, where leave to
7 amend would be futile, the Court may deny leave to amend. See Desoto, 957 F.2d at
8 658; Schreiber, 806 F.2d at 1401.

9 **C. Legal Standard as to Federal Rule of Civil Procedure 9(b)**

10 Where a plaintiff alleges fraud in the complaint, Rule 9(b) requires a plaintiff to
11 “state with particularity the circumstances constituting fraud or mistake. Malice, intent,
12 knowledge, and other conditions of a person’s mind may be alleged generally.” Fed.
13 R. Civ. P. 9(b). A party must set forth “the time, place, and specific content of the false
14 representations as well as the identities of the parties to the misrepresentation.” Odom
15 v. Microsoft Corp., 486 F.3d 541, 553 (9th Cir. 2007) (internal quotation marks
16 omitted). Rule 9(b) also applies to claims that are “grounded in fraud” or “sound in
17 fraud.” Vess v. Ciba-Geigy Corp., U.S.A., 317 F.3d 1097, 1103-04 (9th Cir. 2003).
18 Asserting that the defendant “‘knowingly and purposefully failed to disclose’” the
19 alleged defect is subject to Rule 9(b), since that amounts to an allegation of knowledge
20 of falsity and intent to defraud.” Shin v. BMW of North America, No. CV 09-00395
21 AHM (AJWx), 2009 WL 2163509, at *4 (C.D. Cal. July 16, 2009).

22 Defendants argue that the complaint fails to meet the heightened pleading
23 requirements under Rule 9(b) for failing to allege that they made any affirmative
24 representations specifically to Plaintiffs, that Plaintiffs relied on any such
25 misrepresentations or that Alere had any duty to disclose information not already
26 disclosed by the Alere entities. Plaintiffs do not dispute that the heightened pleading
27 requirement applies but argue that they have sufficiently alleged particularity as to the
28 alleged affirmative misrepresentations and omissions.

1 Plaintiffs allege four causes of action for violations of the CLRA, the UCL,
2 fraud, and unjust enrichment. (Dkt. No. 1. Compl.) All causes of action in the
3 Complaint either allege fraud or sound in fraud where Plaintiffs' allegations are
4 premised on a uniform course of fraudulent conduct, (Dkt. No. 1. Compl. ¶¶ 93, 94, 99
5 (CLRA), ¶¶ 104, 110 (UCL), ¶¶ 113-121 (fraud), and ¶ 125 (unjust enrichment));
6 therefore, all claims are subject to the heightened pleading standard of Rule 9(b). See
7 Vess, 317 F.3d at 1103-04 (holding that when a plaintiff "allege[s] a unified course of
8 fraudulent conduct and rely entirely on that course of conduct as the basis of a claim.
9 . . . the claim is said to be 'ground in fraud' or to 'sound in fraud,' and the pleading of
10 that claim as a whole must satisfy the particularity requirement of Rule 9(b)."). The
11 Ninth Circuit has held that claims of nondisclosure and omissions are subject to the
12 pleading standard of Rule 9(b). Kearns v. Ford Motor Co., 567 F.3d 1120, 1126-27
13 (9th Cir. 2009) (applying Rule 9(b) to fraud claims under the CLRA and UCL).

14 All four causes of action are premised on material misrepresentations and
15 fraudulent omissions; therefore, the Court looks at whether Plaintiffs have satisfied
16 Rule 9(b) in asserting these allegations.

17 **1. Material Misrepresentations**

18 First, Defendants argue that Plaintiffs failed to allege they ever viewed or relied
19 on a representation made by them. In responding, Plaintiffs assert that Defendants
20 made material misrepresentations in their packaging, marketing, advertising and
21 promotional materials where they claimed the INRatio products were "accurate"
22 "convenient" "effective" "reliable" "optimal" and "safe" when in fact they were not.
23 (Dkt. No. 1, Compl. ¶¶ 21, 24-27.) Plaintiffs also argue that they do not need to prove
24 reliance as there is a presumption of reliance in a fraudulent omission case or
25 misrepresentation case.²

27 ²Plaintiffs' citation to cases pleading reliance in federal securities fraud under
28 Rule 10b-5 case are not persuasive. See Binder v. Gillespie, 184 F.3d 1059, 1063-64
(9th Cir. 1999); Affiliated Ute Citizens v. United States, 406 U.S. 128, 153-54 (1972).
In Mirkin, the California Supreme Court rejected the application of the Ute

1 A cause of action under UCL requires that plaintiff must plead reliance and it can
2 do so without alleging that those misrepresentation were the “sole or even the decisive
3 cause of the injury-producing conduct,” In re Tobacco II Cases, 46 Cal. 4th 298, 328
4 (2009). However, where there are underlying allegations of fraud, where the claim is
5 “grounded in fraud”, Rule 9(b) applies to California’s consumer protection statutes.
6 Kearns, 567 F.3d at 1125. The pleading, as a whole, must comply with Rule 9(b). Id.

7 In Kearns, the plaintiff, alleged claims under the CLRA and UCL, for
8 defendants’ misrepresentations and fraud regarding its “certified pre owned” vehicle
9 program. Id. at 1122. The Ninth Circuit upheld the district court’s dismissal because
10 the plaintiff failed to specify when he was exposed to the representations and which
11 sales material he relied on in making his decision to buy the product. Id. at 1126
12 (concluding that plaintiff did not articulate the “who, what, when, where, and how of
13 the misconduct alleged”). A party must set forth “the time, place, and specific content
14 of the false representations as well as the identities of the parties to the
15 misrepresentation.” Odom v. Microsoft Corp., 486 F.3d 541, 553 (9th Cir. 2007)
16 (internal quotation marks omitted); Buckley v. Align Tech., Inc., No. 13cv2812-EJD,
17 2015 WL 5698751, at *3 (N.D. Cal. 2015) (plaintiff failed to identify any false or
18 misleading statements made to her by Defendant.)

19 In addition, “Rule 9(b)’s particularity requirement can be satisfied by ‘identifying
20 or attaching representatives samples’ if the alleged misrepresentations occur in printed
21 form.” Shields v. Alere Home Monitoring, Inc., No. C-15-2580 CRB, 2015 WL
22 7272672, at *6 (N.D. Cal. Nov. 18, 2015) (citations omitted). However, a plaintiff
23 must specify what the misrepresentations stated, when he or she was exposed to the
24 misrepresentation and which ones he or she found material. See Kearns, 567 F.3d at

25 _____
26 presumption of reliance, to California law. Mirkin, 5 Cal. 4th 1082, 1093 (1993) (the
27 “body of law that has developed under Rule 10b-5 is not sufficiently analogous to the
28 law of fraud to justify its importation into the latter.”). The other district court cases
cited by Plaintiffs are not applicable because those cases do not assert UCL or CLRA
claims grounded in fraud. See Shin v. BMW of North America, No. CV 09-398, 2009
WL 2163509, at *4 (C.D. Cal. July 16, 2009); Delarosa v. Boiron, Inc., 275 F.R.D. 582,
586 (C.D. Cal. 2011).

1 1125-26.

2 The Complaint alleges that when Andren and Bludman purchased the INRatio2
3 PT/INR testing kits, they “relied on Alere’s representations that the products were
4 accurate, convenient, effective, reliable, optimal and safe.” (Id. ¶¶ 56, 69.) These are
5 merely general allegations that do not allege where Plaintiffs saw or heard the
6 representations, such as through Defendants’ marketing, advertising, promotional or
7 packaging materials, and when they saw those representations. In addition, Plaintiffs,
8 in the Complaint, insert a copy of a web page for the Alere INRatio2 PT/INR
9 Monitoring System, (Dkt. No. 1, Compl. ¶ 25), concerning the alleged
10 misrepresentations; however, again, Andren and Bludman do not allege that they ever
11 saw or relied on this web page. Therefore, Plaintiffs cannot link their injuries to those
12 alleged misrepresentations. The Complaint makes numerous allegations as to the
13 alleged material misrepresentations in Defendants’ marketing, advertising,
14 promotional, and packaging³ materials but do not specifically allege when and where
15 Andren and Bludman saw the misrepresentations. Accordingly, the Court GRANTS
16 Defendants’ motion to dismiss all claims under Rule 9(b) premised on material
17 misrepresentations.

18 2. Fraudulent Omissions

19 Next, Defendants argue that Plaintiffs have not alleged a duty to disclose the
20 alleged fraudulently omitted facts. Plaintiffs contend that they have sufficiently alleged
21 a duty to disclose.

22 “In order to state a claim of fraudulent omissions under the UCL/FAL, CLRA,
23 or as a claim of common law fraud, a plaintiff must allege facts either showing that the
24 alleged omissions are ‘contrary to a representation actually made by the defendant, or
25 showing an omission of a fact the defendant was obliged to disclose.’” Davidson v.

26
27 ³The Complaint alleges misrepresentations were also made on the packaging.
28 (Dkt. No. 1, Compl. ¶¶ 21, 24, 108, 119.) In their opposition, Plaintiffs discuss the
package insert, the “User Guide”, and state “as a matter of law, any disclosures made
to Plaintiffs after they purchased the INRatio Products are irrelevant.” (Dkt. No. 16 at
17.) It is not clear whether Plaintiffs are alleging reliance on the packaging or not.

1 Kimberly-Clark Corp., 76 F. Supp. 3d 964, 972 (N.D. Cal. 2014) (quoting Daugherty
2 v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 835 (2006)).

3 “The required elements for fraudulent concealment are (1) concealment or
4 suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the
5 plaintiff; (3) the defendant intended to defraud the plaintiff by intentionally concealing
6 or suppressing the fact; (4) the plaintiff was unaware of the fact and would not have
7 acted as he or she did if he or she had known of the concealed or suppressed fact; and
8 (5) plaintiff sustained damage as a result of the concealment or suppression of the fact.”
9 Graham v. Bank of America, N.A., 226 Cal. App. 4th 594, 606 (2014) (citation
10 omitted).

11 The parties argue that there are four circumstances in which an obligation to
12 disclose may arise “(1) when the defendant is in a fiduciary relationship with the
13 plaintiff; (2) when the defendant had exclusive knowledge of material facts not known
14 to the plaintiff; (3) when the defendant actively conceals a material fact from the
15 plaintiff; and (4) when the defendant makes partial representations but also suppresses
16 some material facts.” LiMandri v. Judkins, 52 Cal. App. 4th 326, 336 (1997). The
17 same duty to disclose also applies to UCL and CLRA causes of action. Baba v.
18 Hewlett-Packard Co., No. C 09-05946 RS, 2010 WL 2486353, at *7 (N.D. Cal. June
19 16, 2010).

20 Defendants argue that Plaintiffs have not alleged a duty to disclose.⁴ According
21 to Plaintiffs, the Complaint alleges a duty based on Defendants’ exclusive knowledge
22 of material facts, that INRatio products produced false and erroneous results, not
23 known to them and that Defendants actively concealed material facts from Plaintiffs.
24 (Dkt. No. 1, Compl. ¶¶ 26-41.)

25 A defendant has exclusive knowledge giving rise to a duty to disclose when

26
27 ⁴Defendants also argue that they did not fail to disclose the discrepant results of
28 the INRatio products because the User Guide disclosed such information. Since the
Court denied Defendants’ request for judicial notice of the User Guide, Defendants’
argument based on the User Guide is without merit.

1 “according to the complaint, [defendant] knew of this defect while plaintiffs did not,
2 and, given the nature of the defect, it was difficult to discover.” Collins v. eMachines,
3 Inc., 202 Cal. App. 4th 249, 256 (2011); Falk v. General Motors Corp., 496 F. Supp.
4 2d 1088, 1096 (N.D. Cal. 2007) (a duty to disclose exists “when the defendant [s] had
5 exclusive knowledge of material facts not known to plaintiff[s].”). “[G]eneralized
6 allegations with respect to exclusive knowledge” are insufficient to defeat a dismissal
7 motion. Hovsepian v. Apple, Inc., No. 08–5788 JF (PVT), 2009 WL 5069144, at *3
8 (N.D. Cal. Dec. 17, 2009).

9 Here, Plaintiff alleges that Defendants had exclusive knowledge of material facts
10 and cites to paragraphs 26-37 of the Complaint. (Dkt. No. 16 at 15.) These paragraphs
11 do not support the allegation that Defendants had exclusive knowledge. For example,
12 the Complaint references a publication in 2007 where a study conducted testing on INR
13 testing devices, and the INRatio products performed the worst, with results that
14 deviated most significantly from the results obtained through an outside laboratory.
15 (Dkt. No. 1, Compl. ¶ 27 & n. 4.) In addition, the Complaint references and attaches
16 an FDA warning letter of 2005 posted on its website noting the discrepant values.
17 (Dkt. No. 1, Compl. ¶ 30; Dkt. No. 1-2, Ex. A to Compl.) The Complaint also
18 references and attaches recall letters dated April 16, 2014 and December 5, 2014 that
19 were sent to consumers and healthcare professionals concerning the different test
20 results between INRatio products and INR tested in a laboratory. (Dkt. No. 1-4, Ex.
21 C to Compl; Dkt. No. 1-5, Ex. D to Compl.) These allegations demonstrate that the
22 material facts were not within the exclusive knowledge of Defendants but available to
23 the public. Plaintiffs’ own allegations refute their claim that Defendants had “exclusive
24 knowledge of a material fact.” See Wolph v. Acer Am. Corp., No. C 09–01314 JSW,
25 2009 WL 2969467, at *4 (N.D. Cal. Sept. 14, 2009) (“[b]ased on Plaintiff[‘s] own
26 allegations, Plaintiff [has] not alleged facts that show [Defendants] had exclusive
27 knowledge of the [omitted] material facts and that Plaintiff[] could not have
28 reasonably discovered such facts.”); Stickrath v. Globalstar, Inc., No. C07–1941 THE,

1 2008 WL 344209, at *4 (N.D. Cal. Feb. 6, 2008) (allegation in complaint do not appear
2 to support an allegation of exclusivity since Plaintiffs allege disclosure by Defendant
3 “in public filings” and in “an application with the FCC”). Therefore, Plaintiffs fails to
4 assert a duty to disclose based on exclusive knowledge of a material fact.

5 In addition, as to Plaintiffs’ allegation that Defendants actively concealed
6 material facts from them, Plaintiff must allege specific “affirmative acts on the part of
7 the [D]efendants in hiding, concealing or covering up the matters complained of.”
8 Herron v. Best Buy Co. Inc., 924 F. Supp. 2d 1161, 1176 (E.D. Cal. 2013) (quoting
9 Lingsch v. Savage, 213 Cal. App. 2d 729 734 (1963)). As with exclusive knowledge,
10 “generalized allegations with respect to . . . active concealment” will not do. Id.
11 (citing Hovsepian v. Apple, Inc., No. 08-5788 JF (PVT), 2009 WL 5069144, at *3
12 (N.D. Cal. Dec. 17, 2009).

13 Here, Plaintiffs make general conclusory allegations of active concealment, (Dkt.
14 No. 1, Compl. ¶¶ 50, 120), without specific facts that Defendants actively tried to
15 conceal the discrepant results; therefore, Plaintiffs have failed to assert a duty to
16 disclose based on active concealment. See Herron, 924 F. Supp. 2d at 1176 (granting
17 motion to dismiss on active concealment allegation based on general assertion that
18 defendants “actively concealed material facts from Plaintiff and the Class.”)

19 Because Plaintiffs have failed to assert a duty to disclose, the Court GRANTS
20 Defendants’ motion to dismiss under Rule 9(b) all causes of action premised on
21 fraudulent omission.

22 **D. Unjust Enrichment**

23 Unjust enrichment is not a cause of action but a “principle underlying various
24 doctrines and remedies, including quasi-contract.” Jogani v. Superior Court, 165 Cal.
25 App. 4th 901, 911 (2008). A claim for unjust enrichment cannot stand alone as an
26 independent claim for relief. See Oestreicher v. Alienware Corp., 544 F. Supp. 2d 964,
27 975 (N.D. Cal. 2008) (“since plaintiff's fraud-based claims have been dismissed,
28 plaintiff has no basis for its unjust enrichment claim.”); Sanders v. Apple Inc., 672 F.

1 Supp. 2d 978, 989 (N.D. Cal. 2009) (“[unjust enrichment] claim will depend upon the
2 viability of the Plaintiffs’ other claims.”).

3 In this case, since Plaintiffs have failed to allege a cause of action for relief, the
4 unjust enrichment claim also must be dismissed.

5 **E. Learned Intermediary Doctrine**

6 In their moving papers, in describing that medical devices are not typical
7 consumer products, Defendants raise the learned intermediary doctrine asserting that
8 a manufacturer’s duty to warn runs to the physician and not the patient but does not
9 explain which cause of action is deficient based on this doctrine. In opposition,
10 Plaintiffs notes the deficiency in Defendants’ argument and further argue that if the
11 learned intermediary doctrine applied, it is a fact-based defense to be determined at
12 summary judgment or at trial and they also argue that the doctrine does not apply
13 because INRatio products are not exclusively prescription devices and can be bought
14 without a prescription.

15 California applies the “learned intermediary” doctrine which provides that the
16 duty to warn in the case of medical devices runs to the physician, not the patient.
17 Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 (1992) (prescription implanted
18 medical device case); see also Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996).
19 A manufacturer fulfills its duty to warn if it provides adequate warnings to the
20 physician. Plenger, 11 Cal. App. 4th at 362 n. 6 (citing cases); see also Brown v.
21 Superior Court, 44 Cal.3d 1049, 1062 n. 9 (1998). In order to prove causation, a
22 plaintiff must allege that the inadequate warning or lack of warning about the medical
23 device risk would have altered the prescribing physician’s decision to use the product.
24 Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); Motus v. Pfizer Inc.,
25 358 F.3d 659, 661 (9th Cir. 2004) (“[A] product defect claim based on insufficient
26 warnings cannot survive summary judgment if stronger warnings would not have
27 altered the conduct of the prescribing physician.”). Plaintiffs must also show that the
28 failure to warn caused their injuries. Motus, 196 F. Supp. 2 at 991.

1 One district court has held that the learned intermediary doctrine applies to state
2 consumer protections laws, such as the CLRA and UCL, but only if the claims are
3 predicated on a failure to warn. Saavedra v. Eli Lilly and Co., No. 12cv9366-SVW-
4 MAN, 2013WL 3148923, at *3-4 (C.D. Cal. June 13, 2013). As one district court in
5 Texas noted,

6 The gravamen of all of Plaintiffs' causes of action, including
7 misrepresentation and violation of [Texas's Deceptive Trade Practices
8 Act, "DTPA"], is that [the defendant drug manufacturer] failed to
9 adequately warn of or disclose the severity of Norplant's side effects.
10 Therefore, the learned intermediary doctrine applies to all of Plaintiffs'
11 causes of action. Additionally, whether the failure to warn is couched
12 as an affirmative misrepresentation or a misrepresentation by
concealment, the allegation collapses into a charge that the drug
manufacturer failed to warn. If the doctrine could be avoided by
casting what is essentially a failure to warn claim under a different
cause of action such as violation of the DTPA or a claim for
misrepresentation, then the doctrine would be rendered meaningless.

13 In re Norplant Contraceptive Prods. Liability Litigation, 955 F. Supp. 700, 709 (E.D.
14 Tex. 1997).

15 Here, the Complaint does not assert a failure to warn cause of action; however,
16 it appears that the misrepresentations and omissions claims are based on a failure to
17 warn of the INRatio products' discrepant results. Plaintiffs argue, but do not allege in
18 the complaint, that Andren purchased the INRatio2 testing kit at a pharmacy and
19 therefore, the doctrine does not apply. Given that Plaintiffs are granted leave to amend,
20 they should clarify whether the INRatio2 was prescribed by Andren's doctor or not.
21 If INRatio2 was prescribed by a physician, then the doctrine applies to their case⁵ and
22 if so, Plaintiffs must properly allege a failure to warn Plaintiffs' prescribing physician
23 in an amended complaint. See Tapia v. Davol, Inc., 116 F. Supp. 3d 1149, 1159 (S.D.
24 Cal. 2015) (granting motion to dismiss failure to warn cause of action because the
25 plaintiff failed to allege that the defendants failed to warn his prescribing physician but
26 only alleged "physician" in general); see Buckely v. Align Tech, Inc., No. 13cv2812-

27
28 ⁵Nonetheless, it would appear that the learned intermediary doctrine would apply
as to Plaintiff Bludman because Plaintiffs do not argue that he purchased his INRatio2
PT/INR testing kit at a pharmacy.

1 EJD, 2015 WL 5698751, at *4 (N.D. Cal. Sept. 29, 2015) (to the extent the plaintiff
2 alleges a failure to warn, those claims fail due to the failure to allege that her dentist
3 was misled by the defendant).

4 **F. Leave to Amend**


5 Leave to amend, whether or not requested by the plaintiff, should be granted
6 unless amendment would be futile. Schreiber Distrib. Co., 806 F.2d at 1401. While
7 Plaintiffs do not seek leave to amend, the Court concludes that it would not be futile
8 to allow leave to amend and GRANTS Plaintiffs' leave to amend their complaint. See
9 id.

10 **Conclusion**

11 Based on the above, the Court GRANTS Defendants' motion to dismiss with
12 leave to amend. If Plaintiffs seek to amend the complaint, they shall file an amended
13 complaint within 20 days of the filing date of this order. If Plaintiffs do not seek to file
14 an amended complaint, they shall file a notice of voluntary dismissal within 20 days
15 of the filing date of this order. The hearing date set for September 16, 2016 shall be
16 vacated.

17 IT IS SO ORDERED.

18
19 DATED: September 13, 2016

20 
21 HON. GONZALO P. CURIEL
22 United States District Judge
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