UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

PAMELA COLEMAN, et al., **Plaintiffs,** **v.** **BOSTON SCIENTIFIC CORPORATION, et al.,** **Defendants.**	**1:10-cv-01968-OWW-SKO** **MEMORANDUM DECISION REGARDING MOTION TO DISMISS (Doc. 9)**

I. INTRODUCTION.

Plaintiffs Pamela Coleman ("Coleman"), Mary Bower ("Bower"), and Kathleen Paison ("Paison") (collectively "Plaintiffs") proceed with an action for damages against Boston Scientific Corporation ("Defendant") and various Doe Defendants.

Defendant filed a motion to dismiss Plaintiffs' complaint on February 26, 2011. (Doc. 9). Plaintiffs filed opposition to the motion to dismiss on March 28, 2011. (Doc. 13). Defendant filed a reply on April 4, 2011. (Doc. 17).

II. FACTUAL BACKGROUND.

Plaintiffs are three individuals who underwent medical procedures described as "transvaginal tape, bladder sling, urethral suspension, and cystocele repair" in the United States between August 2005 and December 2006. Coleman, a resident of Bakersfield,

California, underwent her procedures in December 2006. Bower, a resident of Grand Rapids, Michigan, underwent her procedure in April 2006. Paison, a resident of Westland, Michigan, underwent her procedure in August 2005. The complaint does not allege where each Plaintiff had her procedure performed.

Defendant designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed, and sold synthetic surgical mesh devices purported to correct and restore normal vaginal structure secondary to pelvic organ prolapse. Plaintiffs' received implants of mesh devices manufactured, marketed, and sold by Defendant in connection with their respective transvaginal tape, bladder sling, urethral suspension, and cystocele repair procedures. Since implantation of the mesh devices, Plaintiffs have suffered from erosion, shrinkage, and extrusion of mesh from one or more of the mesh devices, causing urinary retention, severe persistent pain, including dyspareunia, and numerous surgical procedures to remove the mesh devices.

At all times relevant, the mesh devices were widely advertised and promoted by Defendants as a safe and effective treatment for pelvic organ prolapse, rectocele, enterocele, and stress urinary incontinence. Defendants minimized the risks posed to patients by implantation of the mesh devices. At all times relevant, Defendants knew that the devices were not safe because the mesh eroded and otherwise malfunctioned causing injuries from erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions, and worsening dyspareunia. Defendants made false representations regarding the consistency, safety, reliability, and performance of the mesh devices in published literature and adverse

event reports. Defendants failed to disclose to physicians, patients, or Plaintiffs that their mesh devices were subject to erosion or scar tissue formation causing injuries.

Defendants continued to promote the mesh devices as safe and effective even when no clinical trials had been done; in doing so, Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the mesh devices for pelvic organ prolapse, rectocele, enterocele, and stress urinary incontinence.

III. LEGAL STANDARD.

Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks sufficient facts to support a cognizable legal theory. Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir.1990). To sufficiently state a claim to relief and survive a 12(b) (6) motion, the pleading "does not need detailed factual allegations" but the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). Mere "labels and conclusions" or a "formulaic recitation of the elements of a cause of action will not do." Id. Rather, there must be "enough facts to state a claim to relief that is plausible on its face." Id. at 570. In other words, the "complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, --- U.S. ----, ----, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (internal quotation marks omitted).

The Ninth Circuit has summarized the governing standard, in light of Twombly and Iqbal, as follows: "In sum, for a complaint to

survive a motion to dismiss, the nonconclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir.2009) (internal quotation marks omitted). Apart from factual insufficiency, a complaint is also subject to dismissal under Rule 12(b)(6) where it lacks a cognizable legal theory, Balistreri, 901 F.2d at 699, or where the allegations on their face "show that relief is barred" for some legal reason, Jones v. Bock, 549 U.S. 199, 215, 127 S.Ct. 910, 166 L.Ed.2d 798 (2007).

In deciding whether to grant a motion to dismiss, the court must accept as true all "well-pleaded factual allegations" in the pleading under attack. Iqbal, 129 S.Ct. at 1950. A court is not, however, "required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir.2001). "When ruling on a Rule 12(b)(6) motion to dismiss, if a district court considers evidence outside the pleadings, it must normally convert the 12(b)(6) motion into a Rule 56 motion for summary judgment, and it must give the nonmoving party an opportunity to respond." United States v. Ritchie, 342 F.3d 903, 907 (9th Cir.2003). "A court may, however, consider certain materials-documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice-without converting the motion to dismiss into a motion for summary judgment." Id. at 908.

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IV. DISCUSSION.

A. Product Identification

As an initial matter, Defendants contend that the complaint does not allege facts sufficient to permit identification of the particular "mesh products" underlying Plaintiffs' claims. Defendants argue that, absent identification of a specific product, the complaint fails to plead the specific facts required to raise a plausible claim for relief. (Doc. 9, MTD at 3-4). Defendants cite *Timmons v. Linvatec Corp.*, 263 F.R.D. 582, 584-85 (C.D. Cal. 2010) and *Adams v. I-Flow Corp.*, Adams v. I-Flow Corp., 2010 WL 1339948 *3 (C.D. Cal. 2010); 2010 U.S. Dist. LEXIS 33066, for the proposition that "if a plaintiff fails to specifically identify the product at issue in their Complaint, they [sic] cannot satisfy the necessary pleading requirements and their claims must be dismissed." (MTD at 4). Neither *Timmons* nor *Adams* support the onerous pleading burden Defendants advance.

In *Adams*, the complaint did not allege that any of the named defendants manufactured the allegedly defective device that caused the plaintiffs injuries:

> The Complaint does not allege that any particular plaintiff was administered a particular drug through a particular pain pump that was manufactured by a particular defendant. Instead, plaintiffs plead only generally that they were injured by pain pumps and anesthetics of the type made by defendants. By suing fourteen (14) "Defendant Pain Pump Manufacturers" and eight (8) "Defendant Anesthetic Manufacturers," the Complaint at most alleges that the individual defendants theoretically could have been the one who manufactured the pain pump or anesthetic used following each plaintiff's surgery. But, the Complaint never specifies that any one of the defendants, as opposed to the 21 other defendants, caused each plaintiff's claimed injury. As such, plaintiffs plead nothing more than the sheer possibility that any particular defendant might have manufactured the product that allegedly injured each

> plaintiff. This sort of speculative pleading is not permitted under the plain text of Rule 8, which requires a "statement of the claim showing that the pleader is entitled to relief."

Id. at 7-8. Similarly, the complaint in *Timmons*:

> allege[d] Mrs. Timmons sustained a shoulder injury as a result of receiving an unidentified "anesthetic medication." Plaintiffs sue[d] AstraZeneca as one of eight "defendant anesthetic manufacturers," but fail[ed] to allege that AstraZeneca manufactured the particular medication administered to Ms. Timmons after her single surgery. Thus, the Complaint [did] not allege that AstraZeneca, as opposed to one of the other anesthetic manufacturer defendants, caused Plaintiffs' alleged injuries.

263 F.R.D. at 584. *Timmons* does not support Defendants' ambitious construction of Rule 8, which would require plaintiffs in any medical product liability case to "specifically identify" the products at issue in order to satisfy federal pleading standards. Rather, *Timmons* stands for the unremarkable proposition that a plaintiff must allege that a particular defendant caused her injury. *See id.* ("The Complaint fails to state a claim against AstraZeneca under Rule 8, Twombly, and Iqbal. To state a claim against AstraZeneca, Plaintiffs must allege that AstraZeneca caused their injuries.").

Imposing on plaintiffs the burden of specifically identifying a device by reference to a specific product line or model number, without the benefit of discovery, could create an insurmountable pleading burden in some cases. For example, where medical records only reflect general information about the type of device used in a given procedure, a plaintiff may be unable to plead with specificity the exact product at issue in the pleading phase of her case. *See Butts v. Tyco Healthcare Group LP*, 2007 U.S. Dist. LEXIS 37847 *4 (N.D. Ga. 2007) (noting difficulty plaintiff faced in

tailoring appropriate discovery where doctor's post-operative report did not identify the specific model of the medical device employed during plaintiff's procedure). Where information regarding the specific medical device at issue is unavailable during the pleading stage, a plaintiff may have to rely on circumstantial evidence, such as contracts between a medical facility and a device manufacturer, to establish that the device that harmed her was manufactured by a particular defendant; the district court's analysis of a discovery dispute in *Butts* is instructive on this point:

> defendants have objected to the plaintiff's discovery requests on the grounds that the plaintiff has failed to establish who manufactured the allegedly defective stapler and, even assuming that it was indeed the defendants who manufactured it, the plaintiff does not identify which of the defendants' products was used during her surgery. Specifically, the defendants assert that because the reference to a single "# 25 EEA stapler" in the post-operative report does not identify any specific stapler, but could describe several different staplers manufactured by the defendants, responding to the plaintiff's interrogatories and requests for production is unduly burdensome and would produce information on unrelated products.
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> ...[P]laintiff asserts that she is not required to specifically identify the allegedly defective product at this juncture and that information on any stapler manufactured by the defendants with similar functions, operations, designation, or nomenclature as the "# 25 EEA stapler" is discoverable.
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> The sole factual basis for the action against the defendants...is the post-operative report by the physician who performed the plaintiff's gastric bypass surgery. That report notes the use and apparent malfunction of a "# 25 EEA stapler," which "was married to the anvil and stapler was closed and fired."
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> ...However, the doctor's post-operative report does not identify the specific model of EEA [] stapler used or its manufacturer. Instead, the report simply refers to a "# 25 EEA stapler." Accordingly, because the plaintiff's complaint uses that report as the basis for her claims against Tyco and United States Surgical, the defendants

> assert that two questions must be answered before discovery can proceed: (1) whether the defendants manufactured the stapler used in the plaintiff's surgery, and (2) if so, which of the defendants' staplers is the one referred to as the "# 25 EEA stapler."
>
> ...[Plaintiff] has made no direct showing that Tyco Healthcare or United States Surgical manufactured the stapler used during her surgery. Rather, the plaintiff points to a contract between the defendants and Emory Hospitals that establishes United States Surgical as the exclusive provider of gastric bypass staplers. Ostensibly, this contract shows that although it is unknown whether the defendants actually manufactured the stapler used in the plaintiff's surgery, it at least establishes a good faith basis to proceed with discovery against the defendants. Without any direct evidence, this court concludes that while the plaintiff is on shaky ground in this regard, the existence of an exclusive contract with the defendants is persuasive circumstantial evidence sufficient to proceed with discovery against the defendants as the manufacturers of the allegedly defective stapler.

Id. at 2-5 (citations to the record omitted).

Like the defendants in *Butts*, Defendant contends that Plaintiffs' failure to identify the specific device subject to their complaint is insufficient. In its reply, Defendant complains that it manufactures "at least nine separate products that involve mesh that could potentially fall within Plaintiffs' vague definition." (Doc. 17, Reply at 2). Defendants state that the mesh products it manufactures

> include, but are not limited to, Advantage Fit System, Advantage Transvaginal Mid-Urethral Sling System, Lynx Suprapubic Mid-Urethral Sling System, Obtryx Tansobturator Mid-Urethral Sling System, Prefyx PPS System, Solyx Sis System, Pinnacle Posterior Pelvic Floor Repair Kit, Uhold Vagindal Support System, and Polyform Synthetic Mesh. The nine above-referenced mesh products are distinguishable, with each having its own separate design, indications, directions for use, techniques for implantation, and warnings.

(Id.).

Rather than suggest more specific pleading is required, Defendant's discussion of its extensive mesh products line reveals the injustice that would result from requiring specific identification of a precise product during the pleading phase of a case, without discovery. It is axiomatic that medical patients such as Plaintiffs are not always in a position to know whether an Obtryx Tansobturator Mid-Urethral Sling System or an Advantage Transvaginal Mid-Urethral Sling System was placed inside of them while they were anaesthetized. Rather, manufacturers are in a better position to ascertain which of their devices was likely used in a given procedure, because they can compare each of their products' unique "design[s], indications, directions for use, [and] techniques for implantation" to the allegations of the complaint concerning when, where, and for what medical purpose a plaintiff's surgical procedure was performed.

As the Seventh Circuit Court of Appeal recognized recently, there are no special pleading requirements for product liability claims or medical device claims in particular. *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). The federal standard of notice pleading applies to defective medical device claims: so long as the complaint alleges facts sufficient to meet the "plausibility" standard applied in *Iqbal* and *Twombly*, dismissal under Rule 12 is inappropriate. *Id.* Pleading defective medical device claims is difficult, and discovery is often necessary before a plaintiff can fairly be expected to provide specific details. *See id.*

Plaintiffs' complaint provides information regarding the types of surgical procedures they underwent, as well as a detailed

technical description of the devices they allege injured them: "mesh devices purported to correct and restore normal vaginal structure secondary to pelvic organ prolapse." The complaint also states that Defendants "sought and obtained [FDA] approval to market mess [sic] products and/or its monofilament polypropylene mesh component under section 510(k) of the Medical Device Amendment." These allegations provide further description of the type of product. Nevertheless, the complaint contains ambiguities.

First, the complaint does not clearly allege where each Plaintiff underwent their respective procedures. When a Plaintiff is unable to identify a specific medical device in her complaint, information revealing when, where, and why a procedure was performed should be pleaded to assist manufacturers in identifying which of its products is implicated. As Plaintiffs do not allege which state they underwent their procedures in, let a alone the names of the medical facilities involved, the complaint does not comply with Rule 8.

Second, the complaint is ambiguous with respect to whether each Plaintiff had the same type of mesh device implanted. The complaint suggests that Plaintiffs seek to assert claims based on the failure of more than one mesh device manufactured by Defendant. Paragraph 11 of the complaint states that the term "mesh devices" refers to Defendant's products "collectively." (Compl. at 3). Critically, paragraph 14 alleges that Plaintiffs were injured by "extrusion of mesh from *one or more* of the Mesh Devices." (Id. at 3) (emphasis added). Plaintiffs complaint must be amended to (1) state clearly whether Plaintiffs' claims are based on one defective device common to all Plaintiffs, or whether claims are asserted

based on multiple mesh devices that share a common defect; and (2) state clearly the location where each Plaintiffs' respective procedure was performed.

B. Implied Warranty Claim

Defendants correctly assert that Plaintiffs' claims for breach of implied warranty are not cognizable. Under California law, privity between parties is required for either claim of implied warranty. *E.g., Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 857 (Cal. Ct. App. 1994) (noting that California Commercial Code section 2315 requires that a buyer rely on sellers' skill or judgment in order to have a cognizable implied warranty claim and rejecting implied warranty claim against medical device manufcaturer); *Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058 (2008) (rejecting implied warranty claim against medical device manufacture because of lack of privity with citation to *Evraets*); *accord Clemens v. Daimler Chrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir.2008) (plaintiff asserting breach of implied warranty claims must stand in vertical contractual privity with the defendant). Plaintiffs do not contend otherwise. Plaintiffs' implied warranty claim is DISMISSED WITH PREJUDICE.

C. Express Warranty Claims

Defendants contention that privity is an element of an express warranty claim is incorrect. *E.g., Evraets*, 29 Cal. App. 4th at 857 n.4 ("privity is not a requirement for actions based upon an express warranty"); *Fieldstone Co. v. Briggs Plumbing Products*, Inc., 54 Cal. App. 4th 357, n.10 (Cal. Ct. App. 1997) ("As a general rule, privity of contract is a required element of an express breach of warranty cause of action. However, there is an

exception where plaintiff's decision to purchase the product was made in reliance on the manufacturers' written representations in labels or advertising materials.") (citations omitted). However, Plaintiffs express warranty claims must be dismissed, as the complaint does not allege facts sufficient to give rise to a plausible basis to believe that Plaintiffs relied on any representations made by Defendants. *See, e.g., id.* Plaintiffs' conclusory allegations that Defendants advertised their products as safe and effective lack even general information describing such alleged conduct. As one district court has aptly noted, conclusory allegations such as those advanced by Plaintiffs are insufficient to support a plausible basis for an express warranty claim:

> Evraets stands as clear authority that at least at the pleading stage, California law permits a claim for breach of an express warranty to go forward under circumstances [where reliance is alleged]. That said, the complaint as presently constituted fails to allege any express warranties actually made by Stryker, except in the most general and conclusory terms. Accordingly, the claim for breach of express warranty will be denied, with leave to amend.

Quatela v. Stryker Corp., 2010 U.S. Dist. LEXIS 133706 * 4-6 (N.D. Cal. 2010). Plaintiffs' express warranty claims are DISMISSED, with leave to amend.

D. Fraud Based Claims

Federal Rule of Civil Procedure 9(b) imposes an elevated pleading standard with respect to claims that "sound in fraud" or are "grounded in fraud." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). "To comply with Rule 9(b), allegations of fraud must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (internal

quotation marks omitted). Allegations of fraud must include the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." Id. (internal quotation marks omitted). The "[a]verments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (internal quotation marks omitted). A plaintiff alleging fraud "must set forth more than the neutral facts necessary to identify the transaction. The plaintiff must set forth what is false or misleading about a statement, and why it is false." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

Plaintiffs' general allegations do not comply with Rule 9(b)'s particularity requirements. Plaintiffs' attempt to rely on cases such as *Glen Holly Ent., Inc., v. Tektronix, Inc.*, 100 F. Supp. 2d 1086, 1095 (C.D. Cal. 1999) for the proposition that "Rule 9(b) may be relaxed as to matters peculiarly within the opposing party's knowlege" is unavailing; the complaint does not allege facts sufficient to support an inference that Defendants knew of the alleged defects of their products at any time relevant to the complaint or that any false representations were made to Plaintiffs on which they relied. Plaintiffs' fraud based claims are DISMISSED, with leave to amend.

E. Negligent Misrepresentation Claims

Plaintiffs' negligent misrepresentation claim is based on Plaintiffs' conclusory contention that "adverse event reports specifically related to the Mesh Devices showed the Mesh Devices to be defective and dangerous when used in the intended manner."

(Compl. at 11). The complaint does not allege facts sufficient to give rise to an inference that, at the time Defendants made alleged representations concerning the safety of their mesh devices, Defendants had reason to know of the dangers Plaintiffs complain of or that they made any misrepresentations without a reasonable basis for believing them to be true. *Inter alia*, the complaint does not allege when such representations were made. Plaintiffs' negligent misrepresentation claims are DISMISSED, with leave to amend.

F. UCL Claims

As discussed above, Plaintiffs' complaint is insufficient with respect fraud and misrepresentation based claims. The complaint is fatally vague with respect to which mesh devices are the subject of this action. As there are no predicate claims alleged in the complaint, Plaintiffs' UCL claims are DISMISSED, without prejudice.

G. Venue and Joinder

Defendant contends that venue for the claims of Plaintiffs who reside in Michigan is improper in the eastern district, and that such Plaintiffs' claims are improperly joined in this action. The propriety of joinder and venue cannot be ascertained due to the pleading deficiencies discussed above. Defendant may renew its objections to joinder and venue after Plaintiffs provide an amended complaint.

ORDER

For the reasons stated, IT IS ORDERED:

1) Plaintiffs' implied warranty claims are DISMISSED, with prejudice;

2) Plaintiff's remaining claims are DISMISSED, without prejudice;

3) Plaintiff's shall file an amended complaint within sixty days of receiving electronic notice of this decision. Defendant shall file responsive pleading within twenty days of service of an amended complaint; and

4) Defendant shall submit a form of order consistent with this memorandum decision within five days of receiving electronic notice of this decision.

IT IS SO ORDERED.

Dated: April 20, 2011

/s/ Oliver W. Wanger
UNITED STATES DISTRICT JUDGE