Lynch v. Olympus America, Inc. et al Doc. 86

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 18-cv-00512-NYW

KATHLEEN LYNCH, an individual,

Plaintiff,

v.

OLYMPUS AMERICA, INC.,
OLYMPUS CORPORATION OF THE AMERICAS,
OLYMPUS MEDICAL SYSTEMS CORP., and
Does 1 through 20 inclusive,

Defendants.

MEMORANDUM OPINION AND ORDER

Magistrate Judge Nina Y. Wang

This case comes before the court on four renewed Motions to Dismiss filed by the three named Defendants in this action, Olympus America, Inc. ("Olympus America"), Olympus Corporation of the Americas ("OCA"), and Olympus Medical Systems Corporation ("Olympus Medical"; collectively, "Defendants") following the court's prior grant of the initial Motions to Dismiss in the Order dated October 30, 2018 [#48] and Plaintiff's subsequent filing of a First Amended Complaint [#49]. The undersigned Magistrate Judge presides over this case pursuant to 28 U.S.C. § 636(c), the Parties' consent, and the Order of Reference dated May 2, 2018. [#11; #14]. In the renewed Motions to Dismiss, Defendants argue for dismissal pursuant to Fed. R. Civ. P. 12(b)(6) ("the Renewed 12(b)(6) Motions"), alleging that Plaintiff Kathleen Lynch ("Plaintiff" or "Ms. Lynch") has failed to state a claim upon which relief can be granted [#55; #56; #57, filed December 4, 2019]. On that same day, Olympus Medical filed a Rule 12(b)(2) motion ("the

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Renewed 12(b)(2) Motion" and collectively with the Renewed 12(b)(6) Motions, the "Renewed Defense Motions"), arguing that it should be dismissed as a defendant for want of personal jurisdiction. [#54]. Plaintiff responded to the Renewed 12(b)(6) Motions on January 2, 2019 [#69; #70; #71] and, after a period for jurisdictional discovery, the Renewed 12(b)(2) Motion on March 18, 2019 [#80]; the Defendants replied to the responses to the Renewed 12(b)(6) motions on January 16 [#72; #73; #74] and to the Renewed 12(b)(2) argument on April 1 [#81]. Oral argument was held before this court on April 16, 2019. [#85]. The Renewed Defense Motions are now ripe for decision. For the reasons set forth in this Memorandum Opinion and Order, the Renewed Rule 12(b)(2) Motion is **DENIED**, and the Renewed 12(b)(6) Motions are **DENIED**.

BACKGROUND

The court has already provided a comprehensive background for this case in the Order ruling on the original Defense Motions. [#48]. The court will therefore focus its attention for this section to the developments following that Order. All substantive assertions of fact are taken from the First Amended Complaint and assumed as true for purposes of this analysis. The discussion on personal jurisdiction will contain a separate statement of facts adduced in briefing Olympus Medical's 12(b)(2) Motion as the court cannot properly consider those facts in ruling on a 12(b)(6) motion.

This is a case about an allegedly defective medical device, the TJF-Q180V Duodenoscope ("Q180V Scope" or "the Scope"), which is manufactured, sold, and supported by Defendants for use by medical professionals in performing numerous medical procedures including, as relevant here, an endoscopy, which is a medical procedure that involves the insertion of an endoscope into a patient's body for therapeutic and/or diagnostic purposes. *See generally* [#49]. In this case,

Plaintiff alleges that she underwent an endoscopy at UCH Hospital ("UCH" or "the Hospital") in January 2016[1] and subsequently contracted a drug-resistant bacterial infection because her Doctor used a Q180V scope that retained biological contaminates from prior use that were not eliminated due to the defective design and cleaning (or "reprocessing") protocol provided with the Scope. [*Id.* at ¶ 1]. The Scope was contaminated primarily due to the defective design of the Scope's distal-end cap which sealed the elevator wire channel from effective cleaning but did not protect against the ingress of microscopic contaminates. [*Id.* at ¶¶ 1, 18, 31, 38, 59, 60]. The gravamen of Plaintiff's claim is that Olympus Medical designed the Scope with the defective end seal as opposed to a more effective open-channel design, allowing contaminates but also easy cleaning, or a fully removable end cap, permitting easier end-user verification of effective reprocessing, which rendered the device unsafe. [*Id.* at ¶¶ 35, 60]. Plaintiff alleges that she fell ill due to the contaminated Q180V Scope used in her January 2016 procedure, and she filed this action on March 1, 2018. [*Id.*].

In May 2018, the Defendants filed an initial set of Motions to Dismiss targeted at the original Complaint, based on Rule 12(b)(2) and Rule 12(b)(6) just as the present Renewed Motions are. [#17; #18; #19; #20]. In the Order dated October 30, 2018 [#48], the court found that the Complaint suffered from numerous fatal deficiencies and dismissed it in its entirety. Specifically, the court found the following issues: (1) the court lacked personal jurisdiction over Olympus Medical, a Japanese corporation, without some evidence that Olympus Medical intentionally targeted Colorado for the Scopes which harmed Plaintiff [#48 at 16]; (2) Plaintiff's claim for a

[1] The court takes judicial notice of filings on its own docket that indicates that Plaintiff underwent the ERCP procedure at UCH Hospital using the Q180V scope on January 20, 2016. [#80 at 7; #80-2].

design defect in the Scope failed as it did not address the relevant factors under Colorado law [*id.* at 21]; (3) Plaintiff's cursory assertion of an unspecified injury contracted an indeterminate time after her procedure was insufficient to plausibly establish causation [*id.*]; (4) Plaintiff's failure to warn claim failed because it was premised on a failure to warn the patient and not the doctor per the learned intermediary doctrine, which the court found applies [*id.* at 24]; (5) Plaintiff's failure to warn claim was conclusory and did not adequately set forth a plausible claim that an effective warning would have prevented her harm [*id.* at 26]; (6) the claims for intentional and negligent misrepresentation did not meet the heightened pleadings standards of Federal Rule of Civil Procedure 9(b) as it did not distinguish between the Defendants or identify the misrepresentations at issue [*id.* at 28–32]. The court granted Plaintiff leave to file an amended complaint to address these deficiencies, which she did on November 20, 2018. [#48].

The Defendants filed the Defense Motions shortly thereafter, arguing that Plaintiff has not adequately remedied the deficiencies identified by the court in the October 30 Order. [#54; #55; #56; #57]. Briefing on the renewed 12(b)(6) motions completed in the usual course, but the court permitted jurisdictional discovery as to Olympus Medical, and therefore the briefing on that motion only completed on April 1, 2019. [#81]. The court held Oral Argument on April 16, 2019 on the Defense Motions. For the reasons stated in this Order, the court finds that Plaintiff has sufficiently remedied these deficiencies, and therefore all Renewed Defense Motions are **DENIED**.

LEGAL STANDARDS

I. Personal Jurisdiction under Rule 12(b)(2)

Rule 12(b)(2) of the Federal Rules of Civil Procedure allows a defendant to challenge the court's exercise of personal jurisdiction. Fed. R. Civ. P. 12(b)(2). Plaintiff bears the burden of demonstrating that the court has personal jurisdiction over the Defendants. *See Dudnikov v. Chalk & Vermilion Fine Arts*, 514 F.3d 1063, 1069 (10th Cir. 2008). When, as here, the court decides a Rule 12(b)(2) motion to dismiss without holding an evidentiary hearing, "the plaintiff need only make a prima facie showing of personal jurisdiction to defeat the motion." *AST Sports Sci., Inc. v. CLF Distrib. Ltd.*, 514 F.3d 1054, 1057 (10th Cir. 2008). "The plaintiff[s] may make this prima facie showing by demonstrating, via affidavit or other written materials, facts that if true would support jurisdiction over the defendant." *OMI Holdings, Inc. v. Royal Ins. Co. of Canada*, 149 F.3d 1086, 1091 (10th Cir. 1998). In considering this question, the court must accept all well pleaded facts as true and must resolve any factual disputes in favor of the plaintiff. *Wenz v. Memery Crystal*, 55 F.3d 1503, 1505 (10th Cir. 1995).

To establish jurisdiction over a non-resident defendant, a plaintiff must show that the exercise of jurisdiction is authorized under the relevant state long-arm statute, and does not offend due process. *Wenz*, 55 F.3d at 1506. Because the Colorado Supreme Court has determined that Colorado's long-arm statute, Colo. Rev. Stat. § 13-1-124 (2018), is coextensive with due process requirements, *Keefe v. Kirschenbaum & Kirschenbaum, P.C.*, 40 P.3d 1267, 1270 (Colo. 2002), the inquiry is thus simplified into one basic question: whether the exercise of personal jurisdiction comports with the requirements of due process under the Fourteenth Amendment to the United States Constitution. *AST Sports*, 514 F.3d at 1057.

However, even if this test is met, a court must still consider whether "the exercise of personal jurisdiction over the defendant offends traditional notions of fair play and substantial justice." *OMI Holdings*, 149 F.3d at 1091. In this inquiry the court considers: (1) the burden on the defendant, (2) the forum state's interest in resolving the dispute, (3) the plaintiff's interest in receiving convenient and effective relief, (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and (5) the shared interest of the several states in furthering fundamental social policies. *Id.* at 1095.

Plaintiff does not assert general jurisdiction over Olympus Medical, nor does it appear she could. This analysis, therefore, is confined to the assertion of specific jurisdiction over Olympus Medical. To determine whether this court may exercise specific jurisdiction over Olympus Medical, this court looks to whether its contacts with this forum associated with the action at hand is sufficient for it to be haled into court in this District: "(a) whether the plaintiff has shown that the defendant has minimum contacts with the forum state; and, if so, (b) whether the defendant has presented a compelling case that the presence of some other considerations would render jurisdiction unreasonable." *Old Republic Ins. Co. v. Cont'l Motors, Inc.*, 877 F.3d 895, 904 (10th Cir. 2017).

II. Failure to State a Claim under Rule 12(b)(6)

Under Rule 12(b)(6) a court may dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In deciding a motion under Rule 12(b)(6), the court must "accept as true all well-pleaded factual allegations" and "view these allegations in the light most favorable to the plaintiff." *Casanova v. Ulibarri*, 595 F.3d 1120, 1124 (10th Cir. 2010) (quoting *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009)). A plaintiff may not

rely on mere labels or conclusions, "and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Rather, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009); *see also Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) (explaining that plausibility refers "to the scope of the allegations in a complaint," and that the allegations must be sufficient to nudge a plaintiff's claim(s) "across the line from conceivable to plausible."). To state a claim that is plausible on its face, a complaint must "sufficiently allege[] facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed." *Forest Guardians v. Forsgren*, 478 F.3d 1149, 1160 (10th Cir. 2007).

The court has subject matter jurisdiction over this case because the parties are completely diverse and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332(a). Therefore, the court applies Colorado law when evaluating whether Plaintiff's state law claims state a claim under Rule 12(b)(6). *Rancho Lobo, Ltd. v. Devargas*, 303 F.3d 1195, 1200 (10th Cir. 2002). Absent clear guidance from the Colorado Supreme Court, a federal court exercising diversity jurisdiction must make an *Erie* guess as to how that court would rule. *Pehle v. Farm Bureau Life Ins. Co.*, 397 F.3d 897, 901 (10th Cir. 2005) ("Because Wyoming has not directly addressed this issue, this court must make an *Erie*-guess as to how the Wyoming Supreme Court would rule."). In making an *Erie* guess, courts look to decisions of the state court of appeals as strongly persuasive, if not governing, authority as to how the state supreme court would rule. *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1230 (10th Cir. 2000) ("Furthermore, this court must follow any intermediate state court decision unless other authority convinces us that the state supreme court would decide

otherwise." (formatting altered) (quoting *Daitom, Inc. v. Pennwalt Corp.*, 741 F.2d 1569, 1574 (10th Cir. 1984)); *see also, e.g., U.S. ex rel. Sun Constr. Co. v. Torix Gen. Contractors, LLC*, No. 07-CV-01355-LTB-MJW, 2011 WL 841277, at *1 (D. Colo. Mar. 8, 2011).

III. Pleading Special Matters Under Rule 9(b)

When a plaintiff alleges fraud or mistake, Federal Rule of Civil Procedure 9(b) requires that the plaintiff "state with particularity the circumstances constituting fraud or mistake." The Rule's purpose is to "to afford [a] defendant fair notice" of a plaintiff's claims and the factual grounds supporting those claims, *George v. Urban Settlement Svcs.*, 833 F.3d 1242, 1255 (10th Cir. 2016) (quoting *Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997)), such that the defendant is provided the "minimum degree of detail necessary to begin a competent defense." *Fulghum v. Embarq Corp.*, 785 F.3d 395, 416 (10th Cir. 2015). Rule 9(b) does not require any particularity in connection with an averment of intent, knowledge or condition of mind, rather it simply refers to only the requirement that a plaintiff identify the circumstances constituting fraud with sufficient specificity. *Schwartz*, 124 F.3d at 1252.

Put simply, Rule 9(b) requires that a complaint "set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof." *Id.* (quoting *In re Edmonds*, 924 F.2d 176, 180 (10th Cir. 1991)). When plaintiff brings a claim against multiple defendants, Rule 9(b) obliges a plaintiff to specify the manner in which each defendant participated. *Brooks v. Bank of Boulder*, 891 F. Supp. 1469, 1477 (D. Colo. 1995); *see also Lillard v. Stockton*, 267 F. Supp. 2d 1081, 1094 (D. Kan. 2003) ("[W]here fraud is alleged against multiple defendants, blanket allegations of fraud couched in language such as 'by the defendants' are insufficient. Instead, the specifics of the alleged fraudulent activity of each

defendant must be set forth.").

Rule 9(b) clearly applies to intentional misrepresentation and fraud, but the law is unsettled on whether it applies to a claim of negligent misrepresentation. *Compare Conrad v. The Educ. Res. Inst.*, 652 F. Supp. 2d 1172, 1183 (D. Colo. 2009) ("Thus, a claim for negligent misrepresentation should not be governed by the pleading standard set forth in Rule 9(b).") *and Denver Health & Hosp. Auth. v. Beverage Distributors Co., LLC*, 843 F. Supp. 2d 1171, 1177 (D. Colo. 2012) ("Rule 9(b) does not apply to the negligent misrepresentation claim before me. The crux of the claim . . . . rings not of fraud but negligence."), *with Gunningham v. Standard Fire Ins. Co.*, No. 07-cv-02538-REB-KLM, 2008 WL 4377451, at *2 (D. Colo. 2008) ("I conclude that the particularity requirement is applicable to the negligent misrepresentation claim. In this context, negligence is a type of mistake and Rule 9(b) concerns allegations of fraud or mistake."). In the October 30 Order dismissing Plaintiff's original Complaint, the court found that Rule 9(b) applied to the negligent misrepresentation claim because it was "rife with allegations of willful misconduct." [#48 at 13]. In the First Amended Complaint, Plaintiff's claim of negligent misrepresentation again contains allegations of willful misconduct, [#49 at ¶¶ 108–126], and now Plaintiff concedes the applicability of Rule 9(b). [#70 at 4].

ANALYSIS

As noted above, the court identified six substantive deficiencies in the original Complaint. Plaintiff's First Amended Complaint brings the same claims and seeks to address these errors, and the Renewed Defense Motions are premised on the Defendants' arguments that the First Amended Complaint has not adequately remedied the deficiencies. Given this overlap, the court will proceed in an abbreviated fashion, analyzing by deficiency as opposed to by claim in determining whether

the First Amended Complaint has cured the deficiencies noted above before considering any secondary issues raised in the pleadings or at oral argument. A federal court "generally may not rule on the merits of a case without first determining that it has jurisdiction over the category of claim in suit (subject-matter jurisdiction) and the parties (personal jurisdiction)." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 430–31 (2007). Therefore, this court will begin by analyzing the exercise of personal jurisdiction over Olympus Medical.[2]

I. Does the Court Have a Basis to Assert Personal Jurisdiction over Olympus Medical?

A. Supplemental & Relevant Facts

Plaintiff, afforded jurisdictional discovery, has submitted additional facts in Response to Olympus Medical's Rule 12(b)(2) Motion. [#80]. Plaintiff presents the following facts to support its argument of specific personal jurisdiction as to Olympus Medical, drawn from both the operative Amended Complaint and additional facts adduced through discovery:

Olympus Medical maintains contact and business relations with UCH Hospital Doctor Steven Edmundowicz, M.D., where is utilized as an evaluator of Olympus Medical's prototype devices. [#49 at ¶ 17]. Relevant here, Dr. Edmundowicz evaluated a prototype Q180V Scope for Olympus Medical in 2009, before the introduction of the Scope to the U.S. market in 2010, and again later in 2013 [*id.*], one year after UCH Hospital purchased the Scope in June 2012 [#80-12], and approximately three years before Plaintiff's procedure in January 2016. [#49 at ¶ 36]. Dr. Raj Shah, Plaintiff's treating physician who performed her ERCP on January 20, 2016, also has ties with Olympus Medical. [#80 at 7]. Specifically, in 2009, Dr. Shah travelled to Tokyo, Japan on

[2] There is no dispute that this court may exercise personal jurisdiction over Defendants Olympus America and OCA.

Olympus Medical's invitation several months prior to the release of the Q180V Scope to the United States market to give feedback to Olympus Medical's R&D team at the "Olympus Endoscopy New Millennium Program." [*Id.*; #80-4]. The Minutes from the 2009 trip indicate that Dr. Shah was participating in his capacity as an Associate Professor of Medicine at the University of Colorado. [*Id.*]. Dr. Shah toured the Olympus Medical manufacturing plants in Aomori and Aizu with members of its marketing department, and heard a presentation from Mr. Kitano—presumably an Olympus Medical employee—on the TJF-180V.[3] [#80-4 at 3–4, 5]. Dr. Shah provided comments on the future scopes exhibited at the presentation and made comments praising Olympus Medical. [*Id.* at 4, 6, 7, 10–11].

Olympus Medical's employees also travelled to Colorado to build their relationships with Dr. Shah and UCH Hospital. In 2010, Olympus Medical "Senior Supervisor" for the "Americas Group," Koya Tsubaki, travelled to Denver for a meeting with Dr. Shah and others at the University of Colorado. [#80 at 7; #80-5]. The stated aim of the trip was to "enhance the doctors' loyalty to Olympus [Medical]" and to boost sales of existing scope lines, which by that time included the Q180V Scope. [*Id.* at 5]. Mr. Tsubaki visited again in February 2011 to attend the "16th Rocky Mountain Interventional Endoscopy Course" where many Olympus Medical products were displayed and demonstrated. [#80 at 7; #80-6; #80-7]. After the trip, Mr. Tsubaki and Olympus Medical Product Manager Charles Lavin were effusive in their mutual praise for the success of the trip and the sales dividends it would provide. [#80-6 at 5–6]. In June 2012, UCH Hospital purchased Q180V Scopes. [#80-12].

[3] The Minutes omit the "Q" from the Scope name, but this appears to merely be a typo or an earlier designation for the Scope at issue.

B. Parties' Arguments

Relevant here, Plaintiff's original assertion of personal jurisdiction over Olympus Medical was predicated on a nationwide marketing plan and the company's shipment of Scopes to a warehouse/distribution point in Pennsylvania, which the court found insufficient as these contacts were not tethered to any Colorado-specific nexus. [*Id.* at 16]. Plaintiff now sets forth additional factual allegations regarding Olympus Medical's agents' travel to Colorado and marketing to Colorado doctors. Olympus Medical maintains Plaintiff's showing remains insufficient because (1) Dr. Edmundowicz's 2009 and 2013 evaluation of Q180V prototypes is not alleged to be connected to Plaintiff's procedure which occurred years later [#54 at 9]; (2) Plaintiff has failed to prove that Olympus Medical ever had more than a general awareness that its Scopes were sold in Colorado [#81 at 2–3]; (3) Dr. Shah's trip to Japan is unrelated to Olympus Medical's targeting of Colorado, citing *Walden v. Fiore*, 571 U.S. 277 (2014) [*id.* at 4]; (4) the two brief visits by Olympus Medical Employee Koya Tsubaki are not related to the conduct forming the basis for this litigation as "both visits appear to be unrelated to any particularized effort to sell the Q180V Scope to UCH or anyone else in Colorado," [*id.* at 5], and finally (6) notions of fair play and substantial justice weigh against the exercise of jurisdiction in this case [*id.* at 7].[4] In doing so, Olympus Medical relies heavily on another court's decision on the same matter, *Quashie v. Olympus Am., Inc.*, 315 F. Supp. 3d 1329 (N.D. Ga. 2018), which found no personal jurisdiction over Olympus Medical.

[4] Some of Olympus Medical's original arguments have been effectively mooted by the subsequent jurisdictional discovery and allegations made in Plaintiff's Response. Those arguments which have been substantively mooted and are not reasserted in the Reply are not addressed here.

C. Legal Standard

Because Colorado's long-arm statute is coextensive to that of the Due Process Clause of the Fourteenth Amendment, this court's analysis collapses into a single inquiry whether the exercise of personal jurisdiction comports with due process. *Nat'l Bus. Brokers, Ltd. v. Jim Williamson Prods., Inc.*, 16 F. App'x 959, 962 (10th Cir. 2001). The Due Process Clause operates to limit the power of a State to assert personal jurisdiction over a non-resident defendant. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 413–14 (1984). Due Process protects an individual's liberty interest in not being subject to the binding judgments of a forum with which he has established no meaningful contacts, ties, or relations. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 471–72 (1985). The standard for determining whether an exercise of jurisdiction over the interests of persons is consistent with the Due Process Clause is the minimum-contacts standard set forth in *International Shoe Co. v. Washington*, 326 U.S. 310 (1945). *Shaffer v. Heitner*, 433 U.S. 186, 207 (1977). *International Shoe* requires that a defendant "have certain minimum contacts with it such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe*, 326 U.S. at 316.

D. Minimum Contacts

In the exercise of specific personal jurisdiction, the minimum contacts requirement encompasses two distinct requirements: (1) the defendant must have purposefully directed its activities at residents of the forum state, and (2) that the plaintiff's injuries must arise out of the defendant's forum-related activities. *Old Republic*, 877 F.3d at 895. The purposeful direction requirement ensures that a defendant will not be haled into a jurisdiction solely as a result of random, fortuitous, or attenuated contacts or of the unilateral activity of another party or a third

person. *Burger King*, 471 U.S. at 475 (quotation marks and citations omitted); *Dudnikov v. Chalk & Vermilion Fine Arts, Inc.*, 514 F.3d 1063, 1071 (10th Cir. 2008). While not necessarily dispositive, forum-specific solicitation of business relationships and regular correspondence with forum residents is strong evidence of purposeful direction. *See Pro Axess, Inc. v. Orlux Distribution, Inc.*, 428 F.3d 1270, 1277–78 (10th Cir. 2005). In general, when considering a foreign defendant's contractual obligations, "parties who reach out beyond one state and create continuing relationships and obligations with citizens of another state are subject to regulation and sanctions in the other State for the consequences of their activities." *Id.* at 1277 (citing *Burger King*, 471 U.S. at 473).

In the October 30 Order, the court surveyed the unsettled landscape in the United States Court of Appeals for the Tenth Circuit ("Tenth Circuit") regarding the appropriate test to apply for minimum contacts when jurisdiction arises by placing an item into the "stream of commerce." [#48 at 4–9]. In 2008, the Tenth Circuit decided *Dudnikov*, which addressed the "welter of confusion" over the applicable framework for analyzing whether a plaintiff's injuries arise out of a defendant's contact with the forum when considering the exercise of specific personal jurisdiction. The *Dudnikov* court rejected one test, the substantial connection test, but did not affirmatively select between the remaining tests, the but-for test and the proximate cause test. *See id.* at 1078 ("[W]e agree . . . that the 'substantial connection' test inappropriately blurs the distinction between specific and general personal jurisdiction[.]"); *see also id.* at 1079 ("As between the remaining but-for and proximate causation tests, we have no need to pick sides today.").

The proximate cause test "look[s] to whether the plaintiff has established cause in fact (i.e.,

the injury would not have occurred 'but for' the defendant's forum-state activity) and legal cause (i.e., the defendant's in-state conduct gave birth to the cause of action)." *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 142 F.3d 26, 35 (1st Cir. 1998) (cited as the representative proximate cause test in *Dudnikov*, 514 F.3d at 1078). By contrast, the but-for test inquires whether, but for defendant's contacts with the forum, plaintiff would have suffered the injury at issue. *Mattel, Inc. v. Greiner & Hausser GmbH*, 354 F.3d 857, 864 (9th Cir. 2003) (cited as the representative but-for test in *Dudnikov*, 514 F.3d at 1078). The Tenth Circuit has characterized the proximate cause test as the more demanding of the two. *Dudnikov*, 514 F.3d at 1078 ("Under the former approach, any event in the causal chain leading to the plaintiff's injury is sufficiently related to the claim to support the exercise of specific jurisdiction. The latter approach, by contrast, is considerably more restrictive and calls for courts to examines whether any of the defendant's contacts with the forum are relevant to the merits of the plaintiff's claim." (formatting altered, quotations omitted)); *see also Newsome v. Gallacher*, 722 F.3d 1257, 1270 (10th Cir. 2013) (referring to "the more restrictive proximate cause test"); *Bartile Roofs*, 618 F.3d at 1161 ("Proximate cause is the most restrictive approach and requires courts to analyze whether any of the defendant's contacts with the forum are relevant to the merits of the plaintiff's claim." (quotation omitted)). The Tenth Circuit has repeatedly declined to definitively adopt one of the two tests outside of the contract context. *See Newsome*, 722 F.3d at 1270 ("We have so far refused to choose one test over the other, and we still need not pick between the two to resolve this case."); *Employers Mut. Cas. Co. v. Bartile Roofs, Inc.*, 618 F.3d 1153, 1161 (10th Cir. 2010) ("We also need not elect in this case between the proximate-cause and but-for-causation approaches."); *id.* at n.7 ("In contract actions, we have consistently applied the more-restrictive proximate-cause

approach.").

District courts in the Tenth Circuit have repeatedly noted this ambiguity, but what is clear is that, however formulated, the test as applied in the Tenth Circuit requires some purposeful availment of the target forum, something greater than mere awareness that the device was sold in the forum. [#48 at 8 n.5 (citing cases)]; *see also Old Republic Insurance*, 877 F.3d at 903 (Due process requires . . . that the defendant "*purposefully* established minimum contacts within the forum State." (emphasis added) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985)). The matter remains unresolved without binding precedent to guide the selection between the two available tests. *Cagle v. Rexon Indus. Corp.*, No. CIV-18-1209-R, 2019 WL 1960360, at *5 (W.D. Okla. May 2, 2019); *Salt Lake City Corp. v. Sekisui SPR Americas, LLC*, No. 2017-cv-01095-JNP-BCW, 2018 WL 4688356, at *6 (D. Utah Sept. 28, 2018). Typically, courts have refrained from selecting between the tests because both tests come to the same conclusion. *See, e.g., Forte Supply, LLC v. Mojo Frozen Yogurt, LLC*, No. 13-CV-00797-RM-BNB, 2013 WL 5477165, at *4 (D. Colo. Sept. 30, 2013).

In this case, the essential issue is not whether Defendant has contacts with the forum as Plaintiff has shown several contacts with Colorado. Rather, the pertinent question is whether those contacts are adequately related to the claims at issue, whether Plaintiff's injuries arose from those contacts. Contacts in the same industry are not relevant to the assertion of personal jurisdiction in this case unless the contacts and Plaintiff's harm share a causal nexus. *RV Horizons, Inc. v. Smith*, No. 1:18-CV-02780-NYW, 2019 WL 1077366, at *9 (D. Colo. Mar. 7, 2019) ("The assertion of specific personal jurisdiction must be based on a defendant's particular contacts with the forum that form the basis for the litigation; unrelated contacts that unavoidably happen to be in the same

industry are simply not relevant.").

1. Does the Selection of the Proximate Cause or But-For Test Affect the Outcome?

Unlike other cases, the selection of the proximate cause or but-for test affects the court's determination with respect to personal jurisdiction. Accordingly, this court analyzes the facts separately to provide a clear record.

A. Proximate Cause.

The proximate cause test is demanding and inquires whether "any of the defendant's contacts with the forum are relevant to the merits of the plaintiff's claim." *Bartile Roofs*, 618 F.3d at 1161. For example, the *Bartile Roofs* court cited *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 318 (3d Cir. 2007) in reciting this test. In *O'Connor*, the Third Circuit held that a Pennsylvania court had specific personal jurisdiction over a Barbados-based hotel when it mailed flyers to plaintiffs after an initial stay, and "traded phone calls with them for the purpose of forming an agreement to render spa services." *Id.* at 317–18. Importantly, the court rejected several contacts as irrelevant or insufficient under this test. Specifically, the court noted that "contacts with a state's citizens that take place outside the state are not purposeful contacts with the state itself." *Id.* at 317; *see also id.* ("A Philadelphia vendor may sell a lot of cheesesteaks to German tourists, but that does not mean he has purposefully availed himself of the privilege of conducting activities within Germany."). In *Harlow v. Children's Hosp.*, 432 F.3d 50, 61 (1st Cir. 2005), the court cautioned that "[t]he relatedness requirement is not an open door; it is closely read, and it requires a showing of a material connection. . . . [T]he defendant's in-state conduct must form an important, or at least material, element of proof in the plaintiff's case." (quotations omitted, formatting altered). The proximate cause test is just what it sounds like—a requirement that

defendant's contacts with the forum are the proximate cause of the resulting harm, in this case, Plaintiff's injury caused by the faulty end-cap design and reprocessing protocol attached to the Q180V Scope.

In reviewing the record, this court concludes Plaintiff falls short of the mark to establish specific personal jurisdiction over Olympus Medical when the proximate cause test is applied. First, the court finds that Dr. Shah's travels to Japan are insufficient under the *O'Connor* standard, because out-of-state contacts cannot, in the usual course, constitute activity directed at the forum. *O'Connor*, 496 F.3d at 318; *see also Walden v. Fiore*, 571 U.S. 277, 285 (2014) ("[The] 'minimum contacts' analysis looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there."). Second, Mr. Tsubaki's two visits to Colorado and Dr. Edmundowicz's 2009 and 2013 in-state evaluation of Q180V prototypes are also too attenuated pursuant to *Harlow*. Plaintiff fails to provide enough evidence to tie the flawed design and reprocessing protocol at issue in this case with Olympic Medical's contacts with Colorado. There is no indication that the 2009 prototype evaluation included the same design challenged herein, or that any reprocessing protocols were even evaluated by Dr. Edmundowicz. The court is left to conclude that Dr. Edmundowicz's services do not relate to the design of the specific Scope at issue, the Q180V, and are insufficient to establish proximate cause for Plaintiff's harm. Accordingly, the court finds that Ms. Lynch's harms do not arise out of the specified contacts between Olympus Medical and Colorado under the proximate cause test.

2. But-For Causation

The but-for test is significantly less demanding. Under this test, "any event in the causal chain leading to the plaintiff's injury is sufficiently related to the claim to support the exercise of

specific jurisdiction." *Dudnikov*, 514 F.3d at 1078; *see also Newsome*, 722 F.3d at 1269; *Bartile Roofs*, 618 F.3d at 1161. All three of these cases cite, if at all, Ninth Circuit precedent in recounting the but-for test. These cases hold that the but-for test is satisfied when defendant's contacts with the forum are a *necessary* event in the causal chain leading to the injury. *Mattel, Inc. v. Greiner & Hausser GmbH*, 354 F.3d 857, 864 (9th Cir. 2003) ("The question can be formulated as this: But for [defendant's] contacts with California, would [plaintiff's] claims against [defendant] have arisen?"); *Harris Rutsky & Co. Ins. Servs. v. Bell & Clements Ltd.*, 328 F.3d 1122, 1132 (9th Cir. 2003) ("But for [defendant's] conduct, this injury would not have occurred."). The less restrictive but-for standard permits the court to focus not on the issue of whether Olympus Medical's Colorado contacts were proximately related to the challenged design of the scope, but rather on the issue of whether Olympus Medical's actions directed at Colorado were for the purposes of developing and promoting the use Q180V by physicians and patients in Colorado. [#80-12].

Defendants point the court to *Quashie*, 315 F. Supp. 3d at 1337, where the court found that plaintiff's allegations were "insufficient to show a sufficient nexus between [Olympus America's] contacts and the litigation" to support their argument that personal jurisdiction is lacking. With due respect to the comprehensive and well-reasoned opinion in *Quashie*, the court finds the present case distinguishable. The *Quashie* court first found Plaintiff had satisfied Georgia's long-arm statute by committing an injury that occurred in Georgia, by placing a product into the stream of commerce with the expectation that consequences would occur in Georgia, and that the defendants had derived substantial revenue from Georgia. 315 F. Supp. 3d at 1335. Unlike Colorado's, Georgia's long-arm statute is not coextensive with due process requirements under the United States Constitution. *Id.* at 1334 ("Jurisdiction under the Georgia long-arm statute is not

coextensive with procedural due process." (quotations omitted)). Therefore, the *Quashie* court went on to consider whether the exercise of personal jurisdiction would offend the Due Process Clause and concluded that the plaintiff failed to allege facts to support the conclusion that Olympus Medical "expected or should have expected their acts to have consequences within the [forum state]." *Id.* at 1339.

Unlike *Quashie*, where there were only generalized allegations of contact with the forum state leading that court to posit, "[w]hich acts?" and "[w]hat consequences," *id.*, jurisdictional discovery adequately answered those questions in this case. Plaintiff has demonstrated that Olympus America purposefully directed its activities related to the Q180V Scope at Colorado.

Which Acts? First, Plaintiff avers that Olympus Medical maintained a relationship with Dr. Steven Edmundowicz of UCH, who evaluated prototype endoscopes including a prototype of the TJF-Q180V in 2009 and again in late 2013. [#49 at ¶ 17]. Even without Dr. Edmundowicz's participation,[5] Olympus Medical physically sent its representative into the forum to solicit business and sent scopes for prototype testing as well in 2010. Compare [#80-4] *with id.* at 1334–35 (only alleging that the device was sold in Georgia). Mr. Tsubaki also traveled from Japan to Colorado to work in conjunction with his American colleagues to build loyalty and increase sales of Olympus Medical's endoscopy scopes in Colorado. To that end, Mr. Tsubaki attended the Rocky Mountain Interventional Endoscopy Course in 2011; asked to meet with Dr. Shah and other MDs at the University of Colorado; and planned to observe a case and discuss it with Dr. Shah. [#80-5

[5] Defendants contend Dr. Edmundowicz's evaluation of the Olympus Medical scopes is irrelevant, because those prototype scopes are not at issue in this action, and Dr. Edmundowicz was not at UCH at the time, but at Washington University School of Medicine in St. Louis, Missouri from at least 2009 to 2014. [#54 at 9-10].

at 3].

What Consequences? Plaintiff alleges that the Q180V Scope was released in the United States in 2010, and was based on an earlier Olympus scope, the TJF-160V. [#49 at ¶ 28]. Though not explicit from the evidence proffered, this court reasonably infers that the purpose of Mr. Tsubaki's 2010 and 2011 trips to Colorado included promoting the Q180V Scope, given there is nothing to suggest that Olympus Medical would have carved out the accused scope in its efforts in promoting loyalty to Olympus and its endoscopy scopes. Indeed, particularly in light of Dr. Shah's visit to Olympus Medical in Japan in 2009, where the future GI scope line-up included the "TJF-180V (New V-scope)," nothing in the jurisdictional discovery suggests that Olympus Medical would have abandoned its efforts given Dr. Shah's feedback as to that particular prototype, and Dr. Shah's affirmative statement that he "look[ed] forward to communicating with your team to discuss my ideas further or to review prototype development for endoscopes or endotherapy products." [#80-4 at 4, 11]. Because all factual disputes are resolved in favor of the plaintiff in determining whether plaintiff has made a prima facie showing, the court finds that Plaintiff's showing is sufficient to satisfy the but-for test for personal jurisdiction. *Old* Republic, 877 F.3d at 903.

In fact, the most closely analogous situation applied the proximate cause test—*O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312 (3d Cir. 2007). In that case, much like the present, the only contacts between the defendant and the forum was the defendant's solicitation of business from the plaintiffs. *Id.* at 318 ("After the O'Connors' initial stay, Sandy Lane continued to cultivate the relationship by mailing seasonal newsletters to their Pennsylvania home."). So too here; Olympus Medical continued to cultivate the relationship by sending its executive to meet with Dr. Shah and

others to promote their products, including the Q180V Scope. A district court in the Central District of California came to a similar conclusion when considering whether advertising to a plaintiff in the forum was a but-for cause of plaintiff availing itself of the advertised products. *Hope v. Otis Elevator Co.*, 389 F. Supp. 2d 1235, 1240 (E.D. Cal. 2005) ("The question, therefore, is this: but for [hotel's] advertising and associations with travel agents, would Plaintiff have stayed at [its] hotel in Hawai[']i? . . . It is reasonable to infer . . . that [hotel's] advertising and association with California travel agents were "but for" causes of Plaintiff's stay . . . .").

The court concludes that Plaintiff has met her burden of establishing minimum contacts under the but-for test but has not met her burden under the proximate cause test.

E. Traditional Notions of Fair Play and Substantial Justice

Having found that there are sufficient minimum contacts to support personal jurisdiction under at least one of the available tests, the court next turns to examine whether the assertion of personal jurisdiction would comport with traditional notions of fair play and substantial justice. *Old Republic*, 877 F.3d at 903. Analyzing whether the exercise of personal jurisdiction would offend traditional notions of fair play and substantial justice "requires a case-specific inquiry into the reasonableness of the exercise of personal jurisdiction over a defendant who has minimum contacts with the forum state." *TH Agric. & Nutrition, LLC v. Ace European Grp. Ltd.*, 488 F.3d 1282, 1292 (10th Cir. 2007). The court weighs five factors: (1) the burden on the defendant, (2) the forum state's interest in resolving the dispute, (3) the plaintiff's interest in receiving convenient and effective relief, (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and (5) the shared interest of the several states in furthering fundamental substantive social policies. *Id.* (quoting *Intercon, Inc. v. Bell Atl. Internet Solutions,*

Inc., 205 F.3d 1244, 1249 (10th Cir. 2000)). In applying this test, the court must be "cognizant of the fact that, with minimum contacts established, it is incumbent on defendants to 'present a compelling case that the presence of some other considerations would render jurisdiction unreasonable.'" *Dudnikov*, 514 F.3d at 1080 (quoting *Pro Axess*, 428 F.3d at 1280). The court finds these factors weigh in favor of exercising jurisdiction.

Olympus Medical argues that the exercise of personal jurisdiction here offends traditional notions of fair play and substantial justice. [#54 at 9–11; #81 at 7–8]. Defendant's argument is exclusively focused on the burden Olympus Medical would incur, and so the court's analysis will be similarly confined. Defendant's argument is centered on an analogy to *Benton v. Cameco Corp.*, 375 F.3d 1070, 1078 (10th Cir. 2004), where the court found the exercise of jurisdiction inconsistent with fair play and substantial justice.

In *Benton*, the Tenth Circuit found the exercise of personal jurisdiction to be inconsistent with traditional notions of fair play and substantial justice despite the existence of sufficient minimum contacts. 375 F.3d at 1078. The *Benton* court began by noting that,

> The reasonableness prong of the due process inquiry evokes a sliding scale: the weaker the plaintiff's showing on minimum contacts, the less a defendant need show in terms of unreasonableness to defeat jurisdiction. The reverse is equally true: an especially strong showing of reasonableness may serve to fortify a borderline showing of minimum contacts.

Id. at 1079 (formatting altered) (quoting *OMI Holdings*, 149 F.3d at 1095).

Applying this framework to plaintiff's just-sufficient showing of minimum contacts, the Tenth Circuit found that the burden on the Canadian defendant was "significant" as it "has no office or property in Colorado, is not licensed to do business in Colorado, and has no employees in Colorado." *Id.* The Circuit further found that defendant's "officers and employees will not only

have to travel outside their home country, they will also be forced to litigate the dispute in a foreign forum unfamiliar with the Canadian law governing the dispute." *Id.* Thus, the exercise of personal jurisdiction was not consistent with fair play and substantial justice. Given the specific circumstances of this case, this court finds *Benton* distinguishable.

If Benton was "a very close case" that just barely rose to the level of minimum contacts, this case—while by no means a clear call—is less arguable and so would require a greater showing of prejudice on the "sliding scale" mentioned above. *Id.* Unlike *Benton*, Colorado law applies and the court has no concern that Defendant, ably represented by counsel, would be forced to litigate a dispute with unfamiliar law, or that the court would be forced to construe unfamiliar foreign law as in *Benton*. Indeed, Olympus Medical shares counsel with its related entities Olympus America and OCA, that are undisputedly subject to personal jurisdiction in this forum. Thus, a significant element of prejudice found in *Benton* is lacking here. Further, the court notes that although Olympus Medical is not physically located in Colorado, it has regularly travelled here to conduct business and promote its products. Unlike in *Benton* where the Canadian defendant's visits to Colorado were limited to a discrete issue—due diligence—in performing one contract, Olympus Medical's visits were not so restricted in time or scope, and a senior executive visited instead of lower-level functionaries charged with a single task. *Id.* at 1076. And courts have long noted that modern telecommunication and travel infrastructure mitigate the burden in litigating in a distant, even foreign, forum. *Pro Axess*, 428 F.3d 1270 (France); *First Am. Mortg., Inc. v. First Home Builders of Fla.*, No. 10-CV-0824-RBJ-MEH, 2011 WL 4963924, at *3 (D. Colo. Oct. 14, 2011) (Florida); *Media Res., Inc. v. Global Paper 3834875 Canada, Inc.*, No. CIV-05-1038-C, 2006 WL 8436512, at *4 (W.D. Okla. May 12, 2006) (Canada).

The primary burden apparent to the court is the substantial need for translation services. Such difficulties have already forced Plaintiff to seek an extension of time to have written discovery translated. [#78 ("Additionally, at least one-third of the 4,500 pages are in Japanese and Plaintiff anticipates some delay in having any relevant pages reviewed and translated by a Japanese linguist in preparation of its opposition.")]. But this burden typically falls on Plaintiff, not Defendant, and so is immaterial to the issue of Defendant's burden. *E&J Gallo Winery v. Cantine Rallo, S.p.A.*, No. 1:04-cv-5153-OWW-DLB, 2006 WL 3251830, at *5 (E.D. Cal. Nov. 8, 2006) ("Normally, in responding to a request for production of documents, the requesting party would bear the cost of translating documents written in a foreign language"); *In re Korean Air Lines Disaster of Sept. 1, 1983*, 103 F.R.D. 357, 357 (D.D.C. 1984) ("While the Court will not condone an unnecessary escalation of such costs by the production of Korean language documents when English translation are equally available, neither will Korean Air Lines or any defendants be required to bear what is rightly Plaintiffs' burden."). To the extent that Olympus Medical puts itself in the situation of bearing these costs through the unnecessary production of Japanese-language materials when an English version is available, or in responding to interrogatories by production of Japanese-language business records under Federal Rule of Civil Procedure 33(d), *Nature's Plus Nordic A/S v. Nat. Organics, Inc.*, 274 F.R.D. 437, 441 (E.D.N.Y. 2011) ("[W]hen a party responds to an interrogatory by producing documents written in a foreign language, Rule 33(d) requires the responding party to provide a translation of those documents."), that is a burden it has voluntarily assumed and does not figure into this analysis.

In sum, the court finds that the Olympus America purposefully directed its activities towards Colorado, that there is a prima facie case that its Colorado-specific activities were a but-

for cause Plaintiff's injuries, and that the exercise of personal jurisdiction does not offend traditional norms of fair play and substantial justice. The court thus concludes that Plaintiff has satisfied its prima facie burden of establishing personal jurisdiction over Olympus Medical is appropriate, and thus Olympus Medical's Motion to Dismiss for Lack of Personal Jurisdiction is DENIED.

II. Does the First Amended Complaint Set Forth a Design Defect Claim Cognizable under Colorado Law?

Having determined that this court may exercise personal jurisdiction over Olympus Medical, this court now considers the issue of whether the First Amended Complaint sets forth a cognizable claim, as challenged by all Defendants.

A. Elements of Design Defect Claims

The court analyzed Colorado law on the design defect claim in the October 30 Order and will not repeat itself here. In brief, the court concluded that the absence of governing Colorado law on the subject left the court to make an *Erie* guess as to how that court would rule, and this court concluded that the Colorado Supreme Court would apply the Restatement (Second) of Torts § 402A. [#48 at 18 & n.7]. There has been no relevant contrary authority from the Colorado Supreme Court since the October 30 Order. Under this test, there are five requirements to establish a products liability claim based on a design defect theory: (1) the product is in a defective condition unreasonably dangerous to the user or consumer; (2) the product is expected to and does reach the consumer without substantial change in the condition in which it was sold; (3) the defect caused the plaintiff's injury; (4) the defendant sold the product and is engaged in the business of selling products; and (5) the plaintiff sustained damages. *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 536–37 (Colo. 1997) (citing Restatement (Second) of Torts § 402A (1965)); *see also Camacho v.*

Honda Motor Co., Ltd., 741 P.3d 1240, 1244 (Colo. 1987). To establish that an accused product is in a "defective condition," Colorado courts apply the seven-element test from *Armentrout v. FMC Corp.*, 842 P.2d 175, 184 (Colo. 1992):

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product—the likelihood that it will cause injury and the probable seriousness of the injury.
>
> (3) The availability of the substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

This list is not exclusive, but merely illustrative of factors which may assist in determining whether a design is unreasonably dangerous. Depending on the circumstances of each case, flexibility is necessary to decide which factors are to be applied, and the list of factors may be expanded or contracted as needed. *Id.*

In the October 30 Order, the court dismissed Plaintiff's claim because Plaintiff did not make a showing that the product was in a defective condition under the *Armentrout* test. [#48 at 21]. The court was not persuaded that Plaintiff had averred sufficient facts so that a factfinder

could conclude that the Q180V was *per se* defective because the device was more than "difficult" to clean. [*Id.* at 21].

B. Analysis

In the First Amended Complaint, Plaintiff asserts additional facts to support the conclusion that the Q180V Scope was defectively designed under the *Armentrout* test. The First Amended Complaint establishes that that Q180V Scope, contrary to numerous other models manufactured by Olympus Medical and contrary to their own internal guidelines, was designed with a fixed distal-end cap that sealed the elevator wire channel from the outside, supposedly preventing the ingress of fluids from a patient during use. [#49 at ¶¶ 30–35]. Plaintiff further contends that the cap did not fully seal the elevator wire channel but did effectively prevent reprocessing under the provided reprocessing protocols. [*Id.* at ¶¶ 38–40]. Until a subsequent May 2015 update, Olympus Medical never subjected the Q180V Scope to a proper validation testing to ensure that the provided reprocessing protocol was sufficient to ensure that the elevator wire channel was free of contaminants and safe for further patient use; Olympus Medical also included the MAJ-1888 Brush in this update, which had been necessary to effective reprocessing from the beginning. [*Id.* at ¶¶ 36–37]. Plaintiff posits that two alternatives were feasible and would have prevented the harm—either remove any end cap, permitting easy cleaning without the MAJ-1888 Brush or to have a removable cap, which would both reduce the inflow of fluids and allow for easy reprocessing. [*Id.* at ¶ 35]. In fact, these systems were used on other Olympus Scopes, including the Q180V's predecessors, the TJF-160VF, and the 160VR. [*Id.*]. Not long after the May 2015 update, the United States Food and Drug Administration issued a recall of all Q180V scopes "to fix the defective sealing mechanism at the distal end of the device." [*Id.* at ¶ 46].

Nonetheless, Defendants argue that Plaintiff's showing on this point remains deficient. Defendants argue that Plaintiff fails to adequately allege causation as merely stating that she was subject to a Scope contaminated with bacteria and then contracted a bacterial infection is insufficient. [#55 at 9]. Further, Defendants argue that Plaintiff has not met the *Armentrout* factors by failing to allege facts demonstrating that the risks outweighed the benefit. [*Id.* at 10–11]. The Q180V Scope offered greater range of motion and Plaintiff "alleges no facts" to establish that the alternatives referenced above "offered the same utility as the Q180V Scope without the same risk" because the elevator channel itself could contain microscopic crevices that could harbor the same contaminates. [*Id.* at 11].

First, as set forth in more detail below, the court finds that the First Amended Complaint adequately sets forth a plausible causal chain of events. The essence of Plaintiff's claim is that, due to the particular design of the Q180V Scope, it was more likely to retain contaminates from prior use and in fact did so during her procedure. As a result of this exposure, Plaintiff contracted a multi-drug resistant bacterial infection, like the ones that had been previously identified as related to the Q180V in the United States and Europe. [#49 at ¶ 43]. Plaintiff further contends that the patient infections at Erasmus Medical Center in Rotterdam, the Netherlands, identified a defective sealing mechanism for the elevator channel in 2012. [*Id.* at ¶ 44]. While clarifying the temporal proximity between the January 2016 procedure and a subsequent diagnosis would be helpful, it is not necessary at this stage in light of the additional allegations and the court did not intend to suggest otherwise in its October 30 Order. Indeed, the purpose of Rule 12(b)(6) is not to require a plaintiff to prove her case at this juncture, but merely to give Defendants adequate notice of a cognizable claim.

Second, the court finds that Plaintiff meets the *Armentrout* test. Defendants miss the mark in focusing on whether the elevator channel could retain contaminates in crevices regardless of the end-cap design. The focus under one of the non-exclusive balancing factors in the *Armentrout* test is the manufacturer's "ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility." 842 P.2d at 184. The unsafe character of the Q180V Scope is alleged to be the fixed end cap which results in a contaminated elevator channel—it is immaterial to Plaintiff's claim that that the Q180V Scope was designed in such a manner that it could still retain contaminates through an entirely different unsafe characteristic. *See Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1174 (Colo. 1993) (discussing alternate design principles). Identifying the unsafe characteristic and pointing to a feasible alternative is sufficient; when a product's design is based on technical and scientific knowledge, it would be manifestly unreasonable and unfair to require a plaintiff to offer a complete redesign as opposed to pointing to a discrete flaw and showing how it could be remedied.

III. Does the First Amended Complaint Plausibly Allege Causation?

In the October 30 Order dismissing Plaintiff's original Complaint, the court found that all of Plaintiff's claims suffered from a failure to adequately allege causation. [#48 at 21]. The court found that Plaintiff's bare allegations that sometime in January 2016 she had an ERCP and then sometime thereafter fell ill with an unspecified condition was insufficient to plausibly link the two. [*Id.* at 21–22 & n.8 ("Plaintiff's only allegations regarding causation are that the procedure happened and sometime thereafter Plaintiff fell ill."); *id.* at n.8 ("[T]he Complaint fails to allege when was Plaintiff was diagnosed and how long after the procedure, so that the court might consider temporal proximity in causation. Similarly, the Complaint does not even identify the

particular infection. . . ."). Defendants seek dismissal on this point, alleging that the same basic failures to establish causation identified in the October 30 Order persist in the First Amended Complaint. The court respectfully disagrees.

Plaintiff's theory of causation is now more detailed, and the court finds it sufficient to allege causation. The First Amended Complaint now specifies that Ms. Lynch contracted "a multi-drug resistant infection" from the "residual microbial contamination" left in the Q180V Scope from a prior patient, presumably in the elevator channel incompletely sealed off from the device by the distal end cap. [#49 at ¶ 53]. As discussed above, although specifying *when* Plaintiff fell ill might assist the court in finding causation through temporal proximity, the court finds that the First Amended Complaint adequately establishes a plausible case for causation by other averments, i.e., identifying the specific mechanism in the Scope that retained bacteria; why it is difficult to clean; generally identifying the type of infection Plaintiff contracted subsequent to her procedure; and indicating that Defendants recalled the Q180V Scope after Ms. Lynch had her ERCP procedure. *See generally* [#49].

IV. Does Plaintiff's Failure to Warn Claim State a Claim?

A. Elements of Strict Products Liability: Failure to Warn

As before, the court will not repeat its analysis of Colorado law on the failure to warn reflected in the October 30 Order but will briefly summarize its conclusion that the Colorado Supreme Court would apply the Restatement (Third) of Torts § 6(d) to a failure to warn claim as the Colorado Court of Appeals does. [#48 at 23]. The court further concluded that the applicable elements of such a claim were: (1) The warning was defective or inadequate; (2) the alleged inadequacy caused her doctor to prescribe the drug or use the medical device; and (3) had the

warning been adequate, the treating physician would not have prescribed that drug or used that device. [*Id.* (quoting *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008))]. Finally, the court concluded that the "learned intermediary doctrine applied to such a claim; in other words, the failure to warn must be presented as a failure to warn the patient's doctor, the party cognizant of the benefits and dangers of specific medical tools like the Q180V Scope and selecting the tool from competing implements based on that judgment. [*Id.* at 24].[6] Plaintiff's original complaint did not apply these elements or the learned intermediary doctrine and now attempts to do so in the First Amended Complaint.

B. Analysis

The First Amended Complaint asserts that Defendants are liable for failure to warn Ms. Lynch or her treating physician that the redesign of the Q180V Scope rendered it unreasonably dangerous for use in her January 2016 ERCP. [#49 at ¶¶ 67–81]. Specifically, Plaintiff alleges that Defendants, in various joint statements issued prior to her procedure, failed to warn users that the redesign of the scope made effective reprocessing extremely difficult, that the device was associated with numerous infections across the globe due to cross-patient contamination, and that the risk of infection due to cross-contamination from biological matter left in the elevator channel from a previous patient was much higher than that in the Defendants' prior scopes, specifically the

[6] To further clarify the court's analysis from the October 30 Order, the learned intermediary doctrine applies to the selection of a specialized medical device like the Q180V Scope because the doctor is the individual selecting the tool from the array of available options based on her professional judgment. The fact that a doctor decides the patient requires an ERCP and performs it is related to this, but the essential fact is the doctor's selection of a specialized tool for the job that justifies application of the doctrine. Application of the doctrine would be less likely when, for example, a doctor decides a patient needs stitches and uses an over-the-counter antiseptic in the procedure. *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992); *O'Connell v. Biomet*, Inc., 250 P.3d 1278, 1281–82 (Colo. App. 2010).

TJF-160F and TJF-160VF scopes. [*Id.* at ¶ 74]. Had Ms. Lynch and her doctor been warned, they would not have used the Scope in her procedure. [*Id.* at ¶¶ 75–76]. The ineffective warnings associated with the device rendered it unsafe for use and caused Plaintiff's subsequent infection. [*Id.* at ¶¶ 77–81].

Defendants argue that Plaintiff's claim is deficient as to each of the three elements described above. [#55 at 13]. Specifically, Plaintiff acknowledges that any prior deficiencies in the instructions provided along with the Q180V Scope were remedied in the May 2015 update, which included a specialized brush, the MAJ-1888, to effectively reprocess the Scope after use. [*Id.* at 13–14; #49 at ¶ 40 (explaining that Defendants waited until May 2015 to provide additional reprocessing instructions and the MAJ-1888 Brush to end-users)]. Further, Defendants claim that Plaintiff fails to "articulate additional or different warnings from the warning disseminated in May 2015 or plead facts showing such warnings would have prevented her harm by causing her physician to use a different device." [#55 at 14]. Finally, Defendants argue that Plaintiff's claim fails on her own pleading because she specifically alleges that *no* warning could have cured the design defect, an argument which this court already considered to effectively preclude a failure to warn claim because it fatally undermines causation. [*Id.*; #49 at ¶ 99 (arguing that "no update to the reprocessing protocol or accessory could mend" the "known design defects or increased risk of infections with [the Q180V Scope]"); *id.* at ¶ 118 (same); #48 at 26 ("If the device cannot be cleaned, then there cannot be an adequate warning regarding proper cleaning procedures, and therefore the failure to include an adequate warning could not have resulted in an injury to the Plaintiff.")].

The court finds that the failure to warn claim does state a claim under Colorado law. The

court begins by clarifying the precise inquiry at issue for this cause of action as the parties appear to disagree over whether the failure to warn claim focuses on the reprocessing protocols as the putatively deficient warnings. Plaintiff alleges that the reprocessing protocol and assorted instructions for the Q180V Scope were inadequate to ensure effective reprocessing between uses. [#49 at ¶ 74]. But Plaintiff's Amended Complaint is contradictory on the adequacy of the May 2015 update. On one hand, Plaintiff argues that "additional steps were needed to adequately reprocess the Q180V Scope" which were "not introduced until May 2015," including the MAJ-1888, which was "required" for adequate reprocessing of the Scope after use. [*Id.* at ¶ 40]. This would seem to indicate that the Scope, as of May 2015 and certainly by her January 2016 procedure, did in fact have an adequate reprocessing protocol.

On the other hand, the First Amended Complaint emphatically states that no warning or reprocessing protocol would have been sufficient. In the allegations specifically supporting the failure to warn claim, Plaintiff states that "there was no reliable way to clean its Q180V Scopes even after they were reprocessed by users, such as UCH Hospital, who correctly followed the device manuals." [*Id.* at ¶ 78]. Rather, to remedy the dangerous propensity of the Q180V Scope, Defendants had to fundamentally change the design of the Scope, a process that was still incomplete at time of Plaintiff's procedure. [*Id.* at ¶ 73 ("[T]he Q180V Scope featured design elements described herein that rendered it extremely difficult or impossible to adequately reprocess absent a design change that had not been initiated until after Ms. Lynch had her ERCP procedure[.]")]. Defendants argue the First Amended Complaint's inconsistent framing of the adequacy of the reprocessing protocols is fatal to her failure to warn claim.

Plaintiff counters that Defendants have missed the mark—the "warning" at issue is not the

reprocessing protocol, but rather a supplemental warning, never given, regarding the increased risk of infection inherent in the Scope's design. [#70 at 11–12]. The First Amended Complaint sets forth a detailed history of Scope infections that led Defendants to issue the May 2015 update, but the update only reformulated the reprocessing protocols, it contained no mention of the greatly enhanced risk of infection and cross-contamination due to the Scope's design, a risk which may have been mitigated but not fully eliminated by the update. [#49 at ¶¶ 43–46]. Whether the Scope was difficult or impossible to reliably clean, the Scope did not contain any advisement that the nature of the elevator channel cap design rendered it more likely to infect subsequent users. Defendants counter that regardless of the framing of the inquiry, Plaintiff's claim still fails because she never sets forth what warning would have been adequate and would have lead her doctor to refrain from using the Scope in her ERCP. [#73 at 3–4].

The court finds Plaintiff's showing on this point to be adequate at this stage to plausibly establish a design defect claim. The court is not persuaded by Defendants' argument that Plaintiff must "articulate" a specific warning that would have been sufficient except as inherent in plausibly alleging causation. [#55 at 13, 14]. Plaintiff identifies the risk her doctor should have been warned about—infection risk due to Scope design—and points to its obvious absence. *Nowell v. Medtronic Inc.*, No. CIV 17-1010 JBSMV, 2019 WL 1434971, at *55 (D.N.M. Mar. 29, 2019) ("[Plaintiff's] failure-to-warn claim requires her to prove that the Defendants provided her with a defective warning, or no warning at all, and that this warning, or lack of warning, caused her injury."). Regardless of the difficulty or ease with which Defendants may have remedied the underlying problem, the fact remains that Plaintiff alleges that the Q180V lacked any warning as to its dangerous propensity, and so could not have "disclose[d] the nature and extent of the danger."

Id. While this theory could be more clearly set forth in the First Amended Complaint as opposed to the Response, the court is persuaded that the Complaint itself is sufficient in this regard, even when disregarding the clarifying Response.

Plaintiff alleges facts supporting the element that the absence of an effective warning led her doctor to use the device. According to Plaintiff, the Q180V was marketed as "easier to clean than its predecessor" when in fact the redesign of the elevator channel with a distal end cap rendered it far more difficult to clean without the MAJ-1888 or the updated reprocessing protocol, and even that was not enough to do so reliably. [*Id.* at ¶¶ 35, 40]. She alleges her doctor would not have used the Q180V had he known of the increased risks of infection associated with it. [*Id.* at ¶ 76]. While this is a brief and somewhat conclusory allegation as to a critical element in a failure to warn claim, the court is convinced that, in context, Plaintiff makes out a plausible case that had her doctor been aware of the increased risks involved in using a Q180V Scope, he would have selected a different device.[7] In the 30 October Order, the court found that Plaintiff's claim failed because the Complaint established that the device was *per se* dangerous after use, and that there could be no warnings that would have prevented her harm. [#48 at 25]. Plaintiff's theory of the case as laid out in the First Amended Complaint, is that the device was hard to clean in general, and impossible to reliably clean with the provided instructions which made the device more

[7] Plaintiff does not make this argument, and so the court need not definitively resolve it, but Colorado courts have recognized a so-called "heeding presumption" when applying Section 402A to products liability cases. *Uptain v. Huntington Lab, Inc.*, 723 P.2d 1322, 1326 (Colo. 1986). The presumption states that "where warning is given, the seller may reasonably assume that it will be read and heeded." *Id.* Several courts have applied this doctrine to failure to warn claims for prescription drugs, although application to medical devices appears to be comparatively less common. *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992) (examining application and rationale for presumption).

dangerous, more likely to carry contaminates, and Plaintiff's doctor should have received a warning as to this propensity. This is sufficient at this juncture. The court thus finds that the First Amended Complaint states a plausible claim for relief for a failure to warn.

V. Do the Intentional and Negligent Misrepresentation Claims Meet the Heighted Pleading Standards of Rule 9(b)?

A. Intentional Misrepresentation

The court's October 30 Order found Plaintiff failed to specify the manner in which each Defendant participated in making the statements at issue. [#48 at 29 ("Plaintiff fails to identify which party is responsible for which misrepresentations, and instead Plaintiff simply asserts this claim against all Defendants. . . . It seems unlikely that all three defendants made the same 'false representations to Plaintiff and/or Plaintiff's physicians', but even if that were the case, neither the court nor the Defendants are given sufficient information to understand that representatives of Olympus America and OCA made the same false representations to the respective Plaintiff and/or her physicians." (citation omitted)). The court concluded that this form of undifferentiated pleading, where neither the specific misrepresentations nor the speakers were identified with any particularity, fell short of the applicable standards of Rule 9(b). [*Id.* at 28–30].

The First Amended Complaint individually identifies the misstatements at issue while alleging that the misstatements were jointly made by all three Defendants. [#49 at ¶¶ 89–107]. Specifically, Plaintiff identifies four statements made between February 2 and May 6, 2015, by OCA and Olympus America with input from Olympus Medical. [*Id.* at ¶¶ 96–99]. By specifically alluding to the time and place of the misrepresentations, Plaintiff seems to have cured the defects. But Defendants counter that this is still an inadequate showing because Plaintiff does not "specify which defendant told which alleged lie and under what circumstances." [#55 at 16]. Defendants

further counter that Plaintiff's generalized allegations are insufficient and merely relabel the originally objectionable "Defendants" with "Olympus Corp. and Olympus America, with input from Olympus Medical." [*Id.* at 17].

The court respectfully disagrees. The First Amended Complaint clearly sets forth four specific statements and identifies the declarants, and so the court's analysis will focus on whether Plaintiff has adequately set forth the individual defendant's participation in the misstatements. Defendants are correct that Plaintiff's claim is substantively the same as before, generally alleging that all three defendants are responsible for the misstatements but using the specific names instead of simply "Defendants." But the Rule 9(b) analysis is holistic, and the court finds that, when read as a whole, the First Amended Complaint's claim of intentional misrepresentation meets the heightened standards of Rule 9(b).

Rule 9(b) requires a plaintiff to identify the person or persons allegedly responsible for making the misstatement, but it does not require the plaintiff to particularize the reasons why the plaintiff believes the alleged speaker to be responsible for the statement. *S.E.C. v. Nacchio*, 438 F. Supp. 2d 1266, 1278 (D. Colo. 2006). For example, where misstatements are made in "group-published documents such as annual reports, which presumably involve collective actions of corporate directors or officers, Rule 9(b) does not require a plaintiff to identify the individual source of a particular statement, so long as it adequately advises which defendants are alleged to be responsible for the contents of the document." *Id.* (internal quotation marks omitted) (quoting *Celestial Seasonings*, 124 F.3d at 1254). Plaintiff's theory of the case is that OCA and Olympus America are "in effect indistinguishable." [#49 at ¶ 7]. A plaintiff may plead collectively when the Defendants participated in joint misstatements and the entities are indistinguishable from an

outsider's perspective in making the identified statements. *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) ("[T]here is no absolute requirement that where several defendants are sued in connection with an alleged fraudulent scheme, the complaint must identify false statements made by each and every defendant."). Accordingly, this court finds that Plaintiff has adduced enough detail such that her reliance on the characterizing the misstatements as mutual, group misstatements is adequate in context. The court is satisfied that Defendants have the "minimum degree of detail necessary to begin a competent defense." *Fulghum v. Embarq Corp.*, 785 F.3d 395, 416 (10th Cir. 2015).

B. Negligent Misrepresentation

Plaintiff concedes that this claim is also subject to Rule 9(b), but argues for a lessened standard applicable to the negligent misrepresentation claim as it is premised on an omission as opposed to affirmative representations. [#70 at 18]. Defendants make the same argument for dismissal of the negligent misrepresentation claim as for the intentional misrepresentation claim. *See, e.g.*, [#55 at 19]. But in the Reply briefs, Defendants make additional argument not found in their original motions. [#72; #73; #74].

For largely the same reasons, the court finds the negligent misrepresentation claim is also sufficient under Rule 9(b), but notes that this is a clearer decision because Rule 9(b)'s heightened standards are lowered or "relaxed somewhat" when the misconduct is predicated on the omission of certain information as opposed to affirmative misrepresentations as a simple logical necessity: one cannot identify the time and place of a misrepresentation for non-disclosure of information. *Martinez v. Nash Finch Co.*, 886 F. Supp. 2d 1212, 1216 (D. Colo. 2012). For claims premised on omissions, a plaintiff must sufficiently identify "the particular information that should have

been disclosed, the reason the information should have been disclosed, the person who should have disclosed it, and the approximate time or circumstances in which the information should have been disclosed." *Id.* (quoting *S.E.C. v. Nacchio*, 438 F. Supp. 2d 1266, 1277 (D.Colo. 2006)). The court is satisfied that the First Amended Complaint meets this standard.

C. Arguments Asserted for the First Time in Reply

For the first time in their Reply briefs, Defendants argue that the intentional and negligent misrepresentation claims should also be subject to the learned intermediary doctrine just as the failure to warn claim is. [#73 at 5]. This argument was not made in any of the Renewed Defense Motions and so Plaintiff was not afforded an opportunity to respond to this argument. Arguments made for the first time in a reply brief are generally deemed waived. *Kerber v. Qwest Grp. Life Ins. Plan*, 727 F. Supp. 2d 1076, 1079 (D. Colo. 2010). And, as Defendants note, no Colorado case has adopted this standard in this context, and thus the application of this doctrine in this context—even if logical—is not required of this court, and the court declines to wade into new state law territory on a matter raised for the first time in reply. This argument is waived.

Also for the first time in Reply, Defendants argue that Plaintiff's claims for negligent misrepresentation must be dismissed because negligent misrepresentation, as recognized in Colorado, only applies to affirmative statements. [#72 at 6]. Plaintiff's claim is that the provided information did not include a proper reprocessing protocol, and so Defendant argues her claims must fail because her claim is premised on non-disclosure. [*Id.* at 6–8]. This argument was not made in any of the Renewed Defense Motions and so Plaintiff was not afforded an opportunity to respond to this argument. As before, this is an unsettled area of law, and as before, the court declines to make an *Erie* guess in this context – particularly given the fact that Plaintiff has not

had an opportunity to address it. *Sheffield Servs. Co. v. Trowbridge*, 211 P.3d 714, 725 (Colo. App. 2009) (assuming but not deciding that Colorado recognizes a claim for negligent nondisclosure), *overruled on other grounds by Weinstein v. Colborne Foodbotics, LLC*, 302 P.3d 26 (Colo. 2013). This argument is waived at this juncture. In so ruling, this court makes no substantive determinations, and Defendants may raise these arguments in conjunction with any motion for summary judgment.

CONCLUSION

For the reasons set forth herein, it is **ORDERED** that:

(1) Defendant Olympus Medical Systems Corporation's Motion to Dismiss Plaintiff's Complaint for Lack of Personal Jurisdiction [#54] is **DENIED**;

(2) Defendant Olympus Medical Systems Corporation's Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim [#57] is **DENIED**;

(3) Defendant Olympus America Inc.'s Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim [#56] is **DENIED**;

(4) Defendant Olympus Corporation of the Americas' Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim [#55] is **DENIED**.

DATED: June 5, 2019

BY THE COURT:

Nina Y. Wang
United States Magistrate Judge