UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

CANDY TRUMP,

Plaintiff,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 18-CV-06414-LHK

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Re: Dkt. No. 60

Plaintiff Candy Trump ("Plaintiff") brings this action against Defendant Intuitive Surgical, Inc. ("Defendant") alleging negligence, products liability, and strict liability claims arising from alleged defects in Defendant's da Vinci robotic surgery system. ECF No. 19 ("Am. Compl."). Before the Court is Defendant's motion for summary judgment.[1] Having considered the parties' briefs, the relevant law, and the record in this case, the Court GRANTS in part and DENIES in part Defendant's motion for summary judgment.

[1] Defendant's motion for summary judgment contains a notice of motion that is separately paginated from the memorandum of points and authorities in support of the motion. See ECF No. 60 at i. Civil Local Rule 7-2(b) provides that the notice of motion and the points and authorities in support of the motion must be contained in one document with a combined limit of 25 pages. See Civ. Loc. R. 7-2(b).

I. BACKGROUND

A. Factual Background

1. The Parties

Plaintiff Candy Trump is a citizen of West Virginia who resides in Fairdale, West Virginia. Am. Compl. ¶ 3. Defendant Intuitive Surgical, Inc. is a Delaware corporation with a principal place of business in Sunnyvale, California. Id. ¶ 4.

2. The da Vinci System

Defendant produces the da Vinci system, which is a robotic, "multi-armed, remote controlled, surgical device." Id. ¶ 9. Defendant also produces "'EndoWrist' instruments for use in surgery by the [da Vinci system]." Id. ¶ 10. "The most commonly used EndoWrist instrument is the Hot Shears Monopolar Curved Scissors" ("MCS"). Id. ¶ 46. The MCS "allows doctors to both cut and cauterize tissue during surgical procedures," and the MCS cauterizes "through the application of monopolar electricity." Id. ¶ 47. The MCS requires use of a "tip cover accessory" ("TCA") which covers the MCS and "insulate[s] the instrument's metal parts" to "prevent the electricity from spreading to unwanted areas." Id. The MCS "is used in virtually all da Vinci hysterectomies." Id. ¶ 46.

3. Plaintiff's Surgery and the MCS Recall

On July 9, 2012, Plaintiff underwent a hysterectomy, and the operating surgeon, Dr. Norman Siegel ("Seigel"), used a da Vinci system with an MCS and TCA. Id. ¶¶ 52, 56. Siegel did not note any injury to Plaintiff during the procedure, and Plaintiff "arrived in the recovery room in good condition." ECF No. 69-3 at 10-55. Plaintiff spent the night in the hospital and was discharged the following day in good condition. ECF No. 69-2 ("Salsbury Decl.") at 2. However, over the following several years, Plaintiff returned to Siegel and other doctors numerous times in order to complain about pelvic pain and bleeding. Id.

On May 8, 2013, Defendant issued a notice that internal testing had revealed an issue in the MCS model used in Plaintiff's surgery. ECF No. 67-5. Specifically, Defendant concluded that Defendant "identified the potential for micro-cracking of the main tube near the distal end of

the shaft." Id. at 1. Defendant indicated that "micro-cracking" of this nature produced the "potential for insulation failure, resulting in a pathway for electrosurgical energy to leak to tissue and potentially cause unintended burns." Id. Defendant further noted that "the micro-cracks . . . are not visible to the naked eye and require magnification to visualize." Id. at 4. On May 16, 2013, Defendant recalled the MCS model used in Plaintiff's surgery. Am. Compl. ¶ 60; ECF No. 66-23.

B. Procedural History

On October 19, 2018, Plaintiff filed a complaint against Defendant in this district and alleged various tort claims arising from injuries that Plaintiff allegedly suffered because of defects in Defendant's da Vinci system. See ECF No. 1.

On January 3, 2019, Defendant filed a motion to dismiss Plaintiff's complaint. ECF No. 11. However, on January 17, 2019, Plaintiff filed an amended complaint, Am. Compl., and on January 22, 2019, United States District Judge Beth Labson Freeman terminated Defendant's motion to dismiss as moot. ECF No. 20. Defendant's amended complaint alleges the following causes of action under California law: (1) negligence; (2) "products liability – design defect"; (3) "products liability – failure to warn"; (4) "strict liability – manufacturing defect"; and (5) punitive damages. Am Compl. ¶¶ 66–100.

On January 28, 2019, the case was reassigned to the undersigned judge, ECF No. 23, and on the same day, the Court related the instant case to Trump v. Intuitive Surgical Inc., No. 5-18-CV-06413-LHK (N.D. Cal. filed Oct. 19, 2018), and to Bohannon v. Intuitive Surgical, Inc., No. 5-18-CV-02186-LHK (N.D. Cal. filed Apr. 12, 2018). ECF No. 22.

On March 6, 2020, Defendant filed Daubert motions to exclude the expert opinions of Dr. Helen Salsbury ("Salsbury") and Mr. Roger Odell ("Odell"). ECF Nos. 61, 62. On April 24, 2020, the Court denied both of Defendant's Daubert motions. ECF No. 74.

On March 6, 2020, Defendant also filed the instant motion for summary judgment. ECF No. 60 ("Mot."). On March 27, 2020, Plaintiff filed an opposition, ECF No. 66-2 ("Opp'n"), and

on April 3, 2020, Defendant filed a reply, ECF No. 71 ("Reply").

II. LEGAL STANDARD

Summary judgment is proper where the pleadings, discovery, and affidavits show that there is "no genuine dispute as to any material fact and [that] the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Material facts are those which may affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. Id.

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery and affidavits that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party meets its initial burden, the nonmoving party must go beyond the pleadings and, by its own affidavits or discovery, "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). If the nonmoving party fails to make this showing, "the moving party is entitled to judgment as a matter of law." Celotex Corp., 477 U.S. at 323.

At the summary judgment stage, the Court must view the evidence in the light most favorable to the nonmoving party: if evidence produced by the moving party conflicts with evidence produced by the nonmoving party, the judge must assume the truth of the evidence set forth by the nonmoving party with respect to that fact. See Leslie v. Grupo ICA, 198 F.3d 1152, 1158 (9th Cir. 1999).

III. DISCUSSION

Defendant argues that Defendant is entitled to summary judgment because Plaintiff has failed to produce any evidence that a defective MCS or TCA was used during Plaintiff's surgery. Mot. at 6. Defendant also argues that Defendant is entitled to summary judgment because Plaintiff cannot show that a defect in the MCS or TCA caused Plaintiff's injury. Id. at 13. First, the Court briefly addresses Plaintiff's TCA claims. The Court then analyzes Defendant's arguments about

the MCS in turn.

A. Summary Judgment on TCA Products Liability Claims Is Appropriate.

As an initial matter, Defendant argues that Defendant is entitled to summary judgment on Plaintiff's products liability claims as to the TCA. Reply at 12. Indeed, although Defendant makes numerous arguments for summary judgment on Plaintiff's TCA-related claims, Plaintiff fails to respond to these arguments. E.g., Mot. at 6 ("Plaintiff has offered no evidence that there was anything defective in the manufacturing of any tip cover, let alone the one specific to Ms. Trump's surgery, that made it different from other tip covers."). Instead, in opposition, Plaintiff focuses exclusively on alleged defects in the MCS, such as the development of micro-cracks. See, e.g., Opp'n at 9 ("Micro-Cracks Caused Ms. Trump's Vaginal Cuff Injury").

"A district court may not grant a motion for summary judgment solely because the opposing party has failed to file an opposition." Van Mathis v. Safeway Grocery, No. C 09–2026 WHA (PR), 2010 WL 3636213, at *1 (N.D. Cal. Sept. 14, 2010) (citing Cristobal v. Siegel, 26 F.3d 1488, 1494–95 & n.4 (9th Cir. 1994)). However, a court may grant summary judgment if the movant's papers are themselves sufficient to support the motion and do not on their face reveal a genuine issue of material fact. See, e.g., Bains v. Director of Corrections, No. C 04-1619 WHA (PR), 2007 WL 2253563, at *1 (N.D. Cal. Aug. 3, 2007). In the instant case, Defendant's arguments as to the TCA are sufficient to entitle Defendant to summary judgment. E.g., Mot. at 6 ("Plaintiff has offered no evidence that there was anything defective in the manufacturing of any tip cover, let alone the one specific to Ms. Trump's surgery, that made it different from other tip covers."). Moreover, Defendant's motion does not on its face reveal a genuine issue of material fact about the TCA that precludes the entry of summary judgment. Accordingly, the Court GRANTS Defendant's motion for summary judgment on Plaintiff's products liability claims insofar as they concern defects in the TCA. The Court now proceeds to consider Defendant's arguments for summary judgment as to the MCS.

B. There Is a Genuine Issue of Material Fact with Respect to Whether a Defective MCS Was Used in Plaintiff's Hysterectomy.

First, Defendant claims that there is no genuine issue of material fact as to whether a defective MCS was used in Plaintiff's surgery. Specifically, Defendant asserts (1) that there is no genuine issue of material fact as to whether the MCS used in Plaintiff's hysterectomy was defectively manufactured; (2) that there is no genuine issue of material fact as to whether the MCS used in Plaintiff's hysterectomy was defectively designed; and (3) that there is no genuine issue of material fact as to whether the MCS used in Plaintiff's hysterectomy was defective because of a failure to warn. The Court considers these arguments in turn.

1. There Is a Genuine Issue of Material Fact as to Whether the MCS Suffered from a Manufacturing Defect.

Defendant argues that summary judgment on Defendant's manufacturing products liability claim is proper. Mot. at 7. Specifically, Defendant argues that "there is no direct evidence that the MCS used in [Plaintiff's] surgery had microcracks." Id. The Court disagrees.

"A product with a manufacturing defect 'is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line.'" Dunson v. Cordis Corp., 2016 WL 3913666, at *6 (N.D. Cal. July 20, 2016) (quoting *Barker v. Lull Eng'g* Co., 20 Cal. 3d 413, 430 (Cal. 1978)). Here, Plaintiff has produced a genuine issue of material fact on the question of whether the MCS used in Plaintiff's surgery suffered from a manufacturing defect.

As noted, Defendant focuses on the absence of "direct evidence" that the MCS used in Plaintiff's surgery suffered from manufacturing defects. Mot. at 7. However, Plaintiff may prove a manufacturing defect with sufficient circumstantial evidence. See, e.g., Notmeyer v. Stryker Corp., 502 F.Supp.2d 1051, 1059 (N.D. Cal. 2007) (explaining that under California law, a plaintiff may "prov[e] a manufacturing defect using only circumstantial evidence"); Hinckley v. La Mesa R.V. Center, Inc., 158 Cal. App. 3d 630, 643 (1984) ("Where a product fails to such an extent that its examination can furnish no clue as to the specific part that failed, the facts (1) the accident occurred shortly after sale, (2) plaintiffs did nothing to bring about the accident, and (3) expert testimony suggests a defect in fact was responsible for the accident, allow the issue of

whether defendants are strictly liable for plaintiffs' injuries to be submitted to the jury.").

Plaintiff has presented sufficient circumstantial evidence that the MCS used in Plaintiff's surgery suffered from a manufacturing defect to raise a genuine issue of material fact on this issue. Indeed, Plaintiff produced an expert report in which Salsbury, an obstetrician and gynecologist, conducted a differential diagnosis and ultimately concluded that Plaintiff "most likely suffered a thermal injury to her vaginal cuff caused by stray electricity from the da Vinci System." Salsbury Decl. at 7. Salsbury surveyed numerous potential causes and concluded that "[a]fter ruling out the possibilities [], all that remains is a defect in the da Vinci System." Id. at 9. Under California law, "[t]he plaintiff's expert may satisfactorily demonstrate proof of a defect by excluding other possible causes." Lowe v. TDY Industries, Inc., No. B172635, 2005 WL 1983750, at *8 (Cal. Ct. App. Aug. 18, 2005).

Salsbury's conclusion is buttressed by additional circumstantial evidence. In May 2013, the MCS model that was used in Plaintiff's surgery was recalled by Defendant due to the fact that testing revealed that the MCS could develop micro-cracks near the scissor end of the shaft, which could "result[] in a pathway for electrosurgical energy to leak to tissue and potentially cause unintended burns." ECF No. 67-5 at 1; Am. Compl. ¶ 60. Further, Defendant's internal documents indicate that micro-cracks on the MCS are "not visible to the naked eye and require magnification to visualize," which is consistent with the defect having gone unnoticed at the time of Plaintiff's surgery.[2] ECF No. 67-5 at 10.

Defendant cites two cases to argue that Plaintiff has failed to present a genuine issue of material fact notwithstanding the foregoing. First, Defendant cites Yun v. Ethicon, Inc., No. C 00-0487 CRB, 2002 WL 732276 (N.D. Cal. Apr. 22, 2002). However, Yun is highly distinguishable. In Yun, the plaintiff's expert declared that the plaintiff's injury appeared to stem from the area in

[2] Because the Court concludes that the expert report of Salsbury and the foregoing circumstantial evidence are admissible and raise a genuine issue of material fact as to the presence of a manufacturing defect in the MCS, the Court need not address whether Plaintiff's Exhibits 16–22 and 27–48 constitute inadmissible evidence. Reply at 7–8.

the plaintiff's body in which allegedly defective sutures were used. Id. at *2. Moreover, the plaintiff presented evidence that allegedly defective sutures, which were subject to a recall, "may not have been removed" from the hospital's shelves, and hence may have been in the hospital at the time of the plaintiff's surgery. Id. at *3. In the instant case, Plaintiff's evidence is far stronger. Unlike the expert in Yun, Salsbury specifically opines that a defect in the MCS is the most likely cause of Plaintiff's injury. Indeed, according to Salsbury, Plaintiff "most likely suffered a thermal injury to her vaginal cuff caused by stray electricity from the da Vinci System." Salsbury Decl. at 7. Moreover, unlike in Yun, it is undisputed that the MCS model used in Plaintiff's surgery was later subject to a recall due to concerns about a manufacturing defect. ECF No. 66-30.

Second, Defendant cites Will*ett v. Baxter Internat'l, Inc.*, 929 F.2d 1094 (5th Cir. 1991) (Wisdom, J.). Willett is even farther afield from the instant case, however. In Willett, the court simply rejected the plaintiffs' bare argument that "the existence of soot pockets in some [heart] valves is sufficient to create a factual issue as to whether their [heart] valves have soot pockets." Id. at 1097. Here, Plaintiff has put forward far more evidence than the existence of a manufacturing defect in other MCSs. Again, Plaintiff has presented expert evidence that ruled out other causes of Plaintiff's injury and deemed a manufacturing defect in the MCS to be the most likely cause.[3] See generally Salsbury Decl.

Thus, the Court concludes that there is a genuine issue of material fact as to whether the MCS used in Plaintiff's surgery suffered from a manufacturing defect. Accordingly, the Court DENIES Defendant's motion for summary judgment on this ground. The Court now turns to Defendant's argument as to Plaintiff's design defect products liability claim.

2. There Is a Genuine Issue of Material Fact as to Whether the MCS Suffered from a Design Defect.

Defendant contends that "[d]esign defect claims against manufacturers of prescription

[3] For the same reason, Defendant is not entitled to summary judgment merely because Plaintiff lacks direct evidence that the "conditions [that] must occur simultaneously for energy to leak from a microcrack during a surgery" in fact existed during Plaintiff's surgery. Reply at 5.

medical devices, like [Defendant], are not permitted in California." Mot. at 9. Accordingly, Defendant argues that summary judgment is proper as to Plaintiff's design defect claim. Id. The Court disagrees.

Defendant is correct that under California law, manufacturers of prescription medical drugs and devices are not subject to strict liability for design defects. See, e.g., Zetz v. Bos. Sci. Corp., 398 F. Supp. 3d 700, 709 (E.D. Cal. 2019) ("Boston Scientific argues that Plaintiffs' claim for design defect under the strict liability theory fails as a matter of law because California precludes liability for design defect under a strict liability theory for manufacturers of prescription medical devices. This is true."). However, unlike Plaintiff's manufacturing defect products liability claim, Plaintiff does not allege a strict liability theory in connection with Plaintiff's design defect products liability claim. Compare Am. Compl. ¶¶ 71–83 (outlining claim for "Products Liability – Design Defect"), with id. ¶¶ 92–95 (outlining claim for "Strict Liability – Manufacturing Defect").

Under California law, "the appropriate test for determining a prescription drug [or device] manufacturer's liability for a design defect involves an application of the ordinary negligence standard." Garrett v. Howmedica Osteonics Corp., 214 Cal. App. 4th 173, 182 (2013). Accordingly, "[u]nder the negligence standard as reflected in comment k to section 402A of the Restatement Second of Torts, adopted in Brown, a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed." Id. Defendant argues that there is no genuine issue of material fact on this question because the expert reports of Plaintiff's two experts, Salsbury and Odell, must be excluded under Daubert. Mot. at 10–12. The Court denied Defendant's Daubert motions in the instant case. ECF No. 74. Accordingly, Defendant's argument that there is no genuine issue of material fact on Plaintiff's design defect products liability claim must fail.

The Court therefore DENIES Defendant's motion for summary judgment on Plaintiff's design defect products liability claim as to the MCS. Finally, the Court turns to Plaintiff's failure to warn products liability claim.

3. There Is a Genuine Issue of Material Fact as to Whether the MCS Was Defective Because of Failure to Warn.

Defendant claims that Defendant is entitled to summary judgment as to Plaintiff's failure to warn products liability claim. Specifically, Defendant claims that Plaintiff "failed to articulate why [Defendant's] warnings were not 'adequate,'" also that "Plaintiff has no evidence that Dr. Siegel would have performed the surgery differently had he been provided the 'adequate' warnings." Mot. at 12. Again, the Court disagrees.

As to Defendant's first argument, Plaintiff does indeed articulate the nature of Plaintiff's failure to warn products liability claim. According to Plaintiff, Defendant "failed to warn physicians about micro-cracks or of the increased risk of injury resulting from compromised insulation integrity." Opp'n at 17. To the extent that Defendant argues that no such warning was in fact required, Defendant raises a question of fact for the jury. Indeed, under California law, "[i]n general, the adequacy of the warning is a question of fact for the jury." Oxford v. Foster Wheeler LLC, 177 Cal. App. 4th 700, 717 (2009).

As to Defendant's second argument, Defendant contends that because Plaintiff never deposed Siegel, Plaintiff lacks evidence that Siegel's behavior would have changed if Siegel had in fact received a different warning. Mot. at 12. However, California courts "have long recognized that proving causation in a defective products case can be difficult and, indeed, that direct evidence of causation may not exist." Corbo v. Taylor-Dunn Manufacturing Company, A135393, 2014 WL 576268, at *7 (Cal. App Ct. Feb. 14, 2014). Accordingly, "a plaintiff may carry his burden of proving causation by circumstantial evidence." Id. Defendant is not entitled to summary judgment on Plaintiff's failure to warn products liability claim merely because Plaintiff failed to elicit direct evidence that Siegel would have acted differently in the presence of a different warning.

Accordingly, the Court DENIES Defendant's motion for summary judgment on Plaintiff's failure to warn products liability claim as to the MCS. The Court now turns to Defendant's argument that Plaintiff lacks evidence as to the whether any defect in the MCS caused Plaintiff's

injury.[4]

C. There Is a Genuine Issue of Material Fact as to Whether a Defective MCS Caused Plaintiff's Injury.

Defendant argues that notwithstanding the foregoing, Defendant is entitled to summary judgment as to all of Plaintiff's claims. Specifically, Defendant contends that "Plaintiff cannot satisfy her burden on causation as a matter of law because her sole expert opinion on cause must be excluded under Daubert." Mot. at 13. The Court disagrees.

Defendant argues that Salsbury's expert report must be excluded because Salsbury's differential diagnosis was unreliable. Mot. at 15. According to Defendant, Salsbury failed to adequately consider and exclude various patient risk factors and intercourse after the surgery as a potential cause of Plaintiff's injury. Mot. at 14–16. However, the Court has already concluded that Salsbury's expert report is sufficiently reliable notwithstanding Defendant's arguments to the contrary and denied Defendant's Daubert motion. ECF No. 74. As the Court explained, "Defendant may cross-examine Salsbury regarding these potential causes at trial." Id. at 9; see Stanley v. Novartis Pharms. Corp., 11 F. Supp. 3d 987, 1001 (C.D. Cal. 2014) ("Defendant can cross-examine [the expert] regarding additional factors that he did not rule out during trial.").

In Reply, Defendant now also asserts that Salsbury failed to consider the "proximity of the microcrack to the injured tissue." Reply at 3. However, Salsbury did consider the location of the MCS relative to the Plaintiff's injury. Indeed, Salsbury explained, "from the perspective of an OB/GYN experienced in robotically assisted hysterectomies," "the da Vinci is known to produce unintended amounts of electrical current which can thermally injure the surrounding tissue." Salsbury Decl. at 6–7 (emphasis added). To the extent that Defendant's expert argues that an

[4] Because the Court rejected Defendant's argument that evidence of a defect in the MCS is lacking, the Court also necessarily DENIES Defendant's motion for summary judgment on Plaintiff's negligence claim based on the same argument. Mot. at 6 n.5. Moreover, "[a] footnote is the wrong place for substantive arguments on the merits of a motion, particularly where such arguments provide independent bases for dismissing a claim not otherwise addressed in the motion." First Advantage Background Servs. Corp. v. Private Eyes, Inc., 569 F. Supp. 2d 929, 935 n.1 (N.D. Cal. 2008).

insulation defect "would not have been touching or even in close proximity to the vaginal cuff," Defendant has produced an issue of fact for the jury to resolve. ECF No. 60-1 Ex. I ("Arendt Decl.") at ECF 62; see Messick v. Novartis Pharma. Corp., 747 F.3d 1193, 1199 (9th Cir. 2014) ("Dr. Jackson's testimony should be admitted as relevant and reliable. Remaining issues regarding the correctness of his opinion, as opposed to its relevancy and reliability, are a matter of weight, not admissibility.").

In light of the foregoing, the Court concludes that there is a genuine issue of material fact as to whether Plaintiff's injury was caused by a defect in the MCS. Thus, the Court DENIES Defendant's motion for summary judgment on the basis of lack of evidence of causation.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Defendant's motion for summary judgment on Plaintiff's products liability claims as to the TCA. The Court DENIES Defendant's motion for summary judgment in all other respects.

IT IS SO ORDERED.

Dated: June 12, 2020

Lucy H. Koh

LUCY H. KOH
United States District Judge

United States District Court
Northern District of California