UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

SUSAN WEBB, Plaintiff, v. ETHICON ENDO-SURGERY, INC., Defendant.	Civil No. 13-1947 (JRT/JJK) **MEMORANDUM OPINION AND ORDER DENYING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

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Susan Webb brings this action against Ethicon Endo-Surgery, Inc. ("Ethicon"), alleging that a surgical stapler manufactured by Ethicon failed to fire properly during Webb's gastroesophageal surgery, causing her to sustain injuries from a postoperative leak. She asserts claims sounding in strict products liability, negligence with respect to manufacturing, and breach of warranty of merchantability. This matter is now before the

[1] John Sear, Bowman & Brooke LLP, represented defendant Ethicon Endo-Surgery, Inc. and provided argument for the motion at the August 5, 2014, hearing. On September 3, 2014, a Notice of Withdrawal and Substitution of Counsel was filed. (Docket No. 169.)

Court on Webb's motion for partial summary judgment with respect to her strict liability claim.

The Court concludes that Webb is not entitled to summary judgment because, considering the record in the light most favorable to the non-moving party, there is sufficient evidence upon which a reasonable jury could conclude that Webb's injuries were not proximately caused by a manufacturing defect. The Court will thus deny Webb's motion for partial summary judgment.

BACKGROUND

I. SUSAN WEBB'S SURGERY

In May 2009, doctors at St. John's Hospital in Maplewood, Minnesota diagnosed a large tumor on the outside of Webb's esophagus, partly encasing the junction between Webb's esophagus and stomach. (Aff. of Michael Gross ("Gross Aff."), Ex. 11 at 800026, 800098, May 19, 2014, Docket No. 42.) Webb experienced a great deal of pain from the tumor. (Id. at 800025.) Two months later, on July 29, 2009, she underwent surgery at United Hospital in St. Paul, Minnesota, where her case was treated as potentially cancerous. (Gross Aff., Ex. 5 (Aff. of William M. Rupp ("Rupp Aff.")) ¶¶ 7, 23.) Dr. William Rupp was Webb's lead surgeon. (Id. ¶ 7.) Dr. Peter Kelly assisted Dr. Rupp with the surgery. (Id.) Robin Henderson was the circulating nurse on duty. (Gross Aff., Ex. 16 (Aff. of Robin Henderson ("Henderson Aff.")) ¶ 1.)

Nurse Henderson prepared the surgical instruments for Webb's surgery. One of the instruments she readied was a TX60B surgical stapler, manufactured by Ethicon. (Id.

¶ 3; id., Ex. 4 at 1, 4.)[2] Ethicon produces the TX60B as part of its Proximate Linear Stapler line, designed to reclose internal tissue incisions after surgery. (Id., Ex. 4 at 1, 4.) The stapler is supplied sterile in a protective pouch. (Id., Ex. 4 at 8.) It is disposable and intended only for use on a single patient. (Id.) The stapler has two triggers. The "closing trigger" is squeezed prior to firing any staples, in order to secure the tissue in the jaws of the stapler. (Id., Ex. 4 at 5-6.) When a surgeon is ready to reclose the incision, he or she then squeezes the second trigger, also known as the "firing trigger," which discharges the staples along the incision. (Id., Ex. 4 at 6.) If staples of the incorrect size are loaded into a TX60B stapler, the stapler will still fire, but the discharged staples will be malformed. (Rupp Aff. ¶ 43.)

United Hospital stores surgical equipment, including TX60B staplers, on shelves in the United Surgical Services department prior to surgery dates. (Gross Aff., Ex. 15 (Aff. of Tyler Lindquist ("Lindquist Aff.")) ¶ 3.) TX60B staplers are sterile instruments. United Hospital stores the staplers and sends them to the Operating Room in their original packaging to preserve sterility. (Id. ¶¶ 3, 6-7.) Prior to Webb's procedure, Nurse Henderson initialed a "Surgical Checklist" form to indicate that the TX60B stapler was present on the surgical cart. (Henderson Aff. ¶ 3.) During the surgery, Nurse Henderson opened the stapler's sealed sterile packaging and handed the stapler to Dr. Rupp for use during the operation. (Id. ¶ 6.) She has only a vague memory of Webb's procedure but does not recall any mishandling or misuse of the stapler prior to the surgery. (Id. ¶ 7.)

[2] All page numbers refer to the CM/ECF pagination unless otherwise noted.

Dr. Rupp was the surgeon who actually operated the stapler during Webb's surgery. When he was ready to remove Webb's tumor, Dr. Rupp pulled the "closing trigger" on the stapler to secure it in place. (Rupp Aff. ¶ 22.) The closing trigger appeared to function normally, so he proceeded to pull the "firing trigger." (Id.) Because of the position of the stapler in a very narrow space, Dr. Rupp was not able to see whether any staples had been discharged when he pulled the firing trigger. (Gross Aff., Ex. 12 (Dep. of William M. Rupp ("Rupp Dep.")) at 11.) Although he was unable to tell whether any staples had discharged, Dr. Rupp assumed the stapler had fully and properly fired, so he proceeded to remove Webb's tumor without incident. (Rupp Aff. ¶¶ 22-24.)

After Dr. Rupp removed the tumor, he unclamped the stapler and realized that no staples had discharged into Webb's tissue. (Id. ¶ 25.) He inspected both the gastroesophageal tissue and also the excised tumor mass for staples, but did not find any. (Id. ¶¶ 25, 40-41.) Because Webb's incision remained open, Dr. Rupp hand stitched a suture line to close the opening. (Id. ¶ 28.) Dr. Rupp felt that hand stitching was a less desirable option because it could have higher rates of postoperative leaks than stapling. (Id. ¶¶ 19-20, 28-30.) Ethicon disputes the medical evidence on this point. (Decl. of William G. Hawkins ("Hawkins Decl.") ¶¶ 4-7, June 9, 2014, Docket No. 74.) Ethicon asserts that the risk of postoperative leaks following gastroesophageal surgeries is not significantly different for hand-stitched closures than it is for stapled closures. (Id.)

Webb did, in fact, develop a postoperative leak at the surgical site. (Rupp Aff. ¶¶ 29, 31.) As a result of complications from the leak, she was rehospitalized one week after her initial surgery. (Gross Aff., Ex. 7 (Records from Susan Webb's July 2009

hospitalizations at United Hospital) at 000136.) During the second hospitalization, Webb underwent an urgent additional surgery to stop the leak, which was performed by Dr. Peter Kelly. (Id.; see also Rupp Aff. ¶¶ 29, 31.) Webb alleges that she has suffered "cognitive deficits (brain injury) secondary to her critical illness caused by the GI leak," which have "persisted and are permanent." (Compl. ¶¶ 35-36, July 19, 2013, Docket No. 1.)

II. THE DISAPPEARANCE OF WEBB'S STAPLER

Sometime between the end of Webb's surgery and the filing of her claim, the TX60B stapler used during Webb's surgery was lost or discarded. United Hospital's standard procedure following surgeries is to discard one-time use equipment, such as a TX60B stapler. (Henderson Aff. ¶ 10; Lindquist Aff. ¶ 8.) In this case, Dr. Rupp testified that he instructed a member of the surgical team to return the stapler to Ethicon for evaluation. (Rupp Dep. at 4.) When asked by counsel at what time he gave that instruction, Dr. Rupp testified that he did so "[i]mmediately after [he] used it and saw that it didn't function correctly." (Id.) Dr. Rupp did not recall to whom he gave this instruction. (Id.)

In a 2013 affidavit, Nurse Henderson stated that she did not remember the details of Webb's surgery and did not know what happened to the stapler. (Henderson Aff. ¶¶ 1, 10.) In a July 2014 deposition, however, Nurse Henderson described placing the stapler in a red bag and setting it on the counter in the equipment room, along with a note stating, "Per M.D., stapler didn't fire." (Decl. of John D. Sear, Ex. 1 (Dep. of Robin Henderson)

at 10, Aug. 11, 2014, Docket No. 146.) Nurse Henderson does not know whether the stapler was ever returned to Ethicon. (Henderson Aff. ¶ 10.) She and Tyler Lindquist, the Business Manager at United Hospital's Surgical Care Center, both agree, however, that the stapler was not given to Webb or any member of her family. (Id. ¶ 11; Lindquist Aff. ¶ 10.) There is no record of United Hospital actually sending the stapler to Ethicon nor is there a record of Ethicon receiving the stapler. The stapler is now unavailable for inspection.

III. TX60B STAPLER MANUFACTURING PROCESS

TX60B staplers are manufactured at Ethicon's facilities in Juarez, Mexico. (Decl. of Michael D. Cronin ¶ 10, June 9, 2014, Docket No. 73.) The staple cartridges are manufactured by a third-party and delivered to Ethicon's Juarez manufacturing facility to be loaded with staples and assembled as part of the final stapler product. (Id. ¶ 10.)

At the Juarez facility, each stapler goes through four of what Ethicon refers to as "quality assurance processes or checks." (Id. ¶ 25.) First, each new, unloaded staple cartridge is visually inspected by a Staple Maker Loader ("SML") machine operator. (Id. ¶ 12.) The operator places each staple cartridge individually into the automated SML. (Id. ¶ 13.) The SML prepares each cartridge to receive the staples and then loads staples into the cartridge. (Id.)

Second, the cartridges are then removed by the operator who performs a second visual inspection to ensure that the staples are in the cartridge. (Id. ¶ 14.) In addition to the operator's visual inspection, Ethicon's facility selects samples from each batch of

cartridges and conducts a test on the ejection of the staples and their conformity to the correct dimensions and shape. (Id. ¶ 15.)

Third, the operator presents the cartridges to Ethicon's "Staple Presence vision system," which "takes a picture of each individual staple pocket and compares those pictures to known pictures of staple pockets which do and do not have staples inside them." (Id. ¶ 16.) If the system detects an empty cartridge, it automatically "ejects the unacceptable cartridge into a locked scrap bin." (Id. ¶ 17.)

The fourth "quality assurance process" is for each staple cartridge to be fitted with a red retaining cap, which prevents the staples from moving or dislodging during transport. (Id. ¶ 18.) The cap remains in place until the nurse or surgical technician removes the cap in the operating room. (Id.)

Finally, each stapler cartridge is visually inspected and photographed with another vision system to ensure that each cartridge has the correct type of staple in it and a red retaining cap. (Id. ¶ 20.) The staplers are then sent to New Mexico for sterilization, packaged in sterilized pouches, and shipped to hospitals. (Id. ¶ 22.) Michael D. Cronin, the Project Director for Ethicon's Research and Development department, asserts that in twenty-seven years of working at Ethicon, he is "unaware of any time that an empty or defective [stapler] cartridge left the manufacturing facility." (Id. ¶ 26.)

ANALYSIS

I. STANDARD OF REVIEW

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences to be drawn from those facts. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

II. RES IPSA LOQUITUR

Webb seeks relief from Ethicon on three grounds: strict products liability, negligence with respect to manufacturing, and breach of warranty of merchantability. With respect to the strict liability claim, Webb alleges that the TX60B stapler used during her surgery was unreasonably dangerous due to a manufacturing defect at the time it left Ethicon's control. (Compl. ¶¶ 9-10, 41.) She now seeks summary judgment only on her strict liability claim.

A. Res Ipsa Loquitur in Minnesota Strict Products Liability Actions

As a federal court sitting in diversity, the Court applies the substantive law of the state in which it sits. Fogelbach v. Wal-Mart Stores, Inc., 270 F.3d 696, 698 (8th Cir.

2001). To recover on a strict liability claim brought under Minnesota products liability law, "the plaintiff must establish (1) that the defendant's product was in a defective condition unreasonably dangerous for its intended use, (2) that the defect existed when the product left the defendant's control, and (3) that the defect was the proximate cause of the injury sustained." Bilotta v. Kelly Co., Inc., 346 N.W.2d 616, 623 n.3 (Minn. 1984); Mack v. Stryker Corp., 748 F.3d 845, 849 (8th Cir. 2014). A manufacturing defect exists when a product is "physically flawed, damaged, or incorrectly assembled . . . [and] such a defect existed in the product when it left the hands of the manufacturer." Restatement (Third) of Torts: Prod. Liab. § 2, cmt. c (1998). Even if a product's design encompasses certain known risks, "'where individual products within a product line are improperly constructed'" such that the product bears risks not reasonably anticipated by a consumer, the improperly-constructed products are considered unreasonably dangerous. Rynders v. E.I. Du Pont, De Nemours & Co., 21 F.3d 835, 842 (8th Cir. 1994) (quoting Peterson v. Safway Steel Scaffolds Co., 400 N.W.2d 909, 912 (S.D. 1987)).

Where the product is missing or the plaintiff is unable to determine the exact defect in the product, a plaintiff may still reach the jury by employing a theory of res ipsa loquitur. Lee v. Crookston Coca-Cola Bottling Co., 188 N.W.2d 426, 434-35 (Minn. 1971). Under a res ipsa loquitur theory, the plaintiff may rely on circumstantial evidence to demonstrate the dangerously defective nature of a product. Kapps v. Biosense Webster, Inc., 813 F. Supp. 2d 1128, 1147-48 (D. Minn. 2011). Once a plaintiff has shown injury from an allegedly defective product, if:

> the claimed defect is such that there is circumstantial evidence from which it can be inferred that it is more probable than not that the product was defective when it left defendant's hands, absent plaintiff's own want of care or misuse of the product, there is an evidentiary basis for submitting the issue of liability to the jury on both the theory of negligence and strict liability in tort.

Id. at 1147 (quoting Holkestad v. Coca-Cola Bottling Co. of Minn., Inc., 180 N.W.2d 860, 865-66 (Minn. 1970)).

In Minnesota, however, "res ipsa loquitur alone cannot make out a products liability case." Trost v. Trek Bicycle Corp., 162 F.3d 1004, 1009 (8th Cir. 1998). Trost allows plaintiffs to proceed to the jury on a theory of res ipsa loquitur in products liability cases, but plaintiffs must be able to show "'something more'" than that an accident or injury occurred. Id. (quoting Peterson v. Crown Zellerbach Corp., 209 N.W.2d 922, 924 (Minn. 1973)); Bhd. Mut. Ins. Co. v. ADT, LLC, No. 13-1870, 2014 WL 2993728, at *5 (D. Minn. July 2, 2014) (quoting Rohwer v. Fed. Cartridge Co., No. 03-2872, 2004 WL 2677200, at *3 (D. Minn. Nov. 18, 2004)). A plaintiff must also introduce some additional evidence supporting a finding that the product was defective when it left the manufacturer and that the defect caused the plaintiff's injury. Peterson, 209 N.W.2d at 924.

B. Webb's Claim

Because the stapler used during Webb's surgery is now missing, Webb relies on a theory of res ipsa loquitur to make out her strict liability claim. She argues that evidence of previous reports of similarly defective staplers, along with the lack of any testimony contradicting Dr. Rupp's account of the stapler malfunction during Webb's surgery,

entitles her to partial summary judgment. Webb bases this claim largely on the Minnesota Supreme Court's analysis in Lee v. Crookston Coca-Cola Bottling Co. In Lee, the court explained that when a plaintiff relies on a res ipsa loquitur theory to prove a strict liability manufacturing defect claim, "a finding that the [product] was defective when defendant put it on the market would **compel** a verdict **for plaintiffs** . . . ." 188 N.W.2d at 435.

Ethicon, in contrast, contends that the reports of other alleged stapler defects are inadmissible because they are hearsay and because Webb has not shown that the other incidents were "substantially similar" to this case. See Katzenmeier v. Blackpowder Prods., Inc., 628 F.3d 948, 951 (8th Cir. 2010). As such, Ethicon asserts that the reports are insufficient to satisfy the "something more" requirement under Trost and Peterson. Further, Ethicon argues that the theory of res ipsa loquitur, as described in Lee, is designed to enable a plaintiff to reach the jury when circumstantial evidence of a defect is all that is available. At most, it can compel a verdict for the plaintiff at trial when the defendant fails to introduce admissible evidence to combat the plaintiff's claims.

Although Webb has produced some circumstantial evidence, the Court finds that summary judgment is not appropriate for Webb's strict liability claim. Webb is unable to point to any Minnesota case – and this Court has found no case – in which a court has entered summary judgment for the plaintiff in a strict products liability action under a theory of res ipsa loquitur. Rather, when courts have found in favor of the plaintiff under such a theory, it has been to allow the plaintiff to survive a defendant's summary judgment motion and proceed to the jury. See, e.g., Lee, 188 N.W.2d at 432-33 ("The

narrow question presented here . . . is whether circumstantial evidence, the core of the res ipsa loquitur doctrine, is sufficient to take the case to the jury on the theory of strict liability . . . ."); Hammes v. Yamaha Motor Corp. U.S.A., Inc., No. 03-6456, 2006 WL 1195907, at *12 (D. Minn. 2006) ("The court determines that [Plaintiff] has presented sufficient evidence of causation to survive summary judgment."); Schafer v. JLC Food Sys., Inc., 695 N.W.2d 570, 576 (Minn. 2005) ("[W]hen the specific harm-causing object is not known[,] circumstantial evidence should be available . . . for purposes of submitting the issue of liability to the jury in defective food product cases."); Holkestad, 180 N.W.2d at 862 ("The dispositive question presented is whether circumstantial evidence . . . is sufficient to justify the trial court's submission of the issue of defendant-appellant's liability to the jury under the theory of res ipsa loquitur . . . .").

While the Court does not rule out the possibility that there could be a case well-suited to summary judgment for a plaintiff under a theory of res ipsa loquitur, the Court finds that in this case, there remains a genuine issue of material fact as to whether the stapler was defective and proximately caused Webb's injuries. Although Dr. Rupp has provided a detailed account of his recollection of the surgery, there were very few people present in the operating room during Webb's surgery, and other witnesses are less certain about the events that transpired. Accordingly, the Court finds that it is appropriate for Ethicon to have an opportunity to cross-examine Dr. Rupp, Nurse Henderson, and other witnesses.

Additionally, to obtain summary judgment, Webb must prove that that "the defect was the proximate cause of the injury sustained." Lee, 188 N.W.2d at 329. Ethicon has

offered the testimony of Dr. William G. Hawkins and several scientific studies as evidence that postoperative leaks are an inherent risk of gastroesophageal surgery, regardless of whether the surgeon uses a surgical stapler or hand-sewn sutures. (Hawkins Decl. ¶¶ 4-7, Exs. B-D.) The rates of postoperative leaks, Ethicon asserts, are not significantly higher with hand-sewn closures than with stapled closures. Webb disputes the relevance of Dr. Hawkins's testimony in light of the unplanned nature of Webb's hand-sewn sutures. The Court finds, however, that Webb's objections are best addressed on cross-examination. Thus, Ethicon's evidence raises a genuine issue of material fact for the jury to decide.

Based on the evidence presented by both parties, a reasonable jury could find that a defect in an Ethicon stapler was not the proximate cause of Webb's injuries from a postoperative leak. Therefore, the Court finds that partial summary judgment is not appropriate for Webb's strict liability claim.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiff's Motion for Partial Summary Judgment [Docket No. 39] is **DENIED**.

DATED: December 17, 2014
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge