

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	Case No.
LIABILITY LITIGATION	*	4:13-cv-42 (K. SANBORN)

O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Karen Sanborn was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Mrs. Sanborn brought this product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Mrs. Sanborn also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mrs. Sanborn's husband Fred asserts a loss of consortium claim. Mentor seeks summary judgment on several of Mrs. Sanborn's claims. For the reasons set forth below, the Court agrees, and Mentor's Motion for Summary Judgment (ECF No. 38 in 4:13-cv-42) is granted in part and denied in part.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the

movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

Viewed in the light most favorable to Plaintiffs, the record reveals the following. Plaintiffs live in North Carolina, but they lived in Texas when they filed their Complaint. All of Mrs. Sanborn's medical treatment relevant to this action occurred in Texas, and she plans to return to Texas for further treatment if necessary.

Mrs. Sanborn visited Dr. Robert Rosen for treatment of her stress urinary incontinence. Dr. Rosen implanted Mrs. Sanborn with ObTape on March 1, 2005. It is undisputed that Mrs. Sanborn did not see, read, or rely on any documents from Mentor in deciding to undergo the ObTape surgery. At the time of Mrs. Sanborn's surgery, Dr. Rosen had confidence in ObTape because of his prior experience with it, and he would have used ObTape even

if Mentor had disclosed that no clinical trials had been done. Rosen Dep. 97:13-19, ECF No. 43-3. Dr. Rosen testified that he relied on the literature in selecting ObTape, that he read the directions for using ObTape, and that he spoke with a Mentor representative about the product. *Id.* at 87:1-4, 87:21-88:11, 97:7-9. He also testified that he relied on Mentor's representation that ObTape was safe; he would not have used ObTape if he knew it was unsafe. *Id.* at 90:16-91:2. Dr. Rosen further testified that he did not receive any information about how certain factors—such as the type of polypropylene, pore size, and other physical characteristics of ObTape—affected ObTape's safety. *Id.* at 88:21-89:25. Plaintiffs contend that these factors made ObTape unsafe.

Mrs. Sanborn remained continent for two years after her ObTape implant, but she developed several symptoms she attributes to ObTape—including pelvic pain, infections, and incontinence. Dr. Christopher Jayne removed Mrs. Sanborn's ObTape in 2013.

Plaintiffs filed their Complaint on February 15, 2013. See *generally* Compl., ECF No. 1 in 4:13-cv-42. Mrs. Sanborn brought claims for personal injury under the following theories: negligence, strict liability design defect, strict liability manufacturing defect, strict liability failure to warn, and breach of implied warranties. She also brought claims for

breach of express warranties, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation, but she abandoned those claims in her response to Mentor's summary judgment motion, so Mentor is entitled to summary judgment on those claims. Mr. Sanborn brought a loss of consortium claim.

DISCUSSION

Plaintiffs filed their action in this Court under the Court's direct filing order. The parties agreed that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. The parties agree that Texas law applies to Plaintiffs' claims because Plaintiffs are Texas residents and all of Mrs. Sanborn's medical treatment relevant to this action occurred in Texas. Mentor seeks summary judgment on Mrs. Sanborn's claim for manufacturing defect. Mentor also seeks judgment on Mrs. Sanborn's failure to warn and implied warranty claims.

I. Manufacturing Defect Claim

Mrs. Sanborn asserts that her ObTape had a manufacturing defect. "A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." *iLight Techs., Inc. v. Clutch City Sports & Entm't*,

L.P., 414 S.W.3d 842, 846 (Tex. App. 2013). To establish a manufacturing defect, a plaintiff must present evidence that the product "deviated in its construction or quality from its specifications or planned output." *Id.*; accord *BIC Pen Corp. v. Carter*, 346 S.W.3d 533, 540 (Tex. 2011).¹

Mrs. Sanborn's claim for manufacturing defect is based on the same evidence that the Phase I Georgia Plaintiffs presented in opposition to summary judgment: evidence that (1) ObTape's product specifications called for pores measuring between 40 and 100 microns and (2) tests of ObTape samples revealed "non-uniform pores, some of which are closed-ended pores and the vast majority of which are smaller than 40 microns." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1376 (M.D. Ga. 2010). Based on that evidence, the Court found a genuine fact dispute on the Phase I Georgia Plaintiffs' manufacturing defect claims. *Id.*

Mentor contends that Mrs. Sanborn cannot make out a manufacturing defect claim because she did not point to any evidence that an expert examined her specific ObTape and opined that it has a manufacturing defect. One way to prove a

¹ The Texas standard for manufacturing defect is substantially the same as the Georgia standard. See *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010) ("[I]n a manufacturing defect case, the 'product's defectiveness is determined by measuring the product in question against the benchmark of the manufacturer's designs.'") (quoting *ACE Fire Underwriters Ins. Co. v. ALC Controls, Inc.*, No. 1:07-CV-606-TWT, 2008 WL 2229121, at *2 (N.D. Ga. May 28, 2008)).

manufacturing defect is to test the specific subject product against manufacturing standards. For example, in *BIC Pen Corp.*, the parties tested the cigarette lighter that caused the plaintiff's injuries. 346 S.W.3d at 540-41. But Mentor did not point the Court to any authority that such testing is the *only* way to establish a manufacturing defect under Texas law. Here, Mrs. Sanborn relies on the same evidence as the Phase I Georgia Plaintiffs, whose specific ObTape was not tested, either. Rather, their experts tested a number of ObTape samples and concluded that a substantial portion of each ObTape tested had pores smaller than 40 microns. *In re Mentor*, 711 F. Supp. at 1376. At this time, the Court remains satisfied that this evidence is sufficient to create a genuine fact dispute on Mrs. Sanborn's manufacturing defect claim. Mentor's summary judgment motion on the manufacturing defect claim is thus denied. The Court may reconsider this issue when ruling on any motion for judgment as a matter of law that may be presented at trial.

II. Failure to Warn Claims

Mrs. Sanborn asserts two claims based on a failure to warn theory: strict liability failure to warn and breach of implied warranties. For these claims, Mrs. Sanborn contends that Mentor either made affirmative misrepresentations about ObTape to her physicians or concealed ObTape's problems from her physicians. Under Texas law, if "a product is unreasonably or inherently

dangerous, a warning is required." *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006) (quoting *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. 1973)). And, if there is a genuine fact dispute on whether a "label is misleading as to the risk level for developing [a] condition, then the adequacy of the warning "is a question of fact to be determined by the jury." *Id.* "Warning the learned intermediary of a much lower risk than the actual risk could render the warning not just misleading, but ineffective." *Id.*

Mentor contends that Mrs. Sanborn cannot prevail on her failure to warn claims because (1) Dr. Rosen did not recall reading the Mentor product insert data sheet and (2) Dr. Rosen would have used ObTape even if he knew that Mentor had not conducted clinical trials. But Dr. Rosen testified that he relied on the literature in deciding to use ObTape and that he would not have used ObTape if he knew it was unsafe. Dr. Rosen further testified that he was not informed about how certain physical characteristics of ObTape—which Plaintiffs contend rendered ObTape unsafe—affected ObTape's safety. Based on this evidence, with all inferences drawn in favor of Mrs. Sanborn, a reasonable jury could conclude that the ObTape warnings understated ObTape's risks and that Dr. Rosen would not have implanted Mrs. Sanborn with ObTape had he known the true risks

of the product. Accordingly, Mentor's motion for summary judgment as to Mrs. Sanborn's failure to warn claims is denied.

III. Breach of Implied Warranty Claim

Mentor contends that even if there is a fact question on Mrs. Sanborn's failure to warn claims, her breach of implied warranty claims are time-barred. The Court agrees. Under Texas law, "[a] cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach." Tex. Bus. & Com. Code Ann. § 2.725(b). "A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered." *Id.* Based on "the clear, unambiguous language of section 2.725(b) . . . an implied warranty cannot be explicitly extended to future performance." *Safeway Stores, Inc. v. Certainteed Corp.*, 710 S.W.2d 544, 547-48 (Tex. 1986). Therefore, breach of implied warranty claims brought under the Texas commercial code accrue on the date of the sale. *Fontenot v. Kimball Hill Homes Tex., Inc.*, No. 14-00-01375-CV, 2002 WL 834468, at *4 (Tex. App. May 2, 2002) (noting that in cases involving the sale of goods, "limitations runs from the date of the sale").

Mrs. Sanborn argues that the discovery rule applies here and that accrual of her implied warranty claim was delayed because her injury was inherently undiscoverable. But the cases Mrs. Sanborn cites in support of her assertion that the discovery rule applies to breach of implied warranty claims involve services, not goods. See *Baleares Link Exp., S.L. v. GE Engine Servs.-Dallas, LP*, 335 S.W.3d 833, 837 (Tex. App. 2011) (faulty aircraft engine repair); *El Paso Assocs., Ltd. v. J.R. Thurman & Co.*, 786 S.W.2d 17, 20-21 (Tex. App. 1990) (mismanaging property by failing to report on structural problems). Mrs. Sanborn did not offer any authority for ignoring the plain language of § 2.725(b) in this case. The Court thus finds that her breach of implied warranty claim is time-barred, so Mentor is entitled to summary judgment on that claim.

CONCLUSION

As discussed above, Mentor's Motion for Partial Summary Judgment (ECF No. 38 in 4:13-cv-42) is granted in part and denied in part. Summary judgment is denied as to Mrs. Sanborn's manufacturing defect and failure to warn claims. Mentor's summary judgment motion is granted as to Mrs. Sanborn's claims for breach of implied warranties, breach of express warranties, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. The only claims that remain

pending for trial are Mrs. Sanborn's negligence, strict liability design defect, strict liability manufacturing defect, and strict liability failure to warn claims and Mr. Sanborn's loss of consortium claim.

Within seven days of the date of this Order, the parties shall notify the Court whether the parties agree to a *Lexecon* waiver.

IT IS SO ORDERED, this 15th day of October, 2015.

S/Clay D. Land

CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA