

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-121 (R. Preston)

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 Rosa Preston was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Preston brought this product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Preston also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor seeks summary judgment on several of Preston's claims, including her claims for manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. For the reasons set forth below, Mentor's Motion for Partial Summary Judgment (ECF No. 30 in 4:13-cv-121) 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 Preston, the record reveals the following. Preston experienced symptoms of stress urinary incontinence. She consulted Dr. Charles Fougousse and decided to proceed with an ObTape implant. Before her surgery, Preston did not speak with anyone from Mentor or see any materials from Mentor.

Preston's ObTape implant surgery was on July 26, 2005. When complications arose during the implant surgery, Dr. Fougousse consulted with Dr. Brent Campbell. Dr. Campbell implanted Preston with ObTape. Dr. Campbell was not aware of

any problems with ObTape, such as the erosion rate and lack of tissue ingrowth, and he was not aware that "Key Opinion Leaders" in Europe were calling for ObTape to be withdrawn from the market. Campbell Aff. ¶¶ 4-8, ECF No. 35-5. Dr. Campbell stated that if Mentor had informed him of these issues, he "would not have used the Ob Tape on Ms. Preston." *Id.* ¶ 9. But Dr. Campbell did not read the product insert data sheet for ObTape and did not speak with anyone from Mentor about ObTape before he implanted it in Preston; Dr. Campbell relied on Dr. Fougousse's selection of ObTape for Preston and did not rely on any statements by Mentor. Campbell Dep. 25:16-26:25, ECF No. 35-4. Preston's ObTape has never been explanted, and she contends that she has suffered injuries due to the ObTape.

Preston filed her Complaint on May 7, 2013. *See generally* Compl., ECF No. 1 in 4:13-cv-121. Preston brought claims for personal injury under a variety of theories, including negligence, strict liability design defect, strict liability failure to warn, strict liability manufacturing defect, breach of warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

DISCUSSION

Preston filed her 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 Preston’s claims because she is a Texas resident and all of her medical treatment relevant to this action occurred in Texas.

I. Manufacturing Defect Claim

Preston asserts that her ObTape has 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.” *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.2d 797, 800 (Tex. 2006) (quoting *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004)). To establish a manufacturing defect, a plaintiff must present evidence that the product did not meet manufacturing specifications and that the defect caused the plaintiff’s injuries. *BIC Pen Corp. v. Carter*, 346 S.W.3d 533, 540 (Tex. 2011).¹

Preston’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

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.*, Civil Action No. 1:07-CV-606-TWT, 2008 WL 2229121, at *2 (N.D. Ga. May 28, 2008)).

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 Preston cannot make out a manufacturing defect claim because she did not point to any evidence that an expert examined her specific ObTape—which is still in her body—and opined that it has a manufacturing defect. It is true that one way to prove a manufacturing defect under Texas law 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, Preston 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 Preston'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 Claim

Preston also argues that Mentor did not provide an adequate warning regarding ObTape to her implanting physician, Dr. Campbell. See *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012) (explaining learned intermediary doctrine). Mentor contends that Preston cannot establish causation because Dr. Campbell did not read the product insert data sheet or speak with anyone from Mentor about ObTape before implanting it in Preston. But Preston presented evidence that Dr. Campbell would not have used ObTape if Mentor had informed him of certain issues with the product. Given the conflict in the evidence, summary judgment is not appropriate, particularly when all reasonable inferences must be construed in favor of Preston as required at this stage of the proceedings.

III. Misrepresentation and Concealment Claims

Preston asserts that Mentor made misrepresentations about ObTape and concealed material information about ObTape, and she asserts claims for fraudulent misrepresentation, fraudulent

concealment, negligent misrepresentation, and breach of express warranty. These claims "all share the common element of reliance." *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 436 (Tex. 1997). Mentor moved for summary judgment on these claims, arguing that Preston could not point to evidence of reliance. Preston did not respond to the summary judgment motion on this issue, and she did not point to any evidence that she or her implanting physicians relied on any false statement or misleading silence in the materials Mentor provided to them. Mentor is thus entitled to summary judgment on Preston's claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and breach of express warranty.

IV. Breach of Implied Warranty Claim

Preston also asserts a claim for breach of implied warranty. Under Texas law, a four-year statute of limitations applies to such claims. *E.g., Fontenot v. Kimball Hill Homes Tex., Inc.*, No. 14-00-01375-CV, 2002 WL 834468, at *4 (Tex. App. May 2, 2002). Preston contends that the discovery rule applies to implied warranty claims under Texas law and that her implied warranty claim thus did not accrue until she could have reasonably discovered that her problems were caused by ObTape. In support of this assertion, Preston cites several Texas cases, but none of them stands for the proposition that the discovery rule delays accrual of an implied warranty claim related to the

sale of goods. Rather, they suggest that the claim accrues on the date of the product sale. See, e.g., *id.* ("In the sale of goods, limitations runs *from the date of the sale.*") (emphasis added); cf. *Grinnell*, 951 S.W.2d at 435 (finding that implied warranty claims accrued when the plaintiff bought the product). Under this authority, Preston's implied warranty claim accrued in 2005. She did not file her Complaint until eight years later, so her implied warranty claim is time-barred.

CONCLUSION

As discussed above, Mentor's Motion for Partial Summary Judgment (ECF No. 30 in 4:13-cv-121) is granted in part and denied in part. The Court denies summary judgment on Preston's manufacturing defect and failure to warn claims. The Court grants summary judgment on Preston's implied warranty, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and breach of express warranty claims.

IT IS SO ORDERED, this 1st day of September, 2015.

S/Clay D. Land

CLAY D. LAND

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