Austin v. Mentor Worldwide LLC et al

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

COLUMBUS DIVISION IN RE MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION

* * *

MDL Docket No. 2004 4:08-MD-2004 (CDL) Case Nos. 4:13-cv-388 (Austin)

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 Susan Austin was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Austin brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Austin also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor seeks summary judgment on all of Austin's claims. As discussed below, Mentor's summary judgment motion (ECF No. 40 in 4:13-cv-388) 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

2 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 Plaintiff Susan Austin was diagnosed with stress urinary incontinence. Dr. Lillian Decosimo implanted Austin with ObTape on April 12, 2005. Austin relied on Dr. Decosimo in deciding to undergo the ObTape implant surgery; she did not rely on any information from Mentor in making the decision. Though Dr. Decosimo does not remember Austin's case, she testified that she counseled all her "patients that come in with urinary issues that the sling may or may not cure the stress urinary continence parts of it and could worsen any overactive bladder symptoms." Decosimo Dep. 50:7-15, ECF No. 40-6 in 4:13-cv-388.

Dr. Decosimo used products, including ObTape, that were selected by a committee of urologists and gynecologists at the hospital where she practiced; Dr. Decosimo was not part of the selection committee. Decosimo Dep. 16:19-17:20, ECF No. 42-3 in 4:13-cv-388. Although Dr. Decosimo does not recall whether she

3 had any conversations with a Mentor representative regarding ObTape, she did testify that Mentor representatives provided her with information about ObTape at conferences she attended, and she relied on that information. Id. at 69:7-21. Dr. Decosimo expected product manufacturers to disclose risks associated with the product; if Dr. Decosimo received information from Mentor regarding the risks of ObTape, she would have relied on it. Id. at 67:11-68:16. And if the frequency of risks associated with a product is a level Dr. Decosimo deems to be unacceptable, then Dr. Decosimo would not recommend that product. Id. at 107:8-22, 114:16-115:12.

After Austin's implant surgery, her incontinence improved for a while. But then her incontinence worsened, and she had several urinary tract infections and yeast infections. Austin Dep. 44:12-21, ECF No. 42-4 in 4:13-cv-388. Over the next several years, Austin sought treatment from several doctors for her symptoms. Before 2012, none of Austin's doctors told her that her problems might be related to ObTape.

In 2012, Austin sought treatment from Dr. Cheryl Iglesia for recurrent incontinence. Dr. Iglesia did not diagnose Austin with an erosion or infection of her ObTape; the only complication Dr. Iglesia found is that Austin's incontinence had recurred because her ObTape was no longer working. Iglesia Dep. 26:20-28:9, ECF No. 42-6 in 4:13-cv-388. According to Dr.

4 Iglesia, a recurrence of incontinence is a known complication that can happen following a sling procedure. But Dr. Iglesia also testified that the problem may have been that Austin's sling was not tight enough. Id. at 66:7-12. According to Austin, Dr. Iglesia never told her that her ObTape may have been implanted too loosely. Austin Dep. 203:5-8, ECF No. 42-4 in 4:13-cv-388.

Austin testified that Dr. Iglesia told her that the ObTape had become "deformed and wasn't working anymore" due to its small pore size. Id. at 202:11-203:2. Dr. Iglesia recommended removing Austin's ObTape; Austin testified that Dr. Iglesia told her that the ObTape "needed to be removed because of the characteristics of it" and also told her that a "new mesh would help" her. Id. at 198:3-7. Dr. Iglesia's notes state that Dr. Iglesia planned to remove Austin's ObTape "given [ObTape's] potential for erosion and infection." Kuntz Decl. Ex. C, Iglesia Medical R., ECF No. 42-5 at 4 in 4:13-cv-388. After Dr. Iglesia removed a portion of Austin's ObTape and implanted Austin with a new sling, she gave Austin photographs of the excised ObTape and told Austin that "ObTape was being recalled and that it had some mechanical deficiencies." Austin Dep. 35:16-20, ECF No. 42-4 in 4:13-cv-388. Austin understood from Dr. Iglesia that the ObTape had "rotted in [her] body." Id. at 206:8-17.

5 Dr. Bruce Rosenzweig, a urogynecologist who offered an expert report on behalf of Austin, opined

that ObTape "has many well-known characteristics that should have caused Mentor to avoid its use in a product intended for permanent implantation into the human vaginal floor[, including]: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) serious chronic infections and Bio-films; (4) microporous construction resulting in poor tissue ingrowth; and (5) stiff non elastic thermal bonded laser cut mesh. Rosenzweig Report 3, ECF No. 42-7 in 4:13-cv-388. Dr. Rosenzweig further opined that ObTape's "poor design increased the risk of serious complications and caused [Austin's] specific complications." Id. at 15. And Dr. Rosenzweig opined, "[t]o a reasonable degree of medical certainty," that "poor tissue ingrowth, degradation, chronic foreign body reaction, chronic inflammation and chronic subclinical infection of the ObTape caused Ms. Austin's worsening SUI, worsening urge incontinence and urgency, mixed urinary incontinence, frequency, nocturia, mild bladder outlet obstruction, urinary retention, difficulty initiating and stopping stream, dyspareunia, tender and tight left levator ani, mesh banding, the need for pelvic floor physical therapy and the need for a mesh removal procedure." Id. at 18. According to Dr. Rosenzweig, "[b]ut for the ObTape procedure and implantation of the heat-welded polypropylene mesh in Ms. Austin, the tissue

6 response, scarring, subsequent surgical intervention, infections, dyspareunia and urinary dysfunction, as set forth above, would not have occurred." Id.

Austin is a Virginia resident, and nearly all of her ObTape-related treatment took place in Virginia. Austin asserts claims for negligence; strict liability design defect; strict liability manufacturing defect; strict liability failure to warn; breach of warranties; fraudulent concealment; constructive fraud; discovery rule, tolling, fraudulent concealment; negligent misrepresentation; negligent infliction of emotional distress; violation of consumer protection laws; and unjust enrichment. Mentor seeks summary judgment on all of these claims. Austin does not challenge Mentor's summary judgment motion on the following claims: strict liability (Counts II-V); warranty (Counts VI-VII); discovery rule, tolling, fraudulent concealment (Count X); negligent misrepresentation (Count XI); negligent infliction of emotional distress (Count XII); violation of consumer protection laws (Count XIII); and unjust enrichment (Count XV). The Court thus grants Mentor's summary judgment motion as to those claims.

DISCUSSION Austin brought this action on August 8, 2013 by filing a short form complaint in MDL No. 2387 in the U.S. District Court for the Southern District of West Virginia. The case was

7 transferred to this Court as part of a multidistrict litigation proceeding regarding ObTape. In her Complaint, Austin stated that if she had not filed her case directly in MDL No. 2387, then venue would be proper in the U.S. District Court for the Eastern District of Virginia. The parties do not dispute that Virginia law applies to Austin's claims because she is a Virginia resident and nearly all of her ObTape-related treatment took place in Virginia. I. Design Defect Claim

Austin brings a design defect claim under a negligence theory. She asserts that ObTape was negligently designed and that the negligent design caused her injuries. Mentor argues that this claim

fails for lack of causation. The Court disagrees.

Under Virginia law, Austin "bears the burden to produce evidence showing that the defendant was the proximate cause of the injury sustained." McCauley v. Purdue Pharma L.P., 331 F. Supp. 2d 449, 461 (W.D. Va. 2004). "Virginia courts follow the 'but for' rule of proximate causation, under which a defendant is not liable unless the harm would not have occurred but for the defendant's act." Id. Mentor contends that Austin did not point to sufficient evidence to create a genuine fact dispute on causation.

8 As discussed above, Dr. Rosenzweig opined that ObTape's characteristics and design increased the risk of complications like degradation and poor tissue ingrowth. He further opined that the problems with ObTape's design caused Austin's complications, including her worsening stress urinary incontinence and the need for the ObTape removal procedure. And he opined that but for the ObTape implant, the complications— including the subsequent surgical intervention—would not have occurred. Mentor argues that because Dr. Iglesia believed that Austin's sling may not have been tensioned properly when it was implanted, there is no genuine fact dispute on whether Austin's worsening stress urinary incontinence was caused by ObTape's design. The Court is not convinced, however, that Dr. Iglesia's opinion on this point requires exclusion of Dr. Rosenzweig's opinion. Dr. Rosenzweig's expert report is sufficient to create a genuine fact dispute on whether Austin's injuries—including the worsening stress urinary incontinence and the ObTape removal surgery—were caused by ObTape's design. For these reasons, the Court denies Mentor's summary judgment motion as to Austin's design defect claim and her derivative gross negligence and punitive damages claims. II. Failure To Warn and Fraud Claims

Austin brings failure to warn claims under a negligence theory, contending that Mentor did not adequately warn her

9 physicians about the true risks of ObTape. Austin also brings fraudulent concealment and constructive fraud claims, asserting that Mentor made fraudulent misrepresentations to her physicians about the risks of ObTape and that Mentor fraudulently concealed the risks of ObTape. Mentor argues that Austin has not presented enough evidence to create a genuine fact dispute on causation for these claims.

To establish causation on her failure to warn and fraud claims under Virginia law, Austin must establish that a different warning or an accurate disclosure of the risks of ObTape would have made a difference in her treatment. Talley v. Danek Med., Inc., 7 F. Supp. 2d 725, 730 (E.D. Va. 1998), aff'd , 179 F.3d 154 (4th Cir. 1999) ("[A] plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff."); Kling v. Key Pharm., Inc., 35 F.3d 556 (4th Cir. 1994) (table) (concluding that there was no proof of causation because the plaintiff did not present evidence that "more explicit warnings would have altered [the doctor's] treatment plan").

Mentor contends that Austin cannot prove causation because Austin did not suffer an erosion or infection, which are the risks she claims were not adequately disclosed. But Dr. Decosimo, who relied on information representatives provided to

10 her about ObTape at conferences, testified that if the risks associated with a product were at a level she deemed to be unacceptable, she would not recommend that product for her patients. And, one of the reasons Dr. Iglesia elected to excise a portion of Austin's ObTape was the risk of erosion and infection. Based on this evidence, the Court is satisfied that there is a genuine fact dispute on causation for Austin's negligent failure to warn and fraud claims. Mentor is therefore not entitled to summary judgment on these claims.

CONCLUSION As discussed above, Mentor's summary judgment motion (ECF No. 40 in 4:13-cv-388) is granted in part and denied in part. Mentor's motion is granted as to the following claims: strict liability (Counts II-V); warranty (Counts VI-VII); discovery rule, tolling, fraudulent concealment (Count X); negligent misrepresentation (Count XI); negligent infliction of emotional distress (Count XII); violation of consumer protection laws (Count XIII); and unjust enrichment (Count XV). Mentor's motion is denied as to the following claims: negligence (Count I), fraudulent concealment (Count VIII), constructive fraud (Count IX), gross negligence (Count XIV), and punitive damages (Count XVII).

11 This action is ready for trial. Within seven days of the date of this Order, the parties shall notify the Court whether they agree to a Lexecon waiver. IT IS SO ORDERED, this 7th day of December, 2016.

s/Clay D. Land CLAY D. LAND CHIEF U.S. DISTRICT COURT JUDGE MIDDLE DISTRICT OF GEORGIA