United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
March 26, 2024
Lyle W. Cayce
Clerk

No. 23-50274

GeorgAnn Oglesby; Stephen Oglesby,

Plaintiffs—Appellants,

versus

Medtronic, Incorporated; Medtronic USA, Incorporated; Integra LifeSciences Corporation,

Defendants—Appellees.

Appeal from the United States District Court
for the Western District of Texas
USDC No. 5:20-CV-1267

Before King, Ho, and Engelhardt, *Circuit Judges*.

Per Curiam:[*]

GeorgAnn Oglesby sued Medtronic, Inc., Medtronic USA, Inc., and Integra LifeSciences Corporation, asserting manufacturing defect, negligence, and failure-to-warn claims after a medical device implanted in Oglesby's body disintegrated. The district court granted summary judgment in favor of Medtronic and Integra. We affirm.

[*] This opinion is not designated for publication. *See* 5th Cir. R. 47.5.

In July 2019, Oglesby had surgery to address a cyst on her cervical spine. During the surgery, Oglesby's physician implanted a Durepair Dura Regeneration Matrix—a medical device designed to be used as a patch to repair dura matter, which is a membrane protecting the brain and spinal cord. The Durepair device was manufactured by Integra and sold by Medtronic.

Soon after the surgery, Oglesby experienced severe headaches and other serious symptoms. Oglesby underwent another surgery in which her physician discovered that the Durepair patch had largely disintegrated, causing a cerebrospinal fluid leak.

Oglesby and her husband sued Medtronic in Texas state court. Medtronic removed the case to federal court, and Oglesby later amended her complaint to include Integra as a defendant. She asserts manufacturing defect, negligence, and failure-to-warn claims.

Medtronic and Integra both filed motions for summary judgment. The magistrate judge's report and recommendation concluded (1) that Oglesby's manufacturing defect and negligence claims failed because she did not identify a specific defect in the Durepair product and (2) that Oglesby's failure-to-warn claim failed because Oglesby could not show that her doctor would have read the warning even if an adequate warning was provided. The district court adopted the magistrate judge's report and recommendation, granted both summary judgment motions, and dismissed the case. Oglesby appealed.

We review a district court's grant of summary judgment de novo. *Norman v. Bodum USA, Inc.*, 44 F.4th 270, 272 (5th Cir. 2022). Courts grant summary judgment "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). Summary judgment is inappropriate, however, if, viewing the evidence in the light most favorable to the

nonmovant, "a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Oglesby's claims are governed by Texas law. We first address her manufacturing defect claim. "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." *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004). "A plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries." *Id.*

While "[a] manufacturing defect may be established exclusively through circumstantial evidence," *Norman*, 44 F.4th at 272, product failure alone is not enough to prevail on a manufacturing defect claim. *See Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 42 (Tex. 2007). Instead, the plaintiff must identify a specific defect in how the product was manufactured. *See Gharda USA, Inc. v. Control Sols., Inc.*, 464 S.W.3d 338, 352 (Tex. 2015) ("To be successful on a manufacturing defect claim, the plaintiff must identify a specific defect by competent evidence and rule out other possible causes of the damage."); *Ledesma*, 242 S.W.3d at 42 ("While a products liability claim does not of course require proof of manufacturer negligence, the deviation from design that caused the injury must be identified.").

However, Oglesby has not attempted to identify any specific way in which the Durepair product deviated from its design. She acknowledges as much in her briefing, which states that she "has not pointed to the specific mechanism by which the Durepair device was defective." Instead, she argues that the law does not require her to allege a specific defect, relying heavily on older cases from this court and the Texas courts of appeals. *See Ayres v. Sears, Roebuck & Co.*, 789 F.2d 1173, 1175 (5th Cir. 1986) (stating that plaintiffs "need not establish the specific feature which made the product

defective"). *See also Bell Aerospace Corp. v. Anderson*, 478 S.W.2d 191, 197 (Tex. Civ. App.—El Paso 1972, writ ref'd n.r.e.); *Baxter Healthcare Corp. v. Grimes*, No. 05-95-01682-CV, 1998 WL 548729, *10 (Tex. App.—Dallas Aug. 31, 1998, no pet.).

But "[t]o determine Texas law, this court looks first to the final decisions of the Texas Supreme Court." *Austin v. Kroger Tex. L.P.*, 746 F.3d 191, 196 (5th Cir. 2014). In recent years, the Texas Supreme Court has repeatedly stated that identifying a specific defect is essential to a manufacturing defect claim. *See Gharda USA*, 464 S.W.3d at 352; *Ledesma*, 242 S.W.3d at 42; *Nissan Motor Co. v. Armstrong*, 145 S.W.3d 131, 137 (Tex. 2004) ("[A] specific defect must be identified by competent evidence."). *See also Norman*, 44 F.4th at 272 ("[P]laintiffs must allege a specific deviation from the product's intended design that allegedly caused the injury.").

Oglesby points to evidence indicating that the Durepair patch was not designed to dissolve, but that it nevertheless sometimes disintegrates. But none of this evidence establishes a specific manufacturing defect. *See Ledesma*, 242 S.W.3d at 42 (noting that deviation from design "serves the essential purpose of distinguishing a manufacturing defect from a design defect"); *Norman*, 44 F.4th at 272 ("In a manufacturing defect case, . . . the plaintiff must present proof of a manufacturer's *intended* design, from which the actual product in question deviated as a result of a defect in the manufacturing process.").

Oglesby also cites expert testimony that, "within a reasonabl[e] degree of engineering and scientific probability, and on a more-likely-than-not basis, the Subject Durepair contained a manufacturing defect and/or reacted adversely with the Adherus sealant which led to its 'disintegration,' as noted by [Oglesby's physician]." But this testimony also does not establish the specific manufacturing defect that allegedly caused the

disintegration. Nor does it support an inference that such a defect, as opposed to an adverse reaction with the sealant, more likely than not caused the disintegration. "When the circumstances are equally consistent with either of two facts, neither fact may be inferred." *City of Keller v. Wilson*, 168 S.W.3d 802, 813 (Tex. 2005) (internal quotation omitted).[1]

While a specific defect may be proven by circumstantial evidence, that does not eliminate the requirement to allege the existence of a specific defect in the first place. Oglesby failed to do so. Under Texas law, this fact alone means that her manufacturing defect claim cannot succeed. The district court therefore correctly granted summary judgment for Integra and Medtronic on Oglesby's manufacturing defect claim.

Oglesby's negligence claim fails for the same reason. "While strict liability focuses on the condition of the product, negligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production." *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (cleaned up). But "a manufacturer logically cannot be held liable for failing to exercise ordinary care when producing a product that is not defective." *Garrett v. Hamilton Standard Controls, Inc.*, 850 F.2d 253, 257 (5th Cir. 1988). Oglesby points to the doctrine of *res ipsa loquitor*, but this doctrine does not relieve plaintiffs of their burden to allege a specific defect. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (holding that the plaintiff failed to state a manufacturing defect claim because the complaint "d[id] not specify the manufacturing defect," notwithstanding the plaintiff's invocation of the *res ipsa loquitor* doctrine).

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[1] Oglesby contends that the district court improperly weighed the evidence under the merits-stage preponderance-of-the-evidence standard instead of using the proper summary judgment standard under Rule 56. But, as explained above, under Texas law, Oglesby's evidence is legally insufficient for a reasonable jury to find in her favor.

That leaves Oglesby's failure-to-warn claim. Because she didn't object to the magistrate judge's recommendation on this issue, we review for plain error. *See Wallace v. Mississippi,* 43 F.4th 482, 494–95 (5th Cir. 2022) ("[I]t has long been established that, when the district court has not made an independent review of the record, failure to object to an issue in the R & R, when warned of the requirement to file timely objections, results in plain-error review applying to that issue when raised in our court.") (citation omitted). Under plain-error review, among other requirements, "the legal error must be clear or obvious, rather than subject to reasonable dispute." *Puckett v. United States*, 556 U.S. 129, 135 (2009).

"Generally, a manufacturer is required to provide an adequate warning to the end users of its product if it knows or should know of any potential harm that may result from the use of its product." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 153–54 (Tex. 2012). Under the learned intermediary doctrine, which "generally applies within the context of a physician-patient relationship," the manufacturer "fulfill[s] its duty to warn end users of its product's potential risks by providing an adequate warning to the prescribing physician." *Id.* at 142. However, even if a warning is inadequate, the plaintiff must still show that the failure to warn was the "producing cause" of the plaintiff's injuries. *Id.* at 170. "In the [learned intermediary] context, causation entails two distinct factual predicates: first, that the doctor would have read or encountered the adequate warning; and second that the adequate warning would have altered his treatment decision for, or risk-related disclosures to, the patient." *In re DePuy Orthopaedics, Inc.*, 888 F.3d 753, 775 (5th Cir. 2018) (emphasis and footnote omitted).

We agree with Medtronic and Integra that Oglesby did not establish a genuine dispute of material fact on causation. Oglesby's physician testified that he could not recall reading a product manual or any other Medtronic resources about the Durepair product, that he "probably" did not read the

Durepair product's instructions for use when preparing for Oglesby's surgery or when he first learned about Durepair, and that he "maybe" had not ever read the instructions for use.

Oglesby therefore cannot show that an adequate warning would have prevented her physician from using the product. *See Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 277 (5th Cir. 2010) ("Dr. Collini did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference. Her lack of memory, of course, does not preclude the possibility that she had read these materials, but neither can it sustain Pustejovsky's [summary judgment] burden."). Oglesby nonetheless contends that she has established a genuine dispute of material fact because her physician cut the Durepair device to size before implanting it in Oglesby's body. According to Oglesby, this indicates that he did read the Durepair instructions. But her physician testified that cutting the device is merely "standard operating procedure" since "[t]hey come in standard sizes." The fact that he cut the device therefore does not create a genuine dispute of material fact as to whether he read the instructions for the Durepair product.

For these reasons, we affirm the district court's decision to grant the defendants' motions for summary judgment.