United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
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Lyle W. Cayce
Clerk

No. 21-60689

DENNIS NELSON; KATHY NELSON,

Plaintiffs—Appellants,

versus

C. R. BARD, INCORPORATED; BARD PERIPHERAL VASCULAR, INCORPORATED,

Defendants—Appellees.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 2:19-CV-135

Before HIGGINSON, WILLETT, and HO, *Circuit Judges*.

STEPHEN A. HIGGINSON, *Circuit Judge*:

In this products liability case, plaintiffs, Dennis Nelson and his wife, Kathy Nelson ("the Nelsons") sued defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. ("Bard"), due to complications Dennis Nelson experienced after implantation of a filter used as a medical device. The Nelsons now appeal the district court's grant of summary judgment to Bard on their failure to warn and design defect claims. We AFFIRM.

I.

A.

The Nelsons brought this product liability action after Dennis Nelson experienced complications following the implantation of an inferior vena cava filter, called the Recovery IVC Filter (the "Filter"). Generally, such filters are placed inside the body in an effort to prevent blood clots from reaching critical organs such as the heart, lungs, or brain. The Filter, a "venous interruption device[] designed to prevent pulmonary embolism," is designed, manufactured, marketed, and sold by Bard. It was approved by the FDA as an optional retrievable filter in 2003 and could thus be used permanently or temporarily.[1]

Each Filter comes with an Information for Use pamphlet ("IFU") that sets forth various pieces of information, including warnings, precautions, and instructions. Under the bolded "**Warnings**" heading, the IFU read, in relevant part:

> 8. Filter fracture *is a known complication* of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
>
> 9. Movement or migration of the filter *is a known complication* of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment,

[1] Though the parties appear to dispute whether the Filter was intended to be used on a permanent or temporary basis when implanted in Dennis Nelson, neither party provides a record cite directly supporting their position.

> deployment into clots and/or dislodgment due to large clot burdens.

(emphasis added). The IFU also contained a section titled "Potential Complications," and this section included the following information (bold at end in original):

> Procedures requiring perculaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.
>
> Possible complications include, but are not limited to, the following:
>
> - Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
> - Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
> - Perforation or other acute or chronic damage of the IVC wall.
> - Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
> - Caval thrombosis/occlusion.

> - Extravasation of contrast material at time of venacavogram.
> - Air embolism.
> - Hemaloma or nerve injury at the puncture site or subsequent retrieval site.
> - Hemorrhage.
> - Restriction of blood blow.
> - Occlusion of small vessels.
> - Distal embolization.
> - Infection.
> - Intimal tear.
> - Stenosis at implant site.
>
> **All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.**

The Filter was restricted to sale "by or on the order of a physician."

As early as May 2004, Bard internal emails referencing the Filter began to note that there were complications associated with it. Then, on December 17, 2004, Bard's medical director issued an internal document titled "Health Hazard Evaluation" concerning a consultant's report on the Filter. The internal Bard document stated, in part:

> An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known,

> significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable . . . . Nevertheless, the number of reported complaints, and the size of the differences between Recovery and other filters, warrant further investigation.

The document continued:

> Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters.

On May 16, 2005, Dr. Daniel DeVun implanted Dennis Nelson with a Filter. Dr. DeVun performed this procedure as a prophylactic measure to prevent deep venous thrombosis and pulmonary embolism prior to Dennis Nelson's temporary cessation of anticoagulation medication in anticipation of a liver transplant. Medical imaging taken fourteen years later in 2019 revealed that the Filter had fractured. Some of the struts of the Filter had penetrated through the inferior vena cava wall, and some migrated to other parts of Nelson's body. Nelson underwent three surgical procedures to remove the Filter and its fragments. Though the procedures were partially successful, one fragment remains in Nelson's pulmonary artery.

B.

In September of 2017, the Nelsons brought a product liability action against Bard, as a part of a multidistrict litigation suit. The case was transferred to the Southern District of Mississippi in September of 2019. In March of 2021, both the Nelsons and Bard filed motions for summary

judgment. Thereafter, the district court held a hearing on the dueling motions.

On August 6, 2021, the district court granted Bard's motion for summary judgment. It first addressed the Nelsons' failure to warn and design defect claims under the Mississippi Products Liability Act (MPLA). The court held that the IFU "expressly warned" the treating physician of the "very complications" that Nelson ultimately suffered; thus, the warnings were adequate as a matter of law. The district court also addressed Plaintiffs' theory that the warning was inadequate "because the IFU did not list the comparative rates of occurrence of complications relative to a predecessor Bard device and other IVC filters," and held that it had no merit. The court reasoned that Mississippi law does not support the conclusion that a failure to provide comparative-risk information renders a warning inadequate and that requiring comparative risk information to be included would be a problematic slippery slope.

On the design defect claim, the district court held that even though the Nelsons' expert, Dr. McMeeking, had testified to a design defect, the Nelsons had nevertheless "failed to adduce sufficient evidence to create [a] jury question on the issue of causation in fact," since "[t]here is no testimony or evidence cited by the Plaintiff that ties the specific design defect identified by Dr. McMeeking to the damages for which Plaintiffs seek recovery." Alternatively, the district court held that the Nelsons had failed to raise a genuine issue of material fact as to a feasible design alternative under Mississippi law.[2] The Nelsons appealed.

[2] It is notable that the Nelsons originally raised numerous other claims, including, *inter alia*, negligent misrepresentation and fraudulent concealment. It appears that the Nelsons agreed, however, that these claims were "subsumed" in their MPLA failure to

II.

We review a grant of summary judgment de novo. *Doe v. United States*, 831 F.3d 309, 317 (5th Cir. 2016). Summary judgment should be granted "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). When weighing the evidence at summary judgment, all factual inferences are viewed in the light most favorable to the party opposing the motion. *Baker v. Am. Airlines, Inc.*, 430 F.3d 750, 753 (5th Cir. 2005).

In diversity jurisdiction actions, the substantive law of the state in which the district court hearing the action sits controls. *Erie R.R. v. Thompkins*, 304 U.S. 64, 78 (1938); *Capital City Ins. Co. v. Hurst*, 632 F.3d 898, 902 (5th Cir. 2011). Both parties agree that Mississippi law controls this case. Under Mississippi law, the Mississippi Product Liability Act (MPLA) "applies 'in *any* action for damages caused by a product,'" including actions asserting failure to warn and design defect claims. *Elliott v. El Paso Corp.*, 181 So. 3d 263, 268 (Miss. 2015) (quoting MISS. CODE ANN. § 11-1-63).

III.

A.

"In a failure-to-warn case, a plaintiff must show by the preponderance of the evidence that the product was defective because it failed to contain adequate warnings or instructions, the defective condition rendered the product unreasonably dangerous to the user or consumer, and the defective and unreasonably dangerous condition of the product proximately caused the

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warn and design defect claims; regardless, the Nelsons raise no issue relating to the district court's resolution of them.

damages for which recovery is sought." *Id.* at 273 (cleaned up). The MPLA describes adequate warnings or instructions as follows:

> (i) In any action alleging that a product is defective because it failed to contain adequate warnings or instructions pursuant to paragraph (a)(i)2 of this section, the manufacturer, designer or seller shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller, the manufacturer, designer or seller knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition.
>
> (ii) An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

MISS. CODE ANN. § 11-1-63(c). Because the district court granted summary judgment for Bard on the failure to warn claim, we must decide whether the Nelsons are able to show a genuine dispute of material fact so that the claim should have gone to the jury.

We begin by addressing the district court's holding that the warnings were adequate as a matter of law. "An adequate warning is one reasonable under the circumstances." *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d

31, 55 (Miss. 2004). "To be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product." *Id.* at 58 (quoting *Thomas v. Hoffman-Laroche, Inc.*, 949 F.2d 806, 815 (5th Cir. 1992)). Ordinarily, the adequacy of a warning is a factual matter that will be determined by the trier of fact. *Union Carbide Corp. v. Nix*, 142 So. 3d 374, 389 (Miss. 2014).

Here, the district court held that the IFU "expressly warned" the treating physician of the "very complications" that Dennis Nelson ultimately suffered; thus, the warnings were adequate as a matter of law. Indeed, the IFU in its bolded "**Warnings**" explicitly warns of fracture and migration as "known complication[s]," the very complications that allegedly caused Nelson's injuries.

This Court has previously confirmed that "[i]n Mississippi, a warning may be held adequate as a matter of law where the adverse effect was one that the manufacturer specifically warned against." *Austin v. Will-Burt Co.*, 361 F.3d 862, 868 (5th Cir. 2004); *see also Williams v. Manitowoc Cranes, L.L.C.*, 898 F.3d 607, 616 (5th Cir. 2018) (same). In *Austin*, a television news van's telescoping mast "became entangled with the power lines, sending 8,000 volts through the mast and electrifying the van," and an employee touched the van leading to "a fatal electric shock." 361 F.3d at 864. This Court held that the "warnings on the mast clearly connected contact with power lines and risk of death" and, thus, they were adequate. *Id.* at 868-69. This Court affirmed the district court's grant of summary judgment to defendants. *Id.* at 864.

Instructively, in *Williams v. Manitowoc Cranes*, the dispute over the adequacy of the warning "center[ed] on whether Manitowoc needed to warn operators about the *specific* hazard that counterweights could fall during a tip-over." 898 F.3d at 616. Manitowoc argued that warning about the general

hazards of tipping over, combined with instructions about how to avoid a tip-over, constituted adequate warning. *Id.* This Court disagreed, holding that the jury had an adequate basis for finding the warning inadequate and finding that a reasonably prudent person "would have informed crane operators about the unique danger posed by falling counterweights." *Id.* at 617. The Court explained:

> Manitowoc[] . . . failed to warn about the specific "adverse effect" of a counterweight falling, crushing the operator cab, and ejecting the operator from the cab. The . . . [manual] provided no guidance about precautions for avoiding the falling counterweight hazard. Instead, it discussed only in broad terms the harms that could result from a tip-over.
>
> We cannot conclude as a matter of law that Manitowoc adequately warned crane operators about the falling counterweight danger.

Id. at 617. In between these confirming decisions from our Court, the Mississippi Supreme Court itself issued the decision *Johnson & Johnson v. Fortenberry*, 234 So. 3d 381 (Miss. 2017). The Court explained that the label at issue "warned physicians that tardive dyskinesia might develop in patients treated with antipsychotic drugs" and additionally "warned that whether antipsychotic drug products differ in their potential to cause tardive dyskinesia was unknown." *Id.* at 393. The Court therefore held that the label warned the treating doctor "specifically of the danger of tardive dyskinesia in no uncertain terms and was sufficiently adequate as a matter of law." *Id.*

Taken together, these cases support the district court's holding that the IFU warnings were adequate as a matter of law. As in *Fortenberry* and *Austin*, and unlike in *Williams*, where the defendants failed to specifically address the hazard of falling counterweights, the IFU warned of the exact complications that allegedly caused Dennis Nelson's injuries. Nor did it do so in uncertain terms: the IFU emphasized that fracture and migration are

"known complication[s]." The Nelsons do not persuasively argue that there were any specific complications of the Filter that the IFU failed to warn of.[3]

Instead, the Nelsons primarily argue that the warning was inadequate because Bard failed to disclose comparative rates of risk associated with other, similar filters. The district court noted the problematic policy concerns that would follow potential liability for failure to include *comparative* device risk information in warnings. We do not address policy considerations, however perceptive; nor do we conclusively decide as a matter of Mississippi law whether a warning, using other language and in other circumstances, might be inadequate for failing to include undisclosed same-device "dangers" (plural, as in the statute). *Cf. Munson v. C.R. Bard, Inc.*, 561 F. Supp. 3d 655 (N.D. Miss. 2021) (statutory analysis of MPLA).[4] Instead, we hold only that the district court correctly entered summary judgment here, on the Nelsons' inadequate warning claim because the Nelsons fail to discuss, in any meaningful way, the warning language itself.

Rather than explaining why the *text* of the warning was inadequate, the Nelsons argue to us that Bard concealed and omitted risk data and thereby provided "insufficient warning of incidence and seriousness" and, specifically, that Bard failed to warn physicians of high complication rates

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[3] The Nelsons spend a portion of the failure to warn section of their brief apparently arguing that the IFU warning was inadequate because it lacked information addressing the timeline of removal. Bard responds that the Nelsons forfeited this argument by failing to raise it in the district court. We agree. Though the Nelsons did discuss "permanent" filters in detail before the district court, it was within the context of comparative risk, not in the context of language in the IFU. Accordingly, we hold that they have forfeited the argument. *See Rollins v. Home Depot USA, Inc.*, 8 F.4th 393, 397-98 (5th Cir. 2021) (holding that a plaintiff forfeits an argument "that a fact dispute precluded summary judgment by failing to raise it first before the district court").

[4] This case was never raised by the Nelsons, but we have benefitted from its statutory analysis.

that it was aware of at the time. They argue that the information that was concealed was so "egregious" that the "IFU is *per se* inadequate." In making this concealed-information argument, they rely on internal documents. Yet in *Fortenberry*, the Mississippi Supreme Court explained that failure to warn cases must be based upon the warning label itself—its text and language—rather than internal documents:

> Taylor's attempt to prove her failure to warn claims through Janssen's marketing materials and internal documents expanded the claim beyond the statutory scope of the Products Liability Act. Based on the terms of the Act, enacted in 1993, the only pertinent question is whether the prescription drug label contained adequate warnings or instructions.
>
> . . .
>
> The Court does not consider Janssen's marketing materials or internal documents as support of Taylor's failure to warn claim under the Products Liability Act in determining the adequacy of the Risperdal label. Taylor's attempt to support her failure to warn claim with Janssen's marketing materials and internal documents improperly expands the statutory scope of her claim.

234 So. 3d at 393 (citations omitted).[5]

Like the plaintiff in *Fortenberry*, the Nelsons quote from internal Bard emails and the 2004 Health Hazard Evaluation to assert that "Bard did not set forth its own internal data or information concerning the failure rates of

[5] It is noteworthy that in *Fortenberry* itself, the label at issue affirmatively stated that "[w]hether antipsychotic drug product differ in their potential to cause Tardive Dyskinesia is unknown," *Fortenberry*, 234 So. 3d at 389, yet the Court still held, as to the failure to warn claim, that comparative risks drawn from internal documents were not pertinent to the label's adequacy. *Id.* at 393. By contrast, the Court in *Fortenberry* explicitly affirmed that a plaintiff can draw inferences from internal documents when that plaintiff is pursuing a negligent misrepresentation claim. *Id.* at 394.

the Recovery filter in the IFU insert provided in the packaging." Yet the Nelsons fail to address the language of the warning itself and how it was inadequate, as required by *Fortenberry*. As noted, Bard's warning label warned in two different locations that Filter fracture and migration were "known complication[s]." The Nelsons have thus failed to raise a genuine issue of material fact as to their failure to warn claim.

B.

"In a design-defect claim under the MPLA, the plaintiff must prove, by the preponderance of the evidence, that 'the product was designed in a defective manner,' that '[t]he defective condition rendered the product unreasonably dangerous to the user or consumer,' and that '[t]he defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.'" *Elliot*, 181 So. 3d at 271 (quoting MISS. CODE ANN. § 11-1-63(a)(i)-(iii)). Additionally:

> In any action alleging that a product is defective because of its design . . . , the manufacturer, designer or product seller shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller:
>
> (i) The manufacturer or seller knew, or in light of reasonably available knowledge or in the exercise of reasonable care should have known, about the danger that caused the damage for which recovery is sought; and
>
> (ii) The product failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability prevented the harm. A feasible design alternative is a design that would have to a reasonable probability prevented the harm without impairing the utility, usefulness, practicality or desirability of the product to users or consumers.

MISS. CODE ANN. § 11-1-63(f).

The district court granted summary judgment to Bard on the design defect claim, holding that the Nelsons failed to show how the design defect they highlighted—"tilting"—caused the fracturing and migration that led to the complications experienced by Dennis Nelson. The district court also held that the Nelsons failed to show a genuine issue of material fact as to a feasible alternative design, because they cited to no testimony explaining that their proposed alternative design would have "*prevented* the harm without impairing the utility, usefulness, practicality, or desirability" of the Filter. We affirm the district court's first holding and so do not reach the second.

Bard argues that the Nelsons' design defect claim must fail because they had no expert testimony on specific causation, *i.e.*, an expert who could have testified that a design defect caused the injuries suffered by Dennis Nelson. Although no requirement exists that an expert must always connect the dots of specific causation,[6] we agree with the district court that the Nelsons failed to draw its attention, at the summary judgment stage, to evidence that the Filter's allegedly defective design proximately caused the device to fracture and migrate after it had been implanted in Dennis Nelson. The district court was explicit about this missing piece:

> [R]egardless of whether Mississippi law requires that causation be addressed in terms of general and specific causation, it is an

[6] Bard relies on *Vaughn v. Miss. Baptist Medical Center*, 20 So. 3d 645 (Miss. 2009). In that case the Mississippi Supreme Court held that "Vaughn's argument that lay-witness testimony can establish the element of proximate cause is without merit" because "[a] lay witness cannot render an opinion as to whether the symptoms exhibited by Vaughn were associated with infection." *Id.* at 654. But the Court expressly limited its holding, explaining that although "diagnosing symptoms has been explicitly held by this Court to be outside of the realm of a lay person and an activity that requires a medical expert," "a medical expert is not necessary in instances in which a layman can observe and understand the negligence as a matter of common sense and practical experience." *Id.* at 653-54. Thus, while Mississippi law requires expert testimony on specific causation in some cases, it does not require such testimony across the board.

> element under the MPLA that a plaintiff show that the defective design, which renders the product unreasonably dangerous, proximately caused the damages for which recovery is sought. *See* Miss. Code. Ann. § 11-1-63(a)[](iii). The Court finds that Plaintiffs have failed to adduce sufficient evidence to create [a] jury question on the issue of causation in fact. There is no testimony or evidence cited by the Plaintiff that ties the specific design defect identified by Dr. McMeeking to the damages for which Plaintiffs seek recovery. His testimony addresses how the design can cause the filter to tilt, but here the issue is fracturing and migration. There is no evidence submitted to the Court that ties a design defect to these particular issues.

The Nelsons make broad statements throughout their brief that presume a design defect must have caused Dennis Nelson's complications—e.g., "[h]ow could [Nelson] have a retained fragment in his lung absent design-induced fracture and migration?"—but actual evidence had to be identified to the district court in order to advance beyond the summary judgment stage for a design defect claim. *See Elliot*, 181 So. 3d at 271; MISS. CODE. ANN. § 11-1-63(a)(iii); FED. R. CIV. P. 56(a). Although not quoted to the district court in the summary judgment proceedings, we discern in one excerpt of Dr. McMeeking's testimony his opinion pointing in the direction of causation—where he used a ruler to testify to the "geometric effect" that tilt brought about, asserting that "the limb will fracture by fatigue that much sooner because of this geometric effect that is associated with perforation of the limb through the wall of the IVC." However, the Nelsons failed to direct the district court's attention to this quote, and so we do not consider it here. *See Malacara v. Garber*, 353 F.3d 393, 405 (5th Cir. 2003) ("Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment." (citation omitted)); *Ragas v. Tenn. Gas Pipeline Co.*, 136 F.3d 455,

458 (5th Cir. 1998) ("The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his or her claim.").[7]

IV.

For the reasons set forth above, we AFFIRM the judgment of the district court. All other pending motions are DENIED.

[7] After choosing not to file a reply brief, the Nelsons brought a binder with several tabs to oral argument and filed a post-argument letter. Bard moved to strike the binder and letter or allow additional briefing on the matter. The Court has not referenced or examined the binder, and it was not entered into the record, so striking it is unnecessary.