United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
December 6, 2022
Lyle W. Cayce
Clerk

No. 22-10201

DENNIS HARRISON; SUSAN HARRISON,

Plaintiffs—Appellants,

versus

MEDTRONIC, INCORPORATED,

Defendant—Appellee.

Appeal from the United States District Court
for the Northern District of Texas
USDC No. 3:20-CV-1407

Before HIGGINBOTHAM, DUNCAN, and ENGELHARDT.

PER CURIAM:*

When a pacemaker allegedly malfunctioned and caused the plaintiff's cardiac arrest, he sued the manufacturer on various products liability and implied warranty claims. The district court dismissed all the plaintiff's claims, concluding the allegations in his third amended complaint were insufficient. We agree with the district court that the plaintiff failed to plead valid manufacturing and marketing defect claims under Texas law. But we

* This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

disagree with respect to the plaintiff's design defect claim and his implied warranty claim, which the plaintiff supported with adequately specific allegations. Accordingly, we affirm in part and reverse and remand in part.

I.

In August 2017, Plaintiff Dennis Harrison underwent heart surgery, in which doctors implanted an external pulse generator ("EPG"), a type of pacemaker manufactured by Defendant Medtronic. A day after the surgery, Harrison went into cardiac arrest, requiring medical staff to resuscitate him by performing CPR and shocking him. Although medical staff saved his life, Harrison alleges the cardiac arrest has left him with permanent injuries, including chest pains and neurological deficits.

Harrison and his wife Susan (we refer to them together as "Harrison") sued Medtronic, claiming the company's EPG caused the cardiac arrest by firing a mistimed electrical pulse in between Harrison's heartbeats. Harrison claims this malfunction was caused by the EPG's loose battery or a corroded lead-connector. He therefore brought products liability claims, under both strict liability and negligence, for manufacturing, marketing, and design defects, and a separate claim for breach of the implied warranty of merchantability.

After Harrison served his second amended complaint, Medtronic moved to dismiss for failure to state a claim. The district court granted the motion, with its order identifying the pleading's factual deficiencies. By leave of court, Harrison was then allowed to file a third amended complaint.

The district court found the third amended complaint substantially similar to the second, with the only difference being two new factual allegations concerning the EPG's allegedly defective design. The new allegations are that (1) the EPG's battery should have been secured by a clip or phalange to prevent power malfunctions, and (2) the EPG's lead

connector should have been made from a non-corrosive metal. The court found that these new allegations were conclusory and insufficiently specific, and consequently that the third amended complaint also failed to plead all essential elements of Harrison's claims. The court thus dismissed the complaint, this time with prejudice. Harrison timely appealed.

II.

We review *de novo* the grant of a motion to dismiss under Rule 12(b)(6), accepting all well-pleaded facts as true and viewing them in the light most favorable to the plaintiff. *Retana v. Twitter, Inc.*, 1 F.4th 378, 380 (5th Cir. 2021). To survive such a motion, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). Although a complaint need not allege facts in minute detail, it must allege "'more than labels and conclusions,' as 'a formulaic recitation of the elements of a cause action will not do.'" *Heinze v. Tesco Corp.*, 971 F.3d 475, 479 (5th Cir. 2020) (quoting *Twombly*, 550 U.S. at 555)). Finally, while our review is generally limited to allegations on the face of the pleadings, we "may consider documents attached to or incorporated in the complaint." *United States ex. rel. Willard v. Humana Health Plan Tex. Inc.*, 336 F.3d 375, 379 (5th Cir. 2003).

III.

Harrison brings products liability claims for manufacturing, marketing, and design defects (both of the strict liability and negligence varieties). He also brings a claim for breach of the implied warranty of merchantability. We address those two groups of claims separately.

A.

We turn first to Harrison's strict products liability claims. To prevail on such claims under Texas law, a plaintiff must show: (1) a defective product that (2) was unreasonably dangerous, (3) did not substantially change from its original condition when it reached the consumer, and (4) caused the plaintiff's injuries. *Syrie v. Knoll Int'l*, 748 F.2d 304, 306 (5th Cir. 1984); *see Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997).[1] Texas recognizes three types of product defects: "marketing, design, and manufacturing." *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006). Harrison alleges that Medtronic's EPG suffers from all three kinds of defects. We agree with the district court that Harrison failed to plead viable manufacturing or marketing claims, but we disagree with respect to his design claim.

1.

To allege a manufacturing defect, a plaintiff must plead that a "product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." *Casey v. Toyota Motor Eng'g & Mfg. N. Am., Inc.*, 770 F.3d 322, 326 (5th Cir. 2014). The "touchstone" of such a claim "is proof that the allegedly defective product differs from other products in the same product line." *Id.* at 329. Harrison concedes he failed to allege a specific manufacturing defect. That is for good reason: his third amended complaint claims only that the EPG "*may*

[1] By contrast, a claim of negligent products liability requires only that we "look[] at the act of the manufacturer and determine[] if it exercised ordinary care." *Garrett v. Hamilton Standard Controls, Inc.*, 850 F.2d 253, 256 (5th Cir. 1988) (quoting *Syrie*, 748 F.2d at 307). Despite these different showings, a negligence claim still presupposes a "defective" product. *Id.* at 257. Consequently, our conclusion with respect to the strict liability claims—which turns on whether Harrison adequately pleaded a particular defect—controls our disposition of the negligence claims. *See infra* p. 4–9.

have contained a manufacturing defect," without identifying anything specific or even alleging the device deviated from Medtronic's specifications. Pleading the "mere possibility of misconduct" does not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

Harrison instead argues *res ipsa loquitur* ("the thing speaks for itself"), an evidentiary rule that allows a factfinder to infer a defendant's negligence from the "circumstances surrounding the accident." *Haddock v. Arnspiger*, 793 S.W.2d 948, 950 (Tex. 1990). But our court has explained that merely "rel[ying] on *res ipsa loquitur*" is not a valid substitute for shouldering the burden of specifying a manufacturing defect. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). That is because "Texas law does not generally recognize a product failure or malfunction, standing alone, as sufficient proof of a product defect." *Casey*, 770 F.3d at 326; *see Cooper Tire*, 204 S.W.3d at 807 ("The mere fact that the [product] failed would amount to evidence of a manufacturing defect so slight as to make any inference a guess and is in legal effect no evidence.") (cleaned up).[2] The district court thus correctly found that Harrison failed to allege a manufacturing defect.

2.

Harrison's marketing defect claim fails for similar reasons. A marketing defect exists "when a defendant knows or should know of a potential risk of harm presented by a product" but fails to adequately warn buyers. *Wright v. Ford Motor Co.*, 508 F.3d 263, 274 (5th Cir. 2007) (citation

[2] *Res ipsa loquitur* is also a poor fit here because it only applies when the product is in the "control of the defendant." *Pearson v. BP Prods. N. Am., Inc.*, 449 F. App'x 389, 391 (5th Cir. 2011). Harrison pleads that his doctor, not Medtronic, inserted the pacemaker, conceding the device was outside Medtronic's control when it allegedly malfunctioned. *See also, e.g.*, *Tyre v. Excel Indus., Inc.*, No. 4:19-CV-951-A, 2020 WL 791052, at *5 (N.D. Tex. Feb. 14, 2020) (holding that *res ipsa loquitur* is inapplicable in a products-liability claim when the product was in the user's possession, not the defendant's).

omitted); *see Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995). The hallmark of this claim is that the "lack of adequate warnings or instructions renders an otherwise adequate product unreasonably dangerous." *Smith v. Robin Am., Inc.*, 484 F. App'x 908, 912 (5th Cir. 2012) (quoting *Ranger Conveying & Supply Co. v. Davis*, 254 S.W.3d 471, 480 (Tex. App.—Houston [1st Dist.] 2007, pet. denied)). Usually, the adequacy of a defendant's warning is a question of fact, but "if a warning specifically mentions the circumstances complained of, then the warning is adequate as a matter of law." *Hale v. Metrex Rsch. Corp*, 963 F.3d 424, 428 (5th Cir. 2020) (quoting *Seifried v. Hygenic Corp.*, 410 S.W.3d 427, 433 (Tex. App.—Houston [1st Dist.] 2013, no pet.)).

Harrison's complaint mostly parrots the legal elements of a marketing defect claim, without identifying which of Medtronic's warnings were allegedly defective. General allegations—such as that the "warnings failed to inform the user of the nature of the danger"—do not meet the pleading standard. *See, e.g.*, *Fearrington v. Bos. Sci. Corp.*, 410 F. Supp. 3d 794, 802 (S.D. Tex. 2019) (dismissing complaint because it only "allege[d] generally" that defendant failed to provide adequate warnings). Harrison's only specific allegations are really design-defect claims in disguise. For instance, he claims Medtronic should have warned doctors that the device's lead connector could result in malfunction. But this allegation does not claim the warning, or lack thereof, renders this "otherwise adequate [pacemaker] unreasonably dangerous." *Smith*, 484 F. App'x at 912 (quotation omitted). The claim is rather that Medtronic's design using lead, instead of a less-corrosive metal,

rendered the pacemaker inherently dangerous.[3] That is a design claim, not a marketing claim.

3.

Harrison's complaint does sufficiently plead a design defect claim, however. Such a claim requires allegations that: (1) the product's defective design made it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect caused the alleged injury. *Casey*, 770 F.3d at 330 (citing *Goodner v. Hyundai Motor Co.*, 650 F.3d 1034, 1040 (5th Cir. 2011)). To overcome a 12(b)(6) motion to dismiss, a plaintiff need not provide "detailed factual allegations" proving each element, but only enough "'to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or evidence." *In re S. Scrap Material Co.*, 541 F.3d 584, 587 (5th Cir. 2008) (quoting *Twombly*, 550 U.S. at 556).

The third amended complaint satisfies that standard. Harrison pleaded the EPG was defectively designed because (1) its battery did not maintain constant connection with the battery drawer, and (2) its lead connector had a propensity to, and did, corrode. These defects, he alleged, caused the EPG to fire a mistimed electrical impulse in between his heartbeats which caused his cardiac arrest. Harrison also alleged that the

[3] The district court alternatively concluded that Medtronic's warnings were adequate as matter of law since its product manual explicitly warned of the EPG's battery failure and potential lead-connector problems. Since Harrison referenced the EPG's warnings in his complaint and Medtronic attached the technical manual containing the warnings to its motion to dismiss, the district court can properly review the manual. *See Sullivan v. Leor Energy, LLC*, 600 F.3d 542, 546 (5th Cir. 2010) ("[T]he court may consider documents attached to a motion to dismiss that 'are referred to in the plaintiff's complaint and are central to the plaintiff's claim.'" (quoting *Scanlan v. Tex. A&M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003))). Harrison fails to challenge on appeal the district court's conclusion that Medtronic's warnings were legally sufficient, so he has forfeited the issue. *See Rollins v. Home Depot*, 8 F.4th 393, 397–98 & n.1 (5th Cir. 2021).

EPG was unreasonably dangerous because Medtronic could have mitigated this risk either by inserting a clip to hold the battery or by using a silver or copper connector less prone to corrosion. Those allegations sufficiently plead a design defect claim by alleging how the product's design caused it to fail, how the failure caused his injury, and how Medtronic could have designed a safer product.[4] In response, Medtronic contends that Harrison's allegations are mere "speculation" thrown against the wall "in the hope one theory might stick." We disagree. At this stage, we must take Harrison's claims as true, and, viewing them as such, they sufficiently allege a design defect claim under Texas law.

The district court rejected Harrison's design defect claims because his complaint did not include a "substantive evaluation" of the EPG's risks versus benefits, nor specifically allege safer alternative designs that are economically and technically feasible. We disagree. Harrison's complaint specified alternative designs that he claimed are both safer and feasible and that, by not using them, the EPG was unreasonably dangerous. That is enough at the pleading stage. Harrison's complaint did not need to include additional specificity with respect to proposed alternative designs.[5] Those "very detailed and specific allegations" can wait until Harrison has an "opportunity for discovery." *Flagg*, 647 F. App'x at 318; *cf. Casey*, 770 F.3d

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[4] *See, e.g.*, *Flagg v. Stryker Corp.*, 647 F. App'x 314, 318 (5th Cir. 2016) (under a similar Louisiana law, finding validly pleaded design defect where the complaint alleged manufacturer could have used a different metal alloy); *Ardoin v. Stryker Corp.*, 2019 WL 4933600, at *2 (S.D Tex. Oct. 7, 2019) (finding validly pleaded design defect where complaint alleged bone screws were designed with defects in their metallurgical integrity).

[5] *See, e.g.*, *Ardoin*, 2019 WL 4933600, at *3 (holding "[p]laintiff's allegations that the components could have been alternatively designed in a safer manner such that they did not contain discrepancies or metallurgical weaknesses must be accepted as true" on a 12(b)(6) motion).

at 330–336 (balancing the tradeoffs of an alternative design at summary judgment after discovery).

We therefore reverse the district court's dismissal of Harrison's design-defect claim.[6]

B.

Finally, we turn to Harrison's claim for breach of implied warranty of merchantability, which the district court also dismissed. Under Texas law, merchants implicitly warrant that their goods are not defective. *See Gen. Motors Corp. v. Brewer*, 966 S.W.2d 56, 57 (Tex. 1998). To recover on such a claim, a buyer must notify the seller "within a reasonable time after he discovers or should have discovered" any defect. *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 705 (5th Cir. 2014) (quoting TEX. BUS. & COM. CODE § 2.607(c)(1)). The reasonableness of notice "is ordinarily a question of fact," but notice can be unreasonable as a matter of law if no reasonable mind could disagree that the notice was untimely. *Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 271 F.3d 624, 628 (5th Cir. 2001).

The district court found that Harrison's implied warranty claim failed for two independent reasons. First, the court concluded Harrison's failure to plead a defect was also fatal to his implied warranty claim. But, as discussed, Harrison did sufficiently plead a design defect, so his implied warranty claim cannot be dismissed on this basis.

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[6] As explained *supra* note 1, Harrison's negligence-based products liability claims also depend on adequately alleging one of the three kinds of product defects. *Garrett*, 850 F.2d at 257. Given our conclusion that Harrison properly alleged only a design defect claim, we reverse the district court's judgment as to that negligence claim only. We affirm as to Harrison's negligence claims based on alleged manufacturing and marketing defects.

Separately, the court found that Harrison's notice to Medtronic was so untimely that his warranty claim failed as a matter of law. We disagree because the court based its ruling on assumptions not warranted on a motion to dismiss. It found that Harrison informed Medtronic of the alleged defect in a July 2019 letter. Because Harrison plead the EPG was the only explainable cause for his cardiac arrest, the court assumed he must have known the device was defective when it malfunctioned in August 2017. But Harrison alleges he realized the EPG was defective only based on his cardiologist's testimony, which occurred sometime after the malfunction. We must accept that plausible allegation as true at this stage. *See Masel v. Villarreal*, 924 F.3d 734, 743 (5th Cir. 2019). Furthermore, even assuming Harrison should have known the EPG was defective at the time of his cardiac arrest, Medtronic does not explain why a delay of less than two years is so unreasonable that the question must be removed from the factfinder. By failing to establish when Harrison "discovered the breach" and "why the period between [Harrison's] discovery of the breach and his giving notice was unreasonable," we cannot conclude Harrison's notice was so unreasonable it fails as a matter of matter of law. *Ketter v. ESC Med. Sys. Inc.*, 169 S.W.3d 791, 799–800 (Tex. App.—Dallas 2005, no pet.) (concluding a two year and seven-month delay from plaintiff's receipt of the product to when notice was provided was not unreasonable as a matter of law).

Ultimately, of course, Harrison still bears the burden to show he did not unreasonably delay notice to Medtronic. *See McKay*, 751 F.3d at 705. But viewing the facts in his favor, as we must do at this stage, we conclude that Harrison alleged a valid implied warranty claim.

IV.

Medtronic separately argues that we should affirm the district court's judgment on alternative grounds because Harrison failed to disclose experts

by the district court's deadline, and, without experts, he cannot prove his claims. But our "powers are limited to reviewing issues raised in, *and decided by*, the [district] court." *Companion Prop. & Cas. Ins. Co. v. Palermo*, 723 F.3d 557, 561 (5th Cir. 2017) (alteration and emphasis in original) (citation omitted). Whether Harrison has run out of time to designate experts is a question better addressed by the district court in the first instance. Harrison previously moved to extend the expert-designation deadline, but the district court dismissed his case before deciding whether good cause warranted an extension. We therefore remand the case to the district court to consider that question and any other questions the court and the parties deem pertinent.

V.

For the foregoing reasons, the district court's judgment is AFFIRMED IN PART, REVERSED IN PART, and REMANDED for further proceedings consistent with this opinion.