IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
October 31, 2017
Lyle W. Cayce
Clerk

No. 17-50010

RAY WILDMAN,

Plaintiff - Appellant

v.

MEDTRONIC, INCORPORATED; MEDTRONIC USA, INCORPORATED,

Defendants - Appellees

Appeal from the United States District Court
for the Western District of Texas

Before WIENER, HIGGINSON, and COSTA, Circuit Judges.

GREGG COSTA, Circuit Judge:

Ray Wildman contends that a Medtronic device implanted in his back to relieve pain did not last as long as the company promised. The result was an infection that required surgery and caused him to miss months of work. Wildman brought suit alleging breach of express warranty under Texas law. If this state-law claim would impose a requirement that is "different from, or in addition to" those imposed by the Food and Drug Administration when it approved the medical device, then federal law preempts the claim. 21 U.S.C. § 360k; *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). On the other hand, if the claim "parallels" federal requirements—that is, if it would enforce a duty also imposed by federal law—then it is not preempted. *Id.* at 330. We

thus must decide whether Wildman's claim alleging false representations about the "device life" of the product would undermine FDA regulation or reinforce it.

I.

Wildman suffered from chronic back and leg pain. In an attempt to manage that pain, he had a Medtronic RestoreUltra neurostimulator (the Device) surgically implanted into his back. The Device is designed, manufactured, and marketed by Medtronic, and once inserted, it "delivers mild electrical signals to the epidural space near [the] spine through one or more thin wires that provide electrical impulses to thin plastic leads." These electrical impulses block pain signals before they reach the brain.

The Device malfunctioned about a year and a half after it had been implanted. Wildman started to experience additional pain and consulted with two doctors about removing the device. He first met with a doctor who determined that the stimulator had stopped working and that the additional pain did not seem to be the result of any physiological change in Wildman's condition. The doctor's notes suggest Medtronic representatives were present at Wildman's medical appointments, and the company was notified of problems with his device. Wildman was then referred to another doctor to "look into getting his stimulator battery replaced."

This doctor concluded that the "left side quit working and Medtronic[] tried to get it to work and they said it need[ed] to come out." Medtronic representatives present at this appointment determined that the "entire device [was] dead." About a month later, Wildman had surgery to remove the Device. The area where the surgical staples had been became infected, with the wound site draining liquid and causing significant pain. After about a month, Wildman saw yet another doctor who discovered that an abscess had formed, which required additional surgery. Wildman maintains that he was unable to

work for five months due to the multiple surgeries required to remove the Device and address the resulting infection.

Wildman sued Medtronic in state court alleging breach of express warranty. He contends that the Device functioned properly for roughly a year and a half when Medtronic claimed in written marketing material that the neurostimulator had a device life of nine years. His amended complaint, filed after the case was removed to federal court, says that Wildman relied on the following statement (the Statement) from Medtronic's website about the Device:

> While other manufacturers may state that their batteries have a longevity greater than 9 years, it's important to understand that many other factors and components are involved in determining the overall longevity of an implanted medical device. The result of extensive design and testing involved in manufacturing rechargeable neurostimulators give Medtronic the confidence that our device is reliable for 9 years.
>
> To achieve this distinction, Medtronic rigorously verified and validated the many components that impact device longevity, not just the battery. The result is a rechargeable neurostimulator that delivers reliable performance over the entire period of predicted service. Medtronic is the only company to offer a Neuromodulation Product Performance Report.

The complaint further alleges that this warranty language was "never reviewed by or submitted to the FDA for approval."

As a Class III device regulated by the FDA,[1] the Device underwent a rigorous premarket approval process that resulted in a finding that there was

[1] The Medical Device Amendments to the Food Drug and Cosmetics Act created three classes of medical devices, the most highly regulated of which is Class III. A Class III device is one that: (1) insufficient information exists to determine that the application of a lower level of control is sufficient to provide reasonable assurance of its safety and effectiveness; (2) is purported or represented to be for a use in supporting or sustaining human life or for a

a "'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)). This process also includes a review of a device's labeling to ensure it is "neither false nor misleading." 21 U.S.C § 360e(d)(1)(A). As part of this process, the FDA reviewed the Device's "System Eligibility, Battery Longevity, Specifications Reference Manual." After considering this report, the FDA approved a statement that the Device's "battery life" was "9 years." The agency also evaluated the criteria for determining battery longevity and verified that nine years after implant, the Device would output the message "EOS (End of service)" when electronically analyzed by a doctor or Medtronic employee. Medtronic has not identified anything in the FDA record showing that the agency endorsed or evaluated any claim about the longevity of Device components other than the battery.[2]

Wildman's original complaint included assertions that the malfunction was due to the battery, but his amended complaint contends that the neurostimulator did not conform to a "nine-year device life." Medtronic moved for judgment on the pleadings under Rule 12(c) on three grounds: (1) that the claim was preempted by federal law, (2) that Wildman failed to adequately plead reliance on the warranty, and (3) that Medtronic's Limited Warranty is the exclusive remedy available to Wildman. The district court concluded the

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use which is of substantial importance in preventing impairment of human health; or (3) presents a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(C).

[2] At the Rule 12 stage, the court is usually limited to considering the pleadings. Because the approval process is part of the public record, however, the court is entitled to take judicial notice of the information presented in the FDA documents. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (holding that it was appropriate for the court to take judicial notice "under Rule 12(b)(6), of the PMA the FDA granted" the defendant because the documents and transcripts produced by the FDA were "matters of public record directly relevant to the issue at hand"); *see also Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.").

claim was preempted. We review *de novo* that Rule 12 dismissal. *See Bass v. Stryker Corp.*, 669 F.3d 501, 506 (5th Cir. 2012).

II.

A.

The FDA, which for decades had been reviewing the safety and effectiveness of drugs before they were allowed to enter the market, began doing the same for medical devices after a 1976 amendment to the Food, Drug, and Cosmetic Act. The Medical Device Amendments of 1976 imposed comprehensive and nationally uniform regulations for an increasing number of complex medical devices. *See Riegel,* 552 at 315-16. The Amendments include an express preemption provision stating that:

> [N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
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> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). In *Riegel*, the Supreme Court concluded that this provision preempts not just state administrative regulation but also state tort law. *Riegel,* 552 U.S. at 325. Tort claims are preempted because jury verdicts holding device manufacturers liable under the common law for requirements the FDA did not impose would undermine the FDA's central oversight role. *See id.* at 323-26.

But preemption of state common law is not absolute. Because preemption's concern is with state requirements that conflict with FDA determinations or that require more than the premarket approval process does, *Riegel* clarified that state claims "premised on a violation of FDA regulations" may go forward. *See id.* at 330; *Bass*, 669 F.3d at 509-10 (finding

state common law claims not preempted when premised on violation of federal requirements); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769-70 (5th Cir. 2011) (same); *see also* Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD & DRUG L.J. 113, 120 (2010) ("In order to avoid preemption by § 360k(a), a state-law claim against a PMA Class III device should be premised on a breach of a state-law duty that is the same as a duty imposed under the PMA or one of its implementing regulations."). These are called "parallel" claims because they enforce FDA regulations rather than add to or undermine them. *Riegel*, 552 U.S. at 330.

Many courts have navigated the course between preempted and parallel express warranty claims. The essence of an express warranty claim is a broken promise.[3] When the promise was one the FDA approved, tort liability for breaking it would conflict with the FDA's view that the representation was a sound one. So when a claim challenges a representation the FDA blessed in the approval process, it is preempted. *See Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931-32 (5th Cir. 2006) (holding a breach of express warranty claim preempted when the warranty was part of a medical device's "Instructions for Use" that was reviewed and approved by the FDA). But when a claim challenges a warranty that goes above and beyond any guarantee the FDA expressly or implicitly approved, it is a parallel one. *See id.* at 932 (discussing the principle that express warranties can escape preemption).[4] It

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[3] The claim has six elements under Texas law: "(1) the defendant sold services to the plaintiff; (2) the defendant made a representation to the plaintiff about the characteristics of the services by affirmation of fact, by promise, or by description; (3) the representation became part of the basis of the bargain; (4) the defendant breached the warranty; (5) the plaintiff notified the defendant of the breach; and (6) the plaintiff suffered injury." *Paragon Gen. Contractors, Inc. v. Larco Constr., Inc.*, 227 S.W.3d 876, 886 (Tex. App.—Dallas 2007).

[4] *See also Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997) ("A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted."); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex.

is parallel because, as we have mentioned, federal law requires that representations about medical devices be truthful.[5] This comes from the Food, Drug, and Cosmetic Act's prohibition on the sale of "any . . . device . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). A device is misbranded if it is sold using "false or misleading advertising." *Id.* § 352(q)(1).[6]

B.

The preemption question thus comes down to whether the warranty on Medtronic's website was consistent with assessments made during the approval process, in which case this lawsuit would be preempted as a challenge to the FDA's determination of safety and effectiveness, or whether the warranty goes beyond what the FDA considered.[7]

2014) (explaining that an "express warranty claim can survive to the extent [the plaintiff] seeks to recover based on false warranties that Medtronic voluntarily and falsely made beyond the federally approved warning") (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 788 (D. Minn. 2009)); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1180 (C.D. Cal. 2013) (same); *Parra v. Coloplast Corp.*, 2017 WL 24794, at *4 (E.D. La. Jan. 3, 2017) (same) (citing *Gomez*, 442 F.3d at 932); *Heisner v. Genzyme Corp.*, 2008 WL 2940811, at *8 (N.D. Ill. July 25, 2008) (holding same).

[5] Medtronic notes that most of the cases recognizing the viability of parallel express warranty claims involved representations about "off-label" uses of a device and suggests that is a limitation. But *Gomez* was not an off-label case and it would not have needed to analyze whether the representation concerned matters reviewed by the FDA if such claims were categorically preempted. 442 F.3d at 931-32. We see no reason why false representations that go beyond matters considered by the FDA should escape preemption only when they relate to off-label use.

[6] Parallel claims sometimes face another obstacle: implied preemption that is in addition to the express preemption dealt with in *Riegel*. Implied preemption precludes state tort claims that "exist solely by virtue of" the federal regulatory scheme. *Buckman Co. v. Plaintiffs Legal Comm.*, 531 U.S. 341, 353 (2001). Such claims—the paradigmatic one being fraud in connection with the FDA approval process—cannot be brought under state law because the FDA is the exclusive enforcer of its regulations. *Id.* at 347-50. But implied preemption does not apply to common law claims that would reach the alleged wrong independent of the FDA process. *Id.* at 352. As a breach of express warranty claim parallels, but does not exist solely because of, the FDA requirement—a warranty claim can be brought against products in all types of industries—implied preemption is not a problem. Indeed, Medtronic does not urge that defense.

[7] The express preemption inquiry normally proceeds in two steps. The first asks whether the FDA established requirements applicable to the medical device at issue. *Riegel*, 552 U.S. at 322. The answer to that question is almost always yes once a device has gone

What did the warranty promise? Medtronic argues that it equates battery life with device life, which makes "eminent sense" because the Device's "primary component [is] the battery." Medtronic goes on to say that its warranty claimed that battery longevity was the limiting factor to overall longevity and thus "battery life *was* the device life."

But a plain reading of the warranty is at odds with Medtronic's interpretation. It repeatedly makes a "distinction" between the battery and the "many components" and focuses on guaranteeing the reliability of the latter. The Statement begins by asserting that although other manufacturers "may state that their batteries have a longevity greater than 9 years, it's important to understand that *many other factors and components* are involved in determining the overall longevity of an implanted medical device" (emphasis added). The next sentence states that "extensive design and testing . . . give Medtronic the confidence that our device is reliable for 9 years." Why does it have that confidence? Because "Medtronic rigorously verified and validated the many components that impact device longevity, not just the battery." By

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through the PMA process. *See id.* at 322-23 ("Premarket approval, in contrast, imposes 'requirements' under the MDA as we interpreted it in *Lohr*."). We conclude it is that simple here, although the question whether the warranty was limited to the battery or extended to other components was considered in the district court as part of this inquiry. But the approval of the Device itself through the premarket approval process seems to be all the first inquiry requires. *See Bass*, 669 F.3d at 508 (holding that an entire device, including its component parts, satisfied the first step of *Riegel* when the FDA reviewed those components during the PMA process). The dispositive question—does the Statement cover topics considered by the FDA—relates to the second *Riegel* inquiry: whether the claim imposes requirements "'different from, or in addition to' federal requirements." *Riegel,* 552 U.S. at 323; *Hughes*, 631 F.3d at 767-68 (analyzing express preemption claim under step two of *Riegel)*; *Houston*, 957 F. Supp. 2d at 1180 ("The Court concludes that Plaintiff's breach of express warranty claim is not expressly preempted because it would not impose any requirement different from or in addition to what federal law demands."); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009) (finding a breach of express warranty claim against a medical device manufacturer passed the second step of *Riegel* and was not preempted).

its own terms, the Statement says that longevity of many components other than the battery contributes to the Device's overall longevity.

The Statement cannot reasonably be read as anything other than a claim of comparative advantage over competitors that vouch only for the life of their batteries. Medtronic is telling consumers why its product is superior. When the Statement says nine years, it means the many components—in its words, "not just the battery"—are guaranteed to last that long. It cannot have it both ways by claiming that as an advantage over competitors in the marketplace and now contending that only the battery life matters. Nor has Medtronic convinced us that battery life would be the only factor affecting the Device's longevity. Of course, when the battery dies, the device would cease to function. But it does not follow that the failure of the device would only be attributable to a drained battery. There are other potential points of failure—such as the casing, the connections between the wires and battery, or the embedded computer and software. The Statement says each of the many components were tested in guaranteeing "reliable performance" over the "entire period of predicted service." So like any number of products—consider a car's drivability which depends not just on a working battery but also a functioning engine or alternator—Medtronic offered an express warranty on the longevity of the entire Device.

Whether Wildman can challenge the truthfulness of that Statement thus depends on whether the FDA evaluated the longevity of the "many components." As we mentioned at the outset, the FDA did test battery life and approved a statement that the Device's "battery life" was "9 years." But Medtronic has not identified anything in the administrative record showing that the FDA evaluated the longevity of other components. At oral argument, it could point to only two pages of the record to support its contention that the nine-year battery life was synonymous with a nine-year device life: first, a

table outlining the physical characteristics of the Device that lists "[b]attery life" at "9 years;" and second, a section on "battery longevity" that states the device will output the message "end of service" nine years after implant. Neither passage indicates the FDA was suggesting that every component was certified to last for nine years in the manner represented by Medtronic on its website.

As a result, the Statement goes beyond what the FDA evaluated in its approval process. Medtronic may make such representations, but it faces state law liability if they are proven false. A verdict finding that Medtronic misled consumers like Wildman in making this representation—something Wildman is a long way from proving as this case is just at the pleading stage—would not undermine any FDA finding concerning the safety of the device. It would instead be enforcing a duty that also exists under federal law: to not make misleading representations about the Device. And to escape such liability, Medtronic would not need to redesign the Device, but only to limit its warranties to those approved by the FDA. Accordingly, the narrow breach of express warranty claim Wildman asserts is not preempted.

III.

Although many courts have recognized that an express warranty claim challenging representations that go beyond what the FDA approved may escape preemption, those claims often fail for other reasons. One is a failure to allege the claim with particularity, which Medtronic says is true of Wildman's allegations and provides an alternative ground for affirming.

Most of the express warranty claims that have been subject to *Twombly/Iqbal* dismissals in medical device cases have failed to plead the specifics of the warranty. Rather than point to a written guarantee from the medical manufacturer, as Wildman has, the unsuccessful plaintiffs have asserted vague allegations about representations the device manufacturer

made to doctors or consumers. *See Schouest*, 13 F. Supp. 3d at 707 ("[W]hat is missing from Schouest's complaint, in its current form, is a description of what specific warranties Medtronic made to Schouest or her physicians."); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1043 (D. Haw. 2014) (same); *Houston*, 957 F. Supp. 2d at 118 (same); *see also Bass,* 669 F.3d at 515-16 (dismissing an express warranty claim because the plaintiff pleaded the company's affirmative representations in "wholly conclusory fashion"). Although Wildman has identified a specific representation on the website, Medtronic alleges another defect in his allegations. It argues that even if claims about longevity of components other than the battery can theoretically escape preemption, Wildman has not sufficiently alleged that one of those other components caused the Device to fail. Wildman ultimately needs to make that showing or he would not be able to establish that Medtronic breached the warranty about those other components.

But initial review of this pleading issue is better suited for the district court. On remand the district court should also consider the other grounds Medtronic asserted in its motion to dismiss, including another argument challenging the plausibility of Wildman's claim: that he did not allege reliance on the warranty.

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The judgment is REVERSED and the case REMANDED for further consideration consistent with this opinion.