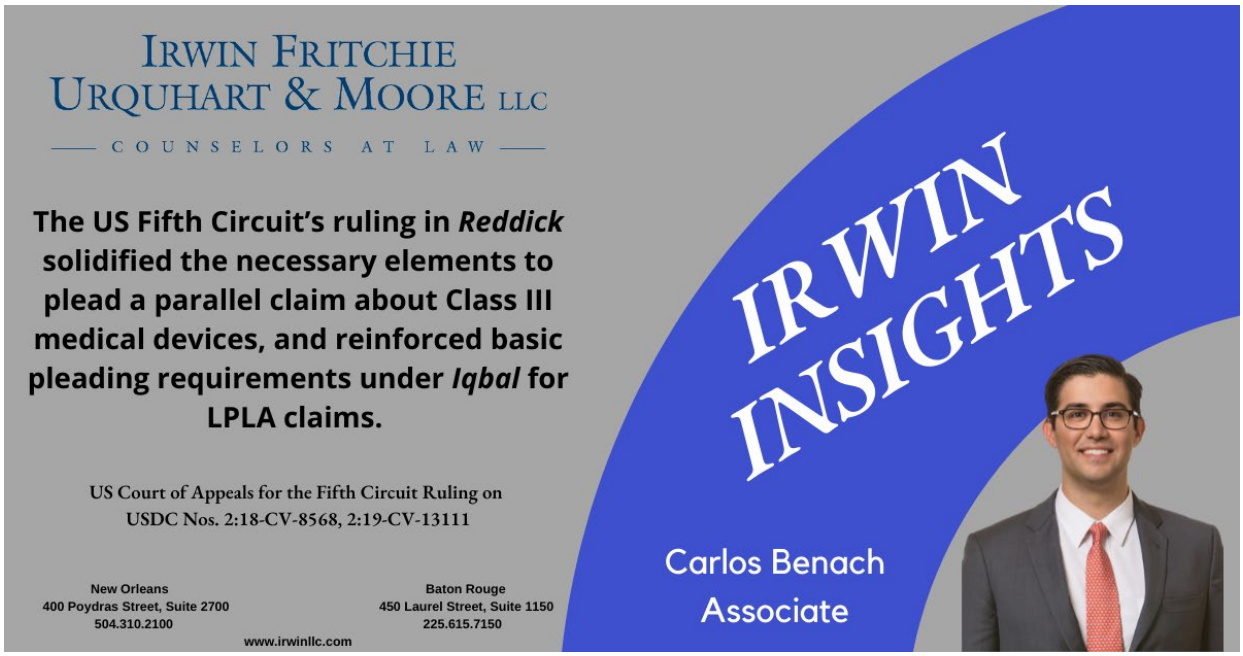

US Court of Appeals for the Fifth Circuit Ruling on
USDC Nos. 2:18-CV-8568, 2:19-CV-13111

The US Fifth Circuit's ruling in *Reddick* solidified the necessary elements to plead a parallel claim about Class III medical devices, and reinforced basic pleading requirements under *Iqbal* for LPLA claims.

On March 9, 2022, the US Fifth Circuit affirmed dismissal of claims related to a Class III implantable cardiac defibrillator (ICD) and integrated Class I and II devices. Plaintiff filed suit under the Louisiana Products Liability Act (LPLA) and contract law alleging the ICD and integrated devices were defective, and the Medtronic breached a contractual agreement related to 24/7 technical support.

With respect to the Class III ICD device, the Fifth Circuit upheld dismissals of all LPLA claims citing *Riegel v. Medtronic* and explaining that Plaintiff failed to allege a state based "parallel claim" related to violation of FDA regulations. Namely, the Plaintiff's design, manufacturing, warning and warranty claims were "impermissibly conclusory and vague."

Turning to the Class I and II devices, the appellate court noted that the Plaintiff's LPLA design claims "failed to plead that there was a reasonable alternative design" and therefore upheld the district court's dismissal under *Ashcroft v. Iqbal*. Finally, the Fifth Circuit affirmed summary judgment on Plaintiff's contract claims because there was no written agreement between the parties, and plaintiff was not a third party beneficiary to a contract between Medtronic and a Louisiana clinic.

United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
March 9, 2022
Lyle W. Cayce
Clerk

No. 21-30169

DAVID REDDICK,

Plaintiff—Appellant,

versus

MEDTRONIC, INCORPORATED,

Defendant—Appellee.

Appeal from the United States District Court
for the Eastern District of Louisiana
USDC Nos. 2:18-CV-8568, 2:19-CV-13111

Before OWEN, *Chief Judge*, and HIGGINBOTHAM and ELROD, *Circuit Judges*.

PER CURIAM:*

This case concerns several allegedly defective medical devices manufactured by Medtronic. A surgeon implanted a defibrillator into Reddick's chest, which he claims shocked him unnecessarily. He sued Medtronic under the Louisiana Products Liability Act ("LPLA") and for

* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

breach of contract. The district court dismissed the LPLA claims and granted summary judgment to Medtronic on the contract issue. We affirm.

I

David Reddick was diagnosed with Brugada syndrome in 2013, a heart rhythm disorder. He was told that he needed a defibrillator. He agreed to the procedure, and the five Medtronic devices relevant to this appeal were surgically implanted in his chest or otherwise used to support the implanted devices: the (1) Evera SVR Implantable Cardiac Defibrillator (the "ICD"), (2) Sprint Quattro Secure Lead (the "lead"), (3) MyCareLink Patient Monitor ("MyCareLink"), (4) Reveal LINQ cardiac monitor ("LINQ"), and (5) WireX cellular device ("WireX"). The first three products are Class III medical devices, which means they underwent a thorough premarket approval ("PMA") process before the Food and Drug Administration ("FDA") greenlighted their commercial use.[1] The others are Class I or II devices, meaning they received less premarket scrutiny.[2]

Soon after his surgery, Reddick started having problems with his devices. According to the Second Amended Complaint ("SAC"), he began experiencing shocks from the ICD and the lead. He went to the hospital almost monthly over the next few years due to those shocks and other "false alarms." However, Reddick was repeatedly reassured that his Medtronic devices only needed reprogramming and that nothing was wrong. By 2016, Reddick was retested, and it was determined that he never had Brugada syndrome. He had a second surgery in 2017 to remove his defibrillator.

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[1] *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

[2] *See id.* at 476-77.

Reddick alleges that all five Medtronic devices were defective, causing him unnecessary shocks and pain. He sued Medtronic in Louisiana state court and Medtronic removed to federal court, asserting diversity jurisdiction. Reddick brought four products liability claims under the LPLA: defective construction, defective design, failure to warn, and breach of express warranty. He also alleged that Medtronic breached a contract with Reddick, failing to provide him with 24/7 service support.

The district court dismissed Reddick's LPLA claims regarding the Class III devices, concluding that his claims were preempted under 21 U.S.C. § 360k(a). It also dismissed Reddick's claims regarding the Class I and II devices under Rule 12(b)(6) for failure to state a claim. Separately, the district court granted summary judgment to Medtronic on the contract issue, reasoning that there was no contract between the parties in the record. Reddick appealed.

II

As a preliminary matter, Medtronic contends that Reddick waived his arguments on appeal by failing to explain how the district court erred. "A party forfeits an argument by . . . failing to adequately brief the argument," and "[t]here are numerous ways" that may happen.[3] Failure to make an argument in the body of a brief, to cite supporting authority or the record, or to engage with the district court's analysis, among other things, may each amount to forfeiture.[4]

We agree that Reddick has forfeited some of his arguments. He identifies two issues that he never addresses in his brief: whether

[3] *Rollins v. Home Depot USA*, 8 F.4th 393, 397 & n.1 (5th Cir. 2021).

[4] *Id.* at 397 n.1.

Medtronic's motion to dismiss should have been continued due to the ongoing COVID-19 pandemic, and whether the district court erred by granting Medtronic's motion to strike several exhibits. With no argument on either issue, Reddick forfeits them both.[5]

Reddick does explain, however, why he believes the district court erred in its handling of his LPLA and breach of contract claims. He maintains that his LPLA claims are not preempted and that he pleaded enough facts for plausible defective design claims on the Class I and II devices. He also argues that a contract existed between him and Medtronic. Reddick's reasoning may be conclusory, but he has nevertheless adequately briefed his claims to avoid forfeiting his arguments.[6] We therefore turn to their merits.

III

We start with the district court's dismissals of Reddick's LPLA claims. The court dismissed the claims regarding Medtronic's Class III devices on the basis of federal preemption, and it dismissed the claims regarding the Class I and II devices under Rule 12(b)(6) for failure to state a claim. We review the dismissals de novo.[7]

A

Reddick argues that his LPLA claims are not preempted under 21 U.S.C. § 360k(a). Section 360k(a) provides the following:

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[5] *See id.* at 397 & n.1.

[6] *Cf. Brinkmann v. Dallas Cnty. Deputy Sheriff Abner*, 813 F.2d 744, 748 (5th Cir. 1987) (concluding that a party forfeited an issue when he submitted only a "one-page recitation of familiar rules governing our review of summary judgments, without even the slightest identification of any error in [the judge's] legal analysis").

[7] *Butts v. Aultman*, 953 F.3d 353, 357 (5th Cir. 2020).

> [N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (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.[8]

Under *Riegel v. Medtronic, Inc.*,[9] we apply a two-prong inquiry to evaluate whether state law claims are preempted under § 360k(a).[10] First, we determine whether the federal government has "established requirements applicable to [the medical device]."[11] Class III devices subject to PMA, like those at issue here, "automatically" satisfy the first prong.[12] Second, we evaluate whether the state law claims are based on "requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness."[13] If they are, the

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[8] 21 U.S.C. § 360k(a).

[9] 552 U.S. 312 (2008).

[10] *Id.* at 321-22.

[11] *Id.* at 321.

[12] *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012). Reddick argues on appeal that he "believes" Medtronic's Class III devices did not go through the traditional PMA process. "A new device need not undergo premarket approval if the FDA finds it is 'substantially equivalent' to another device exempt from premarket approval," which is referred to as § 510(k) approval. *Riegel*, 552 U.S. at 317. Unlike PMA, "the § 510(k) approval process does not impose federal requirements on a device." *Bass*, 669 F.3d at 507. In his SAC, however, Reddick alleged that Medtronic's Class III devices received PMA, not § 510(k) approval. Because Reddick failed to plead sufficient facts in support of his § 510(k) theory, we conclude that *Riegel*'s first prong is met. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[13] *Riegel*, 552 U.S. at 321-22 (quoting § 360k(a)).

state law claim is preempted.[14] "[P]arallel" claims, however, are not preempted even if they relate to the safety and effectiveness of a device.[15] A state law claim is "parallel" if it "provid[es] a damages remedy . . . premised on a violation of FDA regulations."[16]

Even if a state law claim is parallel, a district court may still dismiss it if the claim is "impermissibly conclusory and vague."[17] In *Funk v. Stryker Corp.*,[18] we held that a complaint that does not "specify the manufacturing defect," "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury," or "tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process" is insufficient to state a parallel products liability claim.[19] Similarly, in *Naquin v. Medtronic, Inc.*,[20] a recent unpublished opinion applying *Funk*, we affirmed the district court's dismissal of claims for design defect, construction defect, failure to warn, and breach of express warranty due to inadequate pleading.[21] As in the present case, *Naquin* involved Medtronic's allegedly defective defibrillators.[22] The complaint only "ma[de] numerous conclusory allegations . . . [without] details as to how a violation of federal regulations"

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[14] *See* § 360k(a); *Riegel*, 552 U.S. at 321-22.

[15] *Riegel*, 552 U.S. at 330.

[16] *Id.*

[17] *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011).

[18] 631 F.3d 777.

[19] *Id.* at 782.

[20] No. 20-30793, 2021 WL 4848838 (5th Cir. Oct. 18, 2021) (per curiam) (unpublished).

[21] *Id.* at *3.

[22] *Id.* at *1.

led to a manufacturing defect, a design defect, or an inadequate warning.[23] Naquin's express warranty claims were also conclusory because he did not "reproduce any specific warranty . . . or specify its precise source."[24]

Reddick asserts four theories of liability under the LPLA: defective construction, defective design, failure to warn, and breach of express warranty.[25] Under the *Riegel* inquiry's second prong, all four claims impose "requirement[s]" on Medtronic that relate to the "safety and effectiveness" of its devices.[26] The issue, therefore, is whether Reddick adequately pleaded

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[23] *Id.* at *3.

[24] *Id.* (citing *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 870 (5th Cir. 2017)).

[25] In the SAC, Reddick also references a potential claim regarding "off label" use of the Medtronic devices. The district court determined that an "off label" claim, to the extent that Reddick alleged one, is "not an available theory" under the LPLA. *See* LA. STAT. ANN. § 9:2800.54 (stating that "[a] product is unreasonably dangerous *if and only if*" it is defectively designed, it is defectively constructed, an adequate warning has not been provided, or it does not conform to an express warranty) (emphasis added). In his appellate brief, Reddick links his "off label" allegation to his express warranty claim. To the extent that Reddick otherwise argues that his "off label" claim is distinct from the four liability theories under the LPLA, we agree that it is not an available theory.

[26] *See* § 360k(a); LA. STAT. ANN. § 9:2800.55 (imposing liability if "at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications"); *id.* § 9:2800.56 (imposing liability if "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage" and the potential damage to the claimant "outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product"); *id.* § 9:2800.57 (requiring the manufacturer to use "reasonable care to provide an adequate warning"); *id.* § 9:2800.58 (imposing liability if the product "does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant . . . to use the product and the claimant's damage was proximately caused because the express warranty was untrue"); *see also Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 930-33 (5th Cir. 2006) (holding that design defect, failure-to-warn, and breach of express warranty claims under LPLA were preempted by § 360k(a)).

parallel state law claims to avoid preemption. He did not—all four of Reddick's claims are "impermissibly conclusory and vague."[27]

As to the defective design and construction claims, Reddick alleged only "upon information and belief" that Medtronic's devices were defective without providing sufficient factual support. He did allege that some of Medtronic's devices have been subject to recalls and that the FDA has warned Medtronic about manufacturing adulterated products in Puerto Rico. He failed to plead, however, that his devices in particular were part of those recalls or that the recalls were related to the unnecessary shocks that he experienced. On appeal, Reddick also argues that "[n]ew recent facts" about an April 2021 recall of the ICD provide further support for his claims, but we "may not consider new evidence" that was "not before the district court at the time of the challenged ruling."[28] Lastly, Reddick insists that the *res ipsa loquitur* doctrine makes his allegations sufficient, but *res ipsa loquitur* does not cure an otherwise conclusory pleading that fails to state a claim equivalent to a violation of FDA safety standards.[29]

Similarly, Reddick did not provide any factual support for his failure-to-warn claim. He alleged only that Medtronic "failed to warn [him] . . . regarding the unreasonably dangerous and defective products that were implanted and used in [his] care and treatment," neglecting to plead any applicable FDA-approved warnings or that Medtronic departed from them.

Finally, we agree with the district court that Reddick's breach of warranty claim is preempted as well. Reddick's claim is similar to the one

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[27] *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011).

[28] *Theriot v. Par. of Jefferson*, 185 F.3d 477, 491 n.26 (5th Cir. 1999).

[29] *See Funk*, 631 F.3d at 782.

that we recently addressed in *Naquin*.[30] As we reasoned there, a breach of warranty claim under the LPLA must be pled "with particularity."[31] Reddick alleged that Medtronic violated an oral "lifetime warranty" on the ICD. He also alleged Medtronic violated a separate "10 and 11 year warranty" that applied only to the lead. Reddick failed, however, "to reproduce any specific warranty in his pleadings or specify its precise source," and he did not allege that he was induced to use Medtronic's devices due to those warranties.[32] As in *Naquin*, Reddick "gets more specific" on appeal by arguing that the warranties came from Medtronic's advertisements and its website, but he "still fails to identify a specific web page or specific warranty terms."[33] Thus, we agree with the district court that all four of Reddick's LPLA claims are too conclusory to state a parallel claim that avoids preemption under § 360k(a).

B

Turning to Medtronic's Class I and II devices, the district court dismissed Reddick's LPLA claims under Rule 12(b)(6) for failure to state a claim. To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'"[34] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the

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[30] *See Naquin v. Medtronic, Inc.*, No. 20-30793, 2021 WL 4848838, at *3 (5th Cir. Oct. 18, 2021) (per curiam) (unpublished).

[31] *Id.* (quoting *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 870 (5th Cir. 2017)).

[32] *See id.*

[33] *See id.*

[34] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

defendant is liable for the misconduct alleged."[35] We do not credit conclusory allegations, however, as "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."[36]

A successful action under the LPLA requires four elements: (1) "that the defendant is a manufacturer of the product;" (2) "that the claimant's damage was proximately caused by a characteristic of the product;" (3) "that this characteristic made the product 'unreasonably dangerous';" and (4) "that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else."[37] Under the third element, a product may be "unreasonably dangerous" under any one of LPLA's four liability theories.[38]

As to the Class I and II devices, Reddick alleges only that they were defectively designed. Under Louisiana law, a design defect exists "if, at the time the product left its manufacturer's control . . . [t]here existed an alternative design for the product that was capable of preventing the claimant's damage," and "[t]he likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product."[39]

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[35] *Id.*

[36] *Id.*

[37] *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002) (citing LA. STAT. ANN. § 9:2800.54).

[38] § 9:2800.54.

[39] LA. STAT. ANN. § 9:2800.56.

Reddick failed to plead that there was a reasonable alternative design for either the LINQ or WireX, necessitating the dismissal of his claims. As to the LINQ, Reddick asserts "upon information and belief" that it had "defectively designed software." But he did not provide any detail on that defect, and he failed to plead that there was an alternative design available to Medtronic. Similarly, as to the WireX, Reddick alleged only that the device was "not secure from hacking and was subject to malfunction," not that there was a reasonable alternative design. Indeed, the only reference in the SAC to an alternative design is in one paragraph under the heading titled "FACTS AND ALTERNATIVE DESIGN," but the body of that paragraph discusses the ICD, not the LINQ or WireX. Regardless, even if it did, Reddick alleged only that a more "conservative" treatment plan would have been to use an external heart monitor. That concerns the "choice of treatment" made by Reddick's medical team, not a design decision by Medtronic.[40] The district court therefore properly dismissed Reddick's design defect claims.[41]

IV

We turn finally to Reddick's breach of contract claim. The district court granted summary judgment to Medtronic on this issue because there was no evidence of a contract between the parties in the record.

A district court's grant of summary judgment is reviewed de novo.[42] "Summary judgment is appropriate 'if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment

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[40] *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (per curiam).

[41] *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[42] *Nola Spice Designs, L.L.C. v. Haydel Enters., Inc.*, 783 F.3d 527, 536 (5th Cir. 2015).

as a matter of law.'"[43] Once the moving party informs the court of the basis for its motion, "the non-moving party must 'go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial.'"[44] "In reviewing a grant of summary judgment, we view all evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor."[45] "We may affirm a grant of summary judgment 'based on any rationale presented to the district court for consideration and supported by facts uncontroverted in the summary judgment record.'"[46]

We agree with the district court that there is not a genuine issue on the existence of a written contract between Reddick and Medtronic. There is no written agreement between Medtronic and Reddick in the record. Reddick also was not a third-party beneficiary of the contracts between Medtronic and the Heart Clinic of Louisiana. Looking to Louisiana substantive law, as we must when sitting in diversity jurisdiction,[47] "[t]he most basic requirement" for the existence of a third-party beneficiary "is that the contract manifest a clear intention to benefit the third party."[48] The contracts between Medtronic and the Heart Clinic of Louisiana do not list anyone as an intended third-party beneficiary, let alone Reddick.

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[43] *Id.* (quoting FED. R. CIV. P. 56(a)).

[44] *Id.* (quoting *EEOC v. LHC Grp., Inc.*, 773 F.3d 688, 694 (5th Cir. 2014)).

[45] *Id.*

[46] *Id.* (quoting *Terrebonne Par. Sch. Bd. v. Mobil Oil Corp.*, 310 F.3d 870, 887 (5th Cir. 2002)).

[47] *Cates v. Sears, Roebuck & Co.*, 928 F.2d 679, 683 (5th Cir. 1991).

[48] *Joseph v. Hosp. Serv. Dist. No. 2 of Par. of St. Mary*, No. 2005-2364, p. 9 (La. 10/15/2006); 939 So. 2d 1206, 1212.

The district court also correctly determined that there was not an oral agreement between the parties. Under Louisiana law, oral agreements are valid so long as they contain the required elements for the formation of a contract, including "a meeting of the minds."[49] Reddick argued below that when he read Medtronic's website, an oral contract formed between him and the company based on Medtronic's advertisements. He maintains on appeal that he will be able to prove at trial that such an oral agreement exists. Reddick misunderstands his burden. On appeal of a grant of summary judgment, Reddick must do more than establish that his claim is plausible.[50] He must point to record evidence creating a genuine issue of material fact.[51] Reddick fails to cite any record evidence suggesting that Medtronic intended to be bound to any agreement with Reddick. That dooms his claim. With no contract, there was no breach.

* * *

For the foregoing reasons, we AFFIRM the district court's orders.

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[49] *See Belgard v. Collins*, 628 So. 2d 1254, 1257 (La. Ct. App. 1993).

[50] *See Nola Spice Designs, L.L.C. v. Haydel Enters., Inc.*, 783 F.3d 527, 536 (5th Cir. 2015).

[51] *See id.*