IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 14-40183
Summary Calendar

United States Court of Appeals
Fifth Circuit
FILED
December 31, 2014
Lyle W. Cayce
Clerk

RICARDO A. RODRIGUEZ,

Plaintiff - Appellant

v.

AMERICAN MEDICAL SYSTEMS, INCORPORATED,

Defendant - Appellee

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 7:12-CV-330

Before PRADO, OWEN, and GRAVES, Circuit Judges.

PER CURIAM:*

Plaintiff Ricardo Rodriguez appeals from the district court's dismissal of his state law products liability, deceptive trade practices and breach of contract claims against American Medical Systems, Inc. ("AMS"), the manufacturer of medical devices. We affirm.

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 R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR.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

I. Factual and Procedural Background

In February 2012, Rodriguez filed suit in Texas state court against defendants AMS and Dr. Henry E. Ruiz. According to Rodriguez's pleadings, Dr. Ruiz implanted Rodriguez with a penile inflatable prosthesis called the "AMS 700 MS." AMS designed and manufactured the AMS 700 MS. Rodriguez alleges that the implant has not functioned properly and is causing him pain and disfiguration. The claims against Dr. Ruiz were dismissed in Texas state court. Subsequently, AMS removed the case to the Southern District of Texas on the basis of diversity jurisdiction.

Rodriguez asserts three claims against AMS: (1) products liability claims based on defective design and manufacturing; (2) violations of the Texas Deceptive Trade Practices Act ("DTPA"); and (3) breach of contract. AMS moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that the claims against AMS are preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), and that Rodriguez failed to state a claim upon which relief can be granted. In support of its preemption arguments, AMS provided documentary evidence that the FDA had approved the AMS 700. Because it looked beyond the pleadings to this evidence, the district court converted the part of the motion regarding the claims subject to preemption, specifically the products liability and DTPA claims, into a motion for summary judgment and gave Rodriguez an opportunity to respond. The court considered the breach of contract claim under Rule 12(b)(6). The district court granted summary judgment to AMS on the products liability claims and DTPA claims under Rule 56, and dismissed the breach of contract claim under Rule 12(b)(6). Rodriguez appeals.

II. Discussion

We review both the district court's grant of summary judgment and the dismissal under Rule 12(b)(b)(6) de novo. *See Bass v. Stryker Corp.*, 669 F.3d 501, 506 (5th Cir. 2012) (motion to dismiss); *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 375 (5th Cir. 2012) (summary judgment). Questions of law regarding preemption are also reviewed de novo. *See Lofton*, 672 F.3d at 375.

A. Preemption

"In response to the concern that state-law governance of medical devices was inadequate, Congress passed the MDA, giving the FDA authority to regulate medical devices and expressly preempting certain state regulations." *Bass*, 669 F.3d at 506; *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008); 21 U.S.C. § 360k(a). A state law tort claim to recover for injuries allegedly caused by a medical device is preempted if two requirements are met: (1) "the Federal Government has established requirements applicable to [the device]; and (2) the claims are based on state law requirements that are different from, or in addition to the federal ones, and that relate to safety and effectiveness." *Bass*, 669 F.3d at 507 (internal quotation marks omitted) (quoting *Riegel*, 552 U.S. at 321-22); *see also* 21 U.S.C. § 360k(a)(1). However, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330; *see Bass*, 669 F.3d at 509.

The implant at issue in this case is a Class III medical device under federal law. Class III devices receive the most federal oversight. *See Riegel*, 552 U.S. at 317; *Bass*, 669 F.3d at 506. Class III devices that are approved through the FDA's rigorous pre-market approval process ("PMA") automatically satisfy the "federal requirements" prong of the preemption

analysis. *Riegel*, 552 U.S. at 322-23; *Bass*, 669 F.3d at 507. "[T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323 (citing 21 U.S.C § 360e(d)). After PMA review and approval, the device "must be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* Here, AMS provided a letter from the FDA and a supporting affidavit from one of its employees indicating that the AMS 700 MS pump received FDA approval through the product development protocol ("PDP") provided by 21 U.S.C. § 360e(f), rather than through the most rigorous PMA process. Rodriguez makes no argument that the PDP and PMA procedures should be treated differently under the preemption analysis. *See Betterton v. Evans*, 351 F. Supp. 2d 529, 534-35 (N.D. Miss. 2004) (describing the PDP and PMA processes and concluding that the preemption analysis for each is the same). Further, the MDA provides that a device which has been approved through the PDP process "shall be considered as having [PMA] approval." 21 U.S.C. § 360e(f)(1); *see also* 21 C.F.R. § 814.19 ("A class III device for which a product development protocol has been declared completed by the FDA under this chapter will be considered to have an approved PMA."). Thus, we assume that a device which has been approved through the PDP process meets the federal requirements prong of the preemption analysis.

Rodriguez argues that summary judgment was inappropriate because a genuine issue of material exists as to whether the implant used in his surgery was in fact approved by the FDA. We agree with the district court that there is no genuine dispute of fact whether the AMS 700 MS received FDA approval through the PDP process. The 2006 letter provided by AMS is printed on FDA letterhead, is supported by the affidavit of an AMS employee, and clearly states

that the AMS 700 MS had received PDP approval. Rodriguez argues that the letter reflecting FDA approval is a supplemental letter, rather than an initial approval letter, and mentions the specific AMS 700 MS only in parentheses. He argues that the reference to the AMS 700 MS model could have been a mistake or that the letter could have been falsified, and that a jury could find that this particular model was never approved by the FDA. However, Rodriguez provides no evidence contradicting the FDA letter. His arguments to the contrary are purely speculative and raise no genuine dispute of fact.

Because the PDP approval establishes that there are federal requirements applicable to the implant, Rodriguez's claims survive preemption only if his state claims parallel the federal requirements. *See Riegel,* 552 U.S. at 300; *Bass*, 669 F.3d at 509. The district court granted summary judgment to AMS on Rodriguez's products liability and DTPA claims because it concluded that Rodriguez's complaint was too vague and conclusory to state parallel claims under the applicable law. We agree.

Rodriguez's complaint fails to meet the standards for pleading parallel design or manufacturing defect claims. In *Bass*, we held that "if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the [FDA's Current Good Manufacturing Practices] and that this failure caused the injury, the plaintiff will have pleaded a parallel claim." *Bass*, 669 F.3d at 512; *see also Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011) (affirming summary judgment but stating that a complaint is adequate if it "set[s] forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged" (internal quotation marks omitted)); *In re Medtronic*, 623 F.3d 1200, 1207 (8th Cir. 2010) (noting that a plaintiff must plead that the manufacturer "violated a federal requirement specific to the FDA's PMA approval of th[e] Class III device" and

concluding that classwide claims of generic manufacturing defects could not survive a motion to dismiss). *Bass* addressed a claim that an FDA-approved Class III hip implant malfunctioned because of impurities in the manufacturing process. 669 F.3d at 509. We held that the plaintiff did state parallel claims where the complaint specified which FDA regulations were violated in the manufacturing process, alleged that the manufacturer had received a warning letter from the FDA regarding the manufacturing defect, and eventually recalled the implant due to the defect. *Bass*, 669 F.3d at 510. By contrast, in *Funk* we addressed a similar claim regarding the same hip implant but held that the plaintiff's pleadings were too conclusory to state a parallel claim. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). Specifically, we noted that Funk's complaint did not specify the manufacturing defect, did not specify a causal connection between a failure of the manufacturing process and a specific defect in the process that caused the personal injury, and did not specify how the process deviated from the FDA approved manufacturing process. *Id*.

Applying this case law, it is clear that Rodriguez fails to state parallel manufacturing or design defect claims. Rodriguez's complaint does not plead a violation of any federal requirement relating to design or manufacturing of the implant, either those specific to the AMS 700 MS or those generally applicable to the manufacturing of medical devices, and he cites no facts supporting a finding of any such violation. He fails to allege a specific defect in the manufacturing process or design, any deviation from the FDA-approved design or manufacturing processes, or any causal connection between a violation of federal requirements and his injuries. Thus, he has failed to plead a parallel claim. *See Funk*, 631 F.3d at 782.

Rodriguez likewise fails to plead a parallel DTPA claim. Construed liberally, Rodriguez's DTPA claim alleges that representations in AMS

"brochures and literature" promised a certain performance that did not occur, and constitute a "false, misleading, or deceptive act or practice" and an "unconscionable action or course of action" under the DTPA. *See* Tex. Bus. & Com. Code §§ 17.50(a), 17.46(b), 17.45(5). However, Rodriguez fails to allege whether or how AMS's marketing materials deviated from FDA-approved requirements. Therefore, he fails to plead a parallel DTPA claim. *See Bass*, 669 F.3d at 515 (holding that DTPA claim premised on a "marketing defect" was preempted where the plaintiff did not plead specific facts as to how the marketing violated FDA requirements).

B. Breach of Contract

Rodriguez also argues that the district court incorrectly dismissed his breach of contract claim under Rule 12(b)(6). Rodriguez primarily argues that AMS's motion to dismiss the claim should have been converted to a motion for judgment on the pleadings under Rule 12(c), because it was filed after AMS filed an answer to the petition and a response to a motion for remand. However, a "motion for judgment on the pleadings under Rule 12(c) is subject to the same standard as a motion to dismiss under Rule 12(b)(6)." *Doe v. MySpace Inc.,* 528 F.3d 413, 418 (5th Cir. 2008). Thus, even if there was error, there is no cause to reverse on this basis.

Rodriguez next argues that the district court erred by dismissing his breach of contract claim for failure to state a claim. In his briefing, Rodriguez fails to cite a single case regarding breach of contract claims in Texas. However, even if we consider the claim despite this inadequate briefing, we conclude that it was correctly dismissed. In Texas, the first essential element of a breach of contract action is the existence of a valid contract. *See Valero Mktg. & Supply Co. v. Kalama Int'l, L.L.C.*, 51 S.W.3d 345, 351 (Tex. App. 2001); *Smith Int'l, Inc. v. Egle Grp., LLC*, 490 F.3d 380, 387 (5th Cir. 2007). Rodriguez's complaint does not identify any contract between AMS and

Rodriguez. He merely alleges that the implant did not perform as provided in AMS's "brochures and literature" and as stated by Dr. Ruiz. However, Rodriguez does not allege how the advertising or promotional materials created a valid and enforceable contract, does not describe the terms of any such contract, and does not explain how any statements made by Dr. Ruiz could have given rise to a contract between AMS and Rodriguez. This claim was thus properly dismissed.

III. Conclusion

For the foregoing reasons, the judgment of the district court is AFFIRMED.