United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
February 5, 2021
Lyle W. Cayce
Clerk

No. 20-50462

RAMON D. JOHNSON, II,

Plaintiff—Appellant,

versus

NOVARTIS PHARMACEUTICALS CORPORATION; TARO PHARMACEUTICALS USA, INCORPORATED; BAUSCH HEALTH US, L.L.C.; SUN PHARMACEUTICAL INDUSTRIES, INCORPORATED; TORRENT PHARMA, INCORPORATED,

Defendants—Appellees.

Appeal from the United States District Court
for the Western District of Texas
USDC No. 5:19-CV-1087

Before DAVIS, SOUTHWICK, and COSTA, *Circuit Judges*.

W. EUGENE DAVIS, *Circuit Judge*:*

Pro se Plaintiff, Ramon Johnson, appeals the district court's grant of Novartis Pharmaceuticals Corporation ("Novartis"), Taro Pharmaceuticals USA, Inc. ("Taro"), Bausch Health US, L.L.C. ("Bausch"), Sun

* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

Pharmaceutical Industries, Inc. ("Sun"), and Torrent Pharma, Inc.'s ("Torrent") motions to dismiss. For the reasons that follow, we AFFIRM the district court's judgment.

I. Background

Mr. Johnson was prescribed Minocycline ("Generic Minocin"), a generic form of the brand-name drug Minocin, by his physician in April of 2013 for certain dermatology issues. Roughly a year later, Mr. Johnson developed symptoms of Peyronie's Disease ("PD"), a painful condition caused by a development of plaques and scar tissue in the penis. He sought the advice of three physicians, including PD specialists, who continued to recommend the Generic Minocin treatment. In October of 2014, Mr. Johnson decided to stop taking Generic Minocin, and his PD symptoms began to fade away. Later that October, Mr. Johnson saw his PD specialist and explained what happened when he stopped taking Generic Minocin. Mr. Johnson expressed concern that the drug may be causing PD, but the specialist told Mr. Johnson that Minocycline does not cause PD. In November of 2014, Mr. Johnson returned to his dermatologist and expressed the same concerns. Like the PD specialist, the dermatologist, who regularly prescribes Generic Minocin, also told Mr. Johnson that the drug does not cause PD.

In June of 2017, Mr. Johnson was prescribed Carbamazepine ("Generic Tegretol"), a generic form of the brand-name drug Tegretol, at the recommendation of his pain management physician. After roughly three months of taking Generic Tegretol, Mr. Johnson noticed a worsening of his PD symptoms. During this time, Mr. Johnson began independent research on his issues. Mr. Johnson's research uncovered two findings: (1) that Minocycline and Carbamazepine could cause drug-induced lupus which, like PD, is a connective tissue disease; and (2) that there is a correlation between

high TGF-beta levels and PD. Based on his research, Mr. Johnson asked his rheumatologist to order a TGF-beta blood test for him on September 12, 2017. Around the same time, Plaintiff returned to his PD specialist to report his research and the worsening of his PD, but the PD specialist once again told Mr. Johnson that drugs do not cause PD. On September 13, 2017, Mr. Johnson decided to stop taking Generic Tegretol. On the next day, Mr. Johnson's TGF-beta test came back reporting that his TGF-beta levels were high.

On December 8, 2017, now three months off of Generic Tegretol and Generic Minocin, Mr. Johnson had another TGF-beta test which came back normal. Mr. Johnson continued his independent research into his health condition, and in August of 2019, Mr. Johnson found an article from 1989 that linked Carbamazepine to PD. He also found articles showing that Minocycline and Carbamazepine can increase TGF-beta levels, and he found websites saying that medications can cause PD.

On September 10, 2019, Mr. Johnson filed suit against all Defendants under theories of strict liability, products liability, breach of warranty, and loss of consortium under Texas state law. Plaintiff later clarified the relationship between Defendants. Generic Minocin was manufactured by Ranbaxy, which was acquired by Sun and subsequently "spun off" to Torrent. Sun and Torrent used the label information from brand-name drug Minocin which is manufactured by Bausch. Similarly, Generic Tegretol was manufactured by Taro who used label information from Novartis's brand-name drug, Tegretol. It is undisputed that Sun, Torrent, and Taro (together "Generic Defendants") are manufacturers of the generic version of the two drugs Mr. Johnson actually took which he alleges caused his PD. Similarly, Novartis and Bausch (together "Brand Defendants") are the manufacturers of the brand-name versions of the drugs Mr. Johnson alleges caused his PD.

However, it is uncontested that Mr. Johnson did not ingest the brand-name drugs.

The Generic Defendants and Brand Defendants filed Rule 12(b)(6) motions to dismiss arguing that all of Mr. Johnson's claims are precluded as a matter of law by federal preemption and this Court's precedent. The district court granted the motion. Mr. Johnson timely appealed.

II. Discussion

We review Rule 12(b)(6) dismissals de novo.[1] "To survive a Rule 12(b)(6) motion, a plaintiff must plead enough facts to state a claim for relief that is plausible on its face."[2]

A. Claims against the Generic Defendants and Preemption

In *PLIVA v. Mensing*, the Supreme Court held that state law claims against generic drug manufacturers that turn on the adequacy of the drug's label are preempted by federal law.[3] The *Mensing* Court found that under the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act[4] and accompanying FDA regulations, a generic drug manufacturer "is responsible for ensuring that its warning label is the same as the brand name's [label]."[5] In addition, generic drug manufacturers are not allowed to unilaterally strengthen or change their drug labels through the FDA's process for changing labels.[6] Instead, "[g]eneric drug manufacturers that

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[1] *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 677 (5th Cir. 2014).

[2] *Id.* (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

[3] 564 U.S. 604, 618 (2011).

[4] 21 U.S.C. § 301 *et seq.*

[5] *Mensing*, 564 U.S. at 613.

[6] *Id.* at 614.

become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug."[7] Because a generic drug manufacturer has no ability, on its own, to change its label, the *Mensing* Court held that it was impossible for generic drug manufacturers to comply both with federal law regulations and state law duties to change warning labels.[8] Two years after *Mensing*, the Supreme Court held in *Mutual Pharmaceutical Co., Inc. v. Bartlett* that state law strict liability design-defect claims against generic drug manufacturers are also preempted when the adequacy of a drug's label is at issue.[9]

In light of these two Supreme Court decisions, this Court has twice held that strict liability, breach of warranty, negligence, and products liability claims under Texas law against generic drug manufacturers are preempted under *Mensing* and *Bartlett*.[10] We have emphasized that when analyzing whether a plaintiff's various state law claims against a generic drug manufacturer are preempted, we look at whether the substance of the claims "turn on adequacy of labeling and related information."[11]

Mr. Johnson argues that at least one of his claims somehow escapes preemption because it is a "strict liability marketing defect claim." Under Texas law, "[a] marketing defect occurs when a defendant knows or should know of a potential risk of harm presented by the product but markets it

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[7] *Id.* at 616. Notably, the Supreme Court rejected the plaintiffs' argument that the ability of the generic defendants to ask the FDA for assistance in changing the label allows generic pharmaceutical manufacturers to comply with their state law duties. *Id.* at 620–21.

[8] *Id.* at 618.

[9] 570 U.S. 472, 484–87 (2013).

[10] *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474 (5th Cir. 2014); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678 (5th Cir. 2014).

[11] *Lashley*, 750 F.3d at 474; *see also Eckhardt*, 751 F.3d at 678.

without adequately warning of the danger or providing instructions for safe use."[12] In order to comply with this law, the Generic Defendants would need to update their label when they acquired actual or constructive knowledge of a risk of PD from their drug. This is the same scenario that the *Mensing* Court reasoned was impossible under federal law.[13] Thus, Mr. Johnson's characterization of his claim as a marketing defect claim turns on the adequacy of the Generic Defendants' labels, and his claim is preempted under *Mensing*. The same is true of all claims in Mr. Johnson's complaint which can be accurately characterized as products liability claims for a failure to warn of the side effects of Minocycline and Carbamazepine.[14]

B. Claims against the Brand Defendants and their duties under Texas law

Two prior panels of this Court have held that brand-name pharmaceutical companies cannot be held liable under Texas products liability law when a plaintiff ingests a generic manufacturer's drug rather than the brand-name manufacturer's drug.[15] Products liability law in Texas is governed by statute and defines the actions as "any action against a manufacturer or seller for recovery of damages arising out of personal injury . . . allegedly caused by a defective product . . . ."[16] We found that under this

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[12] *Daimlerchrysler Corp. v. Hillhouse*, 161 S.W.3d 541, 546 (Tex. App. 2004) *aff'd on other grounds*, 161 S.W.3d 541 (Tex. 2004).

[13] *Mensing*, 564 U.S. at 618.

[14] Every claim in the complaint alleges that Defendants failed to adequately warn of the side of effects of the drugs with the exception of the Breach of Warranty and Loss of Consortium claim. Nevertheless, liability for the warranty and tort claim will turn on Defendants' duty to warn.

[15] *Lashley*, 750 F.3d at 477; *Eckhardt*, 751 F.3d at 680.

[16] Tex. Civ. Prac. & Rem. Code Ann. § 82.001(2) (West). This statute was enacted in 1993 which predates the case law beginning in 2011 regarding *Mensing*-preemption and the duties of brand-name manufacturers.

statute, the Texas Supreme Court has held that entities are "'manufacturers' only with respect to their own products."[17] Similarly, the Texas Supreme Court has found that "a fundamental principle of traditional products liability law is that the plaintiff must prove that the defendants supplied the product which caused the injury."[18] Because Mr. Johnson alleges that he only ingested the Generic Defendants' drugs and not the Brand Defendants' drugs, he has failed to state a products liability claim against the Brand Defendants.

In addition to theories of products liability under the statute, this Court has held that brand-name drug manufacturers owe no common-law duty under Texas law to those who do not ingest their drugs.[19] The claims Mr. Johnson advances in his complaint are the same claims that we have held are precluded.[20] Accordingly, Mr. Johnson has failed to state any viable claim against the Brand Defendants under Texas law.

C. Presumption against products liability for pharmaceutical companies

Under the Texas products liability law statute, a plaintiff who sues a pharmaceutical manufacturer under a failure to warn theory must also rebut a presumption that the manufacturer is not liable if the label was approved by the FDA.[21] This statute provides five ways to rebut the presumption, and Mr. Johnson argues that he has satisfied two of the statute's provisions: (1) by

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[17] *Lashley*, 750 F.3d at 477 (citing *Owens & Minor, Inc. v. Ansell Healthcare Prods., Inc.*, 251 S.W.3d 481, 485 (Tex. 2008)).

[18] *Id.* (citing *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989)).

[19] *Eckhardt*, 751 F.3d at 682 (citing *Lashley*, 750 F.3d at 476).

[20] *Compare* ROA.15-16 (products liability claims, strict liability claims, negligence, and breach of warranty) *with Eckhardt*, 751 F.3d at 677 (negligence, strict liability, breach of warranties, misrepresentation, and fraud).

[21] Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a)(1) (West).

alleging that Defendants perpetrated a fraud on the FDA and (2) by alleging that Defendants promoted their drug for an indication not approved by the FDA.[22]

But, we have held that Texas's fraud-on-the-FDA rebuttal is preempted by the Food Drug and Cosmetic Act unless the FDA itself finds fraud.[23] We need not reach the issues surrounding this presumption statute because even if Mr. Johnson could succeed on one of his rebuttal arguments, he still would fail to state a claim against the Generic Defendants because of *Mensing*-preemption and would fail to state a claim against the Brand Defendants because they owe no duty. To be sure, this does not render the presumption statute dead letter law. Had Mr. Johnson's suit involved an over-the-counter drug or a brand-name prescription drug that he actually ingested, we would apply Texas's presumption statute.[24] Because we do not reach the issues surrounding the presumption statute, we do not consider Mr. Johnson's arguments regarding rebuttal of the statute.

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[22] Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1) (West) (stating that a claimant may rebut the presumption by establishing that "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury"); Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(3) (West) (stating that a claimant may rebut the presumption by establishing that "the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration").

[23] *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 381 (5th Cir. 2012).

[24] *See, e.g. Id.* (analyzing the statute when the drug involved was over-the-counter ibuprofen); *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694 (5th Cir. 2014) (analyzing the statute when two Novartis brand drugs were ingested and allegedly caused injury).

III. Conclusion

We recognize that Plaintiff is left without a legal remedy based on the case law interpreting products liability law for generic and brand-name drug manufacturers. But, we are bound by the decisions of the Supreme Court and prior panels of this Court. Based on the foregoing reasons, the judgment of the district court granting Defendants' motions to dismiss is AFFIRMED.