Barbara Tutwiler v. Sandoz, Inc. Doc. 11010047906

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 17-13985
Non-Argument Calendar

D.C. Docket No. 2:16-cv-01246-LSC

BARBARA R. TUTWILER,

Plaintiff - Appellant,

versus

SANDOZ, INC.,

Defendant - Appellee.

Appeal from the United States District Court
for the Northern District of Alabama

(April 9, 2018)

Before MARTIN, JORDAN, and JILL PRYOR, Circuit Judges.

PER CURIAM:

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Barbara Tutwiler appeals the district court's dismissal of her failure-to-warn claim against Sandoz, Inc., a generic drug manufacturer. The district court concluded that Ms. Tutwiler's claim was impliedly preempted by federal law and barred by the learned intermediary doctrine under Alabama law. After a thorough review of the parties' briefs, as well as the record, we affirm.

I

The following factual background summarizes the allegations made in Ms. Tutwiler's amended complaint, which we accept as true at the motion to dismiss stage. *See Hill v. White*, 321 F.3d 1334, 1335 (11th Cir. 2003) (per curiam).

A

In October of 2012, Ms. Tutwiler's physician, Dr. Vance Plumb, prescribed her a drug named amiodarone in order to treat her non-life-threatening atrial fibrillation. Ms. Tutwiler followed the course of amiodarone treatment as prescribed by Dr. Plumb. At some time between the spring and summer of 2014, Ms. Tutwiler began experiencing shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. In July of 2014, Ms. Tutwiler was diagnosed by a second physician with interstitial lung disease and pulmonary fibrosis.

The generic version of amiodarone supplied to Ms. Tutwiler by her pharmacist was produced by Sandoz, Inc. According to the amended complaint,

amiodarone is "a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia . . . ." Amiodarone is not approved by the federal Food and Drug Administration for the treatment of non-life-threatening atrial fibrillation but is heavily marketed for this "off-label" use by both the brand-name manufacturer and Sandoz.

Sandoz is subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for the brand-name manufacturer. This includes producing and making available to distributors a Medication Guide that contains appropriate and current warning labels and that is ultimately disseminated to the patient by the distributor. Ms. Tutwiler did not receive a Medication Guide from her pharmacist as required by the FDA. As a result, Ms. Tutwiler alleges, she was not aware that she was being prescribed amiodarone for an "off-label" use and not as a last resort for her non-life-threatening atrial fibrillation.

B

Ms. Tutwiler's initial complaint asserted eight causes of action: (1) strict products liability (failure to warn); (2) negligence (failure to warn); (3) negligence (marketing and sale); (4) negligence *per se*; (5) fraud and deceit; (6) personal injury; (7) unjust enrichment; and (8) injunctive and declaratory relief. Sandoz filed a motion to dismiss, which the district court granted without prejudice for

certain of Ms. Tutwiler's claims on federal preemption grounds and due to the complaint being insufficiently pled.

Ms. Tutwiler amended her complaint, re-pleading three causes of action: (1) strict products liability (failure to warn); (2) negligence (failure to warn); and (3) negligence (marketing and sale). Sandoz again filed a motion to dismiss, which the district court granted with prejudice, ruling that Ms. Tutwiler's amended complaint contained substantially similar theories or failed to describe the claims with sufficient particularity. Ms. Tutwiler now appeals only the dismissal of her failure to warn claims.

II

We review *de novo* the district court's dismissal of Ms. Tutwiler's amended complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *See Hill*, 321 F.3d at 1335. A complaint "that states a plausible claim for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). But a complaint based on legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" will not. *Id.* at 678 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

We also review *de novo* the district court's interpretation of state law. *See Tampa Bay Water v. HDR Eng'g, Inc.*, 731 F.3d 1171, 1177 (11th Cir. 2013).

III

Ms. Tutwiler argues that dismissal was improper because (1) her state-based failure-to-warn claim is not preempted by federal law and (2) the Alabama learned intermediary doctrine is inapplicable.

A

Preemption is derived from the Supremacy Clause of the United States Constitution. *See* U.S. Const. art. VI, cl. 2; *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017). We first determine whether the Ms. Tutwiler's claim stands under Alabama state law, and only if necessary will we consider the question of preemption. *See Slack v. McDaniel*, 529 U.S. 473, 485 (2000) (articulating that courts should "not pass upon a constitutional question . . . , if there is also present some other ground upon which the case may be disposed of"); *Mink*, 860 F.3d at 1328 (stating that we "only [ ] decide the preemption questions where necessary"). As explained below, Alabama's learned intermediary doctrine bars Ms. Tutwiler's claims. We therefore do not address the issue of preemption. *See Mink*, 860 F.3d at 1328.

B

We apply Alabama law to Ms. Tutwiler's claims. *See, e.g.*, *Guaranty Trust Co. of N.Y. v. York*, 326 U.S. 99, 112 (1945) ("The source of substantive rights enforced by a federal court under diversity jurisdiction . . . is the law of the

States."). The Alabama Supreme Court adopted the learned intermediary doctrine in *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984), a case that addressed whether a manufacturer's duty to warn extended to both the physician and the patient to whom the drug would be prescribed. *Stone* held that pharmaceutical companies, "who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer." *Id*. at 1305 (quoting *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974)).

The doctrine in Alabama acknowledges "the role of the physician as a learned intermediary between a drug manufacturer and a patient." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673 (Ala. 2014). The underlying principle is that "prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient." *Id*. at 672–73. *See also Springhill Hosps., Inc. v. Larrimore*, 5 So. 3d 513, 518 (Ala. 2008) ("The relationship between physician-patient-manufacturer applies equally to the relationship between the physician-patient and pharmacist. In both circumstances the patient must look to the physician, for it is only the physician who can relate the

propensities of the drug to the physical idiosyncrasies of the patient.") (internal quotation marks and citation omitted).

Thus, in Alabama, the "manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product." *Weeks*, 159 So. 3d at 673 (citing *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313–14 (11th Cir. 2000)); *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881, 883 (Ala. 2004) (same). The adequacy of the manufacturer's warning is "measured by its effect on the physician, [ ] to whom it owed a duty to warn, and not by its effect on the consumer." *Weeks*, 159 So. 3d at 673 (alteration adopted); *Walls*, 887 So. 2d at 883 (same).

Once the manufacturer has met its duty to warn, the manufacturer holds no further duty to warn the patient directly. *See Weeks*, 159 So. 3d at 673. If, however, the warning to the learned intermediary is insufficient or is a misrepresentation of risks, "the manufacturer remains liable for the injuries sustained by the patient." *Id.* In such a situation, the patient must show that:

> [T]he manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury. In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient.

Id. at 673–74.

C

We cannot accept Ms. Tutwiler's conclusory allegation that Dr. Plumb is not a learned intermediary without "well-pleaded factual allegations" to support it. *See Iqbal*, 556 U.S. at 679. Ms. Tutwiler contends that the Alabama learned intermediary doctrine is inapplicable because Dr. Plumb—along with all physicians in the United States—was inadequately warned of the dangers of amiodarone by Sandoz. The district court ruled that these allegations were insufficient because Ms. Tutwiler failed to allege that "if her physician had been aware of the risks of prescribing amiodarone . . . he would not have prescribed the drug to her." D.E. 26 at 5. We agree. Assuming Ms. Tutwiler pled sufficient facts to support that Sandoz inadequately warned Dr. Plumb, she has still failed to plead "that the failure to warn was the actual and proximate cause of [her] injury," as required by Alabama law. *Weeks*, 159 So. 3d at 673.

On appeal Ms. Tutwiler again argues that the learned intermediary doctrine does not apply because she alleged that Sandoz did not adequately warn Dr. Plumb. This argument, however, does not address Alabama's separate requirement that she also plead proximate causation—that Dr. Plumb would not have prescribed her amiodarone had he known of its dangers. *See Weeks*, 159 So. 3d at 673–74.

Ms. Tutwiler failed to do this. Instead, she claims that *she* would not have taken amiodarone had *she* known of its dangerous effects. Regardless of what Ms. Tutwiler would or would not have done with the information, Alabama law requires a showing of what *Dr. Plumb* would have done with it. *See Weeks*, 159 So. 3d at 673–74 (requiring a showing that "but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient"). *See also Toole*, 235 F.3d at 1313–14 (noting that adequacy of warnings is measured by the "effect on the physician"). Without more, Ms. Tutwiler fails to allege what "effect on the physician" the allegedly-omitted information would have had on Dr. Plumb's decision to prescribe amiodarone. *See Weeks*, 159 So. 3d at 673–74; *Toole*, 235 F.3d at 1313–14. This failure leaves Ms. Tutwiler short of meeting her burden to plead proximate causation. *See Weeks*, 159 So. 3d at 673–74. Ms. Tutwiler's failure-to-warn claim is therefore barred by the Alabama learned intermediary doctrine.[1]

[1] Ms. Tutwiler requests that we certify a question regarding the application of the learned intermediary doctrine in this case to the Alabama Supreme Court. We decline to do so because the learned intermediary doctrine is well-settled in Alabama and we do not have substantial doubt as to its application here. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 n.2 (11th Cir. 2010) (denying request for certification because "Georgia's long-recognized, unwavering use of the learned intermediary doctrine has cast no 'substantial doubt' on the doctrine's continued validity under Georgia law.").

IV

Alabama's learned intermediary doctrine bars Ms. Tutwiler's failure to warn claim. We therefore affirm.[2]

AFFIRMED.

[2] Given our ruling, we need not address preemption.