IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
April 9, 2015

Lyle W. Cayce
Clerk

No. 14-30468

JOSHUA A. WHITENER, SR., Individually and on Behalf of His Minor Child Lucas C. Whitener; LINDSEY C. WHITENER, Individually and on Behalf of Her Minor Child Lucas C. Whitener,

Plaintiffs - Appellants

v.

PLIVA, INCORPORATED, formerly known as Pliva USA, Incorporated; PLIVA HRVATSKA D.O.O.; BARR LABORATORIES, INCORPORATED; BARR PHARMACEUTICALS, L.L.C.; WATSON PHARMACEUTICALS, INCORPORATED; TEVA PHARMACEUTICAL INDUSTRIES, LIMITED; SCHWARZ PHARMA, INCORPORATED, now known as UCB, Incorporated; ALAVEN PHARMACEUTICAL, L.L.C.; MEDA PHARMACEUTICALS, INCORPORATED,

Defendants - Appellees

Appeal from the United States District Court
for the Eastern District of Louisiana
USDC No. 2:10-CV-1552

Before JOLLY, WIENER, and CLEMENT, Circuit Judges.

PER CURIAM:*

* Pursuant to 5th Cir. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5th Cir. R. 47.5.4.

Lindsey Whitener's son was born prematurely and with birth defects after she was prescribed metoclopramide to treat the nausea and morning sickness she experienced while pregnant. Mrs. Whitener, joined by her son and husband, sued various pharmaceutical entities, alleging that those entities had promoted the prescription of metoclopramide to treat morning sickness, an "off-label" use. The district court dismissed the Whiteners' claim as to each defendant. Because the Whiteners have failed to show that any alleged off-label-promotional activities engaged in by the defendants caused their injuries, we AFFIRM.

I.

Early in her pregnancy, Mrs. Whitener visited her doctor, Dr. John McCrossen, complaining of nausea and morning sickness. Dr. McCrossen prescribed metoclopramide. Metoclopramide is the generic equivalent of the brand-name drug Reglan. Its Federal Drug Administration-approved label does not indicate that it is used to treat morning sickness. After Mrs. Whitener used metoclopramide throughout her pregnancy, her son was born prematurely and with severe birth defects.

In 2010, the Whiteners sued various pharmaceutical entities, alleging, first, that the defendants had failed to warn that metoclopramide could be dangerous when taken during pregnancy; and, second, that the defendants had promoted the prescription of metoclopramide to treat nausea and morning sickness in pregnancy, a dangerous, "off-label" use. Three of the defendants—PLIVA, Inc., Barr Laboratories, Inc., and Teva Pharmaceutical Industries, Ltd.—manufactured generic metoclopramide, the product that Mrs. Whitener used. Three of them—Alaven Pharmaceutical L.L.C., Meda Pharmaceuticals, Inc., and Schwarz Pharma, Inc.—manufactured brand-name Reglan, a product that Mrs. Whitener did not use.

In 2011, the Supreme Court held in *PLIVA, Inc. v. Mensing* that, because federal law requires generic drug labels to be the same at all times as corresponding brand-name drug labels, state-law inadequate-warning claims based on a generic-drug manufacturer's failure to provide a more adequate label are preempted. 131 S. Ct. 2567, 2577–78 (2011). Following *Mensing*, certain defendants filed a motion for judgment on the pleadings, asserting that the Whiteners' claims were preempted. The district court agreed that, to the extent the Whiteners' claims were based on the generic-manufacturing defendants' failure to change metoclopramide's label to warn of the danger of taking it during pregnancy, they were preempted. But to the extent the Whiteners' claims were based on the defendants' affirmative promotion of metoclopramide for use during pregnancy, the district court was unwilling "to conclude that such a claim fails as a matter of law."

The Whiteners amended their complaint to assert more clearly the remaining claim—off-label promotion. Teva Ltd.—which, it is undisputed, is an Israeli corporation with a principal place of business in Israel—moved to dismiss for lack of personal jurisdiction, and the district court granted the motion. The remaining defendants moved for summary judgment, arguing that the Whiteners' off-label-promotion claim was not a viable, non-preempted one under Louisiana law; and that, even if it were, the Whiteners could not establish that any promotional activities engaged in by the defendants had caused their injuries. The district court assumed for the argument asserted that the off-label promotion claim was viable. Nonetheless, it granted summary judgment, concluding that Dr. McCrossen's deposition testimony indicated that his "decision to prescribe the drug to Mrs. Whitener was his own" and was made "independently of any alleged conduct by the" defendants.

The Whiteners appealed, challenging the district court's grant of Teva Ltd.'s motion to dismiss for lack of personal jurisdiction and its dismissal on

summary judgment of their off-label-promotion claim against the other defendants and their other claims against the brand-name manufacturers.

II.

We first address the Whiteners' appeal of the district court's grant of Teva Ltd.'s motion to dismiss for lack of personal jurisdiction. Both in the district court and on appeal, the Whiteners have contended that *general* personal jurisdiction exists over Teva Ltd. But as the Supreme Court has held and this court has recently recognized, it is the "exceptional case" in which "a corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation" subject to general jurisdiction "in that State." *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 n.19 (2014); *see Monkton Ins. Servs., Ltd. v. Ritter*, 768 F.3d 429, 432 (5th Cir. 2014) ("It is . . . incredibly difficult to establish general jurisdiction in a forum other than the place of incorporation or principal place of business."). Nothing in the record shows that Teva Ltd.'s contacts with Louisiana are "'continuous and systematic' enough" to make this such an "exceptional case." *Monkton*, 768 F.3d at 432. Furthermore, because the Whiteners identify no evidence that they are likely to discover that would call our lack of personal jurisdiction into question, the district court did not abuse its discretion in denying the Whiteners' motion for additional jurisdictional discovery. *See id.* at 434; *see also Fielding v. Hubert Burda Media, Inc.*, 415 F.3d 419, 428 (5th Cir. 2005) ("A district court's discovery decision will be reversed only if . . . the appellant demonstrates prejudice resulting from the decision."). Accordingly, we AFFIRM the district court's grant of Teva Ltd.'s motion to dismiss, essentially for the reasons given by the district court.

III.

We turn next to the district court's grant of summary judgment to the remaining defendants. We review the district court's grant of summary judgment de novo, applying the same standard as the district court. *Chaney v. Dreyfus Serv. Corp.*, 595 F.3d 219, 228–29 (5th Cir. 2010). Under that standard, 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 as a matter of law." Fed. R. Civ. P. 56(a). In applying this standard, we "view[] all facts in the light most favorable to the nonmovant and draw[] all reasonable inferences in the nomovant's favor." *Rice v. ReliaStar Life Ins. Co.*, 770 F.3d 1122, 1129 (5th Cir. 2014). But we are "not required to accept the nonmovant's conclusory allegations, speculation, and unsubstantiated assertions which are either entirely unsupported, or supported by a mere scintilla of evidence." *Chaney*, 595 F.3d at 229.

A.

Many of the arguments made by the remaining defendants vary. Although the defendants all assert that the Whiteners' off-label-promotion claim is not a viable, non-preempted one under Louisiana law, they give different reasons why this is so. The defendants who manufacture generic metoclopramide argue, among other things, that the off-label-promotion claim is simply a failure-to-warn claim in a different guise, and thus that it is preempted under *Mensing*. The defendants who manufacture brand-name Reglan, citing our decisions in *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014), and *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177 (5th Cir. 2012) (per curiam), argue that the only claims the Whiteners may assert against them are those arising under the Louisiana Products Liability Act

(LPLA), and that, under that statute, they cannot be held liable because Mrs. Whitener did not use their product. The Whiteners counter each argument.[1]

Despite the variation in their several arguments, however, one argument is common to all defendants: regardless of whether the Whiteners' off-label-promotion claim is characterized as arising under the LPLA or under general Louisiana tort law, the Whiteners can recover only if they show *causation*—that is, they must show that, but for the defendants' off-label promotion of metoclopramide for use by pregnant women, Mrs. Whitener would not have ingested it. *See Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 260–61 (5th Cir. 2002) ("To maintain a successful . . . action under the LPLA, a plaintiff must establish . . . that the claimant's damage was *proximately caused* by a characteristic of the product . . . ." (emphasis added)); *Banks v. N.Y. Life Ins. Co.*, 98-0551 (La. 7/2/99); 737 So. 2d 1275, 1282 ("In a tort action, [the] plaintiff bears the burden of proving by a preponderance of the evidence . . . a *causal*

[1] The Whiteners also argue that we need not reach whether the district court properly granted summary judgment on the merits. Instead, the Whiteners suggest, we should remand on the ground that the district court abused its discretion in not granting their motion for additional discovery before it granted summary judgment to the defendants. *See* Fed. R. Civ. P. 56(d); *see also Freudensprung v. Offshore Tech. Servs., Inc.*, 379 F.3d 327, 347 (5th Cir. 2004) ("[W]e . . . review a district court's decision to deny a discovery request for abuse of discretion.").

To succeed on a Rule 56(d) motion, however, the party requesting discovery must provide an affidavit or declaration in support of the request that "state[s] with some precision the materials he hope[s] to obtain with further discovery, and exactly how he expect[s] those materials w[ill] assist him in opposing summary judgment." *Krim v. BancTexas Grp., Inc.*, 989 F.2d 1435, 1443 (5th Cir. 1993). The Whiteners' Rule 56(d) declaration did not mention how the Whiteners expect the discovery materials would help them oppose summary judgment. The declaration only incorporated by reference the Whiteners' arguments on this point from their memorandum in opposition to certain defendants' motion for summary judgment. But while the Whiteners' memorandum emphasized that discovery would substantiate their theory that the defendants influenced Dr. McCrossen's decision to prescribe metoclopramide through an indirect, "complex scheme," *see infra* p. 8, it made no mention of any *specific* materials that would accomplish that feat. In short, the district court did not abuse its discretion in denying the Whiteners' Rule 56(d) motion.

connection between the injury and the tort." (emphasis added)). The district court held that the Whiteners could not show causation because Dr. McCrossen's testimony indicates that his decision to prescribe metoclopramide to Mrs. Whitener was uninfluenced by the alleged promotional activities of the defendants. This holding is not error. We therefore affirm the district court's dismissal of the Whiteners' claim as to all remaining defendants without reaching whether the Whiteners' off-label-promotion claim is a viable theory of recovery.[2]

B.

In his deposition, Dr. McCrossen testified at length as to why he prescribed metoclopramide to treat Mrs. Whitener's morning sickness. This testimony is unequivocal: he prescribed metoclopramide to Mrs. Whitener not because any defendant suggested that he do so, but because, in his "clinical experience," metoclopramide "works good to control nausea and vomiting associated with pregnancy." Indeed, Dr. McCrossen's testimony makes clear that he *could not* have been directly influenced by the defendants to promote metoclopramide to pregnant women. He testified that he had never had any contact with the defendants or their representatives with regard to metoclopramide; that "[n]o one ha[d] specifically talked to [him] from a company about Reglan or Metoclopramide"; and that samples of the drug were never left at his office or, to his knowledge, provided to anyone else in his practice. Thus, the record is clear that it was Dr. McCrossen's "clinical . . . judgment" and "experience"—and not any promotional activities on the part of the defendants—that led him to prescribe metoclopramide to Mrs. Whitener.

[2] To the extent that the Whiteners raise other claims against the brand-name defendants alleging that they caused the FDA's mislabeling of Reglan and metoclopramide, these claims are foreclosed by *Johnson*. *See* 758 F.3d at 614–16 & n.3.

Conceivably, as the Whiteners point out, they might nonetheless survive summary judgment if they showed that Dr. McCrossen's clinical judgment was *itself* influenced, in some indirect way, by the defendants' promotional activities. The Whiteners, however, make no such showing. Instead, they only argue that the defendants engaged in a "complex scheme to promote metoclopramide through congresses, doctors and medical journals." But evidence of such a "complex scheme"—as opposed to "conclusory allegations, speculation, and unsubstantiated assertions," *Chaney*, 595 F.3d at 229—does not appear in the record.

* * *

Given Dr. McCrossen's testimony, the district court correctly held that there was no genuine issue of material fact to bar the defendants' motions for summary judgment. The failure to show causation, sadly, sinks all claims of the Whiteners. *See Stahl*, 283 F.3d at 260–61; *Banks*, 737 So. 2d at 1282. Accordingly, the judgment of the district court is

AFFIRMED.