IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
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Lyle W. Cayce
Clerk

No. 09-10983

MARTHA PUSTEJOVSKY,

Plaintiff-Appellant, Cross-Appellee,

v.

PLIVA, INC.,

Defendant-Appellee, Cross-Appellant.

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

Before STEWART, PRADO, and ELROD, Circuit Judges.

JENNIFER WALKER ELROD, Circuit Judge:

Martha Pustejovsky appeals the district court's summary judgment on her products-liability claims in favor of PLIVA, Inc., a manufacturer of the generic drug metoclopramide. Specifically, she challenges the district court's conclusion that, under the learned-intermediary doctrine, Pustejovsky failed to present evidence showing that the inadequate warning was the producing cause of her injuries. Because Pustejovsky offered no summary-judgment evidence that her doctor's significant misunderstanding of the risks of metoclopramide resulted from PLIVA's defective warnings, we AFFIRM.

I.

Martha Pustejovsky was hospitalized in January 2002 for an episode of severe gastric problems and was diagnosed as having gastroesophageal reflux disease. Upon discharge, she received a thirty-day prescription for metoclopramide ("MCP"). Pustejovsky underwent her follow-up care with internist Dr. Wendi Collini. Dr. Collini had her continue on a regimen of Protonix, Carafate, and MCP, which effectively controlled her symptoms. In November 2002, Pustejovsky returned to Dr. Collini to refill her prescription for MCP, and Dr. Collini continued to prescribe that medication for her until February 2005.

Following that three-year period, Pustejovsky began to experience tardive dyskinesia ("TD")—a neurological disorder causing involuntary, spasm-like movements—in her tongue and mouth. At the time Pustejovsky was taking MCP, the product label warned that "[b]oth the risk of developing [TD] and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose." A package insert also warned that "[e]xtrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosage of 30 to 40 mg/day of metoclopramide" (the "1/500 Warning") and that a duration of therapy "longer than 12 weeks has not been evaluated and cannot be recommended."

After being diagnosed with TD, Pustejovsky brought this products-liability lawsuit in state court, which PLIVA subsequently removed to federal court. Pustejovsky alleged that PLIVA failed to adequately warn doctors and patients of the true magnitude of the risks associated with the long-term use of MCP. In the course of discovery, the parties deposed Dr. Collini. Dr. Collini testified that she did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference, which reprints the information from the

manufacturers' labels. Similarly, she did not recall learning of possible side effects of MCP use through discussions with other physicians or at continuing-education seminars she had attended. Nevertheless, from her training and experience, she understood that TD was a possible, rare side effect of the drug. "What I mean as rare," she testified, "would be very infrequent, maybe never see during your practice. If I had to give you a number, I would say rare would be, you know, one in a million." She acknowledged that credible information that the risk were higher would affect her prescribing practices. Even a one-percent risk of TD "would be a consideration."

In June 2007, PLIVA moved for summary judgment, arguing that: (1) Pustejovsky could not establish any of the statutory exceptions to the presumption of nonliability under Texas Civil Practice & Remedies Code § 82.007; (2) federal law preempts the exception in § 82.007(b)(1), which permits a plaintiff to rebut the presumption by presenting evidence that the defendant withheld from or misrepresented to the United States Food and Drug Administration ("FDA") material and relevant required information; and (3) the Drug Price Competition and Patent Term Restoration Act preempted her claims. The district court denied PLIVA's motion in November 2007.

In January 2009, PLIVA again moved for summary judgment, reasserting the grounds raised in its first motion and arguing, for the first time, that Pustejovsky had failed to produce evidence sufficient to show that the inadequate warning was the producing cause of her injuries, as required by the learned-intermediary doctrine. On September 4, 2009, the district court granted PLIVA's second motion for summary judgment, reasoning that the learned-intermediary doctrine barred recovery. According to the court, the unrefuted evidence demonstrated that Dr. Collini "was aware of the possible risk involved with MCP use but decided to prescribe it" nevertheless. In making that decision, the court observed, Dr. Collini did not rely on PLIVA's warning, but rather on

"what she learned in medical school, continuing medical education, her own experience, and the experience of her colleagues." Thus, the inadequate warning "had no impact on her decision to prescribe MCP" and was not the producing cause of Pustejovsky's injuries.

In February 2009, while PLIVA's second summary-judgment motion was still pending, the FDA announced that it would require changes to the warning on MCP's label, as well as the addition of a black-box warning that "[c]hronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where the therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia." The FDA also directed that the "Warning" section of the label include the following information: "Although the risk of tardive dyskinesia (TD) with metoclopramide has not been extensively studied, one published study reported a TD prevalence of 20% among patients treated for at least 3 months." Further, the FDA directed Reglan, the manufacturer of the brand-name drug, to develop a risk-mitigation strategy for MCP. The revised warnings did not, however, include any change to the 1/500 Warning, which still appears on the package insert.

Shortly following the FDA's announcement, Pustejovsky requested and received permission to file supplemental briefing regarding its effect on PLIVA's summary-judgment motion. Pustejovsky did not, however, seek to reopen discovery or obtain any additional information from Dr. Collini while the motion was pending. In September 2009—just after the district court decided the motion and nearly seven months after the FDA's announcement—Pustejovsky filed a motion requesting that the district court reconsider its order, vacate the judgment, and grant her leave to redepose Dr. Collini in light of the FDA's intervening imposition of a black-box warning on the MCP label. The district

court denied her motion for reconsideration and additional discovery. This appeal followed.

Pustejovsky challenges the district court's finding that the inadequate warning was not the producing cause of her injuries. She also contends that the district court erred in denying her request to redepose Dr. Collini in light of the black-box warning mandated by the FDA in 2009. PLIVA cross-appeals, challenging the district court's rejection of its preemption arguments.

II.

We first address PLIVA's argument that the Drug Price Competition and Patent Term Restoration Act—also known as the Hatch-Waxman Amendments—preempts Pustejovsky's claim. According to PLIVA, because a generic manufacturer has no ability to unilaterally change its labeling and cannot provide different or additional warnings without prior FDA approval, it could not comply with both the Amendments and its state law duties. Our precedent squarely forecloses this argument, however. *See Demahy v. Actavis, Inc.*, 593 F.3d 428, 447-49 (5th Cir. 2010) (holding that the Hatch-Waxman Amendments do not federally preempt state-law failure-to-warn claims against a manufacturer of a generic drug). Accordingly, we hold that Pustejovsky's claims are not preempted.

Turning to Pustejovsky's appeal, we review a district court's summary judgment *de novo*. *LeMaire v. La. Dep't of Transp. & Dev.*, 480 F.3d 383, 386 (5th Cir. 2007). Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Breaux v. Halliburton Energy Servs.*, 562 F.3d 358, 364 (5th Cir. 2009). "A genuine issue of material fact exists if a reasonable jury could enter a verdict for the non-moving party." *Brumfield v. Hollins*, 551 F.3d 322, 326 (5th Cir. 2008) (citation omitted). We take all the

facts and evidence in the light most favorable to Pustejovsky, the nonmoving party. *Breaux*, 562 F.3d at 364.

Under Texas law, a manufacturer must instruct consumers as to the safe use of its product and warn consumers of dangers of which it has actual or constructive knowledge at the time the product is sold. *See Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984). But where a plaintiff sues the manufacturer of a prescription drug for failing to adequately warn of the drug's effects, Texas courts employ the learned-intermediary doctrine. *See Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986). Under the doctrine, the manufacturer may rely on the doctor—the learned intermediary—to pass on its warnings. Thus, so long as the drug manufacturer "properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug." *Id.* If, on the other hand, "the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." *Id.* at 592 (citations omitted).

An inadequate warning alone is not enough, however. The learned-intermediary doctrine also requires that the inadequate warning was a "producing cause" of the plaintiff's injuries. *See McNeil v. Wyeth*, 462 F.3d 364, 372 (5th Cir. 2006). Therefore, "a plaintiff who complains 'that a prescription drug warning is inadequate must also show that the alleged inadequacy caused her doctor to prescribe the drug for her.'"[1] *Id.* (quoting *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999)); *accord Stewart v. Janssen Pharmaceutica*, 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied).

[1] "Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a 'producing' cause of the injury, because it effectively sabotages the function of the intermediary." *McNeil*, 462 F.3d at 373 (footnote omitted).

Where the evidence demonstrates that "'the physician was aware of the possible risks involved in the use of the product but decided to use it anyway,'" the plaintiff cannot show that the inadequacy of the warning was a producing cause. *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Porterfield*, 183 F.3d at 468). But "[e]ven if the physician is not aware of a risk, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician" would not have prescribed the product. *Id.* (citation and internal quotation marks omitted).

Contrary to the district court's observation, the record evidence refutes the notion that Dr. Collini was aware of the risks of prescribing MCP for long-term use. In Dr. Collini's deposition, she stated that she believed TD to be a "possible[,] rare side effect" of MCP treatment. When pressed to elaborate on her definition of rare in this context, she responded with "very infrequent," or "one in a million"—so infrequent that a doctor might "never see" the side effect during her practice. Further, Dr. Collini testified that, had she been aware of even a one-percent risk of developing TD with use, such information would have affected her prescribing practices. This testimony indicates that Dr. Collini significantly underestimated the danger of long-term MCP usage, as reflected by the new FDA prescription warnings. Her testimony that only "one in a million" MCP users might acquire TD in no way reflects the twenty-percent prevalence rate found among patients treated for at least three months.[2] Nor

[2] PLIVA counters that Dr. Collini's statements do not reflect any misunderstanding of the risks, relying on the fact that the MCP product insert still bears the 1/500 Warning, even after the FDA-mandated changes. It further argues that a study finding a prevalence rate of twenty percent does not necessarily invalidate the 1/500 Warning, which it claims reflects an incidence rate. We need not resolve this question, however, as the record contains sufficient evidence to create a genuine issue of material fact as to whether Dr. Collini was unaware of the risk. Indeed, three years before the FDA's action, we held that a "jury could find that the risk of developing [extrapyramidal symptoms] from long-term use was not just higher, but that it was 'significantly' higher" than the 1/500 Warning suggested. *McNeil*, 462 F.3d at 370.

does it reflect an appreciation of the magnitude of the risk of developing TD, which prompted the FDA to caution against prolonged MCP treatment in "all but rare cases."

Because Dr. Collini was not fully aware of the risk of TD, we proceed to consider whether Pustejovsky has put forth summary-judgment evidence to show that a proper warning would have changed Dr. Collini's decision to prescribe MCP—that is, whether PLIVA's inadequate warning was the producing cause of her injuries. Pustejovsky has not carried her burden. As Pustejovsky admits, Dr. Collini did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference. Her lack of memory, of course, does not preclude the possibility that she had read these materials, but neither can it sustain Pustejovsky's burden.

Lacking any evidence that Dr. Collini was aware of PLIVA's warnings, Pustejovsky instead speculates about other ways an adequate warning might have reached Dr. Collini and altered her decision. She suggests, for example, that a modification to MCP's warning label might have come up in conversations with other physicians or been discussed at a continuing-education seminar. Certainly, these scenarios are possible. Ultimately, however, without any summary-judgment evidence to support them, they remain nothing more than possibilities. Although Dr. Collini did testify that she attended continuing-education seminars where MCP was discussed as a treatment option, there is no evidence of the content of these lectures, and Dr. Collini did not recall whether side effects were ever discussed at any seminar she had attended. Neither did she recall discussing MCP's side effects with any of her colleagues. While Pustejovsky can imagine any number of scenarios to fill the gaps in Dr. Collini's memory, she has provided evidentiary support for none of them. Accordingly, Pustejovsky fails to demonstrate a genuine issue of material fact regarding causation. *See Brown v. City of Houston*, 337 F.3d 539, 541 (5th Cir. 2003)

("Unsubstantiated assertions . . . and unsupported speculation are not sufficient to defeat a motion for summary judgment." (citations omitted)). As Pustejovsky cannot demonstrate that PLIVA's inadequate warning was the producing cause of her injury, the learned-intermediary doctrine bars her recovery.

Pustejovsky also challenges the district court's refusal to allow her to redepose Dr. Collini about the effect that the FDA's action in February 2009 might have had on her prescribing practices. We review a district court's denial of a discovery request for abuse of discretion. *See Beattie v. Madison Co. Sch. Dist.*, 254 F.3d 595, 605 (5th Cir. 2001). While PLIVA's second summary-judgment motion was still pending, Pustejovsky sought and received permission from the court to file supplemental briefing concerning the effect of the FDA's new MCP-labeling requirements. During that time, Pustejovsky never sought additional discovery from Dr. Collini concerning the FDA's actions. Not until after the district court granted summary judgment—about seven months after the FDA's actions—did Pustejovsky first raise the necessity of a second deposition with the court. Under the circumstances, we cannot say that the district court abused its discretion in denying her request.

III.

Although Pustejovsky's claims are not preempted by the Hatch-Waxman Amendments, she has failed to produce sufficient evidence that PLIVA's inadequate warnings were the producing cause of her injuries. Likewise, Pustejovsky has not shown that the district court abused its discretion in refusing to reopen discovery. In light of our disposition of Pustejovsky's arguments, we need not reach PLIVA's remaining preemption argument on cross-appeal. We therefore AFFIRM the summary judgment in favor of PLIVA.