FILED
United States Court of Appeals
Tenth Circuit

June 2, 2010

Elisabeth A. Shumaker
Clerk of Court

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

CANDACE MILLER and GEORGE MILLER,

Plaintiff-Appellant/
Cross-Appellees,

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,

Defendant-Appellee/
Cross-Appellant,

and

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; PRODUCT LIABILITY ADVISORY COUNCIL, INC.; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Amici Curiae.

Nos. 08-5042 and 08-5050
(N. D. Oklahoma)
(D.C. No. 4:03-CV-00393)

ORDER AND JUDGMENT[*]

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[*] This order and judgment is not binding precedent except under the doctrines of law of the case, res judicata, and collateral estoppel. It may be cited, however, for its persuasive value consistent with Fed. R. App. P. 32.1 and 10th Cir. R. 32.1.

Before **BRISCOE**, Chief Judge, and **HENRY** and **HARTZ,** Circuit Judges.

This case requires that we vacate and remand to the district court for application of the "clear error" test for federal preemption recently set forth in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). *See Dobbs v. Wyeth Pharmaceuticals*, no. 08-6018, __ F.3d ___ (10th Cir. 2010) (also remanding for application of *Levine*).

I. BACKGROUND

Candace and George Miller separately sued Glaxosmithkline (GSK) for failing to adequately label its antidepressant Paxil to warn of suicide risk, alleging that this failure to warn caused Ms. Miller's 1998 suicide attempt in which she seriously injured herself. GSK moved for summary judgment, arguing (1) that there was federal preemption of both of the Millers' state law failure to warn claims; (2) that both of the Millers' claims were barred by statute of limitations; and (3) that the learned intermediary doctrine prevented either of the Millers from proving that the alleged failure to warn proximately caused their injuries.

On the preemption issue, GSK argued that under federal labeling regulations it would have been impossible to have added a suicide warning label to protect itself against state law failure to warn claims. GSK argued that the Food and Drug Administration required scientific evidence for such warnings, and

that if it had placed a suicide warning label on Paxil then it would have been prosecuted under federal law for unlawfully misbranding the drug with a scientifically unsubstantiated warning label. On the statute of limitations issue, GSK argued that both of the Millers had received notice of a claim against GSK more than two years before they filed their suits. On the learned intermediary doctrine issue, GSK argued that neither of the Millers could prove proximate causation, because under Oklahoma law the duty to warn runs to the physician not to the patient, and because Ms. Miller's physicians would not have changed their treatment decisions even with a stronger suicide warning label on Paxil.

In a one-page order without an accompanying opinion, the district court granted summary judgment in favor of GSK on federal preemption grounds for both Millers' claims, as well as on statute of limitations grounds for Mr. Miller's claim. The district court denied GSK's motion for summary judgment on statute of limitations grounds for Ms. Miller's claim, as well as on learned intermediary grounds for both Millers' claims.

II. DISCUSSION

The Millers appeal, arguing that the district court erred (1) in finding each of their failure to warn claims preempted, and (2) in finding Mr. Miller's claim to be time-barred. On the preemption issue, the Millers maintain that no conflict existed between state and federal law, because FDA regulations permit pharmaceutical companies to simultaneously change their labels while also

submitting the change for review by the FDA. According to the Millers, at the time of Ms. Miller's suicide attempt in 1998, GSK could have unilaterally added a Paxil suicide warning label using a "Changes Being Effected" (CBE) supplement, which allows a pharmaceutical company to unilaterally "add or strengthen a contraindication, warning, precaution, or adverse reaction," and use that strengthened label while simultaneously filing the CBE application for FDA approval. 21 C.F.R. § 314.70(c)(6)(iii). On the statute of limitations issue, the Millers argue that there is a factual dispute about when Mr. Miller received notice that he had a claim against GSK, and about whether he received notice more than the statutory two years before he filed his suit. The Millers request that we reverse the district court's grant of summary judgment and remand the case to the district court for a trial to determine whether GSK failed its state law duty to properly label its products.

GSK cross-appealed, arguing that (1) Ms. Miller's claim is time-barred for the same reason that the district court found her husband's claim to be time-barred, and (2) both suits should be dismissed under Oklahoma's learned intermediary doctrine because neither plaintiff can prove proximate causation.

After the district court's decision, the Supreme Court in *Levine* changed the legal standard for a successful federal preemption defense against a state law failure to warn claim, holding that "absent *clear evidence* that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was

impossible for [the pharmaceutical company] to comply with both federal and state requirements." 129 S. Ct. at 1198 (emphasis added). After *Levine*, GSK must demonstrate that federal labeling requirements made it impossible to meet its state law duty to warn by proving that there was "clear evidence" that the FDA would have rejected GSK's labeling change had it unilaterally strengthened Paxil's warning label using the CBE supplement. *Id*.

In light of *Levine*'s newly-established "clear evidence" test, we must VACATE the district court's grant of summary judgment to GSK, and REMAND to give the court the opportunity to make evidentiary findings and analyze the record in light of *Levine*'s new "clear evidence" standard.[1]

Entered for the Court,

Robert H. Henry
United States Circuit Judge

[1]In the disposition of this appeal we do not address the statute of limitations and learned intermediary doctrine arguments. The parties are not foreclosed from raising those issues in a subsequent appeal, if appropriate.