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File Name: 11a0271p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 09-5460

LALA SMITH,

Plaintiff-Appellant,

v.

WYETH, INC.; AMERICAN HOME PRODUCTS CORPORATION; PLIVA, INC.; and SCHWARZ PHARMA, INC.,

Defendants-Appellees.

No. 09-5466

ALICE WILSON,

Plaintiff-Appellant,

v.

PLIVA, INC.; BARR PHARMACEUTICALS, INC.; WYETH, INC.; and SCHWARZ PHARMA, INC.,

Defendants-Appellees.

No. 09-5509

DENNIS MORRIS,

Plaintiff-Appellant,

v.

PLIVA, INC.; SCHWARZ PHARMA, INC.; TEVA PHARMACEUTICALS, USA, INC.; and UDL LABORATORIES, INC.,

Defendants-Appellees.

Nos. 09-5460/5466/5509

Appeal from the United States District Court
for the Western District of Kentucky at Paducah, Louisville, and Bowling Green.
No. 07-00018—Thomas B. Russell, Chief District Judge.

Argued: June 9, 2010

Decided and Filed: September 22, 2011

Before: DAUGHTREY, GILMAN, and SUTTON, Circuit Judges.

COUNSEL

ARGUED: Louis M. Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, P.C., Washington, D.C., Claire Patricia Mary Prestel, TRIAL LAWYERS FOR PUBLIC JUSTICE, Washington, D.C., for Appellants. Jeffrey R. Pilkington, DAVIS GRAHAM & STUBBS LLP, Denver, Colorado, Joseph P. Thomas, ULMER & BERNE LLP, Cincinnati, Ohio, for Appellees. **ON BRIEF:** Louis M. Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, P.C., Washington, D.C., Claire Patricia Mary Prestel, TRIAL LAWYERS FOR PUBLIC JUSTICE, Washington, D.C., Daniel J. McGlynn, McGLYNN, GLISSON & MOUTON, Baton Rouge, Louisiana, Jeffrey A. Roberts, ROBERTS LAW OFFICE, Murray, Kentucky, for Appellants. Jeffrey R. Pilkington, Andrew M. Low, DAVIS GRAHAM & STUBBS LLP, Denver, Colorado, Joseph P. Thomas, Linda E. Maichl, ULMER & BERNE LLP, Cincinnati, Ohio, Richard H.C. Clay, DINSMORE & SHOHL LLP, Emily Fritts Whitty, MORRIS & PLAYER, Louisville, Kentucky, Henninger S. Bullock, Andrew J. Calica, MAYER BROWN LLP, New York, New York, for Appellees. Robert E. O'Malley, SEGAL McCAMBRIDGE SINGER & MAHONEY, LTD., Chicago, Illinois, Benjamin S. Kingsley, Douglas N. Letter, Sharon Swingle, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D. C., for Amici Curiae.

OPINION

MARTHA CRAIG DAUGHTREY, Circuit Judge. Plaintiffs Lala Smith, Alice Wilson, and Dennis Morris developed tardive dyskinesia as a result of their use of generic metoclopramide, a drug prescribed for the treatment of gastroesophageal reflux disease. They filed individual actions against various manufacturers of generic metoclopramide, alleging that the defendants failed to include adequate information on product labels concerning the risks of taking the drug long-term and seeking damages under Kentucky state law for failure to warn. They also named as parties Wyeth, Inc., and Schwarz Pharma, Inc., the manufacturers of the name-brand form of metoclopramide, sold as Reglan, alleging fraud and tortious misrepresentation. The district court dismissed the plaintiffs' claims against the generic defendants on federal preemption grounds, finding a conflict between their tort claims and the federal regulation of generic drugs. The district court also dismissed the plaintiffs' action

against the name-brand defendants because the plaintiffs did not allege that they had ingested Reglan, a threshold requirement for a products-liability action under Kentucky law. We find no error with regard to either ruling and affirm.

FACTUAL AND PROCEDURAL BACKGROUND

All three plaintiffs were originally prescribed Reglan to treat gastroesophageal reflux. The active ingredient in Reglan is metoclopramide, which is also available in generic form. Reglan, the name-brand form of metoclopramide, was manufactured by defendant Wyeth from 1989 to 2001 and by defendant Schwarz from 2001 to 2005 (collectively, the name-brand defendants). Kentucky, where the plaintiffs reside, has a generic-substitution law requiring pharmacies to fill prescriptions with a lower-priced, therapeutically-equivalent generic drug unless the doctor or the purchaser explicitly instructs otherwise. *See* KY. REV. STAT. § 217.822(1) (2010). As a result, the plaintiffs' pharmacies filled their prescriptions for Reglan with generic metoclopramide[1] manufactured and distributed by defendants Pliva, Barr Pharmaceuticals, Actavis, Teva Pharmaceuticals, UDL Laboratories, and Morton Grove Pharmaceuticals (collectively, the generic defendants). As a result of their long-term consumption of metoclopramide, all three plaintiffs allegedly developed tardive dyskinesia, a severe neurological disorder that resembles Parkinson's disease.

Plaintiffs Wilson and Morris filed suit against the generic and name-brand defendants in federal court in 2007. Plaintiff Smith initially sued the same defendants in Kentucky state court, and the defendants removed the case to the federal district court in which the other suits were pending. Against the generic defendants, the plaintiffs asserted state-law failure-to-warn claims; against the name-brand defendants, they asserted state-law fraud, fraudulent concealment, and negligent misrepresentation, alleging that Reglan's label and corresponding entry in the Physician's Desk Reference

[1]Although Smith and Wilson claim to have consumed only generic metoclopramide, plaintiff Morris does assert that he consumed some Reglan manufactured by Wyeth (but not Schwarz), a fact that Wyeth did not contest before the district court. Morris, however, has voluntarily dismissed his claims against Wyeth.

falsely and misleadingly represented the risks associated with long-term use of metoclopramide.

The district court initially issued orders granting summary judgment to the name-brand defendants, dismissing the plaintiffs' claims, and holding that Kentucky law does not permit a cause of action for misrepresentation about a product against anyone other than the product's manufacturer or distributor. Subsequently, the district court granted summary judgment to the generic defendants on federal preemption grounds. After denying motions for reconsideration, the district court issued orders dismissing all claims and entered final judgment in favor of the defendants. This appeal followed.

DISCUSSION

Federal Preemption

On appeal, the plaintiffs contend that the district court erred in concluding that their state-law failure-to-warn claims against the generic defendants were preempted by federal law. Their arguments must fail, however, given the recent decision of the Supreme Court in *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), issued on June 23, 2011. Just as in the present case, the plaintiffs in *Mensing* alleged that their long-term use of generic metoclopramide caused tardive dyskinesia, and they predicated the manufacturers' liability under state law on the failure to provide adequate warnings on the product's label. The Supreme Court held unequivocally, however, that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims. The plain language of the *Pliva* decision compels the same result here.

Kentucky Products Liability Law

On appeal, the plaintiffs also argue that the district court erred in granting the name-brand defendants' motion for summary judgment on their state-law claims. The district court first concluded that plaintiffs' tort claims were subject to Kentucky's Products Liability Act, KY. REV. STAT. §§ 411.300 - 411.350 (2010). The court then held that the claims could not succeed because the plaintiffs alleged that generic

metoclopramide, not the defendants' name-brand product Reglan, caused their injuries. As a result, the action against the name-brand defendants was dismissed.

We review the district court's dismissal *de novo*, construing the complaint in the plaintiffs' favor and taking all well-pleaded allegations in the complaint as true. *See Beaudry v. TeleCheck Servs., Inc.*, 579 F.3d 702, 704 (6th Cir. 2009). The Kentucky Products Liability Act, a codification of preexisting common-law principles, defines a "product liability action" as "any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation . . . warning, instructing, marketing, advertising, packaging or labeling of any product." KY. REV. STAT. § 411.300(1) (2010). As the Kentucky Supreme Court has held, "[t]he [Products Liability Act] applies to all damage claims arising from the use of products, regardless of the legal theory advanced." *Mosanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997). We conclude that the district court correctly applied the Act here.

A threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury. *See Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970). The plaintiffs in this case concede that they had consumed only generic versions of metoclopramide and not Reglan. As the district court observed, adopting their theory of liability would require the court to attribute any deficiency in a name-brand manufacturer's labeling and marketing of its products to products manufactured by its generic competitors. Such a theory, however, fails to satisfy the threshold requirement of a products-liability action – that the *defendant's* product have injured the plaintiff. As the district court stated, "Just because a company is in the same business as a tortfeasor, the company is not automatically liable for the harm caused by the tortfeasor's product."

The plaintiffs' argument – that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs – has been rejected by all but one of the courts that have

considered it. The leading case is *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), in which the court held that the manufacturer of a name-brand drug has no duty to patients who ingested only a generic version of the drug manufactured by the name-brand drug company's competitors. *See also Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006) (collecting cases), *rev'd on other grounds*, 521 F.3d 253 (3d Cir. 2008). *But see Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 313 (Cal. Ct. App. 2008) ("[W]e have no difficulty concluding that [the name-brand defendant] should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide."). As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company. Moreover, and most significantly, the plaintiffs have not convinced us that the state courts of Kentucky would adopt their vicarious-liability argument under the Kentucky Products Liability Act.

CONCLUSION

For the reasons set out above, we AFFIRM the judgment of the district court.