IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
February 14, 2013
Lyle W. Cayce
Clerk

No. 12-30319

PENNY MORRIS; JOHN MORRIS,

Plaintiffs - Appellants

v.

PLIVA, INCORPORATED, formerly known as Pliva USA, Incorporated; TEVA PHARMACEUTICALS USA, INCORPORATED; ACTAVIS ELIZABETH, L.L.C., as successor in interest, on behalf of Purepac Pharmaceutical Company,

Defendants - Appellees

Appeal from the United States District Court
for the Western District of Louisiana
USDC No. 3:09-CV-854

Before DAVIS, JONES, and SMITH, Circuit Judges.

PER CURIAM:[*]

Appellants Penny and John Morris sued Appellees PLIVA, TEVA, and Actavis—generic drug manufacturers—for injuries related to use of the drug metoclopramide (brand-name Reglan). This case is yet another in the expanding cohort controlled by *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which held state law claims against generic manufacturers of Reglan preempted by FDA

[*] 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 R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR.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.

regulations. *See also Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011) (per curiam). Accordingly, we AFFIRM the dismissal of this suit.

BACKGROUND

Penny Morris took metoclopramide from early 2006 to July 2008. Ingesting the drug for more than twelve weeks, however, has been contra-indicated on FDA-approved labels since 2004 and by "black box" labeling since 2009. She developed the movement disorders tardive dyskinesia and akathisia as a result of taking the drug and brought this suit in May 2009. Appellants sued under theories of defective construction and composition of the drug; defective design; breach of express warranty; and inadequate warning. The suit was subsequently stayed to await the Supreme Court's decision in *Mensing*—a case dealing with almost identical claims against the same generic manufacturers. While state law "failure to warn" claims are allowed against brand-name manufacturers, *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009), *Mensing* held such claims against generic manufacturers conflict-preempted by federal law as interpreted by the FDA. *Mensing*, 131 S. Ct. at 2580–81.

Finding the Morrises' only factually supported claim—inadequate warning—to be preempted, the district court dismissed the complaint "pursuant to Rule 12(b)(6) and/or 12(c) of the Federal Rules of Civil Procedure." Appellants subsequently moved the district court under Rule 59(e) to amend its earlier ruling based on four theories: (1) Appellant PLIVA failed to comply with the 2004 FDA-approved label change; (2) the generic defendants failed to properly test their products and report that information; (3) breach of express warranty; and (4) Appellant TEVA may be held liable for a "failure to warn" because of its status as a reference listed drug ("RLD") holder.[1] The first three of these had

[1] All of these theories except breach of warranty are predicated on the Louisiana Products Liability Act, La. R.S. 9:2800.51, *et seq*. We need not explore pleading deficiencies under state law, as the claims are preempted.

previously been asserted, but the last theory was raised as "newly discovered information." The district court denied the motion and the Morrises timely appealed its adverse rulings.[2]

DISCUSSION

Judgments on the pleadings are reviewed *de novo*; Rule 12(c) motions are governed by the same standard as Rule 12(b)(6) motions. *Jebaco, Inc. v. Harrah's Operating Co.*, 587 F.3d 314, 318 (5th Cir. 2008). The fundamental question is whether the plaintiff states a claim on which relief may be granted. "To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief . . . ." *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964 (2007)). Alternatively, Rule 59 orders are reviewed for abuse of discretion and "cannot be used to raise arguments which could, and should, have been made before the judgment issued." *Schiller v. Physicians Res. Grp. Inc.*, 342 F.3d 563, 567 (5th Cir. 2003) (quoting *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 863 (5th Cir. 2003)).

I. Failure-to-Warn Claims

Mensing held that federal law demands "generic drug labels be the same at all times as the corresponding brand-name labels." *Mensing*, 131 S. Ct. at 2578. This is known as the "duty of sameness." Whether a warning is placed on the label on the bottle or in letters to distributors, any state law duty requiring generic manufacturers to act unilaterally in this area is preempted by federal law. *Id.* at 2580–81.

[2] Brand-name manufacturers Wyeth, Inc. and Schwarz Pharma, Inc. were included as defendants in the original suit but dismissed with prejudice in November of 2009. The district court denied Appellants' Rule 60(b)(5) motion for relief from judgment. Appellants noticed appeal of the 60(b) denial but it was not briefed or argued to this court.

Appellants first contend that *Mensing* did not dispense with claims concerning a failure to communicate *approved* warnings. They allege the generic defendants are liable for failing to convey FDA-approved information; information communicated by generic manufacturers that is consistent with the brand-name labeling does not violate the duty of sameness.[3]

On the contrary, *Mensing* forecloses such claims because failure to "communicate" extends beyond just a label change. To avoid liability, the manufacturer must take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label. Because the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead. *Id.* at 2576 ("[I]f generic drug manufacturers, but not the brand-name manufacturer, sent [additional warnings such as a 'Dear Doctor' letters], that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'"). Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so. As *Mensing* concluded, preemption is thus triggered since it would be impossible for PLIVA to comply with both the state law duty to warn and the federal law duty of sameness.

Appellants also fault PLIVA specifically for not adopting the 2004 FDA-approved warning label.[4] To reach the merits of this argument, we would have to overlook that no such claim appears in Appellants' live pleading, their Fourth

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[3] This argument has been rejected by other circuits. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012); *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011), *vac'g* 588 F.3d 603 (8th Cir. 2009).

[4] The argument that generic manufacturers may be subject to inadequate warning claims was only pressed against PLIVA. Actavis and TEVA conformed to the 2004 update.

Amended Complaint. The trial court was disinclined to allow yet another amendment and did not thereby abuse its discretion. But any amendment would be futile. First, it is logically incoherent to contend that PLIVA had a duty to apply the 2004 warning label when Appellants also assert repeatedly that no labels predating 2009 were adequate. Tort liability does not arise for failure to attach an inadequate label. Second, a claim that PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted. 21 U.S.C. § 337(a); *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 121 S. Ct. 1012, 1018 n.4 (2001).

Appellants also argue that TEVA may be held responsible for a failure-to-warn claim notwithstanding that it is a generic manufacturer. TEVA's product was designated an RLD by the FDA, making it the equivalent of a brand-name manufacturer's metoclopramide. As the district court noted, the Fourth Amended Complaint did not raise this claim, which Appellants mislabeled in 2010 as "newly discovered." The information was available in the 2003 "FDA Orange Book." Yet even if an amendment were allowed, we agree with the district court's analysis, in rejecting this claim, that it "assumes, without authority, that the FDA considered TEVA to be a brand name manufacturer with the requisite duty to unilaterally change its product's labeling simply because the FDA designated TEVA's metoclopramide as the RLD."[5]

II. Non-Failure-to-Warn Claims

Appellants next argue that the generic defendants failed to test and inspect the product according to federal law. This claim fails for several reasons. First, the Federal Food, Drug, and Cosmetic Act ("FDCA") provides no private right of action for these violations. "[A]ll such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337. Nor can a violation be used as evidence of a breach of

[5] In fact, the metoclopramide ingested by Morris (tablets) may be distinguishable from that for which TEVA was the RLD (oral solution).

duty. While any testing and reports could have been used to alert the FDA of the need to strengthen labels and warnings, the Supreme Court specifically addressed this argument in *Mensing*. A federal duty to ask for such help might have existed but state tort law "did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label." *Mensing*, 131 S. Ct. at 2578. Finally, any "useful" reporting—at least from the standpoint of those injured—would ostensibly consist of some sort of warning. This argument, then, is yet another attempt to circumvent disfavored failure-to-warn claims.

Appellants' final claim is for breach of express warranty based on the generic defendants' introducing a defective product into the stream of commerce.[6] It is urged that the drug is unreasonably dangerous as designed and so, in fact, no warnings would have been sufficient: metoclopramide should not have been sold at all. While this type of claim has been recognized by the First Circuit,[7] it has been rejected by this one. *See Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 186–87 (5th Cir. 2012) (per curiam). *Demahy* is more convincing. A breach of warranty claim that goes directly to the sufficiency of the generic manufacturers' labeling is clearly unacceptable. Metoclopramide has legitimate therapeutic purposes, as evidenced by the FDA's approval of Reglan in the first place. Any state law-based holding that the generic manufacturers should have acted differently with respect to warnings or should have ceased manufacturing these products because of insufficient warnings not only violates the duty of

[6] While Appellants brief this point as three distinct issues (Breach of Express Warranty, Design Defect, and Construction or Composition Defect), each argument goes to the same point—Appellees marketed an inherently dangerous product—and so we examine them together. Appellants recognized this commonality at oral argument by noting that the design defect argument was essentially the same as the breach of warranty claim in the *Bartlett* case.

[7] *Bartlett v. Mutual Pharm. Co.*, 678 F.3d 30 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012).

sameness but conflicts with FDA's exclusive authority to approve drugs and drug labels. This claim is preempted.

CONCLUSION

For the foregoing reasons, we affirm both the district court's denial of Appellants' motion to alter or amend the judgment and the grant of Appellees' motion to dismiss.

AFFIRMED