IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
February 21, 2014

Lyle W. Cayce
Clerk

No. 12-60861
c/w No. 12-41148

WALTER LASHLEY,

Plaintiff-Appellant,

v.

PFIZER, INC.;
WYETH, INC.;
SCHWARZ PHARMA, INC.;
WATSON PHARMA, INC.;
WATSON LABORATORIES, INC.;,

Defendants-Appellees.

MARIA DEL VALLE,

Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.;
PLIVA, INC.;
WYETH, INC.;
SCHWARZ PHARMA, INC.;
VINTAGE PHARMACEUTICALS, LLC.,

Defendants-Appellees.

Appeals from the United States District Courts
for the Southern District of Mississippi and the Southern District of Texas
USDC Nos. 1:09-cv-00749 and 1:11-cv-000113

Before STEWART, Chief Judge, and HIGGINBOTHAM, Circuit Judge.[*]

PER CURIAM:

These appeals arise out of claims against both generic and brand-name manufacturers for injuries related to use of the drug metoclopramide (brand-name Reglan). Because the pertinent facts and legal issues of these cases are nearly identical, we consolidate them for disposition.

In case No. 12-60861, *Lashley v. Pfizer*, et al., Appellant Walter Lashley ("Lashley") appeals the Southern District of Mississippi's grant of Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc.'s ("Watson generic defendants") motion to dismiss, as well as its grant of summary judgment in favor of defendants Pfizer, Inc.; Wyeth, Inc.; and Schwarz Pharma, Inc. ("Pfizer brand defendants"). Lashley's claims against the Watson generic defendants were based upon their sale and distribution of metoclopramide to Lashley. His claims against the Pfizer brand defendants were based on allegedly false and misleading representations they made to the medical community.

In case No. 12-41148, *Del Valle v. Teva Pharm.*, et al., Appellant Maria Del Valle ("Del Valle") similarly appeals the Southern District of Texas's grant of Qualitest Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; PLIVA, Inc.; and Vintage Pharmaceuticals, LLC's ("Teva generic defendants")[1] motion to dismiss and its grant of Schwarz Pharma, Inc. and Wyeth, Inc.'s ("Schwarz

[*] This matter is being decided by a quorum. 28 U.S.C. § 46(d).

[1] Collectively, we will refer to the generic defendants from both cases as the "generic manufacturers."

brand defendants")[2] motion for summary judgment. Del Valle alleged that the Teva generic defendants were liable for damages she experienced as a result of her ingestion of metoclopramide manufactured by these defendants. Her claims against the Schwarz brand defendants were based on alleged misrepresentations they made to the medical community.

For the reasons stated herein, we AFFIRM the district courts' rulings in both cases.

I. Facts

Lashley took generic metoclopramide from 2002 until late 2006. In 2004, brand defendant Schwarz submitted a label update for Reglan adding that "[t]herapy with Reglan tablets should not exceed 12 weeks in duration," which the FDA approved. Not all generic manufacturers modified their labels to conform with the newly approved warnings at that time. Lashley developed the movement disorders tardive dyskinesia and akathisia as a result of taking the drug and brought suit in October 2009. As noted above, he sued the Watson generic defendants based on their sale and distribution of the drug and sued the Pfizer brand defendants for misrepresentations made to the medical community. He brought claims against all defendants under theories including negligence, gross negligence, strict liability, breach of warranty as to merchantability, breach of warranty as to fitness for a particular purpose, misrepresentation, fraud, and suppression of evidence.

Del Valle took generic metoclopramide from 2004 to February 2011. Like Lashley, she developed tardive dyskinesia and akathisia as a result of taking the drug. She brought suit in June of 2011. She sued the Teva generic defendants based on their manufacture and distribution of metoclopramide, under theories of negligence, gross negligence, misrepresentation, fraud, suppression of

[2] Collectively, we will refer to the brand defendants from both cases as the "brand manufacturers."

evidence, strict liability, breach of warranty as to merchantability, breach of warranty as to fitness for a particular purpose, and deceptive trade practices. She brought the same claims against the Schwarz brand defendants for their role in the promotion and manufacture of the drug, with the exception of deceptive trade practices.

The courts below in both cases dismissed the claims against the generic manufacturers, finding them to be either preempted under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (holding failure-to-warn claims against generic manufacturers of Reglan preempted) or deficient for failure to state a claim on which relief could be granted. *See* Fed. R. Civ. P. 12. All the claims against the generic manufacturers were treated as variations of a failure-to-warn claim. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 & n.6 (5th Cir. 2013) (per curiam) ("Appellants next argue that the generic defendants failed to test and inspect the product according to federal law . . . [A]ny 'useful' reporting—at least from the standpoint of those injured—would ostensibly consist of some sort of warning.").[3] The district courts granted summary judgment in favor of brand manufacturers in both cases below, on the grounds that neither Lashley nor Del Valle ever ingested their product, Reglan. These appeals timely followed.

II. Claims Against Generic Manufacturers

Appellants argue that the lower courts erred in dismissing their claims against generic manufacturers as preempted under *Mensing*.[4] We review grants

[3] Citing *Hackett v. G.D. Searle & Co.*, Case No. A-01-CA-399-SS, 2002 U.S. Dist. LEXIS 16246, at *7 (W.D. Tex. Jun. 25, 2002), the magistrate judge in *Del Valle* specifically noted that failure to warn is the "only valid claim" in a suit for personal injuries caused by prescription drugs in Texas.

[4] In *Mensing*, the Supreme Court considered consolidated lawsuits involving state tort claims based on a drug manufacturer's failure to provide adequate warning labels for metoclopramide. The specific question the Court considered was "whether federal drug regulations applicable to generic drug manufacturers directly conflict[ed] with, and thus

of Rule 12(b)(6) motions to dismiss de novo. *Highland Capital Mgmt. LP v. Bank of Am, Nat'l Ass'n*, 698 F.3d 202, 205 (5th Cir. 2012). Judgments on the pleadings are also reviewed de novo; Rule 12(c) motions are governed by the same standard as Rule 12(b)(6) motions.[5] *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.

In order to place their claims outside the ambit of *Mensing*, both Lashley and Del Valle argue for a very narrow interpretation of that case. Their arguments are unavailing. The Court in *Mensing* held that federal law demands "generic drug labels be the same at all times as the corresponding brand-name labels." 131 S. Ct. at 2578. This duty of sameness is overlaid with the agency's pronouncement that "Dear Doctor" letters (or other forms of warning) from a generic manufacturer constitute labeling. Because of this, potential state law duties requiring generic manufacturers to act unilaterally concerning any consumer warnings are preempted. *Id.* at 2580–81. At their core, all Lashley and Del Valle's claims against the generic manufacturers turn on the adequacy of labeling and related information, and can thus be construed as failure-to-warn claims. As such, we find them to be preempted under *Mensing*.

---

pre-empt[ed], these state-law claims." 131 S. Ct. at 2572. The Court held that federal law preempted state laws imposing a duty to change a drug's label upon generic drug manufacturers.

[5] Watson generic defendants and defendant Vintage sought dismissal under Rule 12(b)(6). However, as the district court in *Lashley* noted, while Watson generic defendants invoked the standard applicable to Rule 12(b)(6) in their motion to dismiss, their rebuttal memorandum referenced a motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). Meanwhile, generic defendants PLIVA, Qualitest, and Teva sought dismissal pursuant to Fed. R. Civ. P. 12(c) in the *Del Valle* case. The lower courts in both cases explained that the standard was the same for both motions (*see Guidry v. Amer. Public Life Ins. Co.*, 512 F.3d 177, 180 (5th Cir. 2007)); the *Del Valle* court noted that the motions to dismiss both, in essence, asserted that Del Valle had failed to "provide sufficient facts 'to state a claim to relief that is plausible on its face,'" and so they would be addressed together. *See Porter v. Valdez*, 424 F.App'x 382, 385 (5th Cir. 2011) (per curiam)(unpublished) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009)).

Appellants argue that not all failure-to-warn claims run afoul of *Mensing,* such as those alleging that generic manufacturers could have taken steps that would not require them to differ their labeling from that of the reference listed drug ("RLD") for metoclopramide, Reglan.[6] The duty of sameness, they contend, would not be violated by generic manufacturers communicating information consistent with the brand-name labeling. Under this theory, generic manufacturers would be liable for failing to convey FDA-approved warnings; for example, they could have circulated "promotional labeling"-type communications warning of the dangers of metoclopramide use after twelve weeks. According to the complaints, the generic manufacturers should have made consumers aware of the risks associated with metoclopramide and, by not doing so, negligently or fraudulently caused injuries. This Court addressed an almost identical argument in *Morris v. PLIVA, Inc.*, and rejected such failure-to-warn claims in light of *Mensing*.[7] In *Morris*, we wrote:

> *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. [*Mensing*, 131 S. Ct.] at 2576 ("[I]f generic drug manufacturers, but not the brand-name manufacturer, sent [additional warnings such as '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

---

[6] Under the current law, generic drugs gain FDA approval simply by showing equivalence to an RLD that has already obtained FDA approval. Generic drugs applying for approval under this process must show that the safety and efficacy labeling they propose is the same as the labeling approved for the RLD. *See* 21 U.S.C. § 355(j)(2)(A)(v).

[7] Regardless of the specific form in which the argument is styled (negligence, fraud, deceptive trade practices), each charge is, at base, a failure-to-warn claim.

> 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.

713 F.3d at 777 (second alteration in original).

Thus, following clear precedent, we affirm the dismissal of these failure-to-warn claims here as well.[8]

Like in *Morris*, Appellants also maintain that certain generic manufacturers should be liable for not conforming to the 2004 label change. Assuming arguendo that Lashley or Del Valle adequately pleaded this theory,[9] we disagree that defendants should be held liable. We addressed, and rejected, this argument in *Morris*. There, this court observed that "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." *Morris*, 713 F.3d at 777. Furthermore, we concluded that "a claim that PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Id.* (internal citations omitted).

Appellants further argue that their non-failure-to-warn claims, such as those based on strict liability and breach of warranty theories, are not

---

[8] Even if generic manufacturers could have, hypothetically, provided additional information consistent with the RLD labeling without violating the duty of sameness, such a step is unlikely to have remedied the situation; Appellants' complaints indicate that all allowable pre-2009 warnings were insufficient. Thus, the claim would be dismissed, even if not preempted. *See Morris*, 713 F.3d at 777.

[9] Generic manufacturers in both cases maintain that neither Lashley nor Del Valle properly included this claim in their original pleadings.

preempted under *Mensing*. They contend that generic manufacturers should be liable for any damages caused by the production and/or distribution of an unsafe product; recognizing that generic manufacturers could not have made changes in labeling to add information, Appellants nevertheless argue that generic manufacturers should be held liable for damages caused by the insufficient information they were allowed to disseminate. However, we find these non-failure-to-warn claims to be preempted in light of *Morris* and the Supreme Court's recent decision in *Mutual Pharm., Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013).[10] This is because, assuming distribution of the drug was acceptable in the first place, any useful action (or lack thereof) for which the companies could be held responsible would necessarily involve some form of warning. *See Morris*, 713 F.3d at 778. These theories all rely on the same grounds: the generic manufacturers failure to provide adequate information. In *Morris*, this court recognized that "[a]ny 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 sameness but conflicts with FDA's exclusive authority to approve drugs and drug labels." *Id.* State law claims for damages are not available as an end-run around preemption; the non-failure-to-warn claims against generic manufacturers are "attempt[s] to circumvent disfavored failure-to-warn claims" and are thus preempted as well. *Id.*

Lastly, we do not agree with Lashley or Del Valle that some of their state law claims against generic manufacturers are parallel to federal law claims, and

[10] *Bartlett* forecloses failure-to-warn claims pled as strict liability or breach of warranty. In that case, the First Circuit allowed a claim that a drug was so unreasonably dangerous, as designed, that the manufacturer should have never sold it in the first place; there were safer alternatives that were just as effective. The Supreme Court reversed the First Circuit's ruling, holding that state-law design defects claims that turn on the adequacy of a drug's warnings are preempted by federal law under *Mensing*. 133 S. Ct. at 2470; *see Demahy v. Schwarz Pharm., Inc.*, 702 F.3d 177, 186–87 (5th Cir. 2012).

thus not preempted. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Hughes v. Boston Scientific*, 631 F.3d 762 (5th Cir. 2011). *Medtronic* and *Hughes* concern express preemption; in those cases, "parallel" state law claims against manufacturers of medical equipment were allowed to proceed because there was no express preemption found in the applicable statute. In *Mensing*, as here, the Supremacy Clause—not a statute—made it impossible for the generic defendant to do what state law required of it and, therefore, the state law claim was preempted.[11] In these types of cases, the inquiry is not whether there is a "parallel" claim where one looks for absence of conflict with the statute; the inquiry is whether the state law claim is impliedly preempted.

In sum, the district courts correctly dismissed Appellants' claims against generic manufacturers, as these claims are preempted in light of *Mensing* and *Bartlett*.

III. Claims Against Brand Manufacturers

Lashley and Del Valle next argue that the lower courts erred in granting summary judgment to brand manufacturers. We review motions for summary judgment de novo. *EEOC v. WC&M Enters.*, 496 F.3d 393, 397–98 (5th Cir. 2007). The moving party is entitled to summary judgement if there are no material facts in dispute and that party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56.

We disagree with Appellants' contentions that summary judgment was improper here. Their claims against brand manufacturers are foreclosed by Lashley and Del Valle's respective states' product liability laws (Mississippi's, in Lashley's case, and Texas's, in Del Valle's case), which shield the companies from liability for products they did not create. Miss Code Ann. § 11-1-63; Tex.

[11] Because only the brand-names can make changes to the warning system, those manufacturers are the ones against whom "parallel" claims are normally raised. *See Wyeth v. Levine*, 555 U.S. 555 (2009).

Civ. Prac. & Rem. Code Ann. § 82.001(2) (West 2012). Furthermore, because Appellants did not ingest the brand manufacturers' products, these defendants have no common-law duty to them.

The Mississippi Products Liability Act ("MPLA") applies "in any action for damages caused by a product" and requires a plaintiff to prove that it was the defendant's product that caused the injury. Miss. Code Ann. § 11-1-63; *see also Monsanto Co. v. Hall*, 912 So.2d 134, 136–37 (Miss. 2005). Lashley argues that the Pfizer brand defendants are not "manufacturers or sellers" of the product, relying on a Mississippi case holding that "the MPLA does not preclude claims against defendants who are neither manufacturers nor sellers" of a defective product. *Lawson v. Honeywell Int'l, Inc.*, 75 So.3d 1024, 1030 (Miss. 2011). This argument fails because brand defendants are, indeed, manufacturers—and were they not, there would be no relationship on which to presume liability (since they did not design the drug).[12] In any event, because Lashley did not ingest the Pfizer brand defendants' products, he has not established a duty. *Moore ex rel. Moore v. Miss. Valley Gas Co.*, 863 So. 2d 43, 46 (Miss. 2003) ("[I]t is incumbent upon the plaintiff in any products liability action to show that the defendant's product was the cause of the plaintiff's injuries."); *see also Demahy*, 702 F.3d at 183 n.4 ("[E]ven if the [Louisiana Products Liability Act] did not apply, [plaintiff's] tort claims would fail since [defendants] did not manufacture the generic product giving rise to [plaintiff's] claims, and thus owed [plaintiff] no duty of care."); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011) ("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.").

[12] Del Valle's argument that Schwarz brand defendants are not "manufacturers" similarly fails for these reasons.

Under Texas law, meanwhile, a products liability action is broadly defined as "any action against a manufacturer or seller for recovery of damages arising out of personal injury . . . allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." Tex. Civ. Prac. & Rem. Code Ann. § 82.001(2). The Texas Supreme Court has determined that under this statute, entities are "'manufacturers' . . . only with respect to their own products." *Owens & Minor, Inc. v. Ansell Healthcare Prods., Inc.*, 251 S.W.3d 481, 485 (Tex. 2008) (internal quotation marks omitted). It has also found that "[a] fundamental principle of traditional products liability law is that the plaintiff must prove that the defendants supplied the product which caused the injury." *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989); *see also Firestone Steel Products Co. v. Barajas*, 927 S.W.2d 608, 614 (Tex. 1996) ("A manufacturer generally does not have a duty to warn or instruct about another manufacturer's products, even though a third party might use those products in connection with the manufacturer's own product. . . . Under traditional products liability law, the plaintiff must prove the defendant supplied the product that caused the injury. It is not enough that the seller merely introduced products of similar design and manufacture into the stream of commerce." (citations omitted)). Del Valle admits that she did not ingest the Schwarz brand defendants' product; thus, we find that Schwarz brand defendants are not liable under Texas products liability law.

Furthermore, "[u]nder Texas law, a drug manufacturer enjoys a rebuttable presumption that it is not liable for failure to warn if the FDA has approved 'the warnings or information' accompanying the product alleged to have harmed the plaintiff." *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 374 (5th Cir. 2012)(quoting Tex. Civ. Prac. & Rem. Code § 82.007(a)(1)). It is

undisputed that the "warnings or information" on the Schwarz brand defendants' label were approved by the FDA. Though Del Valle argues that the Schwarz brand defendants lost their presumption of non-liability because of fraud perpetrated on the FDA, the FDA has not made such a finding and, therefore, that avenue for overturning the brand defendants' presumption of non-liability is foreclosed to Del Valle. *See id.* at 380.

In sum, since Appellants did not take the brand manufacturers' products, the brand manufacturers are not liable for Appellants' injuries under Mississippi and Texas law. Therefore, we affirm the district courts' judgments regarding those defendants.

IV.

For the foregoing reasons, we AFFIRM the district courts' dismissals of the claims against both the Watson generic defendants and the Teva generic defendants. We further AFFIRM the grants of summary judgment to both the Pfizer brand defendants and the Schwarz brand defendants.