REVISED May 15, 2014

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
May 13, 2014
Lyle W. Cayce
Clerk

No. 13-40151

ROY ECKHARDT; YOLANDA C. ECKHARDT,

Plaintiffs – Appellants

v.

QUALITEST PHARMACEUTICALS, INCORPORATED; WYETH, INCORPORATED, individually and as Successor-in-Interest to A.H. ROBINS COMPANY, INCORPORATED and AMERICAN HOME PRODUCTS; SCHWARZ PHARMA, INCORPORATED; VINTAGE PHARMACEUTICALS, L.L.C.,

Defendants – Appellees

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

Before JOLLY, HIGGINBOTHAM, and SOUTHWICK, Circuit Judges.

E. GRADY JOLLY, Circuit Judge:

The plaintiff, Roy Eckhardt,[1] appeals the judgment of the district court dismissing his claims again Wyeth and Schwarz Pharma (together, the "Brand Defendants") under Rule 12(b)(6) and granting summary judgment to

[1] Although both Roy and Yolanda Eckhardt are plaintiffs in this case, this opinion will treat Roy Eckhardt as the sole plaintiff because all of the claims before us arise out of Roy's use of metoclopramide.

Qualitest Pharmaceuticals and Vintage Pharmaceuticals (together, the "Generic Defendants"). Eckhardt alleges that as a result of his prolonged use of the drug metoclopramide, he developed tardive dyskinesia, a severe neurological disorder. Eckhardt brought various products liability and general tort claims against the Brand Defendants – who initially developed and received FDA approval for metoclopramide – and the Generic Defendants – who manufactured and sold the product that Eckhardt used. Because we hold that Eckhardt's claims against both the Brand and the Generic Defendants are all either preempted, not adequately pleaded, or not recognized under Texas law, we AFFIRM the judgment of the district court.

I.

In order to provide the necessary background regarding Eckhardt's claims and the defenses asserted, we will begin with a general discussion of the FDA approval process for pharmaceuticals and a brief history of metoclopramide specifically. We then turn to Eckhardt's factual allegations.

A.

Before a manufacturer can market a new drug, the FDA must approve "that it is safe and effective and that the proposed label is accurate and adequate." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011). In 1984, through the Hatch-Waxman Amendments, Congress modified these procedures for generic drug manufacturers, creating an expedited process for approving generic drugs. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 and 35 U.S.C.). In essence, these amendments allow a generic drug manufacturer to piggy-back on the FDA approval of a brand name drug – greatly accelerating the process for receiving approval – provided that the generic drug has active ingredients and labeling identical to that of the FDA-approved brand name drug. *Mensing*, 131 S. Ct. at 2574 & n.2.

After the generic drug receives approval, the generic manufacturer is prohibited from making changes to the drug itself or from unilaterally changing the drug's label. *See Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). In receiving FDA approval for their generic metoclopramide, the Generic Manufacturers used this expedited process.

Metoclopramide was first approved by the FDA in 1980 under the brand name Reglan for use in treating various gastrointestinal problems by speeding the movement of food through the digestive track. Since 1985, when Reglan's patent exclusivity expired, several companies have manufactured a generic version of the drug. Beginning in 1985, the label for metoclopramide was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide," and the package insert included with the drug indicated that "therapy longer than 12 weeks has not been evaluated and cannot be recommended." *Mensing*, 131 S. Ct. at 2572 (citing Physician's Desk Reference 1635–36 (41st ed. 1987)). In 2004, brand-name manufacturers of metoclopramide requested that the FDA approve a change to the labeling of metoclopramide to state that therapy using the drug should not exceed twelve weeks. The FDA granted the request. Subsequently, in 2009, the FDA mandated that a "black box" warning – the strongest warning the FDA can mandate on a drug – be added to metoclopramide making clear the risk of developing tardive dyskinesia.

B.

From late 2007 until at least July 2009, Eckhardt's physician prescribed Reglan, the brand name for metoclopramide, to treat his gastrointestinal problems. When filling this prescription, Eckhardt's pharmacy substituted a less-expensive generic version of metoclopramide manufactured by the Generic Defendants. It is undisputed that Eckhardt never used metoclopramide

manufactured by the Brand Defendants. As a result of his prolonged use of metoclopramide, Eckhardt alleges that he developed tardive dyskinesia.

In 2011, Eckhardt filed his original complaint against Endo Pharmaceutical Holdings and Qualitest. The complaint asserted causes of action for negligence, strict liability, breach of implied warranties, misrepresentation, fraud, and under the Texas Deceptive Practices – Consumer Protection Act. In June 2011, Eckhardt amended his complaint to add Wyeth and Schwarz as defendants, alleging misrepresentations by them to the medical community in their status as owners of the marketing application for Reglan. Eckhardt and Endo later filed a stipulation of dismissal as to the claims against Endo, and the district court granted leave to Eckhardt to add Vintage in Endo's place as a defendant. Eckhardt did so in his second amended complaint. In September, the Generic Defendants moved to dismiss for failure to state a claim. The Brand Defendants subsequently filed a motion for summary judgment. The district court eventually granted both motions and entered a final judgment dismissing all of Eckhardt's claims against all defendants.

Eckhardt then filed a motion to alter or amend the judgment. The district court denied the motion, and Eckhardt brought this appeal.

II.

We will first examine, de novo, the district court's Rule 12(b)(6) dismissal of Eckhardt's claims against the Generic Defendants. *BP Exploration Libya Ltd. v. ExxonMobil Libya Ltd.*, 689 F.3d 481, 490 (5th Cir. 2012). To survive a Rule 12(b)(6) motion, a plaintiff must plead enough facts to state a claim for relief that is plausible on its face. *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007).

Eckhardt brings a number of different claims against the Generic Defendants. And although it is at times difficult to construe precisely what

cause of action Eckhardt is asserting against the Generic Defendants, the claims fit into one of a few categories: products liability claims, strict liability design defect claims, failure-to-warn claims, breach of warranty claims, and consumer protection claims. We analyze each claim in turn.

A.

Though Eckhardt fails to classify it as such, his main claim against the Generic Defendants is a products liability claim for a failure to warn about the dangers of metoclopramide. As the district court correctly pointed out, the Texas Products Liability statute is intentionally broad; that is, it is written to cover products liability claims, even in situations where the plaintiffs do not label their claims thusly. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.001(2) ("'Products liability action' means any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage 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.").

It is not mind-taxing to discern why Eckhardt shies from labeling his claims as products liability claims: A products liability claim against the Generic Defendants simply cannot succeed. In *Mensing*, the Supreme Court explained the extent to which federal law regarding pharmaceuticals preempted state laws applicable to those same products. *Mensing* establishes two points relevant to Eckhardt's claims. First, under federal law, generic manufacturers of a prescription drug are not permitted unilaterally to change the labeling on that drug, even if that change "strengthens" the warnings. *Mensing*, 131 S. Ct. at 2575 (accepting FDA's interpretation of regulations that "changes unilaterally made to strengthen a generic drug's warning label would violate" laws requiring a generic drug label to match the brand name

counterparts). Second, it follows that any state law tort claim that is based on a generic manufacturer's failure to update the labeling on its drug directly conflicts with this federal law requirement and is therefore preempted. *See id.* at 2577–78.

Those two linked principles dispose of Eckhardt's products liability claims against the Generic Manufacturers: Eckhardt's products liability claims are premised on the Generic Defendants' failure to warn adequately about the dangers associated with metoclopramide. More specifically, Eckhardt alleges that Texas state law imposed a duty on the Generic Manufacturers to provide stronger warnings on their product. But *Mensing* makes clear the Generic Defendants were estopped from unilaterally doing so under federal law. *See also Lashley v. Pfizer, Inc.*, Nos. 12-60861 & 12-41148, 2014 WL 661058, at *2–3 (5th Cir. Feb. 21, 2014) (holding failure-to-warn claims in identical factual setting preempted). The district court's dismissal of Eckhardt's products liability claims against the Generic Defendants was therefore proper.

B.

Moving next to Eckhardt's strict liability design defect claim, we find that Eckhardt is again on the wrong side of the Supreme Court. In *Bartlett*, a quite recent decision, the Supreme Court analyzed whether a strict liability claim under New Hampshire law was preempted by federal law. Once again, the Supreme Court found that the state law was trumped by the federal regulatory regime. And while Eckhardt argues that the Texas law is different from New Hampshire law, he simply cannot escape *Bartlett*'s application to this case.

The Court in *Bartlett* held that a New Hampshire strict liability claim was preempted because, as an element of the claim, the fact-finder, in considering the product's labeling, was required to balance the product's harms and benefits. *Bartlett*, 133 S. Ct. at 2474–75. Because generic manufacturers

are, as a matter of federal law, forbidden from changing the labeling of the product regardless of the cost-benefit analysis, the Supreme Court held that the claim was preempted. *Id*. at 2477.

Eckhardt attempts to distinguish Texas law on the basis that Texas law does not require a cost-benefit analysis as a factor in proving a strict liability cause of action. Although this fact is true, it will not save Eckhardt's claim. To prove a strict liability design defect claim under Texas law as alleged here, the plaintiff must prove that "a safer alternative design existed." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). Thus, a fact finder must not only conclude that a safer alternative design existed, but further that the Generic Defendants breached their duty by failing to adopt that alternative design. But the Generic Defendants were prohibited by federal law from changing the design of the drug, and, therefore, *no* alternative design existed. As in *Bartlett*, the state law claim against the Generic Defendants is preempted because the state law claim is in direct conflict with the federal law. *See Lashley*, 2014 WL 661058, *3 (holding that strict liability claims under Texas law are preempted).

C.

Eckhardt raises additional failure-to-warn claims, which are of a slightly different kind than the products liability claims discussed above. Specifically, Eckhardt asserts that he has alleged that the Generic Defendants failed to provide Eckhardt or his physician with any of the FDA-approved warnings. As failing to provide FDA-approved warnings would be a violation of both state and federal law, this is a parallel claim that is not preempted. Nevertheless, the district court was correct in dismissing the claim.

Eckhardt simply does not adequately allege that the Generic Defendants failed to provide him with FDA-approved warnings. As the district court noted, this allegation was most clearly stated in Eckhardt's response to the Generic

Defendants' motion to dismiss below. In that filing, Eckhardt alleges, "Generic Defendants never provided Plaintiff or his physicians with ANY warning or other information with regard to metoclopramide." The district court held that this was a new factual allegation that was directly contradicted by Eckhardt's second amended complaint. The district court interpreted the addition of a new factual allegation as a motion to amend and denied the motion, considering only the factual allegations in the second amended complaint. This denial was not an abuse of discretion. *See Mayeaux v. La. Health Serv. and Indem. Co.*, 376 F.3d 420, 425 (5th Cir. 2004) ("We review the district court's denial of leave to amend a complaint . . . for abuse of discretion).

And looking at the factual allegations in the second amended complaint, it is clear that this untimely factual allegation is contradicted. In the second amended complaint, Eckhardt alleges several times that he was provided warnings by the Generic Defendants. He has thus failed adequately to plead the Generic Defendants' failure to provide any information, and the argument lacks merit.

D.

Turning to the breach of warranty claims, Eckhardt argues that the district court failed to address these claims in its opinion. The Generic Defendants respond that the district court only failed to discuss these claims because Eckhardt failed to press them in opposition to the Generic Defendants' motion to dismiss. Regardless of which party is correct, this court has previously held that such breach of warranty claims are preempted. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013) ("A breach of warranty claim that goes directly to the sufficiency of the generic manufacturer's labeling is clearly unacceptable. . . . This claim is preempted."). This precedent makes clear that Eckhardt's breach of warranty claims are preempted, and thus meritless.

E.

Finally, Eckhardt argues that his claims under the Deceptive Trade Practices – Consumer Protection Act ("DTPA") should have survived the motion to dismiss. Again, it is clear that the district court's dismissal was proper. Eckhardt's claim under the DTPA is based on the same factual allegations as his other claims – namely, that the Generic Defendants failed sufficiently to warn consumers of the harms associated with metoclopramide. As discussed in the foregoing sections, the Generic Defendants' labeling was FDA-approved, and federal law forbade the Generic Defendants from making any changes. Because these actions were mandated by federal law, any state law claim based on these actions is in direct conflict with the federal law and thus preempted. Accordingly, Eckhardt's DTPA claim was properly dismissed.

III.

We turn now to Eckhardt's claims against the Brand Defendants. The district court granted summary judgment to the Brand Defendants on all of Eckhardt's claims. We review a grant of summary judgment de novo. *Royal v. CCC&R Tres Arboles, L.L.C.*, 736 F.3d 396, 400 (5th Cir. 2013).

As with the Generic Defendants, Eckhardt alleges a number of different claims against the Brand Defendants and, again, the parties disagree over how the claims should be categorized. In the view of the Brand Defendants, Eckhardt's various allegations are merely superficial glosses on a products liability action. Eckhardt denies that his complaint alleges a products liability claim at all. Although it is clear to us that the essence of Eckhardt's claim sounds in products liability, we will analyze Eckhardt's claims against the Brand Defendants both as a single products liability claim, and as various general tort claims.

A.

To the extent Eckhardt raises products liability claims against the Brand Defendants, those claims may be quickly rejected. A prior panel of this court held that Texas products liability law does not impose liability in this exact factual situation. *Lashley*, 2014 WL 661058, at *5 ("[The plaintiff] 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.").[2] We are bound by this determination.

In post-argument submissions, Eckhardt argues that *Lashley* did not discuss the possibility that "the control Brand Defendants exercised over metoclopramide's design rendered them manufacturers of the metoclopramide ingested by Plaintiff in this case for purposes of Texas product liability law." This contention is contradicted by the filings in *Lashley*. The plaintiff in *Lashley* advanced this precise argument, and *Lashley* considered the possibility of liability under the Texas products liability statute and rejected any such argument. *Lashley*, 2014 WL 661058, *5. Thus, to the extent that Eckhardt raises products liability claims against the Brand Defendants, the district court properly granted summary judgment to the Brand Defendants on those claims.

B.

Analyzing Eckhardt's claims against the Brand Defendants as general tort claims, we address the three causes of action he asserts: fraud, negligence, and negligent misrepresentation.

[2] *Lashley* was released after oral arguments were heard in this case. It was originally released as an unpublished decision, but the *Lashley* panel has since granted a motion for the opinion to be published. The opinion is thus now binding precedent for this panel.

1.

Reviewing first Eckhardt's fraud claim, we find that Eckhardt fails to allege sufficient facts for his fraud claim to survive. In his second amended complaint, Eckhardt provides only two factual allegations that could support a fraud claim: (1) The predecessor in interest to Wyeth told physicians that Reglan was safe for long-term use, and these statements were intentionally misleading; and (2) Wyeth intentionally disseminated misleading information about the risk of long-term ingestion of Reglan. These two allegations, without any additional factual support in Eckhardt's complaint, are not sufficient to support a fraud charge under the heightened pleading standard of Rule 9. *See Benchmark Elecs., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. 2003) ("Put simply, Rule 9(b) requires the who, what, when, where, and how to be laid out.") (internal quotation marks omitted). The district court's grant of summary judgment on these claims must therefore be affirmed.

2.

Next, Eckhardt advances claims of negligence and negligent misrepresentation against the Brand Defendants. To establish a claim for negligence under Texas law, the plaintiff "must establish a duty, a breach of that duty, and damages proximately caused by the breach." *Kroger Co. v. Elwood*, 197 S.W.3d 793, 794 (Tex. 2006). At this stage of the litigation, the parties now focus their dispute on whether the Brand Defendants owe a duty to consumers of generic versions of Brand Defendants' drugs.

Although Eckhardt concedes that he has never used a product manufactured by the Brand Defendants, he argues that given the structure of the pharmaceutical industry as a result of federal law, the Brand Defendants owe a duty to eventual consumers of the drugs they design, even if those consumers use a generic version of the drug. Several courts have faced this question. Every circuit court has held (under the laws of several different

states) that a brand-name manufacturer does not owe a duty to consumers who use a generic version of the drug. *See Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013) (holding that no duty is owed under Oklahoma law); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251–52 (11th Cir. 2013) (same under Florida law); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1093 (8th Cir. 2013) (same under Arkansas law); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423–24 (6th Cir. 2011) (same under Kentucky law); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170–71 (4th Cir. 1994) (same under Maryland law). These authorities were recently joined by an opinion from this court. *See Lashley*, 2014 WL 661058, at *4–5 (finding no duty under Mississippi or Texas law).

Lashley holds that "because [plaintiffs] did not ingest the brand manufacturers' products, these defendants have no common-law duty to them." *Id.* at *4. Here, Eckhardt advances the same claims, under the same state law, against the same Brand Defendants, for the same reasons as the plaintiffs in *Lashley*. We see no grounds for distinguishing this binding authority.

Consequently, Eckhardt's negligence claim cannot survive because the Brand Defendants do not owe a duty to Eckhardt. And because a duty must also exist for a claim of negligent misrepresentation to succeed, this analysis applies equally to that claim. *See Fed. Land Bank Ass'n of Tyler v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991). The district court's grant of summary judgment to the Brand Defendants on these claims is therefore affirmed.

IV.

We sum up: We hold that Eckhardt's products liability claims against the Generic Defendants are preempted under the holdings and reasoning of *Mensing* and *Bartlett*, and that Eckhardt has failed to adequately plead any parallel claims. Similarly, we hold that Eckhardt's claims against the Brand Defendants fail because Eckhardt did not use the Brand Defendants' products and because Texas does not recognize a duty to a consumer who uses a

competitor's products. For those reasons, the judgment of the district court dismissing Eckhardt's claims against the Generic Defendants and granting summary judgment to the Brand Defendants is AFFIRMED.

AFFIRMED.