United States Court of Appeals
For the Eighth Circuit

No. 13-3663

Shirley J. Brinkley

Plaintiff - Appellant

v.

Pfizer, Inc.; Wyeth, LLC; Schwarz Pharma, Inc.

*Defendant*s

Pliva, Inc., formerly known as Sidmak Laboratories, Inc.

Defendant - Appellee

Appeal from United States District Court
for the Western District of Missouri - Kansas City

Submitted: September 8, 2014
Filed: December 2, 2014

Before RILEY, Chief Judge, SMITH and KELLY, Circuit Judges.

RILEY, Chief Judge.

In this diversity case, see 28 U.S.C. § 1332(a)(1), Shirley Brinkley, a citizen of Blue Springs, Missouri, appeals the district court's[1] prejudicial dismissal of her claims against Pliva, Inc. (Pliva), the New Jersey corporation that manufactured the prescription medication metoclopramide which Brinkley alleges injured her.[2] We affirm.[3]

I. BACKGROUND

In February 2002, Brinkley's doctor prescribed the brand-name drug Reglan to treat her gastroesophageal reflux disease. As allowed by Missouri law, see Mo. Rev. Stat. § 338.056, Brinkley's pharmacist substituted its generic equivalent, metoclopramide, manufactured by Pliva.

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., requires manufacturers of generic metoclopramide like Pliva to prove to the U.S. Food and Drug Administration (FDA) their product was the "same as" Reglan in its design and labeling. 21 U.S.C. § 355(j)(2)(A)(ii)-(v); see also Mut. Pharm. Co. v. Bartlett, 570 U.S. ___, ___, 133 S. Ct. 2466, 2475 (2013) ("[T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based."). Federal law does not allow manufacturers of generic drugs to alter the labeling because it "would inaccurately imply a therapeutic difference between the brand and generic drugs."

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[1]The Honorable Scott O. Wright, United States District Judge for the Western District of Missouri.

[2]Brinkley notes the district court did not enter judgment in a separate document as required by Federal Rule of Civil Procedure 58(a). The parties have waived any such technical defect in the district court's judgment. See Sanders v. Clemco Indus., 862 F.2d 161, 166 (8th Cir. 1988) ("The separate-document requirement . . . 'is not jurisdictional and may be waived by the parties.'" (quoting Moore v. Warwick Pub. Sch. Dist. No. 29, 794 F.2d 322, 323-24 n.1 (8th Cir. 1986))).

[3]We possess appellate jurisdiction under 28 U.S.C. § 1291.

Pliva, Inc. v. Mensing, 564 U.S. ___, ___, 131 S. Ct. 2567, 2575-76 (2011). For the same reason, generic manufacturers are not permitted "to issue additional warnings through" letters to prescribing physicians and other healthcare workers. Id.

In 2004, the FDA approved a request from Schwarz Pharma, Inc. (Schwarz), then the manufacturer of Reglan, to add two bolded statements to the Reglan label indicating usage should not exceed twelve weeks. Pliva did not implement the 2004 change in the label for its generic metoclopramide products.

Between February 2002 and April 2007, Brinkley regularly ingested metoclopramide as prescribed. Brinkley states her doctor, in deciding to prescribe Reglan, relied on statements the brand manufacturers made in the *Physicians' Desk Reference* (PDR)[4] and package inserts that Reglan was safe and effective for long-term use. Brinkley alleges her use of metoclopramide caused her to develop tardive dyskinesia, a severe neurological disorder. Brinkley faults Pliva for defective design and failing adequately to warn of the risk of long-term use.

On March 25, 2010, Brinkley sued Schwarz, Pfizer, Inc., and Wyeth, LLC, the manufacturers of brand-name Reglan at various times (collectively, brand defendants), and Pliva, asserting various claims under Missouri law. On Pliva's motion, the district court stayed the proceedings pending a decision in Mensing. In Mensing, the Supreme Court found it impossible for Pliva, as a manufacturer of generic metoclopramide, "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at ___, 131 S. Ct. at 2578. The Supreme Court held federal law preempts "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide." Id. at ___, 131 S. Ct. at 2572.

[4]Brinkley avers Schwarz did not publish the 2004 revised label in the PDR.

On August 30, 2011, Brinkley filed an amended complaint, asserting strict liability design defect, strict liability failure to warn, negligence, breach of express and implied warranties, and Missouri Merchandising Practices Act claims against Pliva and the brand defendants. Pliva answered and moved for judgment on the pleadings on preemption grounds. See Fed. R. Civ. P. 12(c). On April 12, 2012, the district court granted the motion, "fail[ing] to see how [Brinkley's] allegations differ[ed] from those in Mensing." The district court concluded Brinkley was "simply trying to backdoor claims against Pliva that the Supreme Court ha[s] found to be preempted."[5] On October 24, 2013, Brinkley and the brand defendants filed a joint motion to dismiss without prejudice, which the district court granted.

Brinkley appeals the judgment for Pliva, arguing the district court erred in dismissing her claims arising from Pliva's failure to incorporate the 2004 label change, a non-warning design defect, and breach of implied warranty.

II. DISCUSSION

A. Standard of Review

We review the grant of judgment on the pleadings de novo, viewing Brinkley's factual allegations as true and granting all reasonable inferences in her favor. See St. Jude Med. S.C., Inc. v. Cormier, 745 F.3d 325, 327 (8th Cir. 2014). "Judgment on the pleadings is appropriate if there is no material issue of fact to be resolved and the

[5]In dismissing Brinkley's claims, the district court also determined "there is no state law requiring Pliva to communicate" "FDA warnings to plaintiff's physician(s)." Pliva advances that point on appeal and complains Brinkley is improperly attempting to enforce federal law. See, e.g., Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001). Brinkley adamantly denies both assertions. Because we find it unnecessary to resolve those issues, we assume Brinkley's failure to update claim is cognizable under Missouri law. See Moses.com Sec., Inc. v. Compr. Software Sys., Inc., 406 F.3d 1052, 1062 (8th Cir. 2005) ("Because this is a diversity case, we interpret Missouri law in determining whether the elements of the offenses have been pled."); see also Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938).

moving party is entitled to judgment as a matter of law." Buddy Bean Lumber Co. v. Axis Surplus Ins. Co., 715 F.3d 695, 697 (8th Cir. 2013). We "can affirm on any basis supported in the record." Spirtas Co. v. Nautilus Ins. Co., 715 F.3d 667, 670-71 (8th Cir. 2013).

B. 2004 Label Change

Brinkley asserts Pliva is liable for failing adequately to warn her of the risks of long-term use of metoclopramide. Conceding most of her failure to warn claims are preempted under Mensing, now on appeal, Brinkley limits her warning claims to Pliva's failure to update its label to include the brand-name Reglan manufacturer's 2004 label change indicating usage should not exceed twelve weeks. See, e.g., Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 582, 584 (6th Cir. 2013) (concluding Mensing did not preempt an Ohio claim that "PLIVA's warning was inadequate *to the extent* that it did not include the language contained in the updated Reglan label from 2004"). But see Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (per curiam) ("[I]t 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.").

This is not the first time we have considered this claim. In Bell v. Pfizer, Inc., 716 F.3d 1087, 1097-98 (8th Cir. 2013), and Fullington v. Pfizer, Inc., 720 F.3d 739, 747 (8th Cir. 2013), we concluded the learned intermediary doctrine under Arkansas law vitiated nearly identical claims based on Pliva's failure to incorporate the 2004 label change. Missouri too "adhere[s] to the learned intermediary doctrine." Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (citing Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo. 1967)). Under that doctrine,

> [t]he physician acts as a "learned intermediary" between the manufacturer and the patient and any warning given to the physician is deemed a warning to the patient. The learned intermediary doctrine provides that the failure of a drug manufacturer to provide the physician

> with an adequate warning of the risks associated with a prescription product is "not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially the same knowledge as an adequate warning from the manufacturer that should have been communicated to him.

Id. at 419-20 (internal citations omitted) (quoting Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995)).

Applying these principles in Bell and Fullington, we concluded the prescribing physicians' exclusive reliance on information from the brand-name manufacturers broke any causal link between Pliva's failure to incorporate the label change and the plaintiffs' injuries. See Bell, 716 F.3d at 1097-98; Fullington, 720 F.3d at 747. Pliva urges the same result here. Like the plaintiffs in Bell and Fullington, Brinkley alleges her prescribing physician "relied upon information published in the package inserts and/or the Physicians' Desk Reference . . . or otherwise disseminated by" the brand-name manufacturer. That reliance severs any causal tie Brinkley's injuries had to Pliva's failure to update its label.

Brinkley attempts to distinguish her case from Bell and Fullington and avoid the impact of Missouri's learned intermediary doctrine by asserting that, unlike Bell and Fullington, she "alleged that her prescribing physician was not aware of the 2004 warning against long-term use of metoclopramide and, thus, that Pliva's failure to warn was the proximate cause of her injuries." Brinkley's allegations take her claim out of the frying pan, into the fire.

Even if we assume Brinkley's allegations, liberally construed in her favor, fairly allege her prescribing physician was unaware of the risk of long-term metoclopramide use, Brinkley still has not pled a submissible case. See Winter v. Novartis Pharm.

Corp., 739 F.3d 405, 408 (8th Cir. 2014) (explaining under Missouri law, "[a] submissible case requires substantial evidence that the injury is a natural and probable consequence of the defendant's behavior"); Williams v. Daus, 114 S.W.3d 351, 358-59 (Mo. Ct. App. 2003) (en banc) (same).

> To recover for a failure to warn under [the learned intermediary] doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) *that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.* Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.* that *but for* the inadequate warning, the treating physician would not have used or prescribed the product.

Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1098-99 (5th Cir. 1991) (emphasis added) (footnotes omitted); accord Johnson v. Medtronic, Inc., 365 S.W.3d 226, 232 (Mo. Ct. App. 2012) (concluding that to prevail on a failure to warn claim, the plaintiff had to establish proximate cause by showing the "'warning would have altered the behavior of the individuals involved'" (quoting Moore v. Ford Motor Co., 332 S.W.3d 749, 762 (Mo. 2011) (en banc))); see also Callahan v. Cardinal Glennon Hosp., 863 S.W.2d 852, 860-61 (Mo. 1993) (en banc) (explaining "but for" causation under Missouri law). In other words, Brinkley must show Pliva's inadequate warning "'caused her doctor to prescribe the drug for her.'" Ackermann v. Wyeth Pharm., 526 F.3d 203, 208 (5th Cir. 2008) (quoting McNeil v. Wyeth, 462 F.3d 364, 372 (5th Cir. 2006) (Reglan case)). This she fails to do.

Even if ignorant of the 2004 warning against long-term use, Brinkley's physician prescribed Reglan, not Pliva's generic metoclopramide, and relied on warnings from Reglan's manufacturer, not on information from Pliva. Though

Brinkley's additional allegations alter the context slightly, our reasoning in Bell applies fully to Brinkley:

> Because Bell's physician prescribed Reglan and relied on its labeling, there is nothing to indicate Pliva's failure to update its warning affected Bell's physician's prescribing decision or Bell's injury in any way. Because there is no causal link between Pliva's failure to incorporate the 2004 labeling change and Bell's injury, the district court's dismissal of that claim was not error, regardless of whether Mensing preempted that claim.

Bell, 716 F.3d at 1098. That Brinkley alleges her physician did not receive an adequate warning about Reglan does nothing to bridge the gap between her injury and Pliva's failure to update its label. Furthermore, whether from Pliva or the brand-name manufacturer, "[t]he adequacy of the instructions . . . made no difference in the outcome of [Brinkley's injury] because [Brinkley alleges her prescribing physician] did not read those materials." Johnson, 365 S.W.3d at 232.

To the extent Brinkley alleges failure to warn claims against Pliva based on the allegedly inadequate content or manner of delivery of the 2004 warning, see Winter, 739 F.3d at 408-09 (discussing ways a physician can receive warnings), her claims are squarely preempted by federal law. See Mensing, 564 U.S. at ___, 131 S. Ct. at 2578; Johnson v. Teva Pharm. USA, Inc., 758 F.3d 605, 611-12 (5th Cir. 2014); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1249-50 (11th Cir. 2013).

C. Design Defect and Breach of Implied Warranty

Brinkley next challenges the dismissal of her non-warning design defect and breach of implied warranty claims.[6] Pliva maintains Brinkley's claims are preempted

[6]Brinkley proposes we should reverse the dismissal of these claims and remand "for initial consideration by the district court, as in Bell and Fullington." We find remand unnecessary in this case. The Supreme Court's analysis in Bartlett established

under Mensing and Bartlett, in which the Supreme Court held "that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under [Mensing]." Bartlett, 570 U.S. at ___, 133 S. Ct. at 2470.

In Bartlett, the Supreme Court concluded federal law preempted a New Hampshire design defect claim against a generic drug manufacturer because the FDCA and its supporting regulations prohibited the manufacturer from altering the design of the allegedly defective drug or changing its labeling. See id. at ___, ___, 133 S. Ct. at 2470-71, 2475 (citing 21 U.S.C. § 355(j)(2)(A)(ii)-(v), (8)(B), and 21 C.F.R. § 320.1(c)). Noting "New Hampshire imposes design-defect liability only where 'the design of the product created a defective condition unreasonably dangerous to the user,'" as determined by weighing "'the magnitude of the danger'" against "'the utility of the product,'" the Supreme Court determined a generic drug manufacturer could only avoid liability under state law "either by changing a drug's design or by changing its labeling," which federal law prohibits. Id. at ___, 133 S. Ct. at 2474, 2476 (quoting Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1181-82 (N.H. 2001), and discussing Restatement (Second) of Torts (Restatement) § 402A (1963 and 1964) (strict product liability)).

The Supreme Court concluded the New Hampshire design defect claim was "'without effect'" because it was impossible for the generic manufacturer to comply with both its state law duty to change the drug's design or labeling and its federal law duty to keep the drug and its labeling the same "as the brand-name drug on which it is based." Id. at ___, 133 S. Ct. at 2475-77 (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)). The Supreme Court also rejected the proposition that the

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a clear framework for examining Brinkley's remaining claims, and, unlike Fullington, the parties have had an opportunity to brief and argue these issues after Bartlett, leaving us without reservations about evaluating Brinkley's claims under Missouri law. See Bartlett, 570 U.S. at ___, 133 S. Ct. at 2473-78.

manufacturer "could escape the impossibility" "by simply leaving the market." Id. at ___, 133 S. Ct. at 2477-78.

Thus under Mensing and Bartlett, federal law preempts any state law claim requiring a generic manufacturer to redesign its drug, change its labeling, or leave the market to avoid liability under state law. Since Bartlett, there is a growing consensus in the federal circuit courts that the preemption analysis in Mensing and Bartlett proves fatal to state law claims like Brinkley's. See, e.g., Johnson, 758 F.3d at 612-13; Eckhardt v. Qualitest Pharm., Inc., 751 F.3d 674, 679-80 (5th Cir. 2014); In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II), 751 F.3d 150, 164 (3d Cir. 2014); Drager v. PLIVA USA, Inc., 741 F.3d 470, 476-79 (4th Cir. 2014); Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 396-97 (6th Cir. 2013); Schrock v. Wyeth, Inc., 727 F.3d 1273, 1288-89 (10th Cir. 2013). Analyzing Brinkley's design defect and implied warranty claims under this framework, we conclude the FDCA and its supporting regulations preempt her claims because Pliva could only avoid liability under Missouri law by redesigning its product, changing its labeling, or leaving the market for metoclopramide.

1. Design Defect

Missouri, like New Hampshire, imposes design defect liability if the plaintiff establishes "the product, as designed, is unreasonably dangerous and therefore 'defective', and that the demonstrated defect caused [her] injuries." Nesselrode v. Exec. Beechcraft, Inc., 707 S.W.2d 371, 375-76 (Mo. 1986) (en banc) (noting Missouri has adopted Restatement § 402A). Yet "Missouri courts have consistently refused to impose any 'judicial definition [of unreasonably dangerous] whether derived from consumer expectations, risk-utility, or otherwise.'" Sappington v. Skyjack, Inc., 512 F.3d 440, 446 (8th Cir. 2008) (alteration in original) (quoting Rodriguez v. Suzuki Motor Corp., 996 S.W.2d 47, 65 (Mo. 1999) (en banc)).

Instead, in Missouri, "the concept of unreasonable danger . . . is presented to the jury as an ultimate issue without further definition." Nesselrode, 707 S.W.2d at 378. "The jury gives this concept content by applying their collective intelligence and experience to the broad evidentiary spectrum of facts and circumstances presented by the parties." Id. "The parties are 'entitled to assist the jury in defining the term unreasonably dangerous by presenting evidence that the utility of a design outweighs its risks, or that consumer expectations were violated, or any other theory of unreasonable dangerousness supported by the evidence.'" Sappington, 512 F.3d at 446 (quoting Thompson v. Brown & Williamson Tobacco Corp., 207 S.W.3d 76, 90 (Mo. Ct. App. 2006)).

Despite the considerable overlap between Missouri and New Hampshire design defect law, Brinkley argues Missouri's "open-ended" approach to determining whether a product is defective distinguishes her claims from the one preempted in Bartlett. Brinkley places too much weight on Missouri's approach to determining unreasonable danger. See Drager, 741 F.3d at 478 (concluding any difference between the risk-utility and consumer expectation approaches to evaluating "the unreasonableness of the danger of a product" was "immaterial"); Strayhorn, 737 F.3d at 396-97 (finding implied warranty and design defect claims preempted even though Tennessee had not resolved what "test applies to design-defect claims involving prescription drugs").

As the Sixth Circuit noted in Drager, the Supreme Court "did not determine that the New Hampshire law was preempted because it applied the risk-utility approach. Instead, it concluded that there was no action that the defendant could take under that approach to increase the safety of its product without violating the restrictions of the FDCA." Drager, 741 F.3d at 478. The Sixth Circuit had "no trouble concluding that the same [wa]s true under either the risk-utility or the consumer-expectations approach." Id. ("Regardless of the way in which Maryland assesses the unreasonableness of a product's risks, if PLIVA's metoclopramide is unreasonably

unsafe, there is no apparent action that PLIVA can take in compliance with FDCA restrictions to avoid strict liability.").

Brinkley has not proposed any action Pliva could take that would compel a different result under Missouri law. "Short of exiting the market—which Bartlett rejects—[Brinkley has] failed to identify anything [Pliva] can do [under Missouri's approach] to reconcile [its] conflicting duties under state and federal law." In re Fosamax, 751 F.3d at 165. Because Brinkley fails to explain how Pliva could avoid liability under Missouri law for the alleged design defects without changing its product, changing its labeling, or leaving the market, Brinkley's design defect claims—whether sounding in strict liability or negligence—"are preempted by impossibility." Drager, 741 F.3d at 476-78; accord In re Fosamax, 751 F.3d at 165.

2. Breach of Implied Warranty

Brinkley's non-warning breach of implied warranty claims "fare no better." Strayhorn, 737 F.3d at 395. In her amended complaint, Brinkley alleges Pliva's "metoclopramide was not of merchantable quality or fit and safe for its intended use because it was unreasonably dangerous" and Brinkley and her healthcare providers relied on Pliva's implied warranties to the contrary—to her detriment. The Mensing and Bartlett rationale applies with full force to such claims. See, e.g., Drager, 741 F.3d at 478-79; Schrock, 727 F.3d at 1288-89.

At root, Brinkley's implied warranty claims are an attack on Pliva's product design or labeling. See Schrock, 727 F.3d at 1288 ("Under Bartlett, a claim that a generic drug manufacturer's product is unfit for its intended use or unreasonably dangerous is one that would impose a duty to alter the composition of that drug."). Such claims rush headlong into Pliva's unyielding duty of sameness under federal law. See Bartlett, 570 U.S. at ___, ___, 133 S. Ct. at 2471, 2475; Drager, 741 F.3d at 478-79 ("[T]o the extent that implied warranties of merchantability or fitness for a particular purpose can arise in this context [i.e. prescription drugs,] . . . they are

preempted by the requirements of the FDCA."); Schrock, 727 F.3d at 1289; cf. Johnson, 758 F.3d at 613 ("Any modified or supplemental warranties by Generic Defendants would have run afoul of the 'duty of sameness' identified in Mensing."). Federal law preempts Brinkley's implied warranty claims.

III. CONCLUSION

We affirm the district court's judgment.
