In the

United States Court of Appeals

For the Seventh Circuit

No. 15-2294

KATHLEEN A. WAGNER,

Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Defendants-Appellees.

Appeal from the United States District Court for the
Western District of Wisconsin.
No. 13-CV-497-JDP — **James D. Peterson**, *Judge*.

ARGUED FEBRUARY 12, 2016 — DECIDED OCTOBER 18, 2016

Before WOOD, *Chief Judge*, ROVNER, *Circuit Judge,* and BLAKEY, *District Judge*.*

BLAKEY, *District Judge*. Appellant Kathleen Wagner appeals the decision of the district court granting judgment on the pleadings in favor of Appellees Teva Pharmaceuticals

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* Of the Northern District of Illinois, sitting by designation.

USA, Barr Pharmaceuticals and Barr Laboratories. For the reasons explained below, the decision of the district court is affirmed.

I. Background & Procedural History

Appellant Kathleen Wagner, who is a licensed attorney proceeding *pro se*, took both brand-name and generic hormone therapy drugs as prescribed by her gynecologist to treat her post-menopausal endometrial hyperplasia. After taking the drugs, Wagner developed breast cancer. Wagner sued multiple pharmaceutical companies that designed, manufactured, promoted and distributed the drugs she took. Appellees Teva Pharmaceuticals USA, Barr Pharmaceuticals and Barr Laboratories are the only pharmaceutical companies that manufactured the generic form of the hormone therapy drugs.

In her 12-count First Amended Complaint, Wagner asserted numerous Wisconsin state law tort claims, all based upon allegations that Appellees sold dangerous products and failed to adequately warn of their risks.

After answering the Amended Complaint, Appellees moved for Rule 12(c) judgment on the pleadings, arguing that federal law preempted Wagner's claims. In response, Wagner asserted, for the first time, that Appellees delayed updating their generic brand labels to match the updated, stricter labels on the brand-name drug.

The District Judge granted the motion for judgment on the pleadings, finding that the Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. § 301 *et seq*., preempted Appellant's state law claims. Wagner appealed.

II. Discussion

We review *de novo* a district court's Rule 12(c) decision. *Adams v. City of Indianapolis*, 742 F.3d 720, 727 (7th Cir. 2014). To survive a motion for judgment on the pleadings, a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In assessing a motion for judgment on the pleadings, we draw all reasonable inferences and facts in favor of the nonmovant, but need not accept as true any legal assertions. *Vesely v. Armslist LLC*, 762 F.3d 661, 664–65 (7th Cir. 2014).

On appeal, Wagner raises two challenges. First, she argues that, given the passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA), her claims are not preempted. Wagner also argues that her claims are not preempted to the extent they are based upon Appellees' failure to update their generic drug labels to match the updated label on the brand name drug. We address both issues in turn.

A. Preemption and the FDAAA

The district court found that the FDCA preempted Wagner's state law claims. In support, the district court relied upon two Supreme Court cases: *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. Inc. v. Bartlett*, 133 S. Ct. 2466 (2013). These cases, as the district court correctly explained, impose a "duty of sameness" on generic drug manufacturers that requires "generic drug labels be the

same at all times as the corresponding brand-name labels." *Mensing*, 564 U.S. at 618. Flowing from that duty, federal law preempts state tort laws when the generic drug manufacturer could not have abided by this duty without: (1) changing the drug's formula; (2) changing the drug's label; or (3) withdrawing the generic drug from the market altogether.

By way of background, in *Mensing*, the Supreme Court held that the FDCA preempts any state law that requires companies to improve generic drug labels. *Id*. at 616–20. The Court reasoned that it would be impossible for companies to change both the generic drug label and maintain sameness with the corresponding brand-name drug label. *Id.* In *Bartlett*, the Court extended the principles in *Mensing* to cover state defective-design laws. 133 S. Ct. at 2470. To comply with the defective-design tort law, the Court determined that generic drug companies would have to either change the drug's formula or change its label. *Id.* at 2474. Alternatively, generic drug companies could choose to stop selling the generic drug altogether. *Id.* at 2477. The first two options were impossible because of the FDCA and the last option (withdrawal of the product from the market) was unreasonable. *Id.* at 2470.

Although *Mensing* and *Bartlett* dealt with failure to warn and design defect claims, respectively, federal courts have extended their rationale to similar state law claims. *E.g.*, *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139–40 (8th Cir. 2014) (preempting breach of implied warranty cases); *Johnson v. Teva Pharmaceuticals USA, Inc.*, 758 F.3d 605, 613–14 (5th Cir. 2014) (preempting express warranty claim); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475–76 (5th Cir. 2014) (per curiam) (preempting strict liability and breach of warranty claims).

Such cases do not stand alone, and for good reason. As the Fifth Circuit explained in *Lashley*, these types of claims still rely upon the same essential grounds: "the generic manufacturer's failure to provide adequate information." By extension, federal law preempts Wagner's claims, regardless of how they are styled in her complaint.

Wagner claims that *Mensing* and *Bartlett* are outdated in light of the FDAAA, which the Supreme Court did not consider. Other courts have rejected this argument. *E.g.*, *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, No. CIV. 08-008 GEB-LHG, 2011 WL 5903623, at *7 (D.N.J. Nov. 21, 2011); *Whitener v. PLIVA, Inc.*, No. CIV.A. 10-1552, 2011 WL 6056546, at *3 (E.D. La. Dec. 6, 2011) (citing *In re Fosamax*). We reject it as well, as we did in *Houston v. United States*, 638 Fed. App'x 508, 513–514 (7th Cir. 2016). The FDAAA imposed certain obligations on generic drug manufacturers when they propose labeling changes. But the FDAAA did not remove the prohibition against doing so unilaterally. As we noted in *Houston*, "the amendments still forbid a generic-drug maker from violating the duty of sameness without FDA permission." *Id*. at 514.

B. Wagner's Failure to Update Theory

Wagner, in the alternative, argues that she can still proceed on her claims against Appellees to the extent they are based upon Appellees' failure to update the generic drug label to match the updated label on the brand name drug. The district court denied this claim for two reasons.

First, Wagner failed to raise this theory in her complaint. Having reviewed the First Amended Complaint, we agree with the district court's assessment. Wagner fails to effec-

tively respond to this fact on appeal, and instead makes an untimely request of this Court for leave to file a Second Amended Complaint. Wagner never sought leave to amend her complaint in the proceedings below, and the factual assertions regarding her failure to update theory appeared for the first time in her opposition to the Rule 12(c) motion. This attempt comes far too late. Clearly, the district court did not abuse its discretion by failing to order, *sua sponte*, an amendment to the First Amended Complaint that Wagner never requested.

Second, as an alternate basis for its ruling, the district court found that, even if Wagner were given leave to amend, any amendment would have been legally and factually futile. While acknowledging a split in authority as to whether federal law preempts state law failure-to-update claims, and noting that the question remains open in this circuit, the district court found persuasive the Fifth Circuit's decision in *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (finding federal law preempts failure-to-update claims) (per curiam).[1] Factually, the district court found Wagner's theory of

[1] The Sixth Circuit, by contrast, disagrees, finding that such claims may be viable. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 583–85 (6th Cir. 2013). In *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1137–39 (8th Cir. 2014), the Eighth Circuit noted the circuit split and proceeded to address a failure to update theory on its merits. This ruling suggests, though not conclusively, that the Eighth Circuit would follow the Sixth Circuit. *See also Teva Pharmaceuticals USA, Inc. v. Superior Court*, 217 Cal. App. 4th 96, 108–09, 110 n.3, 115 (2013) (after collecting and summarizing federal district court and state court cases reaching the same decision as the Sixth Circuit, California Court of Appeals expressly stated its disagreement

causation insufficient because she asserted that *both* the generic drug manufacturers' labels *and* the updated brand label were deficient.

In light of the undeveloped record here, we need not answer the open question of preemption of state failure-to-update claims; the factual deficiencies in Wagner's complaint alone preclude reversal of the district court. At various times in the proceedings, Wagner has made conflicting assertions undermining any causation of her failure-to-update claim. Even in her reply brief to this Court, Wagner characterizes both the brand-name and generic labels as deficient. Yet, at oral argument, Wagner maintained that the brand name label was adequate, and that her claim really arose because Appellees failed to bring their labels in line with the brand-name drug in 2007. Putting aside whether Wagner—who began taking the brand-name drug in 1993 and the generic drug in 2000—could establish causation based upon a failure to update in 2007, Wagner never alleged such a claim in her complaint. As a result, she waived the right to press the claim here. *See, e.g.*, *Darif v. Holder*, 739 F.3d 329, 336–37 (7th Cir. 2014) (arguments raised for the first time in a reply brief are waived); *Central States, Southeast and Southwest Areas Pension Fund*, 181 F.3d 799, 808 (7th Cir. 1999) (arguments not developed in any meaningful way are waived).

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with the Fifth Circuit). On January 20, 2015, the Supreme Court denied a petition of certiorari in *Teva Pharmaceuticals*. 135 S. Ct. 1152, 1153 (2015).

III. Conclusion

Because Wagner's complaint in the proceedings below lacked the requisite factual allegations to support a failure to update theory, any further consideration of the legal merits of that issue is unnecessary. For the purposes of this appeal, it is enough to note that federal law preempts Wagner's Wisconsin state-law claims, and that the operative complaint lacks the factual allegations necessary to support any failure to update theory.

For these reasons, the judgment of the district court is AFFIRMED.