United States Court of Appeals
For the Eighth Circuit

No. 12-2945

Joyce Fullington

Plaintiff - Appellant

v.

Pfizer, Inc.; Wyeth, LLC; Schwarz Pharma, Inc.; Pliva, Inc.; Alaven Pharmaceutical, LLC; Mutual Pharmaceutical Company, Inc.

Defendants - Appellees

Appeal from United States District Court
for the Eastern District of Arkansas - Little Rock

Submitted: March 14, 2013
Filed: July 15, 2013

Before MURPHY, SMITH, and GRUENDER, Circuit Judges.

GRUENDER, Circuit Judge.

Joyce Fullington filed a product liability suit against the manufacturers of the prescription drug Reglan and its generic equivalent, metoclopramide. The district court ruled that all of Fullington's claims were either not viable under Arkansas law or were preempted by federal law governing drug product labeling. We affirm in part, reverse in part, and remand for further consideration.

I. Background

From April 2008 through April 2009, Fullington ingested the prescription drug metoclopramide. She subsequently developed a neurological disorder called tardive dyskinesia, allegedly as a result of long-term use of metoclopramide. In response, Fullington filed suit against two groups of pharmaceutical companies, asserting causes of action under Arkansas law for negligence (including gross negligence), strict liability, breach of the implied warranties of merchantability and fitness for a particular purpose, misrepresentation, suppression of evidence, and fraud. One group of defendants are companies that at some point, either directly or through subsidiaries, were involved in the manufacture of Reglan: Pfizer, Inc.; Wyeth, LLC; Schwartz Pharma, Inc.; and Alaven Pharmaceutical, LLC (collectively, "Brand Defendants"). The second group of defendants, consisting of PLIVA, Inc. ("PLIVA") and Mutual Pharmaceutical Company ("Mutual") (collectively, "Generic Defendants"),[1] manufacture generic versions of Reglan, known as metoclopramide.

Metoclopramide is not an exact duplicate of Reglan, but federal regulations significantly constrain its contents and effects. Manufacturers of generic drugs are required, as a condition to entering the market, to establish that their product is "chemically equivalent" and "bioequivalent" to the reference listed drug they are replicating—generally, as here, the brand-name drug. *Mu. Pharm. Co. v. Bartlett*, 570 U.S. --- (2013), 2013 WL3155230, at *4 (citing 21 U.S.C. § 355(j)(2)(A)). Because generic drugs are so similar to their brand-name counterparts, many states, including Arkansas, permit pharmacists to substitute generic drugs when filling a prescription for a brand-name drug. *See* Ark. Code Ann. § 17-92-503. Such a situation in fact occurred in Fullington's case: although her physician wrote a prescription for Reglan, her pharmacist filled her prescription with metoclopramide.

[1]Fullington initially filed suit against Teva Pharmaceuticals USA, Inc. as well, but she voluntarily dismissed her claims with prejudice against this defendant.

Reglan and metoclopramide have been the subject of extensive product liability litigation. These suits have largely been brought by individuals, such as Fullington, who developed tardive dyskinesia after using either or both versions of the drug. Since Reglan and metoclopramide were first approved for sale in the 1980s, the United States Food and Drug Administration ("FDA") has occasionally required manufacturers to update their product's labeling to reflect greater understanding of the risks of long-term use of Reglan/metoclopramide. For example, in 2004, the FDA required the addition of a bolded warning stating that use "should not exceed 12 weeks in duration." Five years later, the FDA mandated the inclusion of a black box warning, which cautions that "Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases."

When a manufacturer applies for FDA approval for a generic drug, it "is responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567, 2574 (2011). The Supreme Court in *Mensing* upheld the FDA's interpretation of its regulations as requiring that "the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" *Id.* at 2574-75 & n.3. As a result of these constraints, a generic drug manufacturer cannot unilaterally strengthen the warnings on its product's labeling. *Id.* at 2575, 2578. The Court in *Mensing* clarified that "impossibility" preemption exists where a party cannot "independently do under federal law what state law requires of it." *Id.* at 2579. Accordingly, tort suits seeking to impose liability based on a manufacturer's failure to strengthen or modify a generic drug's labeling are preempted by federal drug regulations. *Id.* at 2576-81. The logical corollary of this regulatory scheme is that certain design defect claims are preempted as well. As the Supreme Court recently explained, because a generic drug manufacturer is prohibited from unilaterally redesigning either its product's labeling or design, a design defect claim that would impose liability for a failure to undertake one of these two courses of action is similarly preempted. *Bartlett*, 2013 WL 3155230, at *8-10. Moreover,

a generic manufacturer is not obligated to leave the market when it is incapable of complying with both federal and state obligations; imposing such a Hobson's choice would render impossibility preemption "all but meaningless." *Id.* at *10 (quoting *Mensing*, 131 S. Ct. at 2579).

The litigation in this case spans a time period both prior and subsequent to the Court's decision in *Mensing*, and it invokes the scope of claims preempted pursuant to *Mensing* and now *Bartlett*. In September 2010, the district court granted the Brand Defendants' motion for summary judgment. The Brand Defendants argued that because they neither manufactured nor distributed the metoclopramide that Fullington ingested, Fullington's product liability claim against them was not viable under Arkansas law. The district court agreed, interpreting Arkansas law as requiring the plaintiff to make a "product identification," in other words "allege that the actual product manufactured or distributed by the defendant caused the injury to the plaintiff."

While *Mensing* was pending, the Generic Defendants obtained a stay in these proceedings. After the Supreme Court released its opinion, the district court granted the Generic Defendants' motion to dismiss. The district court concluded that all of Fullington's claims against the Generic Defendants were premised on "failure-to-warn allegations" and, as such, were preempted pursuant to *Mensing* because it would be impossible for the Generic Defendants to comply with both federal drug regulations and the more rigorous warnings regarding long-term use that Arkansas law allegedly required. The district court also ruled, in the alternative, that to the extent Fullington pled product liability claims other than failure to warn, namely manufacturing or design defect claims, her allegations failed to meet federal pleading standards. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Fullington then sought and obtained leave to amend her complaint, citing PLIVA's recent disclosure that it had failed to update the labeling on the

metoclopramide it produced, as required by 2003 and 2004 FDA-mandated changes to Reglan's labeling. Fullington did not amend her misrepresentation and implied warranty claims, and the district court subsequently dismissed these claims based on the analysis in its initial opinion. As to Fullington's other, amended claims, the district court determined that each was still premised on allegations of inadequate warnings. The district court also concluded that Fullington's design defect allegations remained too conclusory to meet federal pleading standards. To the extent any of Fullington's claims invoked a new challenge to the adequacy of PLIVA's warnings,[2] based on the failure to update its labeling as required by federal law ("failure to update claim"), the district court ruled that such a claim was not viable. The district court acknowledged reasonable arguments both for and against the proposition that this claim was preempted under *Mensing*, but it elected not to decide the issue. Instead, the district court dismissed the claims based on a perceived fatal internal inconsistency between Fullington's theory of liability and her allegations regarding inadequate warnings. On one hand, Fullington claimed that the Reglan/metoclopramide labeling was deficient until the addition of a black box warning in February 2009; yet on the other hand she faulted PLIVA for failing to incorporate the 2004 label change, a version of labeling that she insisted was still inadequate to fully warn of the dangers of long-term use. In a motion for reconsideration, Fullington argued that she had been pleading in the alternative, a contention which the district court rejected.[3]

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[2]Fullington did not allege that Mutual failed to incorporate the 2003 and 2004 label changes onto its product's labeling.

[3]The district court determined that based on the complaint alone, Fullington's tort claim against PLIVA for use of metoclopramide between February 2009, when the labeling supposedly became adequate with the addition of a black box warning, and April 2009, when Fullington stopped ingesting the drug, could survive. The district court converted PLIVA's motion to dismiss into a motion for summary judgment and offered Fullington fourteen days to present evidence that she had ingested PLIVA-manufactured metoclopramide during this period. In her motion for

Fullington appeals the district court's adverse grant of summary judgment to the Brand Defendants and its dismissal of her claims with prejudice against the Generic Defendants.

II. Claims Against the Brand Defendants

We review *de novo* the district court's grant of summary judgment to the Brand Defendants. *Knutson v. Schwan's Home Service, Inc.*, 711 F.3d 911, 913 (8th Cir. 2013). Fullington stipulated that she only ingested metoclopramide; at no point did she ingest Reglan or any other product manufactured or distributed by one of the Brand Defendants. Nonetheless, Fullington insists she can maintain a product liability suit against the Brand Defendants. Although Fullington concedes that claims based on strict liability or breach of warranty require a product identification, she insists that Arkansas law does not require such a showing if the plaintiff's product liability claims are based on negligence, misrepresentation, suppression of evidence, or fraud.

The Arkansas Product Liability Act ("APLA") defines "product liability action" as "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product." Ark. Code Ann. § 16-116-102(5). Not only do all of Fullington's claims fall within the plain meaning of this definition of "product liability action," but a recent decision by this court regarding nearly identically-pled claims virtually compels the conclusion that Fullington's claims are all "product

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reconsideration, Fullington conceded that she could not do so. Accordingly, the district court entered summary judgment in favor of PLIVA on Fullington's surviving claim that PLIVA's warnings were inadequate after February 2009. On appeal, Fullington does not argue that deficiencies in the warnings accompanying PLIVA's metoclopramide from February to April 2009 caused her tardive dyskinesia.

liability actions" under Arkansas law. *See Bell v. Pfizer, Inc.*, --- F.3d ---, 2013 WL 2661189, at *3 (8th Cir. June 14, 2013). As the court in *Bell* also held, Arkansas law requires product identification for all product liability actions, and there is no indication "the Arkansas Supreme Court would create an exception to the Arkansas product identification requirement to allow [Fullington] to hold the [B]rand [D]efendants liable for injuries caused by their competitor's generic products." *Id.* at *4. We are not at liberty to contradict another panel's interpretation of section 16-116-102(5). *See, e.g.*, *United States v. Collins*, 321 F.3d 691, 698 & n.5 (8th Cir. 2003). Fullington's claims against the Brand Defendants are all "product liability actions," so they are only viable if she is able to make a product identification. Because Fullington stipulated that she never used Reglan manufactured or distributed by any of the Brand Defendants, she "cannot hold them liable under Arkansas law."[4] *Bell*, 2013 WL 2661189, at *4. The district court did not err in granting the Brand Defendants' motion for summary judgment.

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[4]Like the appellant in *Bell*, Fullington argues for the first time on appeal that if a product identification requirement does apply to her claims against the Brand Defendants, she has satisfied it because the Brand Defendants are "manufacturers" of generic metoclopramide as that term is defined in the APLA. *See* Ark. Code Ann. § 16-116-102(3) ("'Manufacturer' means the designer, fabricator, producer, compounder, processor, or assembler of any product or its component parts."). Under this theory, the Brand Defendants are "manufacturers" of the metoclopramide Fullington consumed because they designed the drug upon which the generic version is based, and they, in conjunction with the FDA, determine the labeling generic manufacturers must reproduce on their own products. This claim contradicts Fullington's stipulation to the district court that her "causes of action against [the Brand Defendants] are not based on any claim that [they] *manufactured* or sold the Reglan/metoclopramide ingested by Joyce Fullington." (Emphasis added.) We decline, as the *Bell* court did, to address this novel argument for the first time on appeal because there are no "exceptional circumstances" warranting departure from the general rule that "we cannot consider issues not raised in the district court." *Bell*, 2013 WL 2661189, at *3 n.1 (quoting *Shanklin v. Fitzgerald*, 397 F.3d 596, 601 (8th Cir. 2005)).

III. Claims Against the Generic Defendants

"We review *de novo* a district court's decision to grant a motion to dismiss, accepting the complaint's allegations as true." *Gomes v. Am. Century Cos.*, 710 F.3d 811, 815 (8th Cir. 2013). The outcome of this appeal is controlled in large part by this court's recent decision in *Bell v. Pfizer, Inc*. The appellant in that case, Shirley Bell, also developed tardive dyskinesia following prolonged use of metoclopramide. *Bell*, 2013 WL 2661189, at *1. Like Fullington, Bell brought a product liability action under Arkansas law raising claims based on "negligence; strict liability; breach of warranties; misrepresentation, suppression of evidence, and fraud; and gross negligence." *Id.* The district court allowed Bell to amend her complaint post-*Mensing* but then dismissed her claims with prejudice, finding that they remained preempted failure-to-warn claims and, to the extent her failure to update claim against PLIVA was not preempted, it was barred by Arkansas's application of the learned intermediary doctrine. *Id.* at *6, 8. On appeal, this court "agree[d] with the district court that the vast majority of Bell's allegations in her amended complaint set forth preempted failure to warn claims," with the exception of her "design defect and breach of implied warranty claims, other than those based on an inadequate warning or labeling." *Id.* at *7. The court in *Bell* reversed the dismissal of these latter claims because the district court had incorrectly viewed them as preempted failure to warn claims and had not analyzed whether these claims otherwise "state[d] viable claims under Arkansas law." *Id.* The court did not reach the issue of whether the holding in *Mensing* preempted a failure to update claim, agreeing with the district court that such a claim was in any case not viable given Arkansas's adherence to the learned intermediary doctrine. *Id.* at *8-9.

Like the amended complaint in *Bell*, the vast majority of the allegations in Fullington's amended complaint are premised on preempted failure to warn claims. The exception, as this court determined in *Bell*, are her "non-warning design defect and breach of implied warranty claims." *Id.* at *7. Yet the district court in this case,

just like the *Bell* district court, still categorized these latter claims as failure-to-warn claims. The language in Fullington's amended complaint regarding breach of implied warranty claims is substantially similar to the analogous claims in Bell's amended complaint. *Compare* Fullington Compl. ¶¶ 7.09-7.12 *with* Bell Compl. ¶¶ 4.10-4.14. Accordingly, we reverse the dismissal of Fullington's non-warning breach of implied warranty claims and remand for further consideration as to whether they "adequately state viable claims under Arkansas law" and if so, whether the Generic Defendants can nonetheless establish preemption. *Id.* at *7.

There is one notable distinction between this case and *Bell.* The district court in this case made an alternative holding recognizing that, to the extent Fullington articulated a design defect claim independent of a failure to warn claim, the claim did not satisfy federal pleading standards. The district court later determined that Fullington's amended complaint failed to rectify the problem.

"To succeed on a design defect claim under Arkansas law, the plaintiff must establish that the product was in a defective condition,[5] that the defective condition rendered the product unreasonably dangerous,[6] and that the defect proximately caused the complained-of injury." *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 598 (8th Cir. 2005). We disagree with the district court's conclusion that

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[5]"'Defective condition' means a condition of a product that renders it unsafe for reasonably foreseeable use and consumption." Ark. Code Ann. § 16-116-102(2).

[6]"'Unreasonably dangerous' means that a product is dangerous to an extent beyond that which would be contemplated by the ordinary and reasonable buyer, consumer, or user who acquires or uses the product, assuming the ordinary knowledge of the community or of similar buyers, users, or consumers as to its characteristics, propensities, risks, dangers, and proper and improper uses, as well as any special knowledge, training, or experience possessed by the particular buyer, user, or consumer or which he or she was required to possess." Ark. Code Ann. § 16-116-102(7)(A).

Fullington's design defect allegations were too conclusory to survive a motion to dismiss because her complaint includes "sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Hamilton v. Palm*, 621 F.3d 816, 817 (8th Cir. 2010) (quoting *Aschcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Furthermore, to the extent the district court found Fullington's claims insufficient because she failed to submit "factual allegations that PLIVA or Mutual, as opposed to the brand-name manufacturers, actually designed metoclopramide," such an allegation is unnecessary under Arkansas law. *See Boerner v. Brown & Williamson Tobacco Corp.*, 260 F.3d 837, 841 (8th Cir. 2001) (explaining that Arkansas law authorizes strict liability claims against the "supplier of a product" who "is engaged in the business of manufacturing . . . or otherwise distributing the product." (quoting Ark. Code Ann. § 4-86-102(a))).

Nonetheless, the Supreme Court's recent decision in *Bartlett* casts doubt on the viability of Fullington's design defect claim. In *Bartlett*, the Supreme Court held that the plaintiff's design defect claim, brought under New Hampshire law, was preempted. *Bartlett*, 2013 WL 3155230, at *10. An "unreasonably dangerous" product is an element of a design defect claim under both New Hampshire and Arkansas state law. New Hampshire state courts use a "risk-utility approach" to determining whether a product is unreasonably dangerous. *Id.* at *8. Under this approach, New Hampshire courts tend to balance three factors in determining whether the defendant supplied an unreasonably dangerous product: the product's value to the public, whether the supplier could reduce the product's risks without major expense or serious detriment to the product's efficacy, and whether an alternate warning could mitigate unreasonable risk of harm "from hidden dangers or from foreseeable uses." *Id.* (quoting *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1181 (N.H. 2001)). The first two factors, the Court determined, necessarily required generic drug manufacturers unilaterally to redesign the composition of their drugs, which federal law precludes generic drug manufacturers from doing. *Id.* As a result, the only remaining mechanism by which a generic drug manufacturer could "ameliorate the

drug's 'risk-utility' profile—and thus . . . escape liability—was to strengthen" the drug's warning label. *Id.* at *9. As *Mensing* previously established, this, too, generic drug manufacturers cannot independently do under federal law. The defendant generic drug manufacturer in *Bartlett*, no less than in *Mensing*, was caught between the devil and the deep blue sea: the only way to avoid state-law tort liability was to take actions forbidden by federal law.

In contrast to New Hampshire's risk-utility approach, Arkansas state courts focus on consumer expectations in determining whether a product is unreasonably dangerous. *See* Ark. Code Ann. § 16-116-102(7)(A) (defining "unreasonably dangerous" in terms of the expectations of "the ordinary and reasonable buyer"); *Purina Mills, Inc. v. Askins*, 875 S.W.2d 843, 847 (Ark. 1994); *Berkeley Pump Co. v. Reed-Joseph Land Co.*, 653 S.W.2d 128, 133 (Ark. 1983). Consequently, it is not immediately clear whether Arkansas, unlike New Hampshire, offers generic drug manufacturers an opportunity, consistent with federal obligations, to somehow alter an otherwise unreasonably dangerous drug. Therefore, we reverse the dismissal of Fullington's design defect allegations and remand to the district court for further consideration in light of *Bartlett*. *See Bell*, 2013 WL 2661189, at *6 n.2.

The only claim left to be considered is Fullington's failure to update claim. The court in *Bell* did not reach the question of whether Bell's analogous claim was preempted under *Mensing* because the court concluded it was not viable due to Arkansas's learned intermediary doctrine. Under this doctrine, "a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug." *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991). A manufacturer's inadequate warning is not a proximate cause of a plaintiff's harm so long as the prescribing physician had independent knowledge of the risk that the inadequate warning should have communicated. *Bell*, 2013 WL 2661189, at *8. Bell's physician, like Fullington's, wrote a prescription for the reference listed drug, Reglan, which a pharmacist then filled with metoclopramide. Bell admitted that her

prescribing physician relied on information provided by the manufacturer of the reference listed drug, which included the updated warning. As a result, Bell's prescribing physician had independent knowledge of the risk the updated metoclopramide label would have communicated, and so this court determined that Bell failed to articulate a causal link between her injury and PLIVA's failure to update its labeling. *Id.* at *9. Fullington also admits that "her prescribing doctor relied upon information published in the package inserts and/or the Physicians' Desk Reference . . . or otherwise disseminated by the Reference Listed Drug Company." Arkansas's learned intermediary doctrine applies, then, just as it did in *Bell*. Although the district court relied on alternative reasoning, we can "affirm the district court's dismissal on any basis supported by the record." *Phipps v. FDIC*, 417 F.3d 1006, 1010 (8th Cir. 2005). Accordingly, we affirm the district court's dismissal of Fullington's claims against PLIVA for failing to update its labeling.

III. Conclusion

For the foregoing reasons, we affirm the grant of summary judgment in favor of the Brand Defendants. With respect to the claims against the Generic Defendants, we affirm the dismissal of Fullington's failure to warn and failure to update claims and reverse the dismissal of Fullington's non-warning design defect and breach of implied warranty claims and remand for further proceedings.

MURPHY, Circuit Judge, concurring.

I agree with the majority that this case is controlled by our previous opinion in Bell v. Pfizer, Inc., 2013 U.S. App. LEXIS 12002 (8th Cir. June 14, 2013). I also agree that we cannot consider Fullington's argument that the brand manufacturers were "designers" of the generic drug because it was not raised in the district court. See Dobrovolny v. Moore, 126 F.3d 1111, 1114 n.2 (8th Cir. 1997). If properly

presented, however, such a claim may have merit given recent developments in the Supreme Court's prescription drug liability jurisprudence.

The overwhelming majority of courts which have considered whether brand manufacturers could be held liable for harms caused by their generic counterparts have answered in the negative. These cases have generally been predicated on the assumption that the generic manufacturers could independently safeguard and strengthen their own labels. See, e.g., Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994); Mensing v. Wyeth, Inc., 588 F.3d 603, 612–14 (8th Cir. 2009), rev'd in part on other grounds sub nom. Pliva, Inc. v. Mensing, 131 S. Ct. 2567 (2011). Since the brand and generic manufacturers were assumed to have separate duties to ensure their labels and warnings were adequate, there was no reason for the brand manufacturers to foresee that generic consumers would rely on representations made on the brand drug's label. Foster, 29 F.3d at 170. Consequently we observed in Mensing that the brand manufacturers did not owe a duty of care to generic customers because these manufacturers "intended to communicate with their customers, not the customers of their competitors." 588 F.3d at 613 n.9.

The Supreme Court's decisions in Mensing and Mutual Pharmaceutical Co. v. Bartlett, 2013 U.S. LEXIS 4702 (June 24, 2013), severely eroded the foundation of this analysis. These cases stripped any discretionary authority from the generic manufacturers to ensure the safety of their products or the adequacy of their labels, instead placing the burden entirely on the brand manufacturers. See Mensing, 131 S. Ct. at 2574. The privileged position accorded to the brand manufacturers may alter their state law relationship to the generic drugs whose composition and labeling they control, since at this point such a manufacturer is "the party that actually controls the manufacturing and labeling of the product in question." Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1061 (W.D. Ark. 2009). With the brand manufacturers solely responsible for the content and updating of a generic's labels, it can no longer be

credibly argued that communications regarding the risks of their product are not also directed at consumers of the generic bioequivalents.[7]

With these observations, I join in the majority opinion.

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[7] That is particularly apparent in this case, as Fullington's doctor prescribed Reglan, which was then substituted with generic metoclopramide by her pharmacist.