IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

JOYCE FULLINGTON PLAINTIFF

v. No. 4:10CV00236 JLH

PLIVA, INC., formerly known as
Pliva USA, Inc.; and MUTUAL
PHARMACEUTICAL COMPANY, INC. DEFENDANTS

OPINION AND ORDER

This Court previously dismissed all of Joyce Fullington's claims with prejudice. On appeal, the United States Court of Appeals for the Eighth Circuit affirmed the dismissal of all claims except Fullington's nonwarning design defect and breach of implied warranty claims, and with respect to those claims, the court remanded for further proceedings. *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013). The Eighth Circuit remanded Fullington's implied warranty claims "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 745 (quotation marks omitted). The Eighth Circuit remanded the design defect claims for further consideration in light of the opinion of the United States Supreme Court in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 186 L. Ed. 2d 607 (2013). *Fullington*, 720 F.3d at 746-47.

After remand, the Court directed Fullington to file a short and concise statement of the claims that she believes survive as a result of the opinion of the Eighth Circuit, after which the Generic Defendants moved for judgment on the pleadings as to those claims. In response, Fullington filed a brief arguing that her causes of action for strict liability design defect, breach of the implied warranty of merchantability, and breach of the implied warranty of fitness for a particular purpose remain viable. The Court then ordered Fullington to file a second amended complaint, alleging her

claims for strict liability design defect, breach of the implied warranty of merchantability, and breach of the implied warranty of fitness against the Generic Defendants, omitting all allegations that relate to parties and claims that had previously been dismissed with prejudice. After Fullington filed her second amended complaint, the Court gave the parties one final opportunity to brief the issues and directed Fullington to explain in her brief specifically what the Generic Defendants could have done to comply with Arkansas law, as well as how doing so would not have violated federal law. Those final briefs have been filed, and the issues that the Eighth Circuit directed this Court to consider on remand are now ripe for decision.

The Generic Defendants have not argued, following remand, that Fullington's breach of implied warranty claims fail to state claims upon which relief may be granted under Arkansas law. Upon review of the second amended complaint, the Court is satisfied that Fullington's claims for breach of implied warranty meet the pleading standards of the Federal Rules of Civil Procedure and state claims upon which relief could be granted under Arkansas law. Consequently, the issue to be decided is whether Fullington's breach of implied warranty and design defect claims are preempted, and that issue requires the Court to consider the scope of the Supreme Court's decision in *Bartlett*.

In remanding for further consideration in light of *Bartlett*, the Eighth Circuit explained:

> [T]he 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*, 133 S. Ct. at 2476-78. 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 2474-75. 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.*, 147 N.H. 150, 784 A.2d 1178, 1181 (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 2475-76. As [*PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011)] 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*, 317 Ark. 58, 875 S.W.2d 843, 847 (1994); *Berkeley Pump Co. v. Reed-Joseph Land Co.*, 279 Ark. 384, 653 S.W.2d 128, 133 (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*.

Fullington, 720 F.3d at 746-47.

The Fourth Circuit has recently issued an opinion that decides the issue regarding *Bartlett* that the Eighth Circuit directed this Court to consider. *Drager v. PLIVA USA, Inc.*, __ F.3d __, 2014 WL 292700 (4th Cir. Jan. 28, 2014). *Drager*, like this case, presented a situation in which long-term use of generic metoclopramide resulted in permanent injuries. *Id.* at *1. The plaintiff alleged state-law claims of negligence, breach of warranty, fraud and misrepresentation, strict liability, and failure to warn under Maryland law. *Id.* The plaintiff's strict liability claim included a claim that generic metoclopramide was defective in design. *Id.* at *5. There, as here, the plaintiff contended that *Bartlett* did not control because Maryland, like Arkansas, assesses the reasonableness of the danger

of a product using a consumer-expectations test, in contrast to New Hampshire, the state whose tort laws were at issue in *Bartlett*, which uses a risk-utility approach. *Id*. Rejecting that argument, the Fourth Circuit explained:

> To the extent that there is a difference in approach between the two states, it is immaterial. The Court in *Bartlett* 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 [Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*.]. We have no trouble concluding that the same is true under either the risk-utility or the consumer-expectations approach in Maryland. PLIVA cannot be required to stop selling its product, but at the same time it is prohibited from making any changes to the product itself or the accompanying warnings. 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.

Id. (footnotes omitted). The Fourth Circuit is correct: whether a state follows the risk-utility approach or the consumer-expectations approach does not affect the application of *Bartlett*.[1]

In *Bartlett*, the Supreme Court noted that the Food, Drug, and Cosmetics Act 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. *Bartlett*, 133 S. Ct. at 2475. Consequently, a generic drug manufacturer cannot change the design of the drug to comply with state law. *Id*. Nor can a generic drug manufacturer change the label. *Id*. at 2476. Hence, if a generic drug is defectively designed, the only action the manufacturer can take to comply with both state and federal

[1] In a footnote, the Fourth Circuit observed that Maryland has used both approaches. *Id*. at n.2 (citing *Halliday v. Sturm, Ruger & Co.*, 368 Md. 186, 792 A.2d 1145, 1153 (2002)). Arkansas likewise has used both approaches. *Compare West v. Searle & Co.*, 305 Ark. 33, 40-41, 806 S.W.2d 608, 612-13 (1991) (adopting Comment k to § 402A of the Restatement (Second) of Torts and applying a risk/benefit analysis to a strict liability claim relating to a pharmaceutical product) *with Fullington*, 720 F.3d at 746 (citing Arkansas cases using the consumer-expectations approach).

law is to withdraw the product from the market, but *Bartlett* rejects that as an option that avoids impossibility preemption. *Id*. at 2477. It is therefore impossible for a manufacturer of a generic drug that violates state design-defect laws to comply with both federal and state laws—which leads to the conclusion that the state laws are preempted by the FDCA. *Id*. at 2478. None of this reasoning depends on the distinction between the risk-utility approach and the consumer-expectations approach.

The same logic applies to claims of breach of an implied warranty. Again, the Fourth Circuit explained:

> Because PLIVA was not permitted to change its warnings or formulation, it could not have avoided liability for breach of these implied warranties except by exiting the market. Therefore, to the extent that implied warranties of merchantability or fitness for a particular purpose can arise in this context under Maryland law, they are preempted by the requirements of the FDCA.

Drager, 2014 WL 292700 at *6. The same is true here.

In the Court's order directing final briefing, the Court directed Fullington to explain what the Generic Defendants could have done to comply with Arkansas law without violating federal law. Her brief argues, first, that the defendants could have refrained from selling metoclopramide and, second, that the defendants could have conducted post-marketing surveillance. As noted, *Bartlett* overruled the first argument. *Bartlett*, 133 S. Ct. at 2477. As to the second argument, Fullington does not explain how a failure to conduct post-marketing surveillance constitutes a design defect or breaches one of the implied warranties, nor does she explain how the defendants could have avoided liability on her design defect and implied warranty claims by conducting post-marketing surveillance.

In addition to the implied warranty and design defect claims discussed above, Fullington argues that she has a state-law misbranding claim that parallels a federal misbranding claim and thus

is viable notwithstanding *Bartlett*. Her brief does not specify which factual allegations in the second amended complaint support a misbranding claim, and the only factual allegations that appear to support such a claim are allegations that PLIVA failed to update its warnings to conform to the FDA approved label after 2003. Those allegations were also included in her first amended complaint and were dismissed with prejudice by this Court. On appeal, the Eighth Circuit affirmed the dismissal of those claims, albeit for reasons other than those stated by this Court. *Fullington*, 720 F.3d at 747. Hence, Fullington's misbranding claims were dismissed with prejudice, and that dismissal became the law of the case when the Eighth Circuit affirmed and issued its mandate. *United States v. Castellanos*, 608 F.3d 1010, 1016-17 (8th Cir. 2010).

If Fullington is alleging misbranding claims that were not alleged in her first amended complaint, those claims still fail. Although this Court directed Fullington to file a second amended complaint alleging only her strict liability design defect and breach of the implied warranty claims, the Court did not give, nor did Fullington seek, leave to allege new claims. If Fullington is alleging new claims, she has violated Rule 15, which provides that a party may amend its pleadings only with the opposing party's written consent or leave of court. Fed. R. Civ. P. 15(a)(2). Furthermore, the Court's scheduling order provided that leave to amend pleadings had to be sought no later than January 17, 2012. "If a party files for leave to amend outside of the court's scheduling order, the party must show cause to modify the schedule." *Popoalii v. Correctional Med. Servs.*, 512 F.3d 488, 497 (8th Cir. 2008). Fullington has not shown cause to modify the scheduling order. *Cf. Bell v. Kansas City Police Dept.*, 635 F.3d 346, 347 (8th Cir. 2011) (finding no abuse of discretion in the denial of leave to amend where the plaintiff failed to show good cause for modifying the pretrial scheduling order to allow an untimely amendment of the complaint).

Either Fullington's misbranding claims were presented in her first amended complaint, in which case they were dismissed with prejudice, and that dismissal is the law of the case by virtue of the Eighth Circuit's mandate; or they are new claims that she has not obtained leave to assert.

CONCLUSION

For the reasons stated, Joyce Fullington's second amended complaint is dismissed with prejudice. Document #110.

IT IS SO ORDERED this 28th day of February, 2014.

J. Leon Holmes

J. LEON HOLMES
UNITED STATES DISTRICT JUDGE