IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION

LIRLENE GARDLEY-STARKS PLAINTIFF

v. CIVIL ACTION NO.: 4:10-CV-099-SA-JMV

PFIZER, INC., et al. DEFENDANTS

ORDER ON RECONSIDERATION

Plaintiff moves the Court to reconsider its decision dismissing Plaintiff's claim against the Generic Defendants entered January 10, 2013, and the initial denial of reconsideration on May 23, 2013. Alternatively, Plaintiff requests a reconsideration of the Court's entry of final judgment as to certain defendants on July 9, 2013.[1] Plaintiff contends a recently decided United States Supreme Court case, Mutual Pharmaceutical Co., Inc. v. Bartlett, --- U.S. ---, 133 S. Ct. 2466, 186 L. Ed. 2d 607 (June 24, 2013), impacts the Court's analysis of Plaintiff's claims. After reviewing the pertinent case law, arguments and responses, the Court finds as follows:

Factual and Procedural Background

The Court, in a Memorandum Opinion issued January 10, 2013, held that Plaintiff's claims against the Generic Defendants were all ultimately based on a failure-to-warn theory, and were therefore, preempted under PLIVA, Inc. v. Mensing, --- U.S. ---, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011). The Court additionally relied on the Fifth Circuit's determination of preemption in a factually similar case, Demahy v. Schwarz Pharma, Inc., 702 F.3d 177 (5th Cir. 2012). There, the Fifth Circuit examined the plaintiff's claims and found those claims to be, "at

[1] The July 9, 2013 Order entered by the Court was an agreed Final Judgment as to Defendants Wyeth LLC, Pfizer Inc., and ESI Lederle, Inc. That Order noted that the actions between those Defendants and Plaintiff had been "fully resolved" and that "Plaintiff and these Defendants consent to the entry of this Final Judgment of Dismissal with Prejudice . . . and that Plaintiff and these Defendants agree that this action should be dismissed with prejudice as to all claims by Plaintiff against these Defendants." To the extent Plaintiff is asking the Court to reconsider entry of this agreed Final Judgment, that request is DENIED.

base, failure to warn claims, which would be preempted in light of Mensing." 702 F.3d at 186. The Demahy court noted that the Mississippi Products Liability Act (MPLA) defines a defective product as one which fails to contain adequate warnings or instructions. See MISS. CODE ANN. § 11-1-63(a)(i)(2). Therefore, because the Generic Defendants would have had to alter the labeling or the design of the drug in order to adhere to state law, which would be inappropriate under the federal law "duty of sameness," those claims were preempted.

Plaintiff sought reconsideration of that determination arguing that her claims could not all be construed as "failure-to-warn" claims, and therefore, should not be preempted. Indeed, Plaintiff asserted that her state law claims were "parallel" to the federal law, and thus, were not subject to conflict preemption. The Court denied Plaintiff's request for reconsideration explaining that all of Plaintiff's complaints of preemption were conclusively established by the Fifth Circuit in Morris v. PLIVA, Inc., 713 F.3d 774 (5th Cir. 2013).

Plaintiff now contends that an intervening United States Supreme Court decision impacts this Court's dismissal of Plaintiff's claims against the Generic Defendants. Plaintiff again seeks reconsideration under Federal Rules of Civil Procedure 54 and 59.

Standard of Review

Motions to reconsider are treated as motions to alter or amend a judgment under Federal Rule of Civil Procedure 59(e). Nationwide Mut. Fire Ins. Co. v. Pham, 193 F.R.D. 493, 494 (S.D. Miss. 2000)). Rule 59(e) movants "must clearly establish either a manifest error of law or fact or must present newly discovered evidence." Ross v. Marshall, 426 F.3d 745, 763 (5th Cir. 2005). A Rule 59(e) motion is due "no later than 28 days after entry of the judgment." FED. R. CIV. P. 59(e). Relief under this Rule is considered to be extraordinary and "should be used sparingly." Templet v. HydroChem Inc., 367 F.3d 473, 479 (5th Cir. 2004) (citations omitted).

Plaintiff's other hope for relief is the more stringent Rule 60(b), which requires a showing of either "(1) mistake, inadvertence, surprise, or excusable neglect"; "(2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b)"; or "(3) fraud . . . , misrepresentation, or misconduct by an opposing party." FED. R. CIV. P. 60(b); see also Williamson Pounders Architects, P.C. v. Tunica Cnty., Miss., 2008 U.S. Dist. LEXIS 55145, 2008 WL 2856826, *1 (N.D. Miss. July 21, 2008). A Rule 60(b) motion must be made within a year if the motion is based on mistake, newly discovered evidence, or fraud; or, if based on other grounds, must otherwise be made within a reasonable period of time. FED. R. CIV. P. 60(c).

Plaintiff asserts that because final judgment was not entered as to Plaintiff's claims against the Generic Defendants, as required under Federal Rule of Civil Procedure 54(b), the proper standard of review is pursuant to Rule 59. Regardless of the standard used, the Court finds the reconsideration to be unfounded.

Discussion and Analysis

Plaintiff requests that the Court reinstate her claims against the Generic Defendants based on the United States Supreme Court pronouncement in Mutual Pharmaceutical Co., Inc. v. Bartlett, --- U.S. ---, 133 S. Ct. 2466, 186 L. Ed. 2d 607 (June 24, 2013). Plaintiff contends that based on this newly handed down opinion, the Court's prior preemption analysis was fundamentally flawed. In particular, Plaintiff asserts that the Court should have first determined the requirements imposed by state law to see whether such duties are parallel or conflict with federal law requirements. Here, Plaintiff claims that the MPLA, and especially the design defect claim is based on consumer expectation, rather than a risk-utility analysis, which would not require generic defendants to change the drug labels in order to comply with Mississippi law.

Plaintiff asserts that her state law claims against the Generic Defendants are again, parallel claims to federal causes of action. Thus, Plaintiff contends if there is no requirement to consider the warnings' adequacy, there is no conflict preemption, and the claims should be reinstated against the Generic Defendants. Plaintiff argues that pursuant to Bartlett, only her claims that require a manufacturer to unilaterally change an FDA-approved label are adequately preempted by the federal law. Plaintiff also seeks reconsideration as to the Court's determination of proximate cause as to Defendant PLIVA.

Mutual Pharmaceutical Company, Inc. v. Bartlett

In Bartlett, the United States Supreme Court revisited Mensing impossibility preemption, i.e., the preemption of a state law where it is impossible for a defendant comply with both state and federal requirements. The Court overturned the $21 million judgment against the manufacturer of a generic form of sulindac and concluded that the plaintiff's design defect claim, brought under New Hampshire law, was preempted. That state's law provided that a product is defectively designed only where "the design of the product created a defective condition unreasonably dangerous to the user." Id., 133 S. Ct. at 2474, 186 L. Ed. 2d 607 (citation omitted). To determine whether a product was "unreasonably dangerous," the New Hampshire Supreme Court employs a "risk-utility approach" under which a product is defective "if the magnitude of the danger outweighs the utility of the product." Id., 186 L. Ed. 2d 607. As such, the Supreme Court determined that a manufacturer of a generic drug can only escape liability for defective design if the generic manufacturer could have redesigned the drug or changed the label to add a stronger warning. See id. at 2470, 186 L. Ed. 2d 607. Because a generic manufacturer cannot unilaterally change their label as established in Mensing, the Supreme Court analyzed whether a generic manufacturer can redesign the drug. Id. at 2470-71, 186 L. Ed. 2d 607. The

Court determined a drug's usefulness and its risk of danger are directly correlated with its chemical design and, more importantly, its active ingredients. Id. at 2475, 186 L. Ed. 2d 607. Nonetheless, the Court held redesign is not possible. Id., 186 L. Ed. 2d 607. First, the 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. See 21 U.S.C. § 355(j)(2)(A)(ii)-(v) and (8(B); 21 C.F.R. § 320.1(c). Thus, were the generic defendant to change the composition of its sulindac, the altered chemical would be a new drug that would require its own new-drug application to be marketed in interstate commerce. Second, because of sulindac's simple composition, the drug is chemically incapable of being redesigned. Bartlett, 133 S. Ct. at 2475, 186 L. Ed. 2d 607. Therefore, the Supreme Court held it is impossible for generic manufacturers to comply with both state and federal law. Id. at 2477, 186 L. Ed. 2d 607. Indeed, the Supreme Court held that the New Hampshire products liability claim effectively "imposed a duty on Mutual *not* to comply with federal law." Id. at 2470, 186 L. Ed. 2d 607.

"[S]tate-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal law that prohibit manufacturers from unilaterally altering drug composition or labeling." Id. at 2479, 186 L. Ed. 2d 607. By imposing a duty that mandated non-compliance with federal law, state law violated the Supremacy Clause. As such, state-law design defect claims that turn on the adequacy of a drug's warnings are preempted. Id. at 2470, 186 L. Ed. 2d 607. However, the Court expressly reserved "for another day the question whether a true absolute-liability state-law system could give rise to absolute-liability pre-emption." Id. at 2474 n.1, 186 L. Ed. 2d 607.

Plaintiff contends that her Mississippi state law design defect claim is not preempted

because Mississippi courts focus on consumer expectations in determining whether a product is unreasonably dangerous, as opposed to New Hampshire's "risk utility approach." See Fullington v. Pfizer, Inc., 720 F.3d 739 (8th Cir. 2013) (noting that the Bartlett decisions "casts doubt on the viability of Fullington's design defect claim" based on Arkansas state law and remanding the case to the district court to determine whether Arkansas' consumer expectation approach to the unreasonable dangerous inquiry of design defect claims required preemption).

Because Mississippi adheres to the "risk utility approach," the Court finds no basis for this argument. See Smith v. Mack Trucks, Inc., 819 So. 2d 1258, 1263 (Miss. 2002) (determining that "like most federal and state jurisdictions, however, the Court ha[s] clearly moved away from a consumer expectation analysis toward[] risk utility."); Sperry-New Holland v. Prestage, 617 So. 2d 248, 256 (Miss. 1993) (rejecting the Fifth Circuit's representation that consumer expectation was still the basis for products liability in Mississippi and expressly adopting the risk-utility analysis to products liability). Plaintiff has failed to show that the state law claims vary from the New Hampshire products liability claim at issue in Bartlett. Accordingly, the Court finds that pursuant to Bartlett, the Court's prior determination that Plaintiff's claims were preempted are confirmed.

Moreover, Plaintiff's request for the Court to review her arguments that her claims are not based on a failure to warn theory and her arguments that she has put forth sufficient proximate cause are denied. Plaintiff has failed to provide justification or even novel arguments for reconsideration. See Browning v. Navarro, 894 F.2d 99, 100 (5th Cir. 1990) (holding that motions for reconsideration should not be used to re-urge matters that have already been advanced by a party).

Conclusion

After reviewing Plaintiff's Complaint and arguments, the Court is further convinced the correct conclusions were reached regarding the preemption of Plaintiff's claims against the Generic Defendants as well as Plaintiff's remaining claims and proximate cause. Accordingly, the Motion for Reconsideration is DENIED, and final judgment shall be entered accordingly.

SO ORDERED, this the 26th day of September, 2013.

/s/ Sharion Aycock
U.S. DISTRICT JUDGE