Whitener et al v. PLIVA, Inc. et al Doc. 160

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

JOSHUA A. WHITENER, SR., ET AL.	**CIVIL ACTION**
VERSUS	**NUMBER 10-1552**
PLIVA, INC., ET AL.	**SECTION "L" (4)**

ORDER & REASONS

Before the Court are two motions for reconsideration, one filed by Defendants PLIVA, Inc., Barr Laboratories, Inc., and Teva Pharmaceuticals USA, Inc. (Rec. Doc. 151), and the other filed by Plaintiffs Joshua A. Whitener, Sr., and Lindsey C. Whitener (Rec. Doc. 155). The Court has reviewed the briefs and the applicable law and now issues this Order and Reasons.

I. BACKGROUND

This pharmaceutical products liability action arises out of congenital injuries to Lucas Whitener, son of Plaintiffs Joshua A. Whitener, Sr., and Lindsey C. Whitener, as well as injuries to Mrs. Whitener, allegedly caused by the anti-emetic drug metoclopramide. Plaintiffs allege that while Mrs. Whitener was pregnant with Lucas, she was prescribed metoclopramide to treat nausea and morning sickness. Metoclopramide is the generic form of the brand-name drug Reglan. The FDA-approved label for Reglan did not include prescription to pregnant women for morning sickness as an indication.

Plaintiffs filed suit in the 40th Judicial District Court for the Parish of St. John the Baptist against a variety of pharmaceutical entities alleged to have designed, manufactured, marketed, or sold metoclopramide, as well as the doctor and clinic. (Petition at ¶ 2). The claims against the doctor and clinic were jointly dismissed in state court on grounds of prematurity (Rec. Doc. 1-3 at 39), and the pharmaceutical Defendants removed to this Court.

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The Court previously granted a motion for judgment on the pleadings filed by the Defendants who have appeared in the case. (Rec. Doc. 130). In an Order and Reasons dated December 6, 2011 (the "December Order"), the Court addressed the application to the present case of the Supreme Court's recent opinion in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). *Mensing* holds that federal law "preempts any [state-law] claims that Defendants should have provided more or different warnings than those contained in the label and materials approved by the FDA" with respect to a generic drug. (Rec. Doc. 130 at 9). However, the Court granted Plaintiffs leave to amend their pleadings to attempt to assert a non-preempted state-law claim predicated on "alleged promotion of metoclopramide for off-label purposes in violation of federal law." *Id.* As the Court observed, "if Plaintiffs are attempting to allege that the Defendants promoted or marketed the drug in a manner *inconsistent* with the label or marketed it for an off-label purpose in violation of federal rules and regulations . . . the briefing is insufficient at this time for the Court to conclude that such a claim fails as a matter of law." *Id.* at 8-9. Specifically, the Court instructed that:

> If Plaintiffs wish to pursue such a claim they should plead sufficient factual content regarding what marketing or promotional representations were made, by which Defendants, to whom, and how those statements violated applicable federal law.

Id.

Plaintiffs then filed an amended complaint. (Rec. Doc. 131). In that pleading, they allege that Defendants manufactured or distributed metoclopramide knowing or intending that it would be prescribed off-label to treat morning sickness. (*Id.* at ¶¶ 3a-b, ¶ 7). According to the amended complaint, the Defendants knew that doctors frequently prescribed generic metoclopramide off-label to pregnant women to treat morning sickness. Further, Defendants

maintained sales relationships with OBGYN clinics through the legitimate marketing of other drugs. Therefore, Plaintiffs draw the inference that discovery will reveal that Defendants were promoting metoclopramide off-label to doctors for prescription to pregnant women.

Defendants filed a joint motion to dismiss the amended complaint. (Rec. Doc. 135). They argued that Plaintiffs' amended complaint fails to plead with the requisite factual specificity that any Defendant promoted metoclopramide for off-label use in violation of federal law. Likewise, Defendants contended that the amended complaint persists in attempting to assert a claim predicated on a failure to warn that is preempted by *Mensing*. In response, Plaintiffs argued that their Amended Complaint contains enough facts to state a plausible claim that Defendants violated federal regulations by promoting metoclopramide for off-label uses in violation of federal law (rather than consistent with federal law) and failing to warn of the risks associated with that off-label use, and that Defendants' conduct resulted in metoclopramide being prescribed to Mrs. Whitener.

On June 4, 2012, this Court issued an Order and Reasons (the "June Order") denying Defendants' motion to dismiss. (Rec. Doc. 145). With respect to the sufficiency of the factual pleadings, this Court held that "Plaintiffs have (barely) pleaded enough facts to raise a reasonable expectation that discovery will reveal evidence of such conduct." *Id.* at 5 (internal quotation marks omitted). With respect to preemption, the Court noted that "Plaintiffs have not clearly articulated the legal foundation of their claims" and that the off-label prescription "makes no apparent difference in the *Mensing* preemption analysis." *Id.* at 6. The Court then stated:

> Even if a generic manufacturer knows that its product is prescribed for some other purpose, that manufacturer has no mechanism to unilaterally provide any additional warnings relevant to the off-label use; that inability is the crux of the *Mensing* opinion. . . . The harder question . . . is whether the *Mensing* analysis changes if a

> generic defendant *actively promotes* the drug for off-label use in violation of federal law. . . . [T]here is something troubling about permitting a generic defendant to violate federal law by actively and aggressively promoting a drug for a purpose not contemplated by the label approved by the FDA while also hiding behind an inability to provide warnings connected to that off-label use because it cannot change the approved label.

Id. at 6-7. On this basis, as well as the fact that the parties had not cited a case directly addressing the issue, the Court stated that it was "hesitant to hold as a matter of law that there is not a kernel of a viable claim somewhere in Plaintiffs' allegations." *Id.* at 7. The Court denied Defendants' motion, but noted that it may be appropriate to revisit the issue at a later time.

II. PRESENT MOTIONS

The parties now submit separate motions for reconsideration of the two Orders and Reasons described above. Defendants move for reconsideration of the June Order. They renew their arguments on the grounds of preemption and the specificity of the factual pleadings, and they also argue that Plaintiffs lack standing to bring claims alleging violations of the FDCA because that statute expressly bars a private right of action. Plaintiffs respond that they have stated a valid parallel state-law claim, which is neither preempted nor barred by the FDCA, and that their factual pleadings are sufficiently specific to survive a motion to dismiss.

Plaintiffs move for reconsideration of the December Order. Plaintiffs point to two recent published district court decisions addressing the application of *Mensing* to post-2007 claims and argue that this Court should revise its order to follow those cases. Defendants respond that those cases are not on point and therefore do not dictate reversal of the Court's prior holding.

III. LAW & ANALYSIS

A. Defendants' Motion for Reconsideration (Rec. Doc. 151)

1. Standard of Review

Motions asking a court to reconsider an order are generally analyzed under the standards for a motion to alter or amend a judgment pursuant to Rule 59(e) or a motion for relief from a judgment or order pursuant to Rule 60(b). *See Hamilton Plaintiffs v. Williams Plaintiffs*, 147 F.3d 367, 371 n.10 (5th Cir. 1998). Rule 59(e) governs when the motion is filed within 28 days of the challenged order. *See* Fed. R. Civ. P. 59(e). Because Defendants' Motion was filed within 28 days of entry of the Order and Reasons it challenges, the Court treats the Motion as one pursuant to Rule 59(e).

A Rule 59(e) motion "is not the proper vehicle for rehashing evidence, legal theories, or arguments that could have been offered or raised before the entry of judgment." *Templet v. HydroChem Inc*., 367 F.3d 473, 479 (5th Cir. 2004) (citing *Simon v. United States*, 891 F.2d 1154, 1159 (5th Cir. 1990)). Rather, Rule 59(e) serves the narrow purpose of correcting manifest errors or law or fact, or presenting newly discovered evidence. *Lavespere v. Niagra Mach. & Tool Works, Inc*., 910 F.2d 1667, 174 (5th Cir. 1990); *Templet*, 367 F.3d at 479 (quoting *Waltman v. Int'l Paper Co.*, 875 F.2d 468, 473 (5th Cir. 1989)). "'Manifest error' is one that 'is plain and indisputable, and that amounts to a complete disregard of the controlling law.'" *Guy v. Crown Equip. Corp*., 394 F.3d 320, 325 (5th Cir. 2004) (quoting *Venegas-Hernandez v. Sonolux Records*, 370 F.3d 183, 195 (1st Cir. 2004)). In the Fifth Circuit, altering, amending, or reconsidering a judgment under Rule 59(e) "is an extraordinary remedy that should be used sparingly." *Templet*, 367 F.3d at 479 (citing *Clancy v. Empl'rs Health Ins. Co.*, 101 F. Supp. 2d 463, 465 (E.D. La. 2000)). "A Rule 59(e) motion should not be used to re-litigate prior

matters that . . . simply have been resolved to the movant's dissatisfaction." *Voisin v. Tetra Technologies, Inc.*, 2010 WL 3943522, at *2 (E.D. La. Oct. 6, 2010). District courts have "considerable discretion in deciding whether to grant or deny a motion to alter a judgment." *Hale v. Townley*, 45 F.3d 914, 921 (5th Cir. 1995). Yet at the same time, the Rule 59(e) standard "favors denial of motions to alter or amend." *S. Constructors Group, Inc. v. Dynalectric Co.*, 2 F.3d 606, 611 (5th Cir. 1993).

2. Analysis

a. Private Right of Action

Defendants argue that Plaintiffs are attempting to directly enforce the FDCA and its implementing regulations, despite that statute's explicit statement that it contains no private right of action. They note that Plaintiffs cite only federal regulations in their complaint, and accuse Defendants of violating those regulations. Therefore, Defendants argue, Plaintiffs are attempting to enforce the FDCA via a private right of action, in violation of 21 U.S.C. § 338(a) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001), as well as numerous Fifth Circuit and district court cases.

Plaintiffs respond that although they cite federal regulations in their complaint, they are not attempting to bring a federal claim. Instead, Plaintiffs argue that they are using alleged violations of federal regulations as a basis for a parallel state claim. In other words, they argue that they are using Defendants' alleged violations of federal regulations to establish that Defendants breached a standard for the purposes of a state tort claim. This use of federal regulations, they argue, was explicitly approved by the Supreme Court in *In re Medtronic v. Lohr*, 518 U.S. 470, 495 (1996).

In response to this argument, Defendants emphasize that the allegations in Plaintiffs'

complaint involve only violations of the FDCA; the complaint does not identify any state-law duty that Defendants allegedly breached. However, under the liberal pleading standards set out in the Federal Rules of Civil Procedure, this defect is not necessarily fatal. Under Rule 8, the main purpose of a complaint is to provide the defendant with "fair notice of the nature of the action." Charles A. Wright & Arthur R. Miller, 5 Fed. Prac. & Proc. Civ. § 1216 (3d ed.) To satisfy this purpose, it is sufficient that the plaintiff "set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that these elements exist." *Walker v. S. Cent. Bell Tel. Co.*, 904 F.2d 275, 277 (5th Cir. 1990) (quoting Wright & Miller, 5 Fed. Pract. & Proc. Civ. § 1216 (1st ed.)).

As far as the legal basis of Plaintiffs' claim is concerned, the Court believes that Plaintiffs have satisfied federal pleading standards in setting out a state tort claim. The Court's December Order clearly granted Plaintiffs leave to amend their complaint to pursue "a state-law tort claim based on alleged promotion of metoclopramide for off-label purposes in violation of federal law." (Rec. Doc. 130 at 9). Furthermore, all three Defendants included in their respective answers to Plaintiffs' amended complaint defenses based on Louisiana law. (Rec. Doc. 148 at ¶ 44; Rec. Doc. 149 at ¶¶ 28, 42, 49, 50, 51; Rec. Doc. 150 at ¶¶ 28, 42, 49, 50, 51). Thus, Defendants cannot realistically argue that they had no notice of the legal basis of Plaintiffs' claims. As the Court noted in its June Order, "Plaintiffs have not clearly articulated the legal foundation of their claims." (Rec. Doc. 147 at 6). However, the Court still finds that Plaintiffs have articulated enough of a legal foundation to survive a motion to dismiss.

b. Factual Allegations

The Defendants also ask the Court to reconsider its holding that Plaintiffs have included in their Amended Complaint sufficiently specific factual allegations to survive a motion to

dismiss. Defendants renew their arguments—which were plainly acknowledged in the June Order—relating to Plaintiffs' failure to comply precisely with this Court's December Order in setting forth specific factual allegations regarding the alleged contact between Defendants and the prescribing physician relating to the promotion of metoclopramide. Defendants take particular issue with the fact that certain defendants are never specifically mentioned in that section of the Amended Complaint.

The crux of these arguments was already addressed in the June Order, and Defendants do not show a compelling reason for the Court to revisit them now. The Court explicitly stated in its June Order that Plaintiffs' pleadings presented a close call, and suggested that summary judgment could present a significant hurdle to Plaintiffs' claims. Nonetheless, the Court found that Plaintiffs had "barely" satisfied the standard required to defeat a motion to dismiss. Defendants have not shown "manifest error" with that holding, and the Court does not disturb it now.

c. Preemption

Defendants also ask the Court to reconsider its decision that Plaintiffs' claims are not preempted by federal law under *Mensing*. Citing the original complaint in that case, Defendants argue that off-label promotion was actually among the allegations in *Mensing* itself. Nonetheless, Defendants argue, the Supreme Court did not find that factor significant in its preemption analysis, so this Court should not find it significant either.

Plaintiffs respond that the presence of factual allegations in the lower court case does not mean that those allegations were at issue before the Supreme Court. Plaintiffs argue that *Mensing* preemption centers around the impossibility of compliance with both federal and state law—that is, a drug manufacturer's potential liability under state law for failure to make changes

to a drug label that federal law explicitly forbids. Plaintiffs argue that their complaint involves *parallel* state law claims—in other words, they claim that Defendants' violations of federal law *also* violated Defendants' state law duties to Plaintiffs. Plaintiffs emphasize that their claims do not depend on the accuracy of Defendants' disclosures to the FDA, nor do their claims involve the relationship between Defendants and the FDA. *See Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372, 378-79 (5th Cir. 2012). Instead, Plaintiffs argue that their claims "complement" federal enforcement efforts, as expressly approved by federal appellate courts.[1]

Defendants reply that *Lofton* is inapplicable to this case because *Lofton* involved claims against brand-name manufacturers, not generic manufacturers, and *Mensing* created significant distinctions between the two as far as preemption is concerned. Furthermore, Defendants argue that the presence of allegations of promotion in the original *Mensing* complaint were significant because "*Mensing* was on appeal from decisions on multiple dispositive motions, including motions to dismiss, based on federal preemption." (Def.'s Reply, Rec. Doc. 158 at 6).

This Court did state in its June Order that "[i]t may well be appropriate to revisit [preemption] at a later time." (Rec. Doc. 147 at 7). However, Defendants simply have not managed to overcome the fundamental distinction between this case and *Mensing*: unlike in *Mensing*, Plaintiffs in this case do not allege that Defendants should have changed the contents of the label in violation of federal law. Instead, they allege that Defendants simultaneously violated *both* state *and* federal law by actively engaging in off-label promotion despite known risks not listed on the label.

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[1]Plaintiffs also argue that their claims are not preempted under *Mensing* because that case does not apply to post-2007 claims. *See Mensing*, 131 S. Ct. at 2574 n.1. This argument is addressed in Plaintiffs' motion for reconsideration below.

This distinction is significant because the conflict between state and federal law was the crucial factor upon which the *Mensing* Court rested its holding. Furthermore, it was the only issue listed in both the Petition for Writ of Certiorari, *see* 2010 WL 638478 at *i, and the Court's opinion, *see* 131 S. Ct. at 2572. The Supreme Court simply did not reach the issue of whether federal regulations preempt state tort claims that are *not* based on failure to change the label in violation of federal regulations. Furthermore, the parties still have not cited a case on point for this issue.

Accordingly, the Court remains "hesitant to hold as a matter of law that there is not a kernel of a viable claim somewhere in Plaintiffs' allegations." (Rec. Doc. 147 at 7). Defendants' motion for reconsideration is denied.

B. Plaintiffs' Motion for Reconsideration (Rec. Doc. 155)

1. Standard of Review

As explained above, motions asking a court to reconsider an order are generally analyzed under the standards for either a motion to alter or amend a judgment pursuant to Rule 59(e) or a motion for relief from a judgment or order pursuant to Rule 60(b). Rule 60(b) governs when the motion is filed after 28 days, but "within a reasonable time . . . no more than a year after the entry of the . . . order or the date of the proceeding." Fed. R. Civ. P. 60(b). The Fifth Circuit describes "the scope of Rule 59(e) as 'unrestricted,' while noting that 'Rule 60(b) relief may be invoked only for the causes specifically stated in the rule.'" *Williams v. Thaler*, 602 F.3d 291, (5th Cir. 2010) (quoting *Harcon Barge Co. v. D & G Boat Rentals, Inc.*, 784 F.2d 665, 669 (5th Cir. 1986)). Because Plaintiffs' Motion was filed almost eight months after the issuance of the Court's challenged Order and Reasons, it cannot be construed as a Rule 59(e) motion. *See Halicki v. La. Casino Cruises, Inc.*, 151 F.3d 465, 468 (5th Cir. 1998). Nonetheless, the motion

was filed within a year of the relevant decision, so it may be timely under Rule 60(b).

The decision to grant or deny relief under Rule 60(b) lies within the sound discretion of the district court. *Rocha v. Thaler*, 619 F.3d 387, 400 (5th Cir. 2010). Rule 60(b) permits relief from an order only upon certain enumerated grounds. *See* Fed. R. Civ. P. 60(b). Since Plaintiffs do not argue any of the specific grounds enumerated in Rule 60(b), effectively they are arguing for relief under the catch-all provision in Rule 60(b)(6).

2. Analysis

Plaintiffs argue that this Court erred when it held that *Mensing* applied to their claims despite the fact that those claims were brought under the post-2007 amendments to the FDCA. The *Mensing* Court specifically reserved the issue of preemption under the FDAAA. Nevertheless, after examining the reasoning of *Mensing* and the changes put into place by the FDAAA, this Court concluded that *Mensing* still applied to the Plaintiffs' post-2007 claims. For support, the Court cited *In re Fosamax (Alendodrate Sodium) Prods. Liab. Litig. (No. II)*, MDL 2242, No. 08-008, 2011 WL 5903623, at *7 (D.N.J. Nov. 21, 2011) ("[T]he *Mensing* analysis is not affected by FDAAA.").

Plaintiffs argue that two recent published opinions from other district courts support the opposite conclusion. The first case is *Grinage v. Mylan Pharm., Inc.*, 840 F. Supp. 2d 862 (D. Md. 2011). However, that case cannot lend support to Plaintiffs' position, as the *Grinage* court made clear that it was treating as abandoned any claim that *Mensing* did not apply to post-2007 claims. *Id.* at 867 n.2. Plaintiffs' second case is *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F. Supp. 2d 1125 (D. Minn. 2011). As Defendants point out, this case also does not support Plaintiffs' argument, because it involves a brand-name manufacturer, rather than a generic manufacturer. *Id.* at 1130-1134.

The reasoning in *Mensing* was based on a generic manufacturer's inability to independently change the FDA-approved label of its drugs. Although the FDAAA gave the FDA more power to change labels, it made no change to a generic manufacturer's ability to do so. Accordingly, *Mensing* still applies as stated in the Court's December Order, and Plaintiffs' motion for reconsideration must be denied.

IV. CONCLUSION

For the foregoing reasons, IT IS ORDERED that Defendants' motion for reconsideration (Rec. Doc. 151) is DENIED, and IT IS FURTHER ORDERED that Plaintiffs' motion for reconsideration (Rec. Doc. 155) is DENIED.

New Orleans, Louisiana, this 10th day of September, 2012.

UNITED STATES DISTRICT JUDGE