U.S. Court of Appeals for the Eighth Circuit: No Preemption for Generic Manufacturers, No Liability for Brand Name Manufacturers

On November 27, 2009, the U.S. Court of Appeals for the Eighth Circuit issued an important and consequential decision for manufacturers of both generic and brand name pharmaceutical products in *Mensing v. Wyeth*, No. 08-3850.

The Court addressed two issues. First, the Court addressed whether federal law preempted state-law failure-to-warn claims brought against manufacturers of generic pharmaceuticals. *Mensing* is the first case in which a circuit court has reached this issue. Second, the Court addressed a claim that a patient who took a generic medicine could bring a claim against an innovator company.

The Eighth Circuit held that state-law failure-to-warn claims against generic manufacturers are not preempted by federal law and that brand name manufacturers are not liable for various common law torts where the plaintiff did not purchase or use the brand name manufacturers' product.

Mensing involved failure-to-warn and misrepresentation claims against a number of manufacturers of the drug Reglan® and its generic form. The plaintiff's doctor prescribed Reglan to treat her diabetic gastroparesis, and her pharmacist filled her prescription with its generic bioequivalent, metoclopramide. She alleged that the medication she had taken caused her to develop tardive dyskinesia, a severe neurological movement disorder. Although the plaintiff never ingested the brand name drug, she sued the brand name manufacturers of Reglan for fraud and negligent misrepresentation on the theory that her doctor relied on Reglan's label when assessing the risks and proper use of metoclopramide.

All of the defendants filed motions to dismiss or motions for summary judgment. The district court granted the motions by the generic defendants on the ground of federal preemption, concluding that the plaintiff's failure-to-warn claims conflicted with federal law because they would require generic manufacturers to deviate from the brand name drug label. The Court also granted summary judgment to brand name defendants, holding that they owed no duty of care to the plaintiff under Minnesota law because she never ingested their product.

The Eighth Circuit reversed the district court's holding as to the generic manufacturers and affirmed the decision as to the brand name manufacturers.

Failure-to-Warn Claims Against Generic Manufacturers Not Preempted

In *Mensing*, the plaintiff and the defendants agreed that generic labels must be substantively identical to the brand name label at the time the FDA approves a generic drug's label and after the generic drug enters the market. Because of this "sameness" requirement, the generic manufacturers argued that they were prohibited from implementing a unilateral label change without prior FDA approval through a Changes Being Effected ("CBE") supplement. Although the Court declined to decide "whether generic

manufacturers may unilaterally enhance a label warning through the CBE procedure,"[1] it nonetheless held that there was no conflict with federal law in this case "because the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." Slip op. at 9 (emphasis in original).

In reaching this conclusion, the Court analyzed FDA labeling regulations and interpretative commentary outside the regulations and determined that "[t]he regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug." *Id.*; 21 C.F.R. § 201.57(e) (labeling "shall be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug"). The Court rejected the generic defendants' argument that they comply with § 201.57(e) by simply ensuring that their labels match the brand name label, stating that generic manufacturers cannot "passively [] accept the inadequacy of their drug's label as they market and profit from it." Slip op. at 9.

The Court then turned to the specific question of "impossibility" preemption: "whether generic defendants can both fulfill a state law duty to warn and comply with the FDCA. Does federal law forbid them from taking steps to warn their customers?" Slip op. at 12. The district court had "concluded that generic drug manufacturers 'may seek to add safety information to a drug label' through the prior approval process or by requesting that the FDA send 'Dear Health Care Professional' letters, but it remained uncertain what the FDA might have done had they proposed a label change." *Id*. Consequently, the district court "hesitated to impose liability based on speculation." However, the district court issued its decision before the Supreme Court's decision in *Wyeth v. Levine*.

According to the Eighth Circuit, after *Levine*, "uncertainty about the FDA's response to such measures makes federal preemption less likely." Slip op. at 12. The Court observed that "[t]o support preemption the generic defendants must show the likelihood of FDA *in*action." *Id.* at 13 (emphasis in original). The generic defendants in *Mensing* were unable to make this showing because the "record contain[ed] nothing, let alone 'clear evidence,' to suggest the FDA would have rejected a labeling proposal from any of them." *Id.* In fact, the record showed just the opposite, as the FDA had mandated that metoclopramide manufacturers enhance the label's warning of the risks of tardive dyskinesia earlier in 2009. *Id.*

The Court concluded its "impossibility" analysis by stating that the generic manufacturers always had the option of not selling a generic form of Reglan:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If [plaintiff's] injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

Slip op. at 14.

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[1] There is currently a split in the district courts as to whether a generic manufacturer can use the CBE process to enhance a label warning. *Compare Bartlett v. Mutual Pharmaceutical Co., Inc*., 2009 WL 3126305 (D.N.H. Sept. 30, 2009) and *Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642 (E.D. La. 2008) (generic manufacturers may alter labeling post-approval using CBE) with *Morris v. Wyeth, Inc.*, 582 F. Supp. 2d 861 (W.D. Ky. 2008) and *Smith v. Wyeth, Inc*., 2008 WL 4697002 (W.D. Ky. Oct. 24, 2008) (generic manufacturers may not alter labeling post-approval using CBE).

Next, the Court considered whether state-law failure-to-warn claims were preempted because they "would obstruct the purposes and objectives of federal law." Slip op. at 14. The generic manufacturers argued that the Hatch-Waxman Amendments, rather than the whole FDCA, supplied the relevant statutory framework and that "proposing a label change would necessitate expensive clinical studies, thwarting the goal of the Hatch-Waxman Amendments to bring low cost generic drugs to market quickly." *Id.* The Court disagreed, holding that the "obligation [plaintiff] seeks to impose upon generic manufacturers does not obstruct the purposes and objectives of the Hatch-Waxman Amendments in any way." *Id.* at 15. In support of this holding, the Court determined that the Hatch-Waxman Amendments "must be considered part and parcel of the FDCA" and that the "amendments provided for cheaper, expedited approval of generic drugs, not relief from the fundamental requirement of the FDCA that all marketed drugs remain safe." *Id.* Citing the Supreme Court's decisions in *Levine* and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005), as well the Fourth Circuit's decision in *Foster v. American Home Products Corp.*, 29 F.3d 165, 170 (4th Cir. 1994), the Eighth Circuit "decline[d] to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this country and leave injured parties like [the plaintiff] no legal remedy." Slip op. at 15.

As the Eighth Circuit observed, other courts that have considered the preemption issue after *Levine* "have almost uniformly ruled that tort claims against generic manufacturers are not preempted." Slip op. at 7 (citing *Stacel v. Teva Pharmaceuticals, USA*, 620 F. Supp. 2d 899, 906-907 (N.D. Ill. 2009); *Schrock v. Wyeth*, 601 F. Supp. 2d 1262, 1265-66 (W.D. Okla. 2009). Similar cases involving the generic preemption issue are currently pending in the Fifth and Sixth Circuits. *Demahy v. Wyeth, Inc.*, No. 08-31204 (5th Cir.) (oral argument heard August 5, 2009; court has requested supplemental briefing); *Smith v. Wyeth*, No. 09-5460 (6th Cir.) (appeal docketed April 16, 2009); *Morris v. Wyeth*, No. 09-5509 (6th Cir.) (appeal docketed April 27, 2009).

Brand Name Manufacturers Owed Plaintiff No Duty of Care

The Eighth Circuit joined "the overwhelming majority of courts" in holding that brand name manufacturers cannot be held liable for "various common law torts" where the plaintiff did not purchase or use the brand name manufacturers' product, but allegedly used the generic form of Reglan.[2] Pursuant to Minnesota tort law under such circumstances, brand manufacturers do not owe "a duty of care necessary to trigger liability." Slip op. at 18. To hold otherwise would "stretch[] the concept of foreseeability too far." *Id*. Notably, the *Mensing* court gave no weight to the controversial decision in *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008), in which the California First District Court of Appeals rejected a long line of cases from other jurisdictions to hold that under California law, brand name manufacturers owe a duty to users of the generic versions of their products. Slip op. at 17.

[2] *See, e.g., Foster*, 29 F.3d at 168-170; *Morris v. Wyeth, Inc.*, 2009 WL 4064103, at *4-6 (W.D. La. Nov. 23, 2009); *Meade v. Parsley*, 2009 WL 3806716, at *2-3 (S.D.W. Va. Nov. 13, 2009); *Burke v. Wyeth, Inc.*, 2009 WL 3698480, at *2-3 (S.D. Tex. Oct. 29, 2009); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633-34 (E.D.N.C. 2009); *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056, 1060-61 (W.D. Ark. 2009); *Flynn v. American Home Products Corp.*, 627 N.W.2d 342 (Minn. App. 2001).

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Mensing will offer a powerful tool to plaintiffs suing generic manufacturers who have used preemption with great success in recent years. In addition, the decision likely will energize litigation over Reglan. Finally, the Court's affirmation that traditional product liability law prohibits claims against innovator companies by plaintiffs who did not take a product manufactured by the company will further marginalize the *Conte* decision from California.

Chicago Office
+1.312.583.2300

Frankfurt Office
+49.69.25494.0

London Office
+44.20.7105.0500

Los Angeles Office
+1.310.788.1000

New York Office
+1.212.836.8000

Shanghai Office
+86.21.2208.3600

Washington, DC Office
+1.202.682.3500

West Palm Beach Office
+1.561.802.3230