

PRODUCT LIABILITY

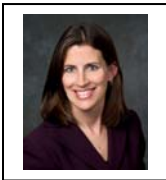
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Stephanie Rippee and Ceejaye Peters examine the recent case trend in the generic preemption defense.

Generic Preemption Defense: Recent Case Trend

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Last year, in *Wyeth v. Levine*, 555 U.S. ___, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), the United States Supreme Court significantly decreased the ability of a drug manufacturer to successfully defeat state law failure to warn claims using the implied preemption defense. *Levine*, however, involved an innovator drug, not a generic drug. Unlike an innovator drug where the applicant must submit to the Food and Drug Administration ("FDA") a New Drug Application ("NDA") demonstrating (after significant, costly studies and tests) that the drug is safe and effective,¹ generic drug manufacturers need only submit an Abbreviated New Drug Application ("ANDA") demonstrating that the generic drug is bioequivalent to a drug that has already been found safe and effective.² Approval of a generic drug is generally easier and more economical, and this allows generic drugs to be made available to the public cheaper and more quickly.

These differences in the regulatory approval schemes give rise to different generic preemption arguments than those arguments made by innovator manufacturers and rejected by the Supreme Court in *Levine*. Key to the "generic preemption" defense is the requirement that the generic drug applicant must include in its ANDA the proposed labeling for the generic drug and must show, in a side by side comparison format, that the generic labeling is "the same as" the approved labeling for the innovator drug.³ Generic manufacturers have argued that in light of this "sameness" requirement, to find them liable under state law for not changing the label creates a direct conflict

between state law and federal law, and compliance with both is indeed impossible. Further, generic manufacturers have argued that requiring them to propose labeling changes would ultimately require them to engage in time consuming, expensive testing of their drugs and would thus defeat Congress's objective of bringing low cost generic drugs to market quickly.

Prior to *Levine*, generic manufacturers had made these arguments with mixed success among the lower courts, and they continued to do so post-*Levine*. A pair of recent decisions from the federal appellate courts seems to signal a negative trend as to the availability of the generic preemption defense.

The Eighth Circuit *Mensing* Decision

The Eighth Circuit Court of Appeals was the first federal appellate court to address the issue. In November 2009, relying heavily on the *Levine* decision's recognition of the central premise that the content of the label is the responsibility of the manufacturer at all times (both before and after approval), the Court held that the regulatory requirements for changing drug labeling, or at least bringing labeling changes issues to the attention of the FDA, apply to manufacturers of generic drugs as well as innovator drugs. *Mensing v. Wyeth, Inc., et al.*, 588 F.3d 603 (8th Cir. 2009). *Mensing* brought state law failure to warn claims against the manufacturers of both the innovator drug Reglan® and various generic metoclopramide manufacturers, and the District Court for the District of Minnesota dismissed *Mensing's* claims against the generic manufacturers holding that requiring generic metoclopramide manufacturers to deviate from the approved language of the Reglan® label created an impermissible conflict with federal law. *Id.* at 604.

¹ 21 U.S.C. § 355(b)(1)(A).

² The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"), Pub. L. No. 98-417, 98 Stat. 1585 (1984); 21 U.S.C. § 355(j)(2)(A)(iv).

³ 21 U.S.C. §355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(i) through (iv).

The generic manufacturers argued that they were prohibited from implementing a unilateral label change without prior FDA approval through the "CBE" or "Changes Being Effected"⁴ process. *Id.* at 608. The Court declined to decide this issue. The Eighth Circuit reversed nonetheless holding that the generic defendants could have at least proposed a label change for consideration by the FDA through the prior FDA approval process used for most labeling changes. *Id.* The Court emphasized 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.* at 608-09. The Court held that generic manufactures are not permitted to simply ensure that their labels are identical to the brand name label. *Id.* (holding that "§201.57(e) does not permit generic manufacturers passively to accept the inadequacy of their drug's label as they market and profit from it.").

The Court noted that commentary by the FDA published contemporaneously with the Hatch-Waxman Amendments "supports the requirement that at a minimum a generic manufacturer should alert the agency to any new safety hazard associated with its products." *Id.* at 609. Specifically, the FDA stated: "After approval of an ANDA, if an ANDA holder [a generic manufacturer] believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." *Id.* (citing 57 Fed. Reg. 17950, 17961 cmt. 40 (Apr. 28, 1992) (emphasis supplied)). Additionally, the Court reasoned that 21 C.F.R. § 314.98 requires that generic manufacturers follow the same post marketing record keeping and reporting of adverse drug experiences as the

name brand manufacturers presumably with the expectation that generic manufacturers will initiate label changes and not just merely make changes to match those initiated by the name brand manufacturer. *Id.* The Court also pointed out that, in addition to proposing labeling changes, generic manufacturers could suggest that the FDA send out warning letters to health care professionals. *Id.* at 610.

Again taking a cue from the *Levine* decision, the Eighth Circuit noted that uncertainty about the FDA's acceptance or rejection of a proposed labeling change makes preemption, in general, less likely. *Id.* at 610. Accordingly, "[t]o support preemption the generic defendants must show the likelihood of FDA inaction" in order to establish that they cannot fulfill a state law duty to warn and comply with the Federal Food, Drug and Cosmetic Act ("FDCA") and its corresponding regulations. *Id.* at 611. The Court found that no such evidence was offered by the generic defendants. *Id.*

The Eighth Circuit also rejected the generic defendants' argument that state law failure to warn claims are preempted because they obstruct the goal of the Hatch-Waxman Amendments to bring low cost generic drugs to market quickly. *Id.* at 611-12. The Court held that generic manufacturers need "scientific substantiation" to support a proposed labeling change and noted that this substantiation need not consist of additional, expensive studies. Rather, the Court pointed out, that the substantiation could come in the form of adverse drug experiences which generic manufacturers are already required, per the regulations, to collect. *Id.*

⁴ 21 C. F. R. §314.70(c)(6)(iii).

The Fifth Circuit Demahy Decision

The Fifth Circuit followed the Eighth Circuit in January 2010 holding that failure to warn claims against a generic manufacturer are not, per se, preempted by the federal regulatory scheme governing generic pharmaceuticals. *Demahy v. Actavis, Inc.*, No. 08-31204, --- F.3d ----, 2010 WL 46513 (5th Cir. Jan. 8, 2010). Demahy filed suit against Actavis, a manufacturer of a generic form metoclopramide. *Id.* at *1. The Fifth Circuit affirmed the Louisiana District Court's denial of Actavis' motion to dismiss the state law failure to warn claims as preempted.

The Court initially emphasized the presumption against preemption and focused as well on the distinction between what the regulations say about the "sameness" of content of the generic and innovator labeling at approval as opposed to *after* approval. *Id.* at *2. The Court pointed out that although per the FDCA the generic drug's labeling must conform to the innovator's label at the time the drug is being approved, the statutory scheme is silent on the issue of the "sameness" of the labeling after the ANDA is granted. *Id.* at *4. In looking at the applicable regulations, however, the Court again held that post approval, generic manufacturers – just like innovator manufacturers – are required to ensure that the labeling accurately reflects evidence of the risks associated with the drug. *Id.* at *5. The Court noted that the regulation authorizing withdrawal of the approval of a generic drug if its labeling is no longer consistent with that of the innovator was not meant to prohibit a generic manufacturer from attempting to strengthen its label, but was instead implemented to give the FDA a weapon to ensure that generic manufacturers change (i.e., update) their labels to mirror changes proposed and made by the innovators. *Id.* at *6.

The Court held that it was not impossible for Actavis to comply with both federal and state law regarding the warnings supplied, saying it is, at best, uncertain whether the CBE regulation available to innovator manufacturers can also be used by generic manufacturers. *Id.* at *7. Furthermore, like the Eighth Circuit, the Fifth Circuit held that Actavis could have used the normal prior FDA approval process to propose a labeling change regarding the warning at issue and/or that Actavis could have, again with prior FDA approval, sent a "Dear Doctor" letter notifying healthcare professionals of the risks at issue. *Id.* at *10-11. The Fifth Circuit similarly rejected the idea that requiring generic manufacturers to bear liability for inadequacies in the drug labeling obstructs the goals of the FDCA saying that the most important goal of the FDA is to make sure drugs are indeed safe and effective. *Id.* at *14-15.

Additional Decisions Expected

This same issue is poised to be decided by the Sixth Circuit Court of Appeals in *Smith v. Wyeth*, No. 09-5460, 2009 WL 4611244 (6th Cir. Dec. 1, 2009); *Wilson v. Pliva*, 09-5466, 2009 WL 4611245 (6th Cir. Dec. 1, 2009); and *Morris v. Wyeth*, 09-5509, 2009 WL 4611243 (6th Cir. Dec. 1, 2009). It would be surprising at this point if those decisions were not consistent with these two initial decisions. Currently, seven out of every ten prescriptions filled are filled with a generic drug. With generic manufacturers enjoying a large and still increasing market share, the Courts appear unwilling to allow a generic manufacturer to benefit from the research and development efforts of the innovator drug and the warning label that those efforts produce, but avoid liability for inadequacies in that label.

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