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Supreme Court's Finding of Preemption for Generic Manufacturers Will Have Significant Implications for Brand-Name Companies

On June 23, 2011, in a 5-4 decision,[1] the Supreme Court held that federal law preempts state law failure-to-warn claims against generic pharmaceutical manufacturers. *Pliva, Inc. v. Mensing*, No. 09-993 (June 23, 2011). The sweeping ruling will likely absolve generic manufacturers from liability on virtually all failure-to-warn claims.

Mensing involved the generic medication metoclopramide (brand name Reglan®). The plaintiffs in the trial courts below brought failure-to-warn claims against the generic manufacturers whose products they took, claiming that the defendants failed to warn that long-term use of the product could cause in a condition called tardive dyskinesia. The defendants in the respective cases won dismissal based on federal preemption. On appeal and after the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), which held that federal law does not preempt state law failure-to-warn claims involving brand-name drugs, the Fifth and Eighth circuits reversed the judgments. The manufacturers petitioned for *certiorari*, and the Supreme Court granted review and consolidated the cases.

The issue before the Court centered on the extent to which, after FDA approval, a generic manufacturer can unilaterally issue warnings about a medication's risks before the brand manufacturer changes its label to issue such a warning. The plaintiffs argued that the manufacturers should have given stronger warnings either by making a unilateral change to the label through the FDA's "Changes Being Effected" (CBE) supplement process, through Dear Doctor Letters without changing the label itself, or by informally asking FDA to strengthen the labeling for both the brand-name and generic drugs. The manufacturers argued that federal law required the generic metoclopramide labeling to be identical to the labeling for the brand-name counterpart and, therefore, that they could not have given different warnings as the plaintiffs urged state law required. And the manufacturers argued that while they could have informally asked FDA to strengthen the brand and generic labeling, they were not required to do so and the speculative possibility that such an informal process could have led to a label change should not defeat preemption. Thus, the manufacturers argued that the doctrine of "implied conflict preemption" barred the plaintiffs' state law claims because it was impossible for the manufacturers to comply with

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federal law – which required maintaining the identical label to the brand product – while also complying with state law – which assertedly required changing the label to strengthen the warning.

The Court agreed that the plaintiffs' claims were preempted on the ground that it was impossible for the manufacturers to comply with both federal and state law:

> It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law. If the Manufacturers had independently changed their labels to satisfy their state law duty, they would have violated federal law. Taking [the plaintiffs'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

Op. at 11-12.

In reaching this conclusion, the Court started by acknowledging that the regulatory scheme governing generic manufacturers differs from the scheme governing brand-name manufacturers. The Court gave deference to FDA's interpretation of the FDCA that the "warning labels of a brand-name drug and its generic copy must always by the same – thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" Op. at 6. Following from this, the Court accepted the FDA's interpretation that the option of a unilateral change to the label under the CBE regulation was not available to generic manufacturers and that generic manufacturers could not use Dear Doctor Letters to issue additional warnings that were inconsistent with the labeling.

The Court then took on the crux of the case: the plaintiffs' and FDA's argument that there is a back door for the generics to initiate a label change, even though the CBE process is not available, by informally asking FDA to strengthen the labeling for the brand and the generics together. They argued that, because all drug manufacturers are responsible for the content of labeling, the generics had a duty to informally propose stronger warnings to the agency when there was reasonable evidence of an association of a serious hazard with a drug (*see* 21 C.F.R. 201.57(e)) and to allow FDA then to determine whether a labeling change should be made. The plaintiffs argued that preemption could apply only if the generics had taken this step and could prove that "FDA would not have allowed compliance with state law." In other words, the plaintiffs contended that the case was essentially indistinguishable from *Levine* and the same preemption analysis pertaining to brand-name manufacturers should apply.

The Court disagreed. It reasoned that, even if the manufacturers had asked FDA to strengthen the label and thereby satisfied the federal duty that the plaintiffs and FDA asserted, the state law duty would remain unfulfilled because the labeling would not be "safer." The Court criticized the plaintiffs' argument as begging a string of possibilities that "would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide." Op. at 13. The Court explained that courts should not entertain hypothetical scenarios to resolve an otherwise clear conflict or strain to find ways to reconcile federal law with seemingly conflicting state law.[2] Op. at 17 ("When the 'ordinary meaning' of federal law blocks a private party from *independently* accomplishing what state law requires, that party has established pre-emption.") (emphasis added). Instead, preemption analysis should turn on the actual provisions of law

as they exist – not counterfactual speculation about informal ways that might be found to get around those provisions. The theoretical ability to comply with state law only by "special permission and assistance" from FDA does not overcome preemption.

The Court distinguished its decision in *Levine* on these grounds. The Court acknowledged that had the plaintiffs taken Reglan® instead of the generics, their failure-to-warn claims would not be preempted. The key distinction, in the Court's view, is the availability of the CBE regulation. The brand-name manufacturer in *Levine* could have used the CBE regulation to change its label unilaterally and independently of any action or permission by FDA. *Levine* held that the CBE supplement process available to brand-name manufacturers thus effectively accommodates state tort law within the federal regulatory scheme by allowing manufacturers to change their labels to comply with state tort duties to warn. In the brand-name context, compliance with state law is not impossible in the ordinary case, but rather only where the manufacturer can show by clear evidence that FDA would not have approved the labeling change required by state law. In the generic context, in contrast, a label change required by state law is ordinarily impossible under federal law. The Court thus explained that "the question in [the generic cases] is not whether the possibility of *impossibility* establishes pre-emption [as was the case in *Levine*], but rather whether the possibility of *possibility* defeats pre-emption [as is the case in *Mensing*]." Op. at 18 n.8.

The Court's decision is good news for generic manufacturers. It is not clear that it is good news for brand manufacturers. On the one hand, the *Mensing* opinion reaffirms that preemption applies even in the brand context where the manufacturer can show that FDA would not have permitted the label change assertedly required by state law. Op. at 17-18 & n.8. After numerous decisions rejecting preemption arguments in the wake of *Levine*, one federal district court recently held that a state law claim involving an SSRI was preempted because it was clear that FDA would not have permitted the warning sought by the plaintiff. *Dobbs v. Wyeth Pharm. Inc.*, No. 04-1762 (W.D. Okla.), slip op. June 13, 2011. Perhaps the *Dobbs* decision, and *Mensing*'s reaffirmation that *Levine* did not definitively rule out preemption in brand cases, will help brand manufacturers turn the tide of no-preemption decisions in contexts, like SSRI cases, where there is a robust regulatory history that can support a finding that FDA would have rejected the warning the plaintiff argues was required by state law.

On the other hand, however, the distinction between clear preemption of claims against generic manufacturers and presumptive non-preemption of claims against brand manufacturers may result in more claims being brought and allowed to proceed against brand manufacturers. Before *Mensing*, a California appeals court held that a plaintiff who took only a generic product could bring a tort suit against the brand manufacturer. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. App. 2008). Most courts that have addressed this issue have disagreed with *Conte*. The danger of *Mensing* for brand-name manufacturers is that it will lead more courts to follow *Conte*. Now that preemption is available to generic manufacturers, courts that may have been reluctant to follow that minority ruling have a greater incentive to do so in order to avoid leaving individuals who took a generic product without any remedy. Brand manufacturers will be able to point to language in both the opinion of the Court and the dissent that suggests that the Justices believed that preemption of claims against generic manufacturers would indeed leave individuals who took a generic product without a remedy. *See* Op. at 18-19; Dissent at 18-21. But it will ordinarily be a question of state law whether a brand manufacturer's duty to include adequate warnings in its label extends to individuals who take a generic product. The Court's emphasis on the generic manufacturer's federal law duty to use the identical label as the brand manufacturer may lead some courts to hold that the brand manufacturer owes a duty to individuals who take a generic product that it does not manufacture but that bears a label that federal law requires to be identical to the brand

manufacturer's product. An especially pro-plaintiff state court could potentially hold that the brand manufacturer has a duty to monitor adverse event reports and scientific literature relating to generic versions of its product, even after the brand product loses patent protection.

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[1] Justice Thomas delivered the opinion of the Court. Chief Justice Roberts and Justices Scalia and Alito joined in full, and Justice Kennedy joined as to all but Section III.B.2. *See infra*, note 2. Justice Sotomayor dissented, joined by Justices Ginsburg, Breyer, and Kagan.

[2] To the latter point, the Court reasoned that the Supremacy Clause contained a *non obstante* provision suggesting that federal law impliedly repeals conflicting state law. Op. 15-17. Justice Kennedy did not join this part of the opinion.