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PRODUCT LIABILITY and APPELLATE PRACTICE
ALERT

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Supreme Court Strengthens Preemption Defense for Manufacturers

By Keith E. Whitson and Julie E. Randolph

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the United States Supreme Court held that certain failure to warn claims against manufacturers of brand-name pharmaceuticals were not preempted by the Federal Food, Drug and Cosmetic Act. This past week, the Supreme Court reached the opposite conclusion with respect to manufacturers of generic pharmaceuticals. In so holding, the Court clarified that "impossibility" preemption (where it is impossible to comply with both federal and state law) may preclude state law claims unless a manufacturer can *unilaterally* comply with both federal and state law.

In *Pliva v. Mensing*, 564 U.S. ___ (2011), the plaintiffs had been prescribed Reglan in 2001 and 2002, and had received the generic form of that drug, metoclopramide, from their pharmacists. Plaintiffs later developed tardive dyskinesia, a neurological disorder. They filed suit against the manufacturers of metoclopramide arguing that the drug caused their disorder and the manufacturers failed to provide adequate warnings labels.

In order to obtain approval from the Food and Drug Administration ("FDA"), manufacturers of a "new drug" must demonstrate that the drug is safe and effective. This can be a lengthy and expensive process. In 1984, Congress passed the Hatch-Waxman Amendments, which allowed "generic drugs" to obtain approval simply by showing that the drug was "bioequivalent" to an approved brand-name drug, and was identical to the brand-name drug in certain other respects. By statute and regulation, the warnings provided with the generic drug must be identical to the warnings required by the FDA on the brand-name counterpart.

In *Pliva*, the plaintiffs argued that these warnings were insufficient due to alleged mounting evidence of a relationship between metoclopramide and tardive dyskinesia. The Court assumed for purposes of its decision that the relevant state law required the manufacturers to provide a stronger warning. The manufacturers contended, however, that the plaintiffs' claims were preempted because federal law required their warnings to be identical to those carried by their name-brand counterparts, making it impossible to provide a different, stronger warning. Plaintiffs acknowledged this federal requirement, but argued that the manufacturers had several routes available to them to change their labels upon discovery of new information. As a result, they argued, preemption did not apply. The United States Courts of Appeals for the Fifth and Eighth Circuits agreed with plaintiffs and found no preemption. In a 5–4 decision, the Supreme Court reversed the Courts of Appeals' decisions.

The Court first accepted the FDA's view that the warning labels on generic drugs must always be identical to those on the brand-name drug. As a result, the manufacturers of generic drugs could not use the "changes-being-effected" process (which allows brand-name drug manufacturers to strengthen warnings or instructions without waiting for advance FDA approval) to change their labels, unless they were changing the label to match changes in the brand-name labels. Similarly, the Court adopted the FDA's position that the manufacturers could not provide "Dear Doctor" letters (letters addressed to doctors that provide information about the drug), because those letters qualify as "labels" and necessarily would effect a change from the brand-name labels.

The Court concluded that to make a change to its label, the manufacturer of a generic drug would have to propose such a change to the FDA. If the FDA agreed that a change was necessary, it would work with the name-brand manufacturer to revise the label for both the name-brand and generic drugs. Absent agreement from the FDA, however, the manufacturer of a generic drug was not permitted to change its label. It was undisputed in these cases that the manufacturers had not requested such a change with the FDA.

Under this statutory framework, the Court concluded that it was impossible for the manufacturers of generic metoclopramide to comply with both state law and federal law. Assuming that, under state law, the manufacturers were required to provide a stronger warning, they could not have done so without intervention by the FDA and cooperation

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by the name-brand manufacturer. The majority opinion characterized the issue as "whether conflict preemption should take into account these possible actions by the FDA and the brand-name manufacturer" in determining whether compliance with state law was impossible. Quoting *Levine*, the Court stated that "[t]he question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it." (emphasis added). Because a label change required action from others, the Court held that the manufacturers could not independently comply with both federal and state law, and therefore preemption was appropriate:

> To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those duties for pre-emption purposes.

The dissent argued that the manufacturers had shown only that they might be unable to comply with both federal and state law. The dissent characterized the conflict here as only "hypothetical or potential" because the manufacturers had never sought FDA approval to have the label changed. The dissent argued that this has never before been sufficient to sustain a defendant's burden of proof on the preemption defense: "the mere possibility of impossibility is not enough." Further, the dissent disagreed that "independent" or "unilateral" action to comply with both state and federal law was required to avoid preemption.

The majority opinion held, however, that if contingencies such as FDA approval could prevent the application of preemption, then conflict preemption could be rendered meaningless. In almost any case, certain contingencies might occur that would allow a manufacturer to comply with both state and federal law. The question therefore is whether it is possible for the manufacturer to take action unilaterally to comply with both federal and state law.

The Court recognized that its decision results in different outcomes depending entirely on which form of the drug — brand-name or generic — was prescribed by a plaintiff's doctor and which form of the drug was provided by the pharmacist. However, the Court explained that these different outcomes are a consequence of differing statutory schemes. "We will not distort the Supremacy Clause in order to create similar preemption across a dissimilar statutory scheme."

This decision reinvigorates a preemption defense that seemingly had been curtailed in *Levine*. ◆

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