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The Supreme Court Finds State Failure-to-Warn Claims Against Generic Drug Manufacturers Impliedly Preempted

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INTRODUCTION

Yesterday, the Supreme Court, in a 5-4 decision, ruled in three consolidated cases—*Pliva, Inc. v. Mensing*, No. 09-993, *Actavis Elizabeth, L.L.C. v. Mensing*, No. 09-1039, and *Actavis, Inc. v. Demahy*, No. 09-1501 (collectively, "*Mensing/Demahy*")—that state law failure-to-warn claims against generic drug manufacturers that would require greater warnings than those approved by the Food & Drug Administration ("FDA") for the original branded version of the drug are preempted by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (the "FDCA"), which require that the generic drug's label warnings must be the same as those of the originally approved branded drug. The Court specifically found implied conflict preemption here because "[i]f the [defendants] had independently changed their labels to satisfy their state-law duty," according to the Court, "they would have violated federal law."

BACKGROUND

The two plaintiffs-respondents, Gladys Mensing and Julie Demahy, were prescribed the brand-name prescription drug Reglan to treat gastrointestinal conditions. Both plaintiffs' prescriptions were instead filled with the generic drug metoclopramide for a number of years, after which they developed tardive dyskinesia, a neurological movement disorder allegedly caused by long-term use of the drug. The plaintiffs each filed suits against the metoclopramide manufacturers, claiming that the drug's label failed to warn them adequately about the risk of developing tardive dyskinesia. The defendants in both cases, various brand-name and generic drug manufacturers, moved to dismiss the plaintiffs' claims.

The district court deciding the action brought by Mensing granted the generic drug manufacturers' motion on preemption grounds, holding that Mensing's failure-to-warn claims would create an impermissible conflict with federal law requiring a generic drug manufacturer to utilize the same label as the brand-name drug for which it is a bio-equivalent. By contrast, the district court in *Demahy* denied the generic manufacturers' similar motion to dismiss. Both cases were appealed.

The Court of Appeals for the Eighth Circuit, deciding the case brought by Mensing, rejected the defendants' arguments that it was impossible to comply with a state law requirement imposing a different label than those found on brand-name equivalents because "defendants could have at least proposed a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers, if approved."

The Court of Appeals for the Fifth Circuit, deciding the case brought by Demahy, also concluded that the state law failure-to-warn claims against a generic drug manufacturer

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were not preempted by the FDCA. The Fifth Circuit found that it was possible for Actavis to comply with both federal labeling requirements and the duty purportedly imposed by state law to warn metoclopramide users adequately about the danger of developing tardive dyskinesia, and that the state law claims therefore did not obstruct the purposes or objectives of the FDCA.

The defendants appealed the respective circuit court decisions, and the United States Supreme Court granted certiorari and consolidated all three underlying cases. Oral argument was held before the Court on March 30, 2011.

SUMMARY OF THE DECISION

The Supreme Court—in a decision written by Justice Thomas and joined by Chief Justice Roberts and Justices Scalia, Kennedy, and Alito, and reversing the Fifth and Eighth Circuits—held that state law failure-to-warn claims against generic drug manufacturers that would require greater warnings than those required by the FDA for the branded bio-equivalent drug are preempted because they are in direct conflict with the Hatch-Waxman Amendments to the FDCA, which require that the generic drug's label warnings must be the same as those of the originally approved branded drug.

The Court first rejected the plaintiffs' contention that generic drug manufacturers are permitted to update unilaterally, *i.e.*, without prior FDA approval, drug labels to include stronger or different warnings through the FDA's "changes-being-effected" (CBE) process. Relying on the FDA's interpretation of its own rules, the Court concluded that a generic drug manufacturer can only use the CBE process to conform its drug's label with that of a corresponding brand-name drug. Similarly, the Court adopted the FDA's view that generic drug manufacturers cannot use so-called "Dear Doctor letters" to obtain FDA permission to use stronger or additional warnings than those already found on the drug's label.

"The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."

OPINION OF THE COURT

The Court then concluded that it was impossible for the defendants to comply with both the state law duty to "attach a safer label to [the defendants'] generic [drug]," and the federal law requirement that "generic drug labels be the same at all times as the corresponding brand-name drugs." "If the [defendants] had independently changed their labels to satisfy their state-law duty," according to the Court, "they would have violated federal law."

"[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, . . . that party cannot independently satisfy those state duties for preemption purposes."

OPINION OF THE COURT

The plaintiffs maintained, with support from the FDA, that generic drug manufacturers could petition the FDA to take action to change the bio-equivalent branded drug labeling to include stronger warnings, which change if granted would have mandated an identical change in the FDCA required generic label. The Court, however, found this argument unpersuasive in defeating "impossibility" conflict preemption because "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." "[W]hen 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 state duties for preemption purposes."

"[C]ourts should not strain to find ways to reconcile federal law with seemingly conflicting state law."

JUSTICE THOMAS, writing for a plurality of the Court

In a portion of the opinion not joined by Justice Kennedy—and therefore not part of the Court's decision—Justice Thomas explained that the Constitution's Supremacy Clause "suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law."

Justice Sotomayor, joined by Justices Ginsburg, Breyer, and Kagan, dissented. Justice

"[The Court] invents new principles of pre-emption law out of thin-air to justify its dilution of the impossibility standard."

JUSTICE SOTOMAYOR, dissenting

Sotomayor emphasized the "demanding standard" imposed on defendants claiming preemption, and accused the Court of "invent[ing] new principles of preemption law out of thin air . . . ." Under yesterday's ruling by the Court, Justice Sotomayor posited, the defendants can prove preemption even though they have demonstrated a mere "hypothetical or potential conflict" between state and federal requirements because the defendants never asked the FDA for a change to the branded label. Before finding preemption in this case, Justice Sotomayor would have required the defendants to produce "clear evidence that the FDA would not have approved a change to the label." According to Justice Sotomayor, this approach is consistent with the Court's ruling in *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Court held that federal law did not preempt state-law labeling requirements imposed on brand-name drug manufacturers.

IMPLICATIONS

The Supreme Court's decision effectively gives generic drug manufacturers more protection from state law failure-to-warn claims than is currently afforded to brand-name drug manufacturers. Unlike the brand-name drug manufacturers, who after *Wyeth v. Levine*, 555 U.S. 555 (2009), were denied a conflict preemption defense to state law claims that FDA approved warnings were insufficient on the ground that the branded drug owner has the ability under the FDA's CBE process to change its labeling immediately pending FDA approval, yesterday's *Pliva, Inc. v. Mensing* decision means that generic drug manufacturers can rely on a federal preemption defense to defeat state law failure-to-warn claims so long as the generic drug label at issue has met the federal requirement of being identical to the corresponding brand-name drug label. Justice Thomas recognized the irony for claimants of this disparity in legal treatment of their claim based solely on whether the drug filled for them was generic rather than the original branded version, but held for the majority that this result is dictated by the statutory and regulatory schemes at issue.

It will also be interesting to learn whether the decision comes to be perceived by consumers to provide added value to purchasing branded rather than generic versions of drugs.

For further information about this decision, please feel free to contact members of the Firm's Litigation Department, including:

New York City:

Mark G. Cunha
212-455-3475
mcunha@stblaw.com

David W. Ichel
212-455-2563
dichel@stblaw.com

Mary Elizabeth McGarry
212-455-2574
mmcgarry@stblaw.com

Barry R. Ostrager
212-455-2655
bostrager@stblaw.com

Washington, D.C.:

Peter C. Thomas
202-636-5535
pthomas@stblaw.com

UNITED STATES

New York
425 Lexington Avenue
New York, NY 10017
+1-212-455-2000

Los Angeles
1999 Avenue of the Stars
Los Angeles, CA 90067
+1-310-407-7500

Palo Alto
2550 Hanover Street
Palo Alto, CA 94304
+1-650-251-5000

Washington, D.C.
1155 F Street, N.W.
Washington, D.C. 20004
+1-202-636-5500

EUROPE

London
CityPoint
One Ropemaker Street
London EC2Y 9HU
England
+44-(0)20-7275-6500

ASIA

Beijing
3919 China World Tower
1 Jian Guo Men Wai Avenue
Beijing 100004
China
+86-10-5965-2999

Hong Kong
ICBC Tower
3 Garden Road, Central
Hong Kong
+852-2514-7600

Tokyo
Ark Mori Building
12-32, Akasaka 1-Chome
Minato-Ku, Tokyo 107-6037
Japan
+81-3-5562-6200

SOUTH AMERICA

São Paulo
Av. Presidente Juscelino Kubitschek, 1455
São Paulo, SP 04543-011
Brazil
+55-11-3546-1000