Pliva, Inc. v. Mensing: Divided Supreme Court Finds FDA Warning Label Regulations Preempt State Tort Claims

On June 23, 2011, in *Pliva, Inc. v. Mensing*, the Supreme Court, in a 5–4 decision, held that federal law and FDA regulations preempted state law tort claims against generic drug manufacturers over the inadequacy of their warning labels.[1] In overturning contrary decisions by the Fifth and Eighth Circuits, the Court clarified the required "impossibility" that defendants must demonstrate to sustain a conflict preemption defense under the Supremacy Clause of the United States Constitution.[2]

I. Facts and Procedural History

Regalin is a brand-name drug consisting of metoclopramide tablets and is used to treat certain digestive tract disorders.[3] Plaintiffs Gladys Mensing and Julie Demahy were both prescribed Regalin in 2001 and 2002, respectively. Following initial FDA approval in 1980, studies of metoclopramide revealed that long-term use of the drug can cause tardive dyskinesia, a severe neurological disorder.[4] Accordingly, the warning labels for both Regalin and its generic counterparts have been strengthened over time.

Plaintiffs each received a generic form of metoclopramide. After taking the drug for several years, both developed tardive dyskinesia. In separate suits,[5] Plaintiffs claimed that Defendants, manufacturers of generic metoclopramide (the "Manufacturers"), violated state tort law when they failed to update their warning labels. Plaintiffs alleged that the Manufacturers knew that the labels did not accurately convey the risks of the drug. The Manufacturers argued that, even if they had an obligation to change their warning labels under state law, federal laws required the Manufacturers to maintain the same warning label as their brand-name counterpart, which, at the relevant time, did not contain the more stringent warnings related to the potential to develop tardive dyskinesia. The Manufacturers argued that because they could not abide by both their state and federal obligations, Plaintiffs' state law claims were preempted by federal law. Both the Fifth and Eighth Circuits held that the federal laws at issue did not preempt state tort law.

II. The Supreme Court's Decision

The Supreme Court, in a 5–4 decision authored by Justice Thomas, reversed the Fifth and Eight Circuits. The Court examined state law and concluded that if the Manufacturers were aware that their warning labels were deficient, they had a duty under state law to provide stronger warning labels.[6] Federal law, however, requires that generic drugs have the same labels as their brand-name counterparts.[7] Moreover, under FDA regulations, the

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1 Nos. 09–993, 09–1039, and 09–1501, slip op. (2011), available at http://www.supremecourt.gov/opinions/10pdf/09-993.pdf.

2 U.S. Const. art. VI, cl. 2.

3 *Pliva* at 2. These include diabetic gastroparesis and gastroesophageal reflux disorder. *Id.*

4 *Id.* "Studies have shown that up to 29% of patients who take metoclopramide for several years develop this condition." *Id*.

5 The Court consolidated Plaintiffs' cases when granting certiorari. *Id*. at 1.

6 *See id.* at 4–5. In particular, this case concerned the tort laws of Minnesota and Louisiana. *See id.* at 4.

7 *Id.* at 6 (citing 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7)).

Manufacturers could not unilaterally change their warning labels unless they did so "to match an updated brand name label or to follow the FDA's instructions."[8]

It was also possible for the Manufacturers to propose updated warning labels if they believed such labels were needed. The Court assumed, for the purposes of its ruling, that federal law imposed upon the Manufacturers a duty to propose new warnings to the FDA when they discovered that their warnings were inadequate. Had the Manufacturers done so, the FDA would have then worked with the brand-name manufacturer to create a new label for both the brand-name and generic drugs. The Court noted, however, that even if the Manufacturers had followed this course of action, there was no guarantee that a stronger label would be adopted.

Based upon this regulatory framework, the Court found that it was "impossible" for Defendants to abide by both their state and federal labeling obligations, and thus federal law preempted Plaintiffs' state law claims. The Court held that "state and federal law conflict where it is impossible for a private party to comply with both state and federal requirements."[9] The Court observed that "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."[10] In the Court's view, the Manufacturers' obligation to "ask the FDA for help in strengthening the corresponding brand-name label" was irrelevant.[11] Simply put, the Court concluded that "[s]tate law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label."[12]

The Court clarified that the proper inquiry for "impossibility" is whether "the private party could independently do under federal law what state law requires of it."[13] The Court opined that any other interpretation of impossibility that took account of conjecture as to what a third party might have done would make conflicts between state and federal law "illusory."[14] In the instant case, for example, the Manufacturers could have petitioned the FDA to help change their warning labels, but they also technically could have petitioned the FDA to change its regulations altogether, or petitioned Congress to change the underlying laws. The Court concluded that if the Supremacy Clause was to have any meaning, such limitless reasoning was unacceptable.

The Court broadly held that "[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."[15] Consistent with that holding, the Court distinguished *Wyeth v. Levine*.[16] In *Wyeth*, the Court found no conflict preemption where the defendant was a brand-name drug manufacturer and FDA regulations permitted the defendant to unilaterally

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8 *Id.* at 7 (interpreting 21 CFR § 314.94(a)(8)(iv)).

9 *Id.* at 11 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995)) (internal quotation marks omitted).

10 *Id*. at 12.

11 *Id*.

12 *Id*. The Court also observed that Plaintiffs denied that "their state tort claims [were] based on the Manufacturers' alleged failure to ask the FDA for assistance in changing the labels." *Id*.

13 *Id*.

14 *Id.* at 14.

15 *Id.* at 17.

16 555 U.S. 555 (2009).

strengthen its warning label, albeit subject to FDA approval.[17] In the instant case, however, the Manufacturers had no such power.

III. The Plurality Opinion

Justice Kennedy did not join Part III.B.2 of Justice Thomas' opinion, in which a plurality of the Court looked at the structure of the Supremacy Clause and concluded that federal courts should not "strain to find ways to reconcile federal law with seemingly conflicting state law."[18] In analyzing the Supremacy Clause, Justice Thomas focused upon the language that federal law shall be supreme, "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[19] Justice Thomas concluded that this provision "plainly contemplates conflict preemption by describing federal law as effectively repealing contrary state law."[20] In interpreting the provision, Justice Thomas relied upon the principle of interpretation "*non obstante*," which "specif[ies] the degree to which a new statute was meant to repeal older, potentially conflicting statutes in the same field."[21] The plurality held that, in resolving questions of preemption, a court should "look no further than the ordinary meanin[g] of federal law" and "should not distort federal law to accommodate conflicting state law."[22]

IV. The Dissenting Opinion

Justice Sotomayor, writing for Justices Ginsburg, Breyer, and Kagan, dissented on the grounds that, in her view, the Manufacturers had not met the "demanding defense" of impossibility preemption.[23] The dissenters believed that the Manufacturers had only asserted the "mere possibility of impossibility"[24] and that by simply stating that they could not change their warning labels without at least first resorting to the mechanism at their disposal — presenting a stronger label to the FDA — they had, at best, "demonstrated only a hypothetical or potential conflict."[25] Noting that the burden of proving impossibility falls on the defendant, the dissent would have held "that federal law does not render it impossible for generic manufacturers to comply with a state-law duty to warn as a categorical matter."[26]

Furthermore, Justice Sotomayor took issue with Justice Thomas's opinion, noting that "a plurality of the Court tosses aside our repeated admonition that courts should hesitate to conclude that Congress intended to preempt state laws governing health and safety."[27] The dissenting opinion characterized Justice Thomas, and a

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17 *Pliva* at 18. *See also id.* at 14 (Sotomayor, J., dissenting) (pointing out that changes to defendant's warning label in *Wyeth* were still subject to FDA approval).

18 *Id.* at 15.

19 *Id.* (quoting U.S. Const. art. VI, cl. 2).

20 *Id.*

21 *Id.*

22 *Id.* at 16 (quoting *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring)) (internal quotation marks omitted) (alterations in original).

23 *Id.* at 9 (Sotomayor, J., dissenting) (quoting *Wyeth*, 555 U.S. at 573).

24 *Id.* at 10.

25 *Id.* at 11 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)) (internal quotation marks omitted).

26 *Id.* at 13.

27 *Id.* at 2.

plurality of the Court's reading of the Supremacy Clause, as a "direct assault" on precedent that applied a "presumption against preemption both where Congress has spoken to the preemption question and where it has not."[28]

V. Significance of the Decision

The decision is potentially very significant for entities working in industries that are heavily regulated by federal agencies. The Court's decision indicates that the mere theoretical availability of a method allowing an entity to comply with state law will not defeat a preemption defense where, in order to comply with state law, the entity must obtain initial approval, as opposed to subsequent approval, from a federal agency.

Moreover, the decision creates distinctions between remedies available to brand-name and generic prescription drug users, which the dissenting opinion observes, in that "[c]onsumers of brand-name drugs can sue manufacturers for inadequate warning; consumers of generic drugs cannot."[29] Given these distinctions, which may or may not have been contemplated when the regulations were promulgated, the FDA may rethink its regulations with respect to labeling requirements.

Finally, the plurality opinion calls into question the validity of the previously established "presumption against preemption."

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Charles A. Gilman at 212.701.3403 or cgilman@cahill.com; John Schuster at 212.701.3323 or jschuster@cahill.com; Jon Mark at 212.701.3100 or jmark@cahill.com; or Whitney Smith at 212.701.3571 or wsmith@cahill.com.

[28] *Id.* at 17.

[29] *Id.* at 21.