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1st Circ. Strengthens Preemption For Brand-Name Drug Cos.

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On Feb. 20, 2015, the First Circuit in In re: Celexa and Lexapro Marketing and Sales Practices Litigation affirmed the dismissal of plaintiffs' state law consumer protection claims against a brand-name pharmaceutical manufacturer, concluding they were impliedly preempted by the Federal Food, Drug, and Cosmetic Act. This decision represents the first time since the U.S. Supreme Court's decision in Wyeth v. Levine, 555 U.S. 555 (2009), that a federal appellate court has dismissed claims against a brand-name drug manufacturer pursuant to the "impossibility" preemption doctrine.

Background

In Marcus, plaintiffs filed a putative class action against Forest Laboratories Inc., the manufacturer of brand-name pharmaceutical Lexapro, contending the label overstated the product's efficacy in treating major depressive disorder in adolescents. To establish efficacy for this indication, Forest previously submitted to the U.S. Food and Drug Administration the results of four clinical studies, two of which found no efficacy and two of which found "positive efficacy that was statistically significant, but only barely so." Notwithstanding these findings, the FDA approved the indication in March 2009, and approved the text of the Lexapro label, finding it was not "false or misleading in any particular." The district court granted Forest's motion to dismiss and the plaintiffs appealed.

Preemption Analysis

On appeal, the First Circuit found the plaintiffs' state law claims were impliedly preempted by the FDCA pursuant to the "impossibility" preemption doctrine. This doctrine recognizes state law is preempted when it "requires a private party to violate federal law," thus rendering it impossible to comply with both. In reaching its conclusion, the First Circuit examined the Supreme Court's recent decisions governing application of the "impossibility" preemption doctrine in pharmaceutical litigation.

In PLIVA Inc. v. Mensing, 131 S.Ct. 2567 (2011), the Supreme Court held that state law claims against manufacturers of generic pharmaceuticals were preempted because FDA regulations require the warning labels of generic drugs and their brand-name counterparts to always be the same. Although generic manufacturers can modify the language of a warning label with FDA preapproval, the Supreme

Court held this was not enough to avoid preemption. Mensing, 131 S.Ct. at 2581 ("[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.").

In contrast, the Supreme Court in Levine held that identical claims against a brand-name manufacturer were not preempted. Under the FDA's Changes Being Effected (CBE) regulation, 21 C.F.R. § 314.70(c)(6)(iii), brand-name manufacturers under certain circumstances are permitted to independently modify the language of an FDA-approved label. Thus, where the CBE procedure is available, a state law penalizing brand-name manufacturers for not exercising their ability to modify their warning labels is not preempted.

Reconciling Mensing and Levine, the First Circuit held "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." Marcus, 779 F.3d at 41 (quoting Mensing, 131 S.Ct. at 2579).

In Marcus, the plaintiffs' allegations of inadequate labeling were based on information the FDA had already considered in its approval of Lexapro, namely the clinical studies purportedly showing no or minimal efficacy. Because the CBE procedure is only available to make changes that, among other things, are based on "newly acquired information," the First Circuit concluded that the procedure was not available to Forest, as the plaintiffs' claims were not premised upon old information the FDA had already considered, not "newly acquired information." Accordingly, Forest could not have independently done what plaintiffs contended was required by California law, and the plaintiffs' claims were preempted.

Significance

The Marcus decision represents a significant victory for manufacturers because it is the first time since Levine was decided that a federal appellate court has applied "impossibility" preemption in the context of brand-name pharmaceuticals. Following Levine, district courts overwhelmingly rejected preemption arguments proffered by brand-name manufacturer defendants, even in cases where the CBE procedure was unavailable, preferring instead to limit the reasoning of Mensing to generic pharmaceuticals only. The Marcus decision parts from this line of cases and breathes new life into the argument that implied preemption should apply, regardless whether the product is brand-name or generic when a manufacturer defendant cannot, without FDA approval, do what the plaintiffs contend should have been done under state law.

There are many actions, including labeling actions, that manufacturers are not authorized to perform unilaterally in the absence of prior FDA approval. For example, a black box warning can be added to a drug label only when specifically required by the FDA. Likewise, a manufacturer cannot unilaterally modify a drug label in a manner that "has a substantial potential to have an adverse effect on the identity, strength, quality, purity or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." 21 C.F.R. § 314.70(b). This includes modifications to the dosage strength or dosage form. Under the reasoning of Marcus, any contention that a defendant manufacturer should have unilaterally performed these actions (i.e., that it should have added a black box warning in relation to a particular risk or should have offered an approved drug in a different dosage) should be preempted.

Accordingly, while the result in Marcus hinged on the court's conclusion that plaintiffs' claims were not based on information that was "newly acquired" — thereby rendering the CBE procedure unavailable to defendant — the reasoning of the decision should have a practical impact that extends well-beyond the facts of the case, and that should bolster preemption arguments in other contexts where FDA involvement is required before manufacturers are authorized to take action.

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