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202.588.0302

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FIRST CIRCUIT BREATHES NEW LIFE INTO BRANDED DRUG PREEMPTION DEFENSE

by
Andrew T. Bayman, Mark S. Brown,
Jeffrey S. Bucholtz & Todd P. Davis

On February 20, 2015, the U.S. Court of Appeals for the First Circuit held that federal law preempts claims that a branded drug manufacturer violated California consumer protection laws. In doing so, the court focused on interpreting the U.S. Supreme Court's 2009 *Wyeth v. Levine* decision in the context of the justices' 2001 *PLIVA Inc. v. Mensing* ruling. The appeals court held that these two cases "draw [a line] between [labeling] changes that can be independently made… and changes that require prior FDA approval."[1] *In re Celexa & Lexapro* breathes renewed life into preemption as a defense for branded drug companies.

Background. The Food and Drug Administration (FDA) approved Forest Laboratories' Lexapro to treat major depressive disorder in adolescents in 2008. The plaintiffs alleged that Forest omitted material efficacy information from Lexapro's label in violation of California's Consumer Legal Remedies Act and two other California laws, including that Lexapro was no more effective for adolescents than a placebo. They also alleged that Lexapro's FDA-approved labeling overstated the medication's efficacy for adolescents because Forest supposedly manipulated Lexapro's efficacy data, and the efficacy data did not actually show a true statistically significant difference from the placebo.

The district court dismissed the claims under a California state-law doctrine and did not rule on Forest's federal preemption defense.[2] On appeal, the First Circuit affirmed the dismissal on the basis of federal preemption.

Basis for Preemption. The court evaluated the two pathways manufacturers can utilize to change a product's labeling under the federal Food, Drug, and Cosmetic Act (FDCA). The first requires FDA approval of a proposed labeling change prior to distribution with the new label. The second—the Changes Being Effected (CBE) regulation—permits a manufacturer to make certain changes to product labeling unilaterally, without prior FDA approval, but only if newly acquired information supports the modification under the standards set forth in the CBE regulation.

In *Mensing*, which involved a state-law claim against a generic drug maker, the Supreme Court reasoned that a manufacturer can only be required under state law to do what it can do independently under federal law. Applying that reasoning, the First Circuit determined that *Mensing* limited *Wyeth*'s rejection of a preemption defense to "situations in which the drug manufacturer can, 'of its own

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[1] *In re Celexa & Lexapro Mktg. Sales Practices Litig. (Marcus v. Forest Labs., Inc.),* 2015 WL 727970, *7 (C.A.1 (Mass.)) (*Hereinafter* "*In re Celexa & Lexapro*").

[2] *See In re Celexa & Lexapro Mktg. Sales Practices Litig. (Marcus v. Forest Labs., Inc.*), No. 13-11343-NMG, 2014 WL 866571 (D. Mass. Mar. 5, 2014).

volition … strengthen its label in compliance with its state tort duty.'"[3] The court explained how drawing the line at this point lets FDA be the exclusive judge of safety and efficacy information provided to it. It determined that *Wyeth* circumscribes the initial evaluation and approval of labeling for prescription medications as solely FDA's territory.

Within that intellectual framework, the court examined whether the plaintiffs identified a labeling deficiency that Forest could have remedied through the CBE pathway. Because the CBE pathway may only be used to change the labeling to reflect "newly acquired information," and FDA had considered the information that the plaintiffs claimed Forest had manipulated, the court found that the plaintiffs failed to allege any new information. Without new information to justify a change to Lexapro's labeling under the CBE regulation, Forest could not have independently changed its labeling, and thus the FDCA preempted the plaintiffs' state-law claims.

Analysis. After *Wyeth*, the plaintiffs' bar sounded the death knell for preemption as a viable defense for branded drug makers. The First Circuit's decision, as well as others, shows that this view is incorrect.[4] Instead, *Mensing* refocused the preemption inquiry on a straightforward legal question: could the manufacturer have used the CBE pathway to unilaterally change its labeling in the way the plaintiff contends state law required? The CBE regulation does not permit any and all labeling changes, but rather only ones that meet its legal standards, and *In re Celexa & Lexapro* presented a situation where a CBE labeling change was not appropriate. Because the First Circuit clarified that *Mensing*'s rationale applies equally to claims against generic *and* branded drug makers, brand defendants should carefully evaluate and apply *In re Celexa & Lexapro* in future cases involving state-law claims.

Andrew T. Bayman and **Todd P. Davis** are partners in the Atlanta office of the law firm King & Spalding LLP. **Mark S. Brown** and **Jeffrey S. Bucholtz** are partners in the firm's Washington, D.C. office.

[3] *In re Celexa & Lexapro* at 6.

[4] *See, e.g., Glynn v. Merck Sharp & Dohme Corp. (In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.,* 951 F. Supp. 2d 695 (D.N.J. 2013).