Client Update
First Circuit Holds That Federal Law Preempts State-Law Claims Involving a Branded Drug Label

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On February 20, 2015, the U.S. Court of Appeals for the First Circuit (the "First Circuit" or "Court") affirmed a district court's dismissal of a consumer fraud complaint by holding that state-law claims asserting that a branded drug label is false or misleading are impliedly preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 301 *et seq.* ("FDCA"). The decision in *In re Celexa & Lexapro Marketing & Sales Practices Litigation*[1] applied principles from recent U.S. Supreme Court cases concluding that state-law claims challenging generic drug manufacturers' labeling are preempted. The First Circuit's ruling demonstrates that preemption remains a viable defense for branded drug manufacturers faced with state-law claims challenging the adequacy of drug labeling.

BACKGROUND

Prior to approving a new or supplemental drug application, the U.S. Food & Drug Administration ("FDA") must evaluate the drug's proposed labeling and make a determination that the labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d)(7); *see also* 21 C.F.R. § 314.125(b)(6). Once the drug is approved, manufacturers are required to distribute the drug with its FDA-approved labeling. Failure to do so can give rise to potential criminal liability for distributing a misbranded drug. *See* 21 U.S.C. §§ 331(c), 333(a), 352(a), (c).

Following approval, changes to an FDA-approved drug label must be preauthorized by the FDA except in limited circumstances. *See* 21 C.F.R. § 314.70(b)(2)(v)(A). The FDA's "Changes Being Effected" Regulation (the "CBE Regulation") permits manufacturers to unilaterally amend drug labels in order to make certain "moderate" or "minor" changes based on "newly acquired information." *Id.* § 314.70(c)(6)(iii). Such changes can include adding or

[1] *In re Celexa & Lexapro Mktg & Sales Practices Litig. (Marcus v. Forest Labs., Inc., et al.)*, No. 14–1290, 2015 WL 727970 (1st Cir. Feb. 20, 2015).

strengthening warnings regarding drug safety and administration, or deleting false, misleading, or unsupported indications for use or claims of effectiveness.

In May 2012, plaintiffs filed a putative class action complaint (the "Complaint") alleging that Forest was marketing the antidepressant Lexapro in violation of California consumer protection laws by distributing the drug with a misleading label. The Complaint alleged that Lexapro's label contains misleading information about the drug's efficacy for the treatment of adolescent depression (an FDA-approved use) by incorrectly or incompletely describing the results of applicable clinical studies. *In re Celexa & Lexapro*, 2015 WL 727970, at *3–4. In addition to monetary relief, plaintiffs sought a permanent injunction barring Forest from selling Lexapro with its FDA-approved label. *Id.*

THE FIRST CIRCUIT'S RULING

On March 5, 2014, U.S. District Judge Nathaniel M. Gorton, District of Massachusetts, dismissed the Complaint, concluding that plaintiffs' claims were barred by California's safe harbor doctrine.[2] The safe harbor doctrine exempts from liability conduct that was specifically authorized by state or federal law. The District Court concluded that distribution of an FDA-approved drug label qualifies for such exemption. On appeal, the First Circuit affirmed the District Court's dismissal of the Complaint on the alternative ground of federal preemption, and did not address the safe harbor ruling.[3] The First Circuit concluded that plaintiffs' claims are preempted because it is impossible for Forest to comply with both federal law and the state-law requirements plaintiffs sought to impose.

The First Circuit carefully examined the Supreme Court's recent preemption decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013). *Mensing* and *Bartlett* both concluded that the federal "Sameness Requirement" applicable to generic drugs[4] preempts state-law claims against generic drug

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2 *See In re Celexa & Lexapro Mktg. & Sales Practices Litig. (Marcus v. Forest Labs., Inc., et al.)*, No. 13–11343–NMG, 2014 WL 866571 (D. Mass. March 5, 2014).

3 The First Circuit expressly did not consider the District Court's dismissal of the Complaint based on California's safe harbor doctrine. Defenses based on state-law safe harbors remain viable.

4 The "Sameness Requirement" mandates that generic drugs bear the same product labeling as their branded drug equivalents. *See* 21 U.S.C. § 355(j)(2)(A)(v).

manufacturers premised on allegedly deficient drug labels.[5] By contrast, the *Levine* court found that state-law claims premised on an allegedly deficient branded drug label were not preempted because the manufacturer could have unilaterally made the labeling changes sought by plaintiffs pursuant to the CBE Regulation.[6] *Levine* found that new safety information had come to light following FDA approval, which enabled the manufacturer to pursue a unilateral labeling change under the CBE Regulation.

Interpreting these decisions, the First Circuit concluded that, under federal law, the FDA is the "exclusive judge of safety and efficacy based on information available at the commencement of marketing." *In re Celexa & Lexapro*, 2015 WL 727970, at *7. As such, state-law claims may only seek to impose labeling requirements that differ from an FDA-approved label "when new information not considered by the FDA develops" and where the CBE Regulation would permit the manufacturer to make a unilateral change without prior FDA approval. *Id.* at *6–7. By contrast, state-law claims premised on information already considered by the FDA amount to an improper attempt to second-guess the FDA's prior decision, and are preempted. *See id.*

The First Circuit scrutinized the allegations in the Complaint, concluding that plaintiffs had not identified any new information not considered by the FDA. Rather, they merely presented their own interpretations of clinical study data previously submitted to the FDA, and cited academic articles opining on the proper interpretation of that data. *Id.* at *8–9. As a result, the Court found that plaintiffs' claims, if successful, would require that Forest amend Lexapro's label to state conclusions inconsistent with those reached by the FDA. Because Forest could not make such changes unilaterally through the CBE Regulation without prior FDA approval, plaintiffs' claims were preempted. *Id.* at *9.

IMPLICATIONS

The First Circuit's decision makes clear that preemption defenses are available not only to generic drug manufacturers, but also to branded drug manufacturers. Plaintiffs' attorneys have argued that the Supreme Court precedents taken together mean that generic manufacturers are shielded by preemption (because

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5 *See Bartlett*, 133 S. Ct. at 2476–80 (holding state-law design-defect claims against generic manufacturer premised on inadequate labeling preempted because federal regulations require that generic labels conform to branded labels); *Mensing*, 131 S. Ct. at 2574–75 (same with respect to state law failure-to-warn claims).

6 *See Levine*, 555 U.S. at 568–81 (holding state-law failure-to-warn claims did not conflict with federal law).

they are required to follow the branded label), but branded manufacturers (who are free to make changes to their labels via the CBE Regulation) are not. As the First Circuit held, however, the CBE Regulation permits very limited changes based on information unknown to the FDA. Where plaintiffs argue that a defendant should have changed a branded drug label based on information that was known to the FDA, the claims are preempted.

The First Circuit's ruling may also support preclusion defenses to federal claims premised on FDA-approved drug labeling, including those brought under the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961 *et seq.* Federal claim preclusion is an evolving area of law, particularly in light of the Supreme Court's recent decision in *PomWonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), which held that a Lanham Act claim premised on allegedly misleading beverage labeling did not conflict with, and thus was not precluded by, the FDCA. In the context of prescription drugs, however, *In re Celexa & Lexapro* recognizes that an impossible conflict is presented by state-law claims that seek to impose labeling changes at odds with prior FDA determinations and which require FDA preapproval. As a result, any federal statutory claim premised on alleged deficiencies in an FDA-approved label that cannot be changed unilaterally by the manufacturer should also be precluded.[7]

Defendants seeking to establish preemption and preclusion defenses should take care to establish a clear record demonstrating that information on which plaintiffs rely in arguing for a different drug label was known (or at a minimum available) to the FDA when it reviewed and approved the label.

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Please do not hesitate to contact us with any questions.

[7] *See, e.g., Sandoz Pharm Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231-32 (3d Cir. 1990) (affirming rejection of Lanham Act claim premised on misleading pharmaceutical label).