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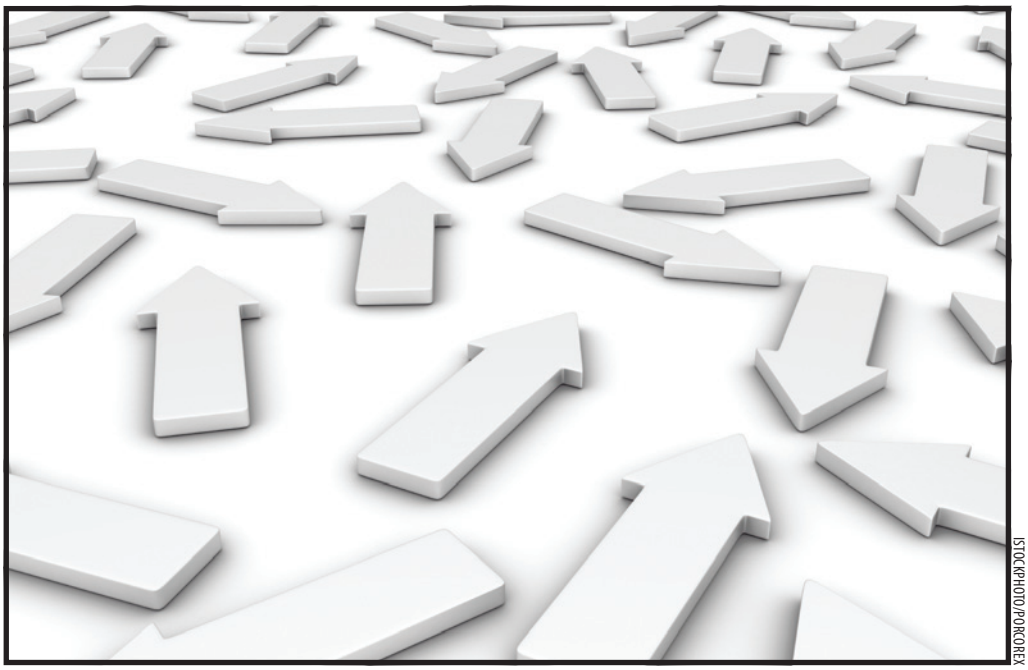
# Pre-emption jurisprudence yields few answers

Case law may vary by product, agency, state law cause of action or the particular judge ruling in the lawsuit.

BY J. RUSSELL JACKSON



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THE PRACTICE
Commentary and advice on developments in the law

The case law governing when federal law pre-empts state products liability law is perhaps the most infernal jurisprudence in the field of civil law. The answer to this seemingly simple question often can seem to depend on the product involved, the agency involved, the state law cause of action that is pleaded or the particular judges deciding the case.

For example, a few years ago the U.S. Supreme Court concluded that a state-law failure-to-warn claim would not conflict with federal regulation of brand-named prescription medicines, relying on the purely theoretical possibility that a manufacturer could change its label in limited circumstances without first obtaining Food and Drug Administration (FDA) approval. See *Wyeth v. Levine*, 555 U.S. 555 (2009). And yet, shortly thereafter, the court concluded that the same type of state-law failure-to-warn claim would conflict with federal regulation of the generic equivalent of such a brand-name medicine. See *Pliva v. Mensing*, 131 S. Ct. 2567 (2011).

So, for one doctor's prescription, the patient's state-law failure-to-warn claim is pre-empted if the pharmacist filled the prescription with a generic, but not if she filled it with a brand-name medicine. To nonlawyers—and many lawyers, too—this result makes no sense at all.

Predictably, the scattershot nature of pre-emption rules spawned by *Levine* and *Mensing* has led plaintiffs to creatively reshape their claims into other common-law causes of action. So for generic medicines, plaintiffs avoid pleading a traditional failure-to-warn claim. Instead, they plead that the manufacturer breached a duty to disclose facts to the FDA, or they allege that the manufacturer "defectively designed" the medicine because it was "unreasonably dangerous" and the manufacturer did not remove it from the market.

Judicial responses to these arguments have been mixed, with many recent decisions appearing to rest on whether the analysis should begin with a "presumption against pre-emption."

For example, in *Stengel v. Medtronic Inc.*, 2013 WL 106144 (9th Cir. January 10, 2013), an en banc panel of the U.S. Court of Appeals for the Ninth Circuit was faced with whether the state-law negligence claim of a plaintiff injured by a spinal-pain pump device had been pre-empted by the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act. The plaintiff claimed that the manufacturer had a duty to issue post-sale warnings about newly discovered risks associated with the product.

The MDA has an express provision that pre-empts state requirements that are "different from, or in addition to" the federal requirements. 21 U.S.C. 360k(a)(1). However, the implementing regulation has a savings clause that says the MDA "does not preempt State or local requirements that are equal to, or substantially identical to" the federal requirements. 21 C.F.R. 808.1(d).

Seven of the 11 judges on the en banc panel recognized that any traditional failure-to-warn claim based on a post-sale duty to warn would be pre-empted because although federal regulation allowed manufacturers to issue such warnings to doctors, it did not require post-sale warnings. Thus, the proposed state-law requirement would conflict with federal law. *Stengel*, 2013 WL

106144 at *9 (Watford, J., concurring).

But plaintiffs' counsel had been creative, pleading a new "duty" previously unrecognized in Arizona law requiring the manufacturer to notify the FDA of post-sale risk information about its products. Such a duty was not pre-empted, the plaintiff argued, because federal law already requires such reporting; this would be a state requirement that was consistent with, not different from, federal requirements. The concurring judges acknowledged that this newly created state-law duty would create difficult causation problems for plaintiff. To prevail, he would have to prove that if the defendant had reported to the FDA, the warnings would have reached his doctor in time to prevent his injuries. Id. at *10.

Nevertheless, the entire en banc panel held that this new state-law post-sale duty to warn was not pre-empted because it was consistent with and parallel to federal reporting requirements. In doing so, the en banc panel relied heavily on the presumption against pre-emption of state laws, based on the states' powers to protect the health and welfare of their citizens. See *Tigert v. Ranbaxy Pharmaceuticals Inc.*, 2012 WL 6595806 (D.N.J. December 18, 2012).

To reach this conclusion, the *Stengel* court had to distinguish *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in which the U.S. Supreme Court had held that so-called state "fraud-on-the-FDA" claims were pre-empted because they "inevitably conflict with the FDA's responsibility to police fraud [perpetrated on itself] consistently with the Administration's judgment and objectives." 531 U.S. at 350. *Buckman* held that there should be no presumption against pre-emption for "fraud on the agency" claims because "the relationship between a federal agency and the entity it regulates is inherently federal in character" in that it originates in federal—not state—law. Put differently, policing "fraud on the federal agency" is not the historic province of state governments, and thus state attempts to exert such power deserve no deference.

A number of decisions have refused to apply the presumption against pre-emption to state fraud-on-the-agency claims, ultimately holding that they are pre-empted because they conflict with federal enforcement powers. See, e.g., *Marsh v. Genentech Inc.*, 693 F.3d 546 (6th Cir. 2012) (claim that manufacturer failed to comply with federal regulations and thereby lost immunity under state statute "triggers the same concerns that animated *Buckman*… it is premised on violation of federal law, implicates the relationship between a federal agency and the entity it regulates, and asks the court to assume a role usually held by the FDA—and is thus preempted"); *Lofton v. McNeil Cons. & Specialty Pharm.*, 672 F.3d 372, 378 (5th Cir. 2012).

Indeed, last fall a federal court applied *Buckman* outside the products liability context to hold that a fraud-on-the-Coast-Guard claim was pre-empted. See *Offshore Service Vessels Inc. v. Surf Subsea Inc.*, 2012 WL 5183557 (E.D. La. October 17, 2012) (collecting other fraud-on-the-agency cases in various contexts).

## DESIGN-DEFECT CLAIMS

After the Supreme Court held that traditional failure-to-warn claims against generic drug makers were pre-empted in *Pliva v. Mensing*, a second way that plaintiffs sought to repackage their claims was by denominating them as "design defect" claims. A few courts have been receptive to such semantic changes. For example, in *Arters v. Sandoz Inc.*, No. 2:10-cv-142 (S.D. Ohio January 25, 2013), the plaintiff allegedly was blinded by the defendant's generic medicine and claimed that the company had a duty to refrain from selling the medicine because it was unreasonably dangerous and therefore defectively designed. Yes, the medicine was approved by the FDA and, as a generic manufacturer, federal law imposed upon the defendant a duty to make the medicine identical to the design of the brand-name drug. But, the plaintiff argued, no federal statute required the manufacturer to sell the drug in the first place, and thus a state could impose a requirement to refrain from selling it without "conflicting" with federal requirements. The district court agreed, holding that the state-law design-defect claim was not pre-empted.

However, as a federal district court recently reported in litigation over the anti-seizure drug Dilantin, "[T]he weight of authority overwhelmingly concludes that a failure to withdraw [a drug from the market] claim against a generic manufacturer is preempted by *Mensing*." *Frazier v. Mylan Inc.*, 2012 WL 6641626, at *5 (N.D. Ga. December 18, 2012) (collecting cases); see also *Demahy v. Schwarz Pharma Inc.*, 702 F.3d 177, nn. 7-8 (5th Cir. 2012) (collecting cases). In finding this form of design-defect theory against the generic drug maker to be pre-empted, the court noted that "the plaintiffs in *Mensing* raised a failure to withdraw claim in their petition for rehearing before the U.S. Supreme Court, but the Court denied the petition.…On remand, the Eighth Circuit interpreted *Mensing* to encompass a claim for failure to withdraw a drug from the market, and it vacated the portion of its earlier opinion that accepted a failure to withdraw theory." *Frazier*, 2012 WL 6641626 at *4 (citations omitted). Thus, according to the *Frazier* court, the Supreme Court and the Eighth Circuit already had held that the design-defect claim against manufacturers of generics is pre-empted.

The issue now is squarely before the Supreme Court in *Bartlett v. Mutual Pharmaceutical Co.*, 678 F.3d 30, 38 (3d Cir. 2012), cert. granted, 133 S. Ct. 694 (November 30, 2012) (No. 12-142). Regardless of how the Supreme Court handles the question, one can be certain that pre-emption questions will continue to be heavily disputed with increasingly creative theories and causes of action.

**J. RUSSELL JACKSON** *is a partner at New York's Skadden, Arps, Slate, Meagher & Flom.*