Latest Generic Preemption Decision

Friday, December 09, 2011

Those of you who check our post-Mensing generic preemption scorecard regularly are aware that a preemption massacre has been going on in Louisiana federal court. By our count, just since October there have been eight preemption-related dismissals down in pelican country (don't blame us, y'all put it on your license plate). Most of them have been pretty cut and dried, but the recent decision in Whitener, v. PLIVA, Inc., 2011 WL 6056546 (E.D. La. Dec. 6, 2011), warrants special mention.

In Whitener the plaintiffs made three arguments against preemption. The court rejected two and told plaintiffs to replead if they wanted to pursue the third. The first argument played off a footnote in Mensing, 131 S.Ct. at 2574 n.1, that the Court "express[ed] no view on the impact of the 2007 [FDAAA]." Plaintiffs claimed that, since their use of the drug was after FDAAA was passed, Mensing didn't apply. Okay, but so what? The plaintiff couldn't say. It was a distinction without a difference. The court found absolutely nothing FDAAA that altered the Food, Drug and Cosmetic Act ("FDCA") in any relevant way:

"Plaintiffs have not articulated, and the Court cannot find, any changes in the FDAAA to a generic drug manufacturer's ability to alter the FDA-approved brand-name label for a drug."

Whitener, 2011 WL 6056546, at *3. Because the FDAAA didn't change anything, Mensing preemption didn't change either. " In the absence of any such change . . . , compliance with both state and federal requirements remains impossible." Id.

Plaintiffs next tried to argue that, because their use of the drug had been off-label, that somehow allowed them to demand different warnings. The court found the argument peculiar because regardless of the nature of the actual use, the label was the label:

"There was an FDA-approved label without which Defendants could not have sold [the drug]. Defendants had no choice but to use that label and could not say more in warning, just as the generic manufacturers in Mensing could not. Thus, the fact that a doctor prescribed [the drug off-label] does not distinguish this case from Mensing. Defendants were bound by federal law to use the FDA-approved label and could not provide the additional warnings Plaintiffs allege should have been given. Plaintiffs' failure-to-warn claims are preempted."

Whitener, 2011 WL 6056546, at *4.

Beyond that plaintiffs in Whitener muttered darkly about "illegal" off-label promotion. The court told them that, if they wanted to make any argument on that ground, plaintiffs had better state explicitly who made what statements to whom, and how they were purportedly illegal under the FDCA. Id. at *5.

Thus the court did not pass on the legal viability of a supposed parallel violation claim in the Mensing implied preemption context. In that vein we simply note that the concept of "parallel" violations arose as an exception to the "different from, or in addition to" **express** preemption language in the Medical Device Amendments. It really should have nothing to do with the **implied** preemption analysis of Mensing, which deals with conflict, and not with comparing federal and state legal duties. See Guarino v. Wyeth LLC, ___ F. Supp.2d ___, 2011 WL 5358709, at *3 (M.D. Fla. Nov. 7, 2011).

Thanks to Kurt Karst at the FDA law blog for the tip.