# Not All Sunshine and Santa Claus For Generics Post-Mensing

**Tuesday, October 04, 2011**

When the Supreme Court decided Mensing, we imagine generic drug manufacturers felt like Stephen Sondheim's "Everything's Coming Up Roses" was written just for them. But, to borrow from another Broadway hit, they may now be asking the District of South Carolina "Don't Rain on My Parade."

Not surprisingly, as our generic preemption scorecard reveals, generic plaintiffs are throwing anything and everything at the walls in the hope that something sticks. And, some courts have been more accommodating to them than others. The most recent decision to keep claims against generic manufacturers alive is Fisher v. Pelstring, C.A. No. 4:09-cv-00252-TLW, slip op. (D.S.C. Sept. 30, 2011). Due to our involvement in the metoclopramide litigation, we can't offer extensive comment, but we can report what happened.

Unlike the other post-Mensing decisions we've discussed, this one turns on a factual uncertainty that was not addressed by the Supreme Court. Plaintiff argued that the generic defendant did not timely incorporate in its metoclopramide label certain FDA-approved warnings that were added to the brand label. Fisher, slip op. at 6. Because the plaintiff in Fisher was prescribed metoclopramide at a time when the generic label may not have been consistent with the brand label (which does not appear to have been the case in Mensing), the court found this "possible deviation" significant to the motion to dismiss. Id. at 6-7 & n.4. In essence, "[o]nce the FDA approved the addition of these warnings to the [brand] label" no "federal law prevented [the generic manufacturer] from also adding these warnings to its generic . . . products." Id. at 7. No conflict, no preemption.

So -- because plaintiffs will try anything -- we expect to see some additional probing by them on the question of whether generic drug labeling timely included the most recent update to brand warnings – at least in cases where the ingestion period coincides with any alleged lag time. And, therefore, we also expect generic manufacturers will have to defend the timeliness of their actions. But since absent the timeliness issue, preemption may well have won the day here, we won't call a rain delay yet – the parade is still going strong.

And the decision wasn't completely soggy, on the "bright lights and lollipops" side, the court did find several, of plaintiff's claims (express warranty, negligent misrepresentation and fraud) preempted because "plaintiffs have not identified any mechanism by which [defendant]

could have independently changed the [express warranty or allegedly false representations] without first seeking the federal government's special permission and assistance." Id. at 32-33, 38.