Generic Drug Preemption Scorecard

Tuesday, September 20, 2011

We've decided that, since PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), product liability preemption in the context of generic drugs has come into its own and should no longer be lumped in with the overall topic of drug/vaccine preemption. Thus we're bestowing a new scorecard on post-Mensing generic drug preemption decisions. We'll start with Mensing itself and go from there:

1. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (U.S. June 23, 2011) (metoclopramide). Hatch Waxman Act's requirement that generic drug labeling must stay the same as branded labeling preempts failure to warn claims against generic drug makers. Generic drug manufacturers cannot change their labels without prior FDA approval. Dear Doctor/DHCP letters cannot vary from generic drug labeling. The bare chance that the FDA, if approached, might agree to change both the generic and branded labels simultaneously, is insufficient to prevent preemption.

2. Keck v. Endoscopy Center, 2011 WL 3921690, slip op. (Nev. Dist. Aug. 19, 2011) (propofol). Granting partial summary judgment against preemption defense. Claim that generic defendants should have sent a Dear Doctor/DHCP letter consistent with the drug's labeling, and without any new or additional warnings, are not preempted. Plaintiffs cannot argue that the label on the drug itself should be changed. Refusing to defer to FDA view that generic manufacturers could not unilaterally send any such letters. State law failure to warn claims are preempted.

3. Demahy v. Actavis, Inc., ___ F.3d ___, 2011 WL 3659409 (5th Cir. Aug. 22, 2011) (metoclopramide). *Per curiam* order on remand from the Supreme Court, vacating and remanding for entry of judgment in favor of defendant on grounds of preemption.

4. Henderson v. Sun Pharmaceuticals Industries, Ltd, ___ F. Supp.2d ___, 2011 WL 4015658 (N.D. Ga. Aug. 22, 2011) (phenytoin and fosphenytoin). Motion to amend denied; motion to dismiss granted. Manufacturing-related warning letter sent to defendant did not relate to drug in question or to the plaintiff's alleged

injury. None of the allegations plead causation. State law failure to warn claims are preempted.

5. Scott v. Baxter Healthcare Corp., 2011 WL 4007675 (S.D. Ala. Sept. 9, 2011) (phenergan). Unopposed summary judgment granted. State law claims challenging the adequacy of generic drug labeling are preempted.

6. Brasley-Thrash v. Teva Pharmaceuticals USA, Inc., 2011 WL 4025734 (S.D. Ala. Sept. 12, 2011) (metoclopramide). Motion to amend granted in part and denied in part. Claim that generic defendants should have sent a Dear Doctor/DHCP letter consistent with the drug's labeling, and without any new or additional warnings, are not preempted. At the time of the prescription, the FDA did not require pre-approval of such letters. S tate law claims challenging the adequacy of generic drug labeling are preempted.

7. Beck v. Teva Pharmaceutical Industries Ltd., 2011 WL 4062219 (E.D. La. Sept. 13, 2011) (methotrexate). Motion to dismiss granted. State law claims challenging the adequacy of generic drug labeling are preempted.