Client Alert

March 14, 2013

Mind the Gap: Sixth Circuit Finds Room for Suit Against Generic Manufacturers After *Mensing*

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Yesterday, the Sixth Circuit issued its decision in *Fulgenzi v. PLIVA, Inc.*, a case involving a state law claim for failure to warn against a generic drug manufacturer. Case No. 12-3504 (6th Cir. March 13, 2013). The court held that a failure-to-warn claim could proceed against a generic manufacturer that had failed to timely follow the brand-name label, creating a narrow exception to the preemption defense established by *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

In *Mensing*¸ the Supreme Court held that failure-to-warn claims against generic drug manufacturers were preempted. The Court reasoned that, because federal law requires generic manufacturers to maintain the "same" labels as that of the branded drug, generic manufacturers cannot independently change their drugs' labels.

After *Mensing*, numerous courts have dismissed failure-to-warn claims against generic manufacturers, finding that federal law preempted the claims. *See, e.g.*, *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011); *Gross v. Pfizer, Inc*., 825 F. Supp. 2d 654, 659 (D. Md. 2011); *Bowdrie v. Sun Pharm. Indus.*, No. 12-CV-853, 2012 U.S. Dist. LEXIS 161239, at **14-18 (E.D.N.Y. Nov. 9, 2012).

However, recent appellate court decisions have identified potential avenues for users of generic drugs seeking relief in court. *See Weeks v. Wyeth*, No. 1101397, 2013 Ala. LEXIS 2 (Ala. Jan. 11, 2013) (brand-name manufacturer could be liable for failure to warn a patient who ingested the generic drug); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (manufacturer could be liable for failing to report adverse events to the FDA). The Sixth Circuit's decision provides yet another path for plaintiffs claiming injury from a generic drug.

Eleanor Fulgenzi had taken metoclopramide, a generic equivalent of Reglan, from September to November 2004 and again in 2006 and 2007, resulting in tardive dyskinesia.

In July 2004, the FDA had approved a change to the brand-name labeling for Reglan: "**Therapy should not exceed 12 weeks in duration."** PLIVA did not update its own label for generic metoclopramide, and Fulgenzi sued. The district court applied *Mensing* in dismissing Fulgenzi's failure-to-warn claims. Fulgenzi appealed.

The Sixth Circuit found that PLIVA could not invoke preemption under this set of facts. The court emphasized that *Mensing* had relied on the impossibility for a generic drug manufacturer to comply simultaneously with its duty of sameness to the branded label and an alleged duty to strengthen its warning. In *Fulgenzi*, no such impossibility existed. The branded drug's label had already been updated. PLIVA could have updated its label without violating its duty of sameness.

The Sixth Circuit was careful to limit its holding. Liability might be found only to the extent a generic manufacturer's actions would be permitted under federal law. The decision does not allow plaintiffs to claim the generic manufacturer should have included a warning different than the FDA-approved warnings for the branded drug.

The court rejected the notion that Fulgenzi was simply attempting to enforce a federal law violation even though the Federal Food, Drug and Cosmetic Act excludes a private cause of action. Instead, Fulgenzi was asserting a failure-to-warn claim grounded firmly in state law. Where a traditional, preexisting independent state law tort was brought parallel to federal safety requirements, the state law claim would be allowed to continue. The Sixth Circuit did concede that evidence of federal law violations might be excluded under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that fraud-on-the-FDA claims are preempted) but noted there is a "gap" between *Mensing* and *Buckman* through which a plaintiff may pass.

Generic drug manufacturers should note this "gap" of liability and take steps to minimize their exposure. Under *Fulgenzi*, manufacturers cannot simply cite *Mensing* and rely on a preemption defense, but must show diligence and timeliness in keeping their labels up to date. Delay may be enough to defeat a motion to dismiss.

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