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Mind the gap: Sixth Circuit finds room for suit against generics after *Mensing*

Contributed by **Morrison & Foerster LLP**

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On March 13 2013 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.(1) The court held that a failure-to-warn claim could proceed against a generic manufacturer that had failed to follow the brand-name label in a timely manner, creating a narrow exception to the pre-emption defence established by *PLIVA, Inc v Mensing*.(2)

In *Mensing* the Supreme Court held that failure-to-warn claims against generic drug manufacturers were pre-empted. 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 pre-empted the claims.(3) However, recent appellate court decisions have identified potential avenues for users of generic drugs seeking relief in court.(4) 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 Food and Drug Administration (FDA) had approved a change to the brand-name labelling 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 pre-emption under this set of facts. The court emphasised 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 that a generic manufacturer's actions would be permitted under federal law. The decision does not allow plaintiffs to claim that 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, pre-existing 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*,(5) but noted that there was 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 minimise their exposure. Under *Fulgenzi*, manufacturers cannot simply cite *Mensing* and rely on a pre-emption defence; rather, they 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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Endnotes

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(1) Case 12-3504 (6th Cir March 13 2013).

(2) 131 S Ct 2567 (2011).

(3) See, eg, *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*, 12-CV-853, 2012 US Dist LEXIS 161239, at **14-18 (EDNY November 9 2012).

(4) See *Weeks v Wyeth*, 1101397, 2013 Ala LEXIS 2 (Ala January 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).

(5) 531 US 341, 348 (2001) (holding that fraud-on-the-FDA claims are pre-empted).