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And Yet Another Twist in Product Liability Litigation, Preemption and Generic Drug Liability

To quote Michael Corleone from the forgettable The Godfather: Part III, "Just when I thought I was out, they pull me back in." In 2011, we thought we had heard the last from the courts on whether preemption prevented generic drug manufacturers from being held liable under state failure-to-warn statutes. The answer was yes – preemption exists because they cannot comply simultaneously with their state duty to adequately warn in the labels and their federal obligation to have the same label as their branded drug counterpart. See PLIVA v. Mensing, 131 S. Ct. 2567 (2011). The 2011 decision followed the Court's 2009 holding that, regarding branded drug manufacturers, state failure-to-warn lawsuits were not preempted by federal law because branded manufacturers may strengthen the warnings in labels on their own initiative. See Wyeth v. Levine, 555 U.S. 555 (2009). Now, the trilogy continues with Fulgenzi v. PLIVA, (6th Cir. No. 12-3504, March 13, 2013). While this case has not reached the Supreme Court, it attempts to further define preemption and potential product liability claims against generic drug companies. In short, preemption might not apply in certain cases, as discussed below. The Sixth Circuit pulls us back in.[1]

Background

A woman brought a state tort lawsuit against a generic drug manufacturer for failing to include in its label the risks of developing tardive dyskinesia from extended treatment with metoclopramide. The branded drug's label had previously been updated with such a warning. By not including this risk in its label, the generic drug company failed to adequately warn, the plaintiff alleged. The generic drug company responded that the lawsuit was preempted, citing the Mensing decision. The district court granted the motion to dismiss, finding preemption under Mensing, among other reasons. The Sixth Circuit reversed and remanded the case.

While we will not summarize the Mensing and Wyeth cases here or detail the general requirements of generic drug labeling and the "sameness" requirement, we will review the Sixth Circuit's analysis and tease out the nuances, which might affect future failure-to-warn cases involving generic drug companies.

1 One month before the Sixth Circuit decision, the Fifth Circuit ruled in a strikingly similar case (same generic drug manufacturer and drug product, but slightly different state-law claims) and rejected the argument that a generic manufacturer could be held liable for failing to update the generic drug label to match a revised brand-name label. Morris v. PLIVA, (5th Cir. No. 12-30319, Feb. 14, 2013). This article focuses on the Fulgenzi ruling.

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The Sixth Circuit looked at two types of preemption – impossibility preemption and "purposes and objectives" preemption. The court found that the first type, where it is "impossible for a private party to comply with both state and federal requirements," (Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)) did not apply. Here, the generic drug company could have, and indeed was required to have, revised its product labeling to mirror the brand through a changes-being-effected supplement. (The court noted it was unlikely that FDA would have rejected the change.) Therefore, because compliance with state and federal rules was possible, and even required, impossibility preemption was "inappropriate."

The Sixth Circuit also reviewed whether state tort lawsuits against generic drug companies would frustrate the "purposes and objectives" of Congress and, therefore, require preemption. The court looked at the Federal Food, Drug, and Cosmetic Act and legislative intent and found that, "[i]t is hard to see how permitting state tort suits to go forward against sameness-violating generic defendants frustrates federal policies where permitting suits against FDA-*compliant* branded defendants does not." The Sixth Circuit concluded that "state laws that provide damages for inadequate warnings in violation of the federal duty of sameness do not conflict with federal drug policy, with respect to purposes-and-objectives preemption."

The court noted that the lawsuit was based on an independent state duty, not a violation of federal law. That is, the plaintiff alleged the inadequacy of the label warnings (i.e., old, outdated warning) as the cause of her injuries and did not rely primarily on the federal argument of sameness of brand and generic drug labels. Therefore, the Sixth Circuit said, "This is simply not grounds for preemption."

The Sixth Circuit acknowledged that, to avoid preemption, the plaintiff's claims would need to walk a fine line between Mensing and Buckman (which held state tort suits based on violations of federal law are preempted). That is, the plaintiff would have to argue that the generic drug company should have included the warning in the updated brand drug's label once that label was updated, and the failure to update proximately caused her injuries. Additionally, the court cautioned that the plaintiff will face potential federal law preemption challenges and must use the language of the updated brand drug label in the proximate-cause argument and not only the failure to update claim.

The Sixth Circuit did not find that the plaintiff would necessarily win her case. Rather, preemption did not apply and the lower court had to review the factual allegations. In addition, the case holding is limited to those courts in the Sixth Circuit (KY, MI, OH, and TN). It is too early to tell whether the Fulgenzi decision will become the prevailing view of other courts, particularly in light of the aforementioned Morris Fifth Circuit holding. In fact, it is not implausible that the circuit split may make the case more attractive for Supreme Court review. Ultimately, the cases are important as they attempt to further explain courts' interpretations of preemption principles in the context of generic drug labeling and liability. It is further evidence that each case is fact-based, and the final chapter in this area likely has not yet been written.