Products Liability Law Daily Wrap Up, PREEMPTION—DRUGS—Ill. App.: Widow's claims are on 'Target' in generic drug liability case, (Mar. 30, 2015)

By Bryant Storm, J.D.

Target Corporation and Teva Pharmaceuticals USA, Inc. (Teva) cannot rely on a federal preemption argument in a state law products liability and fraud action in which a patient who took a generic drug, which was manufactured by Teva and marketed by Target, became a spastic quadriplegic and died allegedly as a result of taking the medication, an Illinois appellate court ruled. The court would not adopt a position which would allow Target and Teva to market a generic drug—without economic consequence—that was known by the two companies to be useless and harmful simply because they were neither the brand name manufacturer nor officially halted by the Food and Drug Administration (FDA). The court held that the claims brought by the patient's widow were not preempted because she did not challenge the specifics of the labeling or design of the drug. Rather, she asserted that the drug should never have been sold at all (*Guvenoz v. Target Corp., Inc.*, March 27, 2015, Johnson, M.).

Injury. Lewis Guvenoz was given a prescription for a pain reliever, Darvocet. He filled his prescription at a Target pharmacy and purchased and ingested tablets of generic propoxyphene, allegedly manufactured by Teva. After ingesting the recommended dose, on May 13, 2010, he suffered a cardiac arrest, which caused serious brain injury. Later, allegedly as a result of his injuries, Guvenoz died. Nicole Guvenoz, Lewis' widow, brought a variety of fraud and products liability claims against Target, Teva, and Lewis' prescribing physician. Target and Teva moved to dismiss the complaint on the grounds that federal law preempted the widow's claims. The companies contended that at their core, her claims were an attack on the sufficiency of the labeling and warnings associated with the drug. According to Mrs. Guvenoz, her claims more broadly challenged the drug as unsafe and she maintained that the drug "should not have been sold at all." Her complaint stated clearly her belief: "this action is not, never has been, and never will be a failure to warn claim."

Darvocet. Risks associated with the drug were known prior to Guvenoz's injury. In 2005, the British government recalled the drug "because it could not identify any group of patients for whom the drug's benefits outweighed its risks." In January 2009, the FDA held an Advisory Committee meeting that voted against the continued marketing of propoxyphene. Also in 2009, the European Medicines Agency recommended the marketing authorization for propoxyphene be withdrawn across the European Union as a result of safety concerns. Six months after Guvenoz's cardiac arrest, the FDA required manufacturers to withdraw any products containing propoxyphene, including Darvocet from the U.S. market. The FDA decided that the drug's risks outweighed its benefits after a study showed that "propoxyphene causes significant changes to the electrical activity of the heart even when taken at recommended doses."

Preemption. After the trial court denied Target and Teva's motion to dismiss, the defendants filed a motion seeking appellate review of several preemption questions regarding whether precedent required the dismissal of an action for negligence in the design, manufacture, or distribution of a generic drug. Target and Teva relied on a line of cases preventing consumers from holding generic manufacturers liable for inadequacies in their products safety or warnings because of the FDA requirement that a generic drug serve as an equivalent of a brand name drug, in both chemical and labeling terms. Before the appellate court, Target and Teva asked whether each of Guvenoz's claims were preempted by the federal Food, Drug, and Cosmetics Act (FDC Act) (21 U.S.C. §301) requirement of sameness between a generic and brand name drug.

Safety. On appeal, Mrs. Guvenoz asserted that if Target and Teva's position was adopted, then purchasers of generic drugs would never have recourse against generic drug manufacturers and marketers simply because they chose a less expensive product. Additionally, the widow stressed that her case was unlike any precedent related to preemption and generic manufacturers because in the case of propoxyphene, there was no improved design or label which could have made the drug safer for certain patients because, as the FDA ultimately decided, the drug was unsafe for all patients.

Questions. In essence Target and Teva asserted that even though the drug was unsafe, they were operating

under a safe harbor provided by federal law. The court found that for each of the questions asked by Target and Teva on appeal, the marketer and manufacturer were mistaken in their readings of federal precedent. The court held that a claim against a generic manufacturer could proceed under Illinois law when the claim does not allege that the manufacturer should have altered the design or labeling of a drug in contravention of federal requirements. Therefore, the court ruled that irrespective of the FDC Act's sameness requirement, because Mrs. Guvenoz claimed that the drug should not have been sold or that Target and Teva engaged in fraud, the claims survived preemption.

The case is No. 12 L 005162.

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Companies: Target Corp.; Teva Pharmaceuticals U.S.A., Inc.

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