Alabama Supreme Court Holds Brand-Name Drug Manufacturer Liable for Ad Representations Made by Generic Drug Manufacturer

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The Alabama Supreme Court recently held in *Wyeth, Inc. v. Weeks*, – So.3d –, No. 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013) that a drug company may be held liable for fraud or misrepresentation (by affirmative misrepresentation or omission), based on statements it made in connection with the manufacture and distribution of a brand-name drug, by a plaintiff claiming physical injuries from the ingestion of a generic drug manufactured and distributed by a different company.

In *Weeks*, the plaintiff brought suit against Wyeth LLC and Schwartz Pharma, Inc., the manufacturers of the brand-name heartburn medication "Reglan," and Actavis Elizabeth LLC and Teva Pharmaceuticals USA, the manufacturers of a generic equivalent – metoclopramide – alleging that all defendants misrepresented and failed to adequately warn of the risks of using metoclopramide. The plaintiff filed his lawsuit in the U.S. District Court for the Middle District of Alabama, claiming that he had developed tardive dyskinesia, a movement disorder, after taking metoclopramide. He conceded that he did not ingest any Reglan. Wyeth and Schwartz Pharma moved to dismiss the lawsuit, claiming that they were not liable for injuries caused by another company's product, and the District Court certified the question to the Alabama Supreme Court. The Alabama Supreme Court determined that a brand-name manufacturer could be held liable for fraud or misrepresentation based on statements made concerning a brand-name prescription drug, even if the plaintiff claims that the injury was caused by the generic version of that drug manufactured by a different company. According to that court, it is reasonably foreseeable that a physician prescribing a drug would rely on the warning drafted by the brand-name manufacturer regardless of whether the plaintiff will ingest the generic equivalent.

The Alabama Supreme Court applied a 2011 U.S. Supreme Court decision – *Pliva, Inc. v. Mensing*, – U.S. –, 131 S. Ct. 2567 (2011) – which held that FDA regulations governing generic drug products directly conflict with and preempt state laws. More specifically, in *Mensing*, the Court held that generic drug manufacturers that use the same warning labels as those provided on brand-name drugs (and by the brand-name manufacturers) are shielded from liability under state tort law. Previously, generic drug manufacturers could be held liable under state law requiring that manufacturers strengthen the warnings on labels if they have knowledge of dangers associated with use of a drug. The federal Food, Drug & Cosmetic Act and related implementing regulations, in contrast, prohibits changes to generic drug labels except to match FDA-approved brand-name drug labels.

In December 2012, the U.S. Supreme Court granted certiorari in *Mutual Pharmaceutical Co. v.*

Bartlett, No. 12-142, to review whether a generic manufacturer can be held liable for design flaws in the brand-name drugs they copy. At the trial court and court of appeals, Mutual Pharmaceutical argued that, because it is a generic drug manufacturer and did not design the brand-name drug from which its drug was derived, it could not be liable for the drug's side-effects. A jury found Mutual Pharmaceutical liable and awarded the plaintiff more than $21 million in damages.

A Supreme Court decision in favor of the plaintiff could mean that consumers injured by generic drugs may be able to pursue liability against the brand-name drug manufacturer for the generic manufacturer's advertisements much in the same way as the Alabama Supreme Court held in Weeks. Such exposure to potential liability underscores the importance of a brand-name drug manufacturer ensuring that its advertising statements are truthful, non-misleading, and supported by competent and reliable scientific evidence, and that its product warnings are appropriate.