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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Mass. Court Ruling Eases Way For Brand Drug Label Claims

By **Emily Field**

Law360 (March 19, 2018, 11:10 PM EDT) -- The Massachusetts high court's ruling that Merck & Co. and other name-brand drugmakers can be liable under state law for mislabeled generics as long as consumers claim that a company acted recklessly in not updating the drug's label opens up a new path for consumers to bring claims against brand manufacturers in the state.

The Massachusetts Supreme Judicial Court's closely watched ruling creates a new standard for consumers of generic drugs who claim they were not warned of serious side effects to pursue claims against the original brand-name manufacturers.

This places Massachusetts in the minority of courts that have imposed a duty to warn generics consumers on brand-name manufacturers and makes it the only one to impose a standard of recklessness, as the court acknowledged in its opinion.

But while the state high court attempted to carve out a standard that sets a higher bar for plaintiffs, as compared to the negligence claims other courts have allowed, the standard might not work the way the high court intended, noted Susan Burnett of Bowman and Brooke LLP, as the definition of recklessness used by the court involves reasonableness.

"I'm not sure in practice that standard is really going to offer much protection to brand companies, although it's notable that the court tried to circumscribe a narrower duty than negligence," Burnett said.

The ruling found that while generic companies are immune from state law claims, as they have to copy the brand-name manufacturer's drug labeling, consumers can seek recompense from the brand-name company if they allege that it made a reckless decision to withhold information that should have been on the drug label.

Unlike negligence claims, claims brought by consumers alleging that a company acted recklessly must show the company knew about the risk and disregarded it, not just that the company acted unreasonably, Max Kennerly of Kennerly Loutey LLC said.

Proving recklessness does require some degree of showing the intent or knowledge of wrongdoing, Kennerly said.

The Massachusetts high court said in vacating a lower court's dismissal of Brian Rafferty's negligence claim against Merck over the erectile dysfunction, hypogonadism and testosterone deficiency allegedly caused by a generic

version of Merck's prostate drug Proscar that Rafferty could amend his complaint to bring claims that the company acted recklessly in deciding not to update the warning label if it knew of an unreasonable risk of death or grave bodily injury.

Another state high court has recently found that brand-name manufacturers could be liable for generic drug labeling, although it did not attempt to carve out a new standard as the Massachusetts high court did. At the end of 2017, the California high court ruled in T.H. et al. v. Novartis Pharmaceuticals Corp. that the company could be liable for negligent misrepresentation and failure to warn about the alleged dangers of a generic version of one of its drugs.

The issue of innovator liability has been left open since the U.S. Supreme Court decided in its 2011 ruling in Pliva Inc. v. Mensing that product liability and other claims against generic-drug makers are preempted by federal law mandating they copy brand-name warning labels, as the decision shielded generic manufacturers but didn't shift culpability to brand-name companies.

In carving out its recklessness standard, the state high court weighed the public policy implications of imposing negligence liability on brand name manufacturers, which could siphon away money that would otherwise be used to fund the research and development of new drug products, against consumers who would be left without a remedy for injuries tied to generic drugs.

Ultimately, the high court decided that brand name companies will have a greater financial incentive to update their warning labels, the court said, especially after their patents expire and their share of the market goes down.

The ruling creates a "time-unlimited" liability exposure to a brand drug company, said Alan Klein of Duane Morris LLP.

"The liability goes on forever, provided the plaintiff filed a timely complaint," Klein said.

There's an implication in the ruling that a brand-name manufacturer can never stop selling a drug because it will have an ongoing responsibility to monitor for adverse events, report them and update its label long after there's no longer an economic reason to keep selling the drug, Peter Goss of Blackwell Burke PA said.

"There's always an argument to be made by the plaintiffs' bar that the decision to discontinue selling the drug and no longer update labels was in reckless disregard of the safety of future patients," Goss said. "It really puts the innovator manufacturers in a quandary because they just can't follow the normal course when a drug goes generic."

In allowing Rafferty to replead his complaint, the state high court didn't define what it meant by grave bodily injury, David Geiger and Richard Baldwin of Foley Hoag LLP.

"Based on the fact that the court's allowing it to be repled under this alleged injury, it opens the door for other plaintiffs with other injuries to say well, when the court said grave bodily injury, they obviously included things more than severe limitations, paralysis, things like that," Baldwin said.

--Additional reporting by Alison Noon. Editing by Pamela Wilkinson and Alanna Weissman.