Makers of Opioid Addiction Treatment Drug Suboxone Accused of Conspiring to Keep Monopoly Profits

BALTIMORE, MD (September 22, 2016) - Maryland Attorney General Brian E. Frosh and 35 other attorneys general today filed an antitrust lawsuit against the makers of Suboxone, a prescription drug used to treat opioid addiction, alleging that the companies conspired to block generic competitors and cause purchasers to pay artificially high prices.

Reckitt Benckiser Pharmaceuticals, now known as Indivior, is accused of illegally conspiring with MonoSol Rx to switch Suboxone from tablet form to a film version that dissolves in the mouth in order to prevent or delay competition from generic alternatives and maintain monopoly profits. The companies are accused of violating state and federal antitrust laws.

Suboxone is a brand-name prescription drug used to treat heroin addiction and other opioid addictions by easing addiction cravings. No generic alternative to the film version is currently available.

“The defendants in this case have preyed on a vulnerable population—men and women trying overcome the scourge of opioid addiction,” said Attorney General Frosh. “Free and fair competition is necessary to keep drug prices affordable and to keep much-needed prescription drugs accessible to those who rely on them for treatment.”

According to the lawsuit, when Reckitt introduced Suboxone tablets in 2002, it had patent exclusivity protection that lasted for seven years, meaning no generic version could enter the market during that time. Before that period ended, however, Reckitt worked with MonoSol to create a new version of Suboxone—a dissolvable film, similar in size to a breath strip. Over time, Reckitt allegedly converted the market away from the tablet to the film through marketing, price adjustments, and other methods. Ultimately, after the majority of Suboxone prescriptions were written for the film, Reckitt removed the tablet from the U.S. market.

The attorneys general allege that this conduct was illegal “product hopping,” by which a company makes modest changes to its product to extend patent protections; other companies cannot then enter the market and offer cheaper generic alternatives. Reckitt also allegedly expressed unfounded safety concerns about the tablet version and intentionally delayed FDA approval of generic versions of Suboxone. In fact, according to the suit, the Suboxone film provided no real benefit over the tablet and Reckitt continued to sell the tablets in other countries even after removing them from the U.S. market.
As a result, the attorneys general allege, consumers and purchasers have paid artificially high monopoly prices since late 2009, when generic alternatives of Suboxone might otherwise have become available. During that time, annual sales of Suboxone topped $1 billion.

The lawsuit, filed in the U.S. District Court for the Eastern Division of Pennsylvania, accuses the companies of violating the federal Sherman Act and state laws including the Maryland Antitrust Act. Counts include conspiracy to monopolize and illegal restraint of trade. In the suit, the attorneys general ask the court to stop the companies from engaging in anticompetitive conduct, to restore competition, and to order appropriate relief for consumers and the states, plus costs and fees.

In addition to Maryland, the following jurisdictions have joined in the lawsuit: Alabama, Arkansas, California, Colorado, D.C., Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington and Wisconsin.

Attorney General Frosh thanks Assistant Attorneys General Ellen Cooper and Gary Honick for their work on this case.

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