

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

Delaware Attorney General Matt Denn and other attorneys general yesterday filed an antitrust lawsuit against the makers of Suboxone, a prescription drug used to treat opioid addiction, over allegations that the companies engaged in a scheme to block generic competitors and cause purchasers to pay artificially high prices.

Reckitt Benckiser Pharmaceuticals, now known as Indivior, is accused of conspiring with MonoSol Rx to switch Suboxone from a tablet version to a film (that dissolves in the mouth) in order to prevent or delay generic alternatives and maintain monopoly profits.

The companies are accused of violating state and federal antitrust laws.

“Deaths from opioid abuse remain a significant problem in Delaware, with statistics showing Delaware having the ninth highest drug overdose rate in the country in 2013,” said Attorney General Denn. “Medically assisted treatment of substance use disorder is an important part of addressing this problem, and the cost of such treatment is one of the barriers to providing it. So although we are concerned with any behavior that violates antitrust laws, our concern is heightened when the result is artificially heightened prices for a drug used to help address this critical problem in our state.”

According to the lawsuit, when Reckitt introduced Suboxone in 2002 (in tablet form), it had 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,” where a company makes modest changes to its product to extend patent protections so other companies can’t enter the market and offer cheaper generic alternatives. 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. Reckitt also allegedly expressed unfounded safety concerns about the tablet version and intentionally delayed FDA approval of generic versions of Suboxone.

As a result, the attorneys general allege that 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 antitrust laws. 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 Delaware, 35 attorneys general joined in the lawsuit.