A.G. Schneiderman Sues Manufacturer Of Opioid Addiction Drug For Illegally Blocking Competition

Indivior Abused Its Monopoly To Keep Generic Versions Of Suboxone Off The Market

Multistate Suit Seeks To Disgorge Indivior's Ill-Gotten Gains From Violations Of Antitrust Law

Schneiderman: My Office Continues To Combat Opioid Abuse, And Will Not Stand For Anticompetitive Conduct That Limits Treatment Options For Opioid Dependent Patients

NEW YORK – Attorney General Eric T. Schneiderman today announced that, together with the Attorneys General of 34 other states and the District of Columbia, his office has filed a lawsuit against Indivior, the manufacturer of the branded drug Suboxone, and MonoSolRX , the company that licensed its patented sublingual film technology to Indivior. Suboxone is used to treat patients addicted to heroin and other drugs, including painkillers. The lawsuit alleges that Indivior (which was spun off from Reckitt Benckiser in 2014) tried to coerce patients to switch from a tablet to a dissolvable oral strip version of Suboxone and engaged in other anticompetitive business practices to maintain Indivior's monopoly over Suboxone.

"My office will not permit drug companies to engage in anticompetitive conduct that unlawfully extends their monopolies – and their monopoly profits – on drugs," said **Attorney General Schneiderman**. "We will take decisive action against drug companies that engage in schemes to manipulate the cost and availability of treatment options to maximize corporate profits. Opioid abuse is a public health crisis, and opioid-dependent patients should have access to the most affordable addiction treatment options available."

Suboxone combines buprenorphine, an opioid used to treat people addicted to heroin and other drugs, with naloxone, which causes intense withdrawal symptoms and is intended to prevent abuse. Suboxone tablets were first approved for sale in the U.S. in 2002. Although Suboxone tablets lacked any patent protection, the FDA granted Indivior a seven-year "orphan drug" monopoly on Suboxone sales because the company was not expected to recoup its research and development costs (although Suboxone did in fact generate $2 billion in U.S. sales by 2010). Because Indivior's exclusive right to sell and market the drug in tablet form was set to expire in 2009, Indivior sought to prevent lower cost generic competition and maintain its monopoly by engaging in a range of anticompetitive conduct from 2008 until generic entry in 2013.

First, to thwart the entry of a generic version of Suboxone, Indivior informed the FDA in 2007 that it planned to introduce a new sublingual film (a dissolvable oral strip), version of Suboxone. Because the film version of Suboxone would not be the pharmaceutical equivalent of the tablet form, pharmacists would not be able to substitute a generic manufacturer's tablet version for the film version. If Indivior could introduce a film version of Suboxone and convince doctors and patients to switch to the film, they could prevent loss of sales to the generic tablet. To persuade the FDA to approve Suboxone film, Indivior claimed that the tablet version – which Indivior itself had marketed in the U.S. for nearly ten years – was unsafe because it presented a high exposure risk to children. The FDA approved Indivior's patented film version of Suboxone in August of 2010 but acknowledged that the film version may actually present more of a threat to children in the case of accidental exposure.

Indivior later reiterated its unfounded pediatric safety concerns as part of its strategy to delay the regulatory approval of a generic tablet version of Suboxone. In early 2012, the FDA ordered Indivior and potential generic manufacturers of the tablet version to participate in a shared Risk Evaluation and Mitigation Strategy to reduce the risk of pediatric exposure to the tablets. Indivior did not cooperate in this shared process. Instead, in September 2012, it filed a Citizen's Petition with the FDA requesting that the agency withhold approval of the tablet version – which Indivior had itself been marketing since 2002 – unless generic manufacturers could satisfy certain procedures to minimize pediatric exposure risks. This petition was ultimately rejected by the FDA, but, by the time generics were finally able to enter the market, Indivior had pulled its tablet

version from the market and converted the vast majority of the market to the film version (for which there was no generic substitute).

The multistate lawsuit alleges that Indivior engaged in these business practices with the purpose and effect of delaying regulatory approval of a cheaper generic tablet. New York and the other States seek disgorgement of the profits Indivior made as a result of the forced product switch from tablet to film. But for this "product hop," most patients taking Suboxone would have purchased generic tablets.

Defendant MonoSolRX conspired with Indivior to help Indivior thwart generic entry and achieve its illegal and anticompetitive "product hop" by licensing MonoSolRX 's patented film technology to Indivior.

The complaint was filed in the United States District Court for the Eastern District of Pennsylvania.

This matter is being led by Assistant Attorney Generals Amy McFarlane and Saami Zain of the Antitrust Bureau, with supervision by Elinor R. Hoffmann, Deputy Bureau Chief. The Antitrust Bureau is part of the Economic Justice Division, led by Executive Deputy Attorney General for Economic Justice Manisha M. Sheth.

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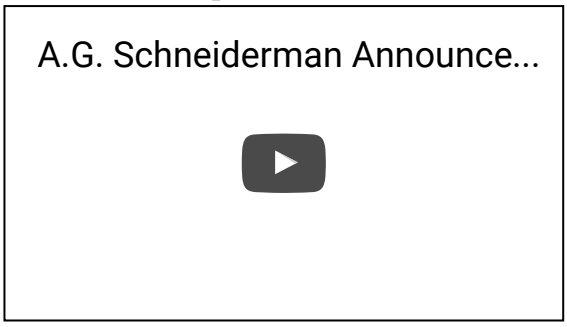

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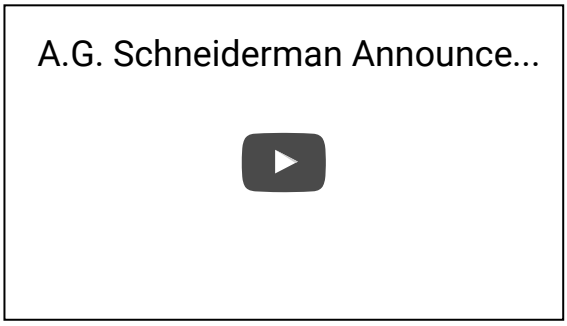

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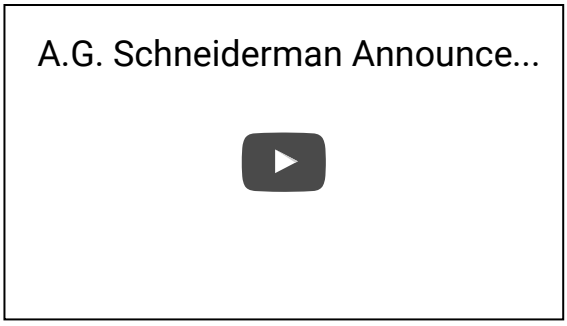

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