Reckitt Benckiser Group plc to Pay $50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone

FTC alleges company used anticompetitive tactics to impede competition from lower-cost generics

FOR RELEASE
July 11, 2019

Reckitt Benckiser Group plc has agreed to pay $50 million to settle Federal Trade Commission charges that it violated the antitrust laws through a deceptive scheme to thwart lower-priced generic competition to its branded drug Suboxone. Suboxone is a prescription oral medication used to minimize withdrawal symptoms in patients recovering from opioid addiction.

“Buprenorphine products are approved for use in the treatment of Americans struggling to overcome opioid addiction, and, in the middle of the nation’s opioid crisis, RB Group allegedly sought to deny those consumers a lower-cost generic alternative to maintain its lucrative monopoly on the branded drug,” said Gail Levine, a Deputy Director of the FTC’s Bureau of Competition.

Introduced in 2002, Suboxone quickly became a mainstay of opioid addiction treatment, according to the FTC’s complaint against Reckitt. But in 2009, Reckitt’s regulatory exclusivity for Suboxone was set to expire, and the company expected to face competition from lower-cost generics. According to the complaint, before the generic versions of Suboxone tablets became available, Reckitt and its former subsidiary Reckitt Benckiser Pharmaceuticals, now known as Indivior, Inc., developed a dissolvable oral film version of Suboxone and worked to shift prescriptions to this patent-protected film. Worried that doctors and patients would not want to switch to Suboxone Film, Reckitt allegedly employed a “product hopping” scheme where the company misrepresented that the film version of Suboxone was safer than Suboxone tablets because children are less likely to be accidentally exposed to the film product.

Additionally, according to the complaint, to buy more time to move patients to the film version of Suboxone, Reckitt, through Indivior, filed a citizen petition with the FDA reciting the same unsupported safety claims and requesting that the agency reject any generic tablet application.

The complaint alleges that the petition was intended to delay the approval of generic competitors while the FDA reviewed it.

The proposed stipulated order for a permanent injunction and equitable monetary relief bars Reckitt from similar future conduct. If Reckitt introduces a reformulated version of an existing product, it must provide the FTC with information about that product and the reasons for its introduction. If generic companies file for FDA approval of competing versions of the branded drug, the order requires Reckitt to leave the original product on the market on reasonable terms for a limited period so that doctors and patients can choose which formulation of the drug they prefer. The order also requires that if Reckitt files a citizen petition, the company must simultaneously submit any data or information underlying that petition to the FDA and FTC. The fencing-in relief in the stipulated order is specific to this case and appropriate given the egregiousness of Reckitt's alleged conduct.

In 2014, the FTC's non-public investigation of Reckitt's conduct was largely put on hold due to a parallel federal criminal investigation for related conduct that ultimately resulted in a 28-count indictment of Indivior by a grand jury in the Western District of Virginia. The grand jury charged Indivior with health-care fraud, mail fraud, and wire fraud. This settlement resolves all of the FTC's claims against Reckitt Benckiser Group plc, but does not resolve any claims against its former subsidiary, Indivior Inc.

The proposed FTC settlement is also part of a broader government settlement with Reckitt, which resolves criminal and civil fraud claims by the U.S. Attorney's Office for the Western District of Virginia and Department of Justice. The FTC is grateful to the U.S. Attorney's Office and DOJ for their cooperation and for their vigorous prosecution in this important area.

The Commission vote authorizing the staff to file the complaint and the proposed stipulated order was 4-0-1, with Commissioner Christine S. Wilson recused. Commissioner Rohit Chopra issued a concurring statement. The complaint was filed on July 11, 2019, in the U.S. District Court for the Western District of Virginia.