

A.G. Schneiderman Announces Settlement With Drug Manufacturer For Engaging In Anticompetitive Conduct To Prevent Competition For A Life-Saving Drug For Infants

Joint Investigation Found That Mallinckrodt Illegally Acquired Rights To Competitor Drug

Schneiderman: We Will Vigorously Enforce The Antitrust Laws To Prevent Consumers And Taxpayers From Being Saddled With The Out-Of-Control Pricing That Can Result From Unlawful Conduct

NEW YORK—Attorney General Eric T. Schneiderman announced a joint settlement with four other Attorneys General and the Federal Trade Commission with Mallinckrodt plc and its U.S. subsidiary, formerly known as Questcor Pharmaceuticals (“Questcor”), a drug manufacturer. The complaint and settlement, filed jointly, alleges that Questcor unlawfully acted to prevent competition for its drug H.P. Acthar Gel, which is typically used as a last resort to treat certain life-threatening diseases, including infantile spasms and multiple sclerosis.

“This is an egregious case of a monopolist doing a deal to eliminate potential competition and keep its power over pricing. It is abhorrent that lifesaving drugs cost New Yorkers tens of thousands of dollars.” said **Attorney General Schneiderman**. “This settlement will restore the competition that was prevented by Questcor’s illegal actions, and my office will continue to vigorously enforce antitrust laws to prevent consumers and taxpayers from being saddled with the out-of-control drug prices that can result from unlawful conduct.”

In 2001, Questcor bought the rights to Acthar, known as an adrenocorticotrophic hormone (ACTH)-based therapeutic drug, which are used to treat certain life-threatening diseases, and is the standard of care for infantile spasms. It is the only such drug sold in the United States. Since then, Questcor has increased the price of Acthar 85,000%, from \$40 per vial to over \$34,000 per vial. The complaint alleges that Questcor monopolized the market for ACTH drugs by purchasing the rights to Synacthen, which was being sold by Novartis Pharma A.G. in 2012. Synacthen is used to treat patients with the same life-threatening conditions as Acthar, but is sold in Europe and Canada at a fraction of the price.

The complaint alleges that three other companies had all conducted due diligence and submitted formal offers for Synacthen with plans to develop and launch Synacthen in the United States in direct competition with Questcor. However, perceiving the threat to its U.S. monopoly if a rival drug company purchased the assets, Questcor stepped in to outbid the three other companies, offering Novartis \$135 million in guaranteed payments with only vague plans for Synacthen and after very limited due diligence. Through the acquisition, Questcor sought to extinguish the most likely challenges to its Acthar monopoly. According to the complaint, this allowed Questcor to continue charging over \$34,000 per vial for H.P. Acthar Gel.

Under the settlement, Mallinckrodt will pay \$100 million. The company will also be required to license a competitor to the rights it acquired from Novartis to commercialize and develop Synacthen in the United States, including the Synacthen trademark, along with clinical trial data and certain intellectual property related to manufacturing and formulation. Mallinckrodt is also prohibited from taking actions that would interfere with clinical trials or clinical plans for Synacthen.

The defendants named in the antitrust action are Mallinckrodt ARD, Inc., formerly known as Questcor Pharmaceuticals, Inc., and its Ireland-based parent company Mallinckrodt plc. In addition to New York, the Attorneys General of Alaska, Maryland, Texas, and Washington entered into this settlement.

The matter was led for New York by Assistant Attorney General Saami Zain, Antitrust Bureau Chief Beau Buffier and Deputy Bureau Chief Elinor R. Hoffmann, under the supervision of Executive Deputy Attorney General for Economic Justice Manisha M. Sheth.