FEDERAL TRADE COMMISSION
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Mallinckrodt Will Pay $100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants

Settlement requires the company to license rights to develop a synthetic alternative to Acthar

FOR RELEASE

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TAGS: Health Care | Prescription Drugs | Bureau of Competition | Competition

Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., and its parent company, Mallinckrodt plc, have agreed to pay $100 million to settle Federal Trade Commission charges that they violated the antitrust laws when Questcor acquired the rights to a drug that threatened its monopoly in the U.S. market for adrenocorticotropic hormone (ACTH) drugs. Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, as well a drug of last resort used to treat other serious medical conditions.

The FTC's complaint alleges that, while benefitting from an existing monopoly over the only U.S. ACTH drug, Acthar, Questcor illegally acquired the U.S. rights to develop a competing drug, Synacthen Depot. The acquisition stifled competition by preventing any other company from using the Synacthen assets to develop a synthetic ACTH drug, preserving Questcor's monopoly and allowing it to maintain extremely high prices for Acthar.

"Questcor took advantage of its monopoly to repeatedly raise the price of Acthar, from $40 per vial in 2001 to more than $34,000 per vial today – an 85,000 percent increase," said FTC Chairwoman Edith Ramirez. "We charge that, to maintain its monopoly pricing, it acquired the rights to its greatest competitive threat, a synthetic version of Acthar, to forestall future competition. This is precisely the kind of conduct the antitrust laws prohibit."

Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, and a drug of last resort to treat several other serious medical conditions – including nephrotic syndrome, flare-ups of multiple sclerosis, and rheumatoid disorders. According to the complaint, Acthar treatment for an infant with infantile spasms can cost more than $100,000.

In Europe, Canada, and other parts of the world, the complaint notes that doctors treat patients suffering from these conditions with Synacthen Depot, which is available at a fraction of Acthar's price in the United States. The complaint alleges that Questcor has consistently viewed Synacthen Depot as a significant competitive threat to its Acthar monopoly in the United States.

The FTC alleges that in June 2013, Questcor acquired the U.S. rights to Synacthen from Novartis AG, outbidding several other companies that were seeking to acquire the rights to Synacthen. Those alternative bidders were interested in developing the drug and had plans to sell it at a significant discount to Acthar's price, capturing a substantial amount of Questcor's business. The FTC charges that Questcor's acquisition of Synacthen stifled competition and eliminated the possibility that an alternative bidder would make the drug available in the U.S. market and compete with Acthar.

In addition to the $100 million monetary payment, the proposed stipulated court order requires that Questcor grant a license to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission.

A monitor will ensure that Questcor complies with its obligation to grant the license within 120 days of the entry of the order; after that time, a trustee will be appointed to effectuate the license. The order also requires Questcor to provide periodic reports on its efforts, and provide the Commission with advance notice of any future acquisitions of U.S. rights to ACTH drugs.

The states of Alaska, Maryland, New York, Texas and Washington joined in the FTC's complaint. Under the settlement, the states will receive $10 million from the $100 million judgment and an additional $2 million as payment for attorney's fees and costs.

The Commission vote authorizing staff to file the complaint and the proposed stipulated order in federal court was 3-0. Commissioner Maureen K. Ohlhausen issued a concurring statement. FTC staff filed the complaint and proposed order in the U.S. District Court for the District of Columbia.

NOTE: The Commission files a complaint when it has "reason to believe" that the law has been or is being violated and it appears to the Commission that a proceeding is in the public

interest. Stipulated orders have the force of law when approved and signed by the District Court judge.

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