DOJ's Prosecution of Generic Drug Companies Continues as it Announces Price-Fixing Charges Against Glenmark Pharmaceuticals, Inc.

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On June 30, 2020, the Department of Justice’s Antitrust Division (“DOJ”) announced the filing of a one-count criminal information in the U.S. District Court for the Eastern District of Pennsylvania against Glenmark Pharmaceutical, Inc. (“Glenmark”). The information alleges that Glenmark conspired with Apotex Corporation (“Apothex”) to fix prices for pravastatin, a prescription medication used to reduce cholesterol. The DOJ alleges that Glenmark overcharged consumers by at least $200 million from approximately May 2013 through December 2015. This announcement comes amidst the DOJ’s ongoing investigation of the generic pharmaceutical industry—an industry that also faces increased scrutiny in light of the COVID-19 pandemic.

Over the past year, the DOJ has announced charges against a number of generic drug manufacturers. All have entered into settlements via deferred prosecution agreements (“DPAs”), agreeing to pay criminal penalties and/or civil damages, and cooperate with the investigation. Apotex, the co-conspirator in this case, entered into a DPA in May 2020 and will pay a $24.1 million criminal penalty to settle the charges. Sandoz, a Novartis division (“Sandoz”), also entered into a DPA in March 2020, agreeing to pay a $1 million criminal penalty for allegations that it conspired to allocate customers, engaged in bid rigging, and fixed prices for generic drugs. Rising Pharmaceuticals (“Rising”) entered into a DPA in December 2019, agreeing to pay over $3 million in criminal penalties and civil restitution, and civil damages for allegations that Rising conspired to fix prices for a hypertension medication. Heritage Pharmaceuticals Inc. (“Heritage”) entered into a DPA in May 2019 and agreed to pay over $7 million in criminal penalties and civil damages. The civil damages in both Rising and Heritage are the result of False Claims Act violations arising from their antitrust violations.

Additionally, a number of executives have been indicted and/or pleaded guilty to charges in connection with this investigation. In February 2020, the DOJ announced the guilty plea of Hector Armando Kellum, a former Sandoz executive, who pleaded guilty to conspiring to restrain trade through price fixing, bid rigging, and customer allocation for generic drugs, and the indictment of Ara Aprahamian, a former Taro Pharmaceutical Industries Ltd. executive, for fixing prices of antibiotics and diabetes drugs. Prior to that, the DOJ had announced enforcement actions against individuals in December 2016, when two Heritage executives pleaded guilty to price fixing and bid rigging for antibiotics and diabetes drugs.

Unlike other generic drug manufacturers and individuals that have been investigated by the DOJ thus far, Glenmark denies the allegations and plans to challenge them, stating that it “will continue to vigorously defend against these allegations that [it] knows to be false.” If Glenmark is criminally convicted, the statutory maximum penalty for the offense is $100 million, which can be adjusted to twice the gain from the crime or twice the loss to the victims, whichever sum is greater. Additionally, it may be excluded from federal healthcare programs and reimbursements under Medicare and Medicaid. Healthcare providers with a felony antitrust conviction could be subject to a five-year exclusion from federal and state health care programs.

The generic pharmaceutical industry also faces antitrust challenges on the civil front. A civil case brought by 44 state attorneys general is currently pending in the Eastern District of Pennsylvania. The additional civil cases have been consolidated into a multidistrict litigation, with bellwether trials expected to begin this year. The allegations implicate a number of drug manufacturers, including, but not limited to, Glenmark, Sandoz, Heritage, and Teva Pharmaceuticals, and allege a multimillion-dollar price-fixing conspiracy in violation of the Sherman Antitrust Act.

The announcement of the criminal charges against Glenmark is significant given that it is the fifth such announcement in the last year. It signals the DOJ’s efforts to focus on alleged collusion in the generic pharmaceutical industry and demonstrates that the DOJ has scaled back its inquiry in the face of the COVID-19 pandemic. Given that the DOJ has stated that this is an on-going investigation, generic drug manufacturers should be vigilant and tread carefully when collaborating with other companies in the production of generic drugs. O’Melveny has robust antitrust, pharmaceutical, healthcare, and life sciences practices, and pharmaceutical companies with any questions about the potential antitrust implications of their actions should contact the undersigned attorneys.

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5. Until the DOJ’s investigation into the generic pharmaceutical industry, DPAs were a rare outcome in Antitrust Division prosecutions. The last DPA that the Antitrust Division entered into, prior to its 2019 DPA with Heritage, was in 2013 with the Royal Bank of Scotlan PLC for its role in an alleged price-fixing conspiracy related to LIBOR. This was also the Antitrust Division’s first ever DPA.
It is worth noting that the DOJ brought charges against Glenmark pursuant to an information as opposed to a grand jury indictment. Glenmark's comments that it plans to fight the charges raises questions about whether it consented to the filing of the information and, if it did not, the propriety of the information under the Federal Rules of Criminal Procedure.


This memorandum is a summary for general information and discussion only and may be considered an advertisement for certain purposes. It is not a full analysis of the matters presented, may not be relied upon as legal advice, and does not purport to represent the views of our clients or the Firm. Ben Bradshaw, an O'Melveny partner licensed to practice law in California and the District of Columbia, Riccardo Celli, an O'Melveny partner licensed to practice law in the Capital Region of Brussels, the Law Society England & Wales, and Roma, Courtney Dyer, an O'Melveny partner licensed to practice law in the District of Columbia and New York, Andrew Frackman, an O'Melveny partner licensed to practice law in New Jersey and New York, Yoji Maeda, an O'Melveny partner licensed to practice law in New York and Japan, Philip Monaghan, an O'Melveny partner licensed to practice law in the Capital Region of Brussels, Hong Kong, the Law Society England & Wales, and the Law Society Ireland, Anna T. Pletcher, an O'Melveny partner licensed to practice law in California, Katrina Robson, an O'Melveny partner licensed to practice law in California and the District of Columbia, Youngwook Shin, an O'Melveny partner licensed to practice law in California and New York, Ian Simmons, an O'Melveny partner licensed to practice law in the District of Columbia and Pennsylvania, Michael Tubach, an O'Melveny partner licensed to practice law in California and the District of Columbia, Stephen McIntyre, an O'Melveny counsel licensed to practice law in California, Philippe Nogues, an O'Melveny counsel licensed to practice law in the Capital Region of Brussels and France, Charles Paillard, an O'Melveny counsel licensed to practice law in France and Hong Kong, Scott Schaeffer, an O'Melveny counsel licensed to practice law in the District of Columbia and California, Sergei Zaslavsky, an O'Melveny counsel licensed to practice law in the District of Columbia and Maryland, and Trisha Parikh, an O'Melveny associate licensed to practice law in California, contributed to the content of this newsletter. The views expressed in this newsletter are the views of the authors except as otherwise noted.