

Client Alert

Business Litigation & Antitrust Practice Group

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FTC and States Reach \$100 Million Antitrust Settlement with Mallinckrodt

On January 18, 2017, the Federal Trade Commission (“FTC”) announced that it reached a \$100 million settlement with pharmaceutical company Questcor Pharmaartineuticals, Inc. and its Irish parent company, Mallinckrodt plc. The settlement resolves charges of alleged monopolization and other antitrust violations. The investigation involved Mallinckrodt’s adrenocorticotrophic hormone (“ACTH”) specialty drugs, primarily prescribed to treat infantile spasms, a rare disease that is costly to treat. The settlement also includes several state attorneys general, including Alaska, Maryland, New York, Texas and Washington.

According to the FTC complaint, Mallinckrodt originally acquired the rights to Acthar, a brand-name ACTH drug in 2001 for \$100,000. Twelve years later, Mallinckrodt acquired the rights to a competing ACTH drug named Synacthen Depot, which had been prescribed in Europe, Canada, and other countries. The FTC did not challenge the acquisition of Synacthen Depot at the time. It now alleges, however, that the acquisition violated the antitrust laws, because it 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 high prices for Acthar. Specifically, FTC Chairwoman Edith Ramirez stated “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.”

Mallinckrodt agreed to settle the FTC’s charges for \$100 million, entering into a proposed consent order with the FTC that also requires that Mallinckrodt (and Questcor) to grant a license to develop Synacthen Depot to a licensee approved by the FTC. In addition, a monitor will ensure that the settling companies comply with their 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 FTC order also requires the settling companies to provide reports regarding its compliance with the order and provide the FTC with advance notice of any future acquisitions of U.S. rights to ACTH drugs. Although no FTC Commissioner’s dissented from the settlement, in a concurring statement Commissioner Ohlhausen disagreed with the FTC’s choice to seek disgorgement in federal court, rather than pursuing the case through internal administrative adjudication.

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The settlement, however, leaves Mallinckrodt free to unilaterally set any price it wants for Acthar.

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There have been only a few FTC monetary settlements for antitrust violations in the past 20 years, and the Mallinckrodt settlement of \$100 million matches the highest civil penalty in FTC antitrust enforcement history, as Mylan entered settlement with the FTC for the same amount in 2000 over allegations of price-fixing.

The Mallinckrodt settlement is in the context of increased bi-partisan rhetoric from Congress on the unfairness of high drug prices. Similarly, in a recent press conference, President-Elect Trump expressed his desire to curb high drug prices, stating that many companies were “getting away with murder.” Although U.S. antitrust law does not directly prohibit “excessive pricing” without evidence of additional anticompetitive conduct – as recognized in the case law and in previous statements by individual Commissioners – the Mallinckrodt settlement may signal a new wave of U.S. enforcement actions involving drug price hikes. Even transactions that may not initially receive FTC scrutiny at the time may face a subsequent investigation and enforcement action if the company subsequently raises prices. Central to the FTC’s monopolization claim were large price hikes for Achthar – the price allegedly jumped overnight from \$1,650 to \$23,269 in one instance – as direct evidence of Mallinckrodt’s market power. Moreover, drug price hikes have received increasing scrutiny by competition authorities and legislatures across several jurisdictions. The issue came to widespread media attention in the U.S. over Turing Pharmaceutical’s price increases for its antiparasitic drug, Daraprim. Last month, the U.K.’s Competition and Markets Authority alleged that it committed antitrust violations by charging excessive prices for its hormone replacement tablet. Thus, the Mallinckrodt settlement serves as a cautionary tale for pharmaceutical companies.

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The FTC’s press release, complaint, stipulated order, and the concurring statement are available at <https://www.ftc.gov/enforcement/cases-proceedings/1310172/mallinckrodt-ard-inc-questcor-pharmaceuticals>

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