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Client Alert

A Harder Pill to Swallow? International Working Group Aims to Enhance Pharmaceutical-Merger Reviews

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The Acting Chair of the Federal Trade Commission has organized an international working group of antitrust enforcers to revamp and strengthen their approach to pharmaceutical mergers. In collaboration with these enforcers, Acting Chair Slaughter plans for the FTC to "take an aggressive approach to tackling pharmaceutical mergers." The formation of the working group and Acting Chair Slaughter's views on prior pharmaceutical merger enforcement actions indicate that the FTC's investigations of such mergers are likely to be deeper, broader, longer, likely to consider cutting-edge theories of harm, and ultimately will make pharma-merger clearance more difficult. Notably, the approach, lessons, and conclusions of this working group could have significant implications for other industries.

On March 16, Acting FTC Chair Rebecca Slaughter announced the formation of a multi-lateral working group of antitrust enforcers to "update their approach to analyzing the effects of pharmaceutical mergers." In addition to the FTC, the working group consists of the Canadian Competition Bureau, the European Commission Directorate General for Competition, the U.K.'s Competition and Markets Authority, the Antitrust Division of the U.S. Department of Justice, and the State Attorneys General Offices of California, Wisconsin, and Pennsylvania, with others who may join later.

According to Acting Chair Slaughter, it is "imperative" to "rethink" the agency's approach to pharmaceutical mergers because of the high volume of such transactions, "skyrocketing" drug prices, and "ongoing concerns about anticompetitive conduct in the industry." The FTC announcement of the working group promises that this initiative will "ensure that FTC investigations include fresh approaches that fully analyze and address the varied competitive concerns that these mergers and acquisitions raise."

As part of this rethink, the FTC will consider several key questions that portend a more rigorous, if not skeptical, approach to pharma-merger enforcement, including:

- How can current theories of harm be expanded and refreshed?
- What is the full range of a pharmaceutical merger's effects on innovation?
- In merger review, how should [the FTC] consider pharmaceutical conduct such as price fixing, reverse payments, and other regulatory abuses?
- What evidence would be needed to challenge a transaction based on any new or expanded theories of harm?
- What types of remedies would work in the cases to which those theories are applied?
- What [has the agency] learned about the scope of assets and characteristics of firms that make successful divestiture buyers?

Acting Chair Slaughter is reported as saying that the working group may review past mergers to take lessons for future enforcement, but also, perhaps, to take "corrective action" when needed. This suggests that the FTC might bring enforcement actions against consummated mergers.

The likely intensification of antitrust enforcement in pharmaceutical mergers is not unexpected. Acting Chair Slaughter, along with (likely outgoing) Commissioner Rohit Chopra, have been critical of the FTC's traditional product-overlap-and-divestiture approach to such mergers. Indeed, now-Acting Chair Slaughter and Commissioner Chopra have dissented and issued dissenting statements in the last three pharmaceutical mergers (BMS/Celgene, AbbVie/Allergan, Mylan/Upjohn), which were cleared by a majority of the Commission subject to divestitures of overlapping products or products in development.

Takeaways

1. While the Biden Administration is still filling Commissioner seats at the FTC and needs to name a permanent Chair, Acting Chair Slaughter's desire for stronger enforcement in pharmaceutical mergers and the formation of this international working group is likely to bring more uncertainty and risk to such mergers gaining clearance, not just in the U.S., but also abroad. Notably, under its current approach to pharma mergers, the FTC already often demands divestitures in transactions that would still leave four competitors in a market ("5 to 4" mergers), and even when the overlap is a result of one of the merging parties having only a product in development, rather than a marketed product. A more aggressive or expansive approach could significantly increase merger risk for deals in the pharma and biotech industries.
2. At a minimum, parties contemplating mergers in the pharma and biotech industries should plan earlier and more thoroughly for more rigorous and lengthy antitrust scrutiny of their mergers. The scope of the parties' analysis should include potential theories of harm that go beyond the traditional drug overlap analysis to focus on theories of harm around innovation competition and so-called "killer acquisitions."
3. Additionally, the FTC is likely to give greater scrutiny to potential divestiture buyers and potentially increase the scope of assets required to be divested as a condition of merger clearance. Therefore, merging parties likely will have to vet potential divestiture buyers even earlier and more carefully, and may need to include additional assets and rights in divestiture agreements.
4. One potential silver lining is that the international working group may bring a more consistent global approach to how pharma mergers are analyzed and the remedies required in such mergers. The risk, however, is that this international alignment might be around a more rigorous analytical approach and more stringent remedies.
5. Companies in other industries should keep an eye on the progress and results of this working group. Acting Chair Slaughter reportedly said that if this working-group model succeeds, it could be applied to other industries. But even if there aren't separate working groups for different industries, she said, the lessons from this working group could be applied to other industries.

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