CLIENT ALERT

Increased Antitrust Scrutiny of Pharma Deals

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On March 16, 2021, the European Commission's Directorate General for Competition (DG COMP); the U.S. Federal Trade Commission (FTC); the Canadian Competition Bureau; the UK's Competition and Markets Authority; the U.S. Department of Justice; as well as three Offices of Attorneys General launched a multilateral working group to analyze the competitive effects of pharmaceutical mergers (Working Group).

Executive Vice-President of the European Commission Margrethe Vestager, in charge of the EU's competition policy, said "the European Commission has taken new initiatives in scrutinizing global pharmaceutical mergers to ensure effective competition in the sector". The Working Group will bring "together some of our closest partners worldwide to take stock of the lessons learned in recent years and explore new ways to foster vibrant competition to the benefit of citizens."[1]

On the U.S. front, FTC Acting Chair Rebecca Kelly Slaughter intends to refresh the agency's approach to "fully analyze and address the varied competitive concerns that [pharmaceutical] mergers and acquisitions raise," strongly implying that the traditional template of reviewing overlapping on-market and pipeline products is too narrow.[2] The FTC's interest in a full reassessment of its merger review framework springs from the "high volume of pharmaceutical mergers in recent years, . . . skyrocketing drug prices and ongoing concerns about anticompetitive conduct in the industry."[3]

1 Press Release, European Comm'n, Competition: The European Commission forms a Multilateral Working Group with leading competition authorities to exchange best practices on pharmaceutical mergers (Mar. 16, 2021), here.

2 Press Release, Fed. Trade Comm'n, FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers (Mar. 16, 2021), here.

3 *Id.*

What could this mean for pharma deals?

Closer exchange and cooperation between competition authorities across the globe may help harmonize merger assessment and create a more efficient and predictable merger control environment, which would be much welcomed by dealmakers. However, DG COMP suggests that the Working Group will result in an "enhanced scrutiny and a more detailed analysis" of pharmaceutical mergers.[4] Ms. Slaughter intends "to take an aggressive approach to tackling anticompetitive pharmaceutical mergers."[5] This suggests that pharmaceutical companies should generally prepare for a more extensive and critical review, both when contemplating large global mergers and when looking into acquisitions of innovative smaller companies or newly developed pharmaceuticals.

Substantive review. The FTC's press release identified a broad palette of new issues for consideration by the Working Group:

- how current theories of harm can be expanded;
- innovation effects;
- impact of anticompetitive industry behavior (*e.g.*, price fixing, "reverse payments," and "other regulatory abuses") on merger review;
- what evidence would be necessary or sufficient to challenge a transaction based upon a new or expanded theory of harm;
- what types of remedies would alleviate those harms; and
- what are the characteristics of successful divestiture buyers.

The FTC thus intends to rethink its pharmaceutical merger review process from stem to stern and make that review stricter and more searching at every stage.[6]

A study of Ms. Slaughter's dissenting statements and speeches may outline some of the new approaches that may result from the FTC's collaboration in the Working Group. In her dissenting statement in AbbVie/Allergan, in particular, Ms. Slaughter noted that the FTC should "scrutinize closely" whether the merged firm would be incentivized to "curtail its

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4 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1203

5 https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach

6 Press Release, Fed. Trade Comm'n, FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers (Mar. 16, 2021), here.

innovative efforts" and should gather ample evidence on innovation effects "at the earliest stage possible in an investigation."[7]

In a similar vein, effects on innovation are also at the heart of merger enforcement in Europe. Over the past years, DG COMP extended its assessment beyond existing- and late-stage pipeline products into early-stage pipeline products and R&D, in some cases requiring the parties to offer divestitures of R&D activities to keep early-stage development alive.[8] In AbbVie/Allergan, DG COMP raised concerns that the deal would lead to a loss of innovation for a specific treatment and would prevent a promising drug from entering the market, leading to potentially less choice and higher prices for patients and health systems. To address this concern, AbbVie was required to divest a pipeline product, including the development, manufacturing and marketing rights at the worldwide level, to a purchaser that would continue the drug's development.[9]

Procedure. By referring to evidence necessary to challenge a deal, the FTC addresses another hot topic.[10]

U.S. "second requests" last as long as is necessary for the parties to substantially comply with the extensive demands for documents and interrogatories and are often extended contractually by "timing agreements" between the agency and the parties. Given the broader scope of inquiry with respect to "theories of harm" that Ms. Slaughter expects, and the uncertainty of the evidence that would support new theories under established law, we may expect even more far-ranging and perhaps longer second request review processes.

Although mergers are assessed in an administrative system in Europe, DG COMP increasingly follows the example of U.S. merger control by requesting from the parties large volumes—sometimes hundreds of thousands, even millions—of pages of internal documents to support the competitive assessment. This significantly extends review periods (triggered by stop-the-clock orders to allow compliance with such requests) and raises fundamental legal questions.[11]

It is to be hoped that cooperation within the Working Group will not result in an even heavier burden on the merging parties but, rather, in a more efficient review while respecting the parties' rights.

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7 Dissenting Statement of Commissioner Rebecca Kelly Slaughter, In the Matter of AbbVie/Allergan, FTC File No. 191-0169 (May 5, 2020), here.

8 *See e.g.,* EC Decisions of 9 June 2017, M.8401 - J&J/Actelion; of 4 August 2015, M.7559 - Pfizer/Hospira; of 28 January 2014, M.7275 – Novartis/ GSK Oncology Business; *see also* the parallel assessment in the (agro)chemical industry: decisions of 21 March 2018, M.8084 - Bayer/Monsanto and of 27 March 2017 M.7932 - Dow/Dupont.

9 *See* the EC's press release in Case M.9461 – AbbVie/Allergan, here. The EC raised similar concerns and requested similar commitments in Case M.8955 - Takeda/Shire (here) but waived the commitments in 2020 (here).

10 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1203

11 *See*, for example, the decision of the General Court of the EU of 20 October 2020, Case T-451/20 R – Facebook vs Commission concerning information requests in an EU antitrust investigation.

Similarly, with an increased focus on remedies, divestitures may be subject to more extensive requirements, discovery, and scrutiny. But, again, the Working Group may also create efficiencies and leaner procedures.

Jurisdiction. When recently discussing the future of EU merger control, Executive Vice-President Vestager explained that one of the main issues was whether the EU filing thresholds, which were based on the companies' turnovers, were still the right way to spot mergers that could harm competition. *Inter alia*, in the pharmaceutical industry, competition could strongly depend on new products or services that did not yet generate significant sales. According to Ms. Vestager, there were a handful of mergers each year that could seriously affect competition, but which DG COMP did not see because the companies' turnovers were below the thresholds.[12] Apparently, Ms. Vestager had "killer acquisitions" in mind, in which an incumbent buys a potential rival still in nascent stages, with the aim of terminating upcoming competition post acquisition. While mentioning that new thresholds based on the value of the merger could be a solution, Ms. Vestager was still skeptical as to whether or not this was feasible.

At a press conference, FTC Acting Chair Slaughter suggested that the FTC may review previously cleared pharmaceutical mergers to assess whether "it made obvious mistakes."[13] The FTC may also examine whether non-reportable transactions have resulted in "stealth consolidation" or "killer acquisitions" involving products likely to be discontinued.[14] In the EU, retroactive review of cleared mergers and an ex-officio review of non-reportable mergers are not possible.

It will be interesting to see whether the Working Group will be a breeding ground for a sectoral revision of the merger control thresholds.

Conclusion. In summary, this formation of a new cross-border, multi-agency Working Group is an important development for pharmaceutical companies. We will report further on the Group's activities as developments become available. Please contact the authors with any questions.

[12] https://ec.europa.eu/commission/commissioners/2019-2024/vestager/announcements/future-eu-merger-control_en

[13] Brent Kendall and Jared S. Hopkins, FTC Prepares to Take Tougher Stance on Pharmaceutical Mergers, WSJ.COM (Mar. 16, 2021), here.

[14] *See* Statement of Commissioner Christine S. Wilson joined by Commissioner Rohit Chopra, Concerning NonReportable Hart-Scott Rodino Act Filing 6(b) Orders (Feb. 11, 2020), here.

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