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Pharmaceutical Transactions in Spotlight as FTC Announces Multilateral Working Group to Develop Fresh Approaches to Merger Reviews

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- *Announcement represents latest effort among U.S., EU, UK, and Canadian enforcers to ratchet up scrutiny of pharma deals with an eye toward challenging more sector transactions*
- *New approaches likely to focus on effects of transactions on innovation in broad therapeutic categories and the merged entity's ability to engage in exclusionary conduct, including restricting smaller firms' formulary placement*
- *Announcement has, at a minimum, a number of potential practical implications for companies evaluating or pursuing certain pharma transactions, including longer investigations, broader discovery, and associated delays*

On March 16, 2021, the U.S. Federal Trade Commission announced that it is teaming up with antitrust enforcers in the European Union, United Kingdom, Canada, and the State Attorneys General in the U.S. in an effort "to update their approach to analyzing the effects of pharmaceutical mergers."[1] The working group will analyze such questions as "how can current theories of harm be expanded and refreshed," the impact posed by particular transactions on drug innovation generally, and the predictive role of an acquirer's past anticompetitive conduct in assessing the consumer impact of a merger. To date, it is not clear whether or how this working group might consider input from the pharmaceutical industry or other stakeholders.

The announcement follows several statements by current Acting FTC Chair Rebecca Slaughter, joined by fellow Democratic Commissioner Chopra, charging that divestitures and remedies accepted by the agency in large pharma deals did not go far enough to protect consumers from a potential decrease in innovation and higher future drug prices.[2] Acting Chair Slaughter has criticized the established framework and methods embraced across jurisdictions for analyzing pharmaceutical deals, urging the FTC to dig deeper and take a "more expansive approach" during investigations, including through more discovery from both parties and non-parties. And Lina Khan, who was recently nominated for appointment to the Commission, has advocated forcefully for more aggressive and expansive antitrust enforcement across sectors.

The concern about pharma deals is shared by other leading agencies. Commenting on the launch of the working group, Margrethe Vestager, the European Commission's Executive Vice-President in charge of competition policy, noted that "[o]ver the past years the European Commission has taken new initiatives in scrutinising global pharmaceutical mergers to ensure effective competition in the sector.... I therefore warmly welcome this initiative, which brings together some of our closest partners worldwide to take stock of the

Related People

Stephen Weissman

Michael J. Perry

Kristen C. Limarzi

Ali Nikpay

lessons learned in recent years and explore new ways to foster vibrant competition to the benefit of citizens."

While the Democratic majority at the FTC is likely to share an interest in reining in the number and size of pharmaceutical mergers, the likely results of such efforts to develop more aggressive theories to tackle pharma deals is less certain. Given the well-established framework adopted by U.S. courts and the agency's own Merger Guidelines, new FTC leadership's ambition to more aggressively challenge deals in the pharma sector faces important legal obstacles, at least in deals where merging parties have the commitment to take the FTC to court. Specifically, settled U.S. merger case law and the agency's Merger Guidelines, which are viewed as instructive by courts, make it difficult for enforcers to block deals without demonstrating likely anticompetitive effects within well-defined relevant markets that, according to U.S. precedent, are almost always defined quite narrowly. Thus, a challenge to a pharmaceutical merger based principally on a theory that both companies have an important presence and strong incentives to innovate in a therapeutic area generally (such as in cardiology or neurology) is likely to be rejected by the U.S. courts as lacking the requisite proof of anticompetitive effects in a properly defined relevant market. So, too, is a merger challenge based on a concern that a merger without significant overlaps is likely to increase the merged entity's ability to offer bundled pricing on complementary products to attain advantageous placement on healthcare provider or insurance companies' formularies.

The situation in other jurisdictions may however be different because of the legal frameworks under which their agencies work and the limited role for the courts. For example, in 2019, the UK's Competition and Markets Authority concluded – contrary to the views of most legal commentators – that it could intervene in pharma transactions on the basis of a company's R&D efforts alone, *i.e.*, in the absence of both parties being active in an overlapping area of supply in the UK.

Despite the legal obstacles in the U.S., the joint announcement by the FTC and other enforcers, coupled with changing leadership at the FTC, portends a number of practical considerations for any company evaluating or pursuing a pharmaceutical transaction. These practical considerations include the following:

- **Certain types of deals likely under increased scrutiny.** In addition to the transactions that traditionally have sparked in-depth antitrust reviews (i.e., deals that seek to combine overlapping assets in an already concentrated indication or mechanism of action), we expect that the FTC and other enforcers will be giving deeper scrutiny to:
    - High-profile transactions involving large R&D-based pharma companies who participate in one or more therapeutic areas broadly, even if there is no direct overlap in certain indications;
    - Transactions that involve direct overlaps, even when both companies have pipeline projects at an early development stage (e.g., Phase 1 or early Phase 2, before pivotal clinical trials demonstrate the theoretical potential of an asset in development). These transactions are likely to attract questions when, in the past, such transactions would be viewed as virtually per se non-problematic because of the speculative nature of any theory of harm based on combining untested products still in early stages of development;
    - Transactions in which a company is acquiring an asset or technology, access to which is potentially important for innovation, such as in combination therapies; and
    - Transactions that are reportable in more than one working-group jurisdiction, especially those transactions that fit into any of the paradigms above, because those will be the most fertile ground for the working group to exchange information and fulfill its stated goals.

- **Lengthier investigations.** While the FTC and Canada, unlike other jurisdictions like the EU and the UK, do not have the ability to block transactions without court intervention, which requires a significant investment of resources, they have the authority by statute to conduct in-depth probes, including by issuing burdensome and broad requests for additional information (in the U.S., so-called "Second Requests"). Use of these investigative tools invariably delay closing pending collection and review of relevant information, and sometimes provide an important lever for enforcers in demanding remedies. Whereas pharmaceutical companies have avoided full compliance with Second Requests in the past, increasingly such companies will need to comply in order to force a decision from the agencies. And, if antitrust enforcers are unwilling to accept a proposed divestiture or other remedy, the only realistic path to antitrust clearance may be through litigation. In certain cases, this possibility may warrant actions to proactively address any direct overlaps (through a "fix-it-first" strategy), effectively focusing the government's case on a novel theory of harm. Moreover, the threat of extensive antitrust reviews and corresponding closing delays may deter companies from pursuing certain pharma transactions in the first place.

Other practical implications flowing from the recent emphasis on more aggressive enforcement in pharma deals include increased cooperation between U.S. and foreign enforcers and more FTC use than in the past of oral depositions of company executives to secure relevant information.

We will continue to monitor closely and report on the working group's efforts to develop new analytical approaches for pharma transactions. If you have any questions or would like additional information about these or other developments, please reach out to any of your contacts at Gibson Dunn.

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[1] *See* https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach.

[2] *See* https://www.ftc.gov/public-statements/2019/11/statement-commissioner-rebecca-kelly-slaughter-matter-bristol-myers-squibb; https://www.ftc.gov/public-statements/2020/05/dissenting-statement-commissioner-rebecca-kelly-slaughter-regarding; https://www.ftc.gov/public-statements/2020/10/dissenting-statement-commissioner-rohit-chopra-joined-commissioner-rebecca.

The following Gibson Dunn lawyers prepared this client alert: Stephen Weissman, Michael Perry, Kristen Limarzi and Ali Nikpay.

Gibson Dunn lawyers are available to assist in addressing any questions you may have regarding these developments. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any member of the firm's Antitrust and Competition practice group:

Antitrust and Competition Group:

Washington, D.C.
Adam Di Vincenzo (+1 202-887-3704, adivincenzo@gibsondunn.com)
Scott D. Hammond (+1 202-887-3684, shammond@gibsondunn.com)
Joseph Kattan (+1 202-955-8239, jkattan@gibsondunn.com)
Kristen C. Limarzi (+1 202-887-3518, klimarzi@gibsondunn.com)
Joshua Lipton (+1 202-955-8226, jlipton@gibsondunn.com)
Richard G. Parker (+1 202-955-8503, rparker@gibsondunn.com)
Michael J. Perry (+1 202-887-3558, mjperry@gibsondunn.com)

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Cynthia Richman (+1 202-955-8234, crichman@gibsondunn.com)
Jeremy Robison (+1 202-955-8518, wrobison@gibsondunn.com)
Stephen Weissman (+1 202-955-8678, sweissman@gibsondunn.com)
Andrew Cline (+1 202-887-3698, acline@gibsondunn.com)
Chris Wilson (+1 202-955-8520, cwilson@gibsondunn.com)

New York
Eric J. Stock (+1 212-351-2301, estock@gibsondunn.com)
Lawrence J. Zweifach (+1 212-351-2625, lzweifach@gibsondunn.com)

Los Angeles
Daniel G. Swanson (+1 213-229-7430, dswanson@gibsondunn.com)
Christopher D. Dusseault (+1 213-229-7855, cdusseault@gibsondunn.com)
Samuel G. Liversidge (+1 213-229-7420, sliversidge@gibsondunn.com)
Jay P. Srinivasan (+1 213-229-7296, jsrinivasan@gibsondunn.com)
Rod J. Stone (+1 213-229-7256, rstone@gibsondunn.com)

San Francisco
Rachel S. Brass (+1 415-393-8293, rbrass@gibsondunn.com)
Caeli A. Higney (+1 415-393-8248, chigney@gibsondunn.com)

Dallas
Veronica S. Lewis (+1 214-698-3320, vlewis@gibsondunn.com)
Mike Raiff (+1 214-698-3350, mraiff@gibsondunn.com)
Brian Robison (+1 214-698-3370, brobison@gibsondunn.com)
Robert C. Walters (+1 214-698-3114, rwalters@gibsondunn.com)

London
Patrick Doris (+44 20 7071 4276, pdoris@gibsondunn.com)
Charles Falconer (+44 20 7071 4270, cfalconer@gibsondunn.com)
Ali Nikpay (+44 20 7071 4273, anikpay@gibsondunn.com)
Philip Rocher (+44 20 7071 4202, procher@gibsondunn.com)
Deirdre Taylor (+44 20 7071 4274, dtaylor2@gibsondunn.com)

Brussels
Peter Alexiadis (+32 2 554 7200, palexiadis@gibsondunn.com)
Attila Borsos (+32 2 554 72 11, aborsos@gibsondunn.com)
Christian Riis-Madsen (+32 2 554 72 05, criis@gibsondunn.com)
Lena Sandberg (+32 2 554 72 60, lsandberg@gibsondunn.com)
David Wood (+32 2 554 7210, dwood@gibsondunn.com)

Frankfurt
Georg Weidenbach (+49 69 247 411 550, gweidenbach@gibsondunn.com)

Munich
Michael Walther (+49 89 189 33 180, mwalther@gibsondunn.com)
Kai Gesing (+49 89 189 33 180, kgesing@gibsondunn.com)

Hong Kong
Kelly Austin (+852 2214 3788, kaustin@gibsondunn.com)
Sébastien Evrard (+852 2214 3798, sevrard@gibsondunn.com)

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