THE MERGER CONTROL REVIEW

Tenth Edition

Editor
Ilene Knable Gotts

THE LAWREVIEWS

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US MERGER CONTROL IN THE PHARMACEUTICAL SECTOR

Margaret Segall D'Amico and A Maya Khan[1]

I INTRODUCTION

In the United States, mergers and acquisitions are reviewed by the Department of Justice (DOJ) or the Federal Trade Commission (FTC). These agencies are also responsible for imposing and enforcing appropriate remedies to maintain a competitive market. Parties seeking to merge must receive approval from the relevant agency with jurisdiction over the industry. The DOJ and FTC divide review by subject matter, based on each agency's previous experience and expertise. Mergers between pharmaceutical companies are reviewed by the FTC, which has developed principles and patterns for evaluating the effects of transactions involving prescription drugs. The FTC division known as Mergers I is responsible for examining transactions in healthcare-related industries, including pharmaceuticals.[2] The FTC also has a separate Health Care Division, which investigates business practices of health professionals, pharmaceutical companies, institutional providers and insurers, in addition to reviewing transactions involving healthcare products and services.[3] Pharmaceuticals are also regulated by the US Food and Drug Administration (FDA), and the FTC's review accounts for the complexity of this highly regulated industry.

This chapter contains three main sections. Section II provides an overview of the FTC's general review process, including the steps merging firms generally must follow and a brief discussion of the FTC's view of the relevant geographic and product markets. Section III discusses merger remedies in the pharmaceutical sector, and what parties can expect from an FTC consent decree. Section IV discusses recent developments in US merger review in the pharmaceutical sector, including potential changes to FTC policy towards certain divestiture remedies.

II OVERVIEW OF FTC REVIEW

Under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR), a merger or acquisition above a minimum dollar threshold must be reported to and receive pre-merger clearance from the antitrust regulatory agencies. The minimum thresholds are updated annually. The critical thresholds are the minimum 'size-of-transaction' and 'size-of-person' tests. If a merger or acquisition meets the minimum size-of-transaction threshold, and the parties meet the minimum size-of-person thresholds, the transaction is HSR-reportable. As

1 Margaret Segall D'Amico is a partner and A Maya Khan is an associate at Cravath, Swaine & Moore LLP.

2 See FTC, Inside the Bureau of Competition at 11 (June 2018), available at www.ftc.gov/system/files/attachments/inside-bureau-competition/inside_the_bureau_of_competition_2018_2.pdf.

3 id. at 19.

of February 2019, the minimum size-of-transaction threshold is $90 million. The minimum size-of-person thresholds are $18 million and $180 million in either annual sales or total assets, respectively. For transactions valued at less than $90 million, no HSR filing is required. For transactions valued between $90 million and $359.9 million, HSR notification is only required if one or both parties satisfy each of the size-of-person thresholds. For transactions valued above $359.9 million, an HSR filing is required regardless of whether the parties meet the size-of-person thresholds. These values are adjusted annually for inflation.

For HSR-reportable transactions, the FTC's review of pharmaceutical deals generally follows the same process as mergers in other industries: reviewing a submitted HSR filing, engaging in discussions with the parties, requesting and reviewing additional information about any overlapping products and, if necessary, negotiating and approving a settlement. However, the FTC's experience with prescription drugs has also led to some particular procedures in reviewing mergers in this industry, as described further below.

The process begins when the transacting parties submit general information about their companies and the proposed transaction in the HSR filing form. Once each of the parties have filed their respective HSR forms, the FTC has 30 days for its preliminary review. The parties may not close the transaction during this 30-day waiting period. In its preliminary review, the FTC may require additional documents and information from the companies, and engage in discussions and meetings with the parties. For pharmaceutical transactions, the FTC will provide the parties with a standardised chart to be completed with specific information about each company's existing and pipeline products to expedite the agency's identification and review of any potential overlaps. If the FTC determines that the proposed transaction does not raise any antitrust concerns or questions warranting further investigation, it may terminate the 30-day waiting period (referred to as 'early termination'), or simply allow the waiting period to expire without further action. Following early termination or the expiration of the waiting period, the parties may close the transaction. If, however, the FTC cannot resolve its questions or concerns about the potential competitive effects of the transaction in the initial waiting period, it may issue a Second Request, which extends the timeline of the agency's review and allows the FTC to delve more closely into a transaction.[4] A Second Request is a detailed request for additional information from each of the parties, including both documents and data, and its issuance 'stops the clock' for the FTC's review period. Once each of the parties has declared that they have 'substantially complied' with their respective Second Requests, the FTC has 30 days either to complete its review, by closing its investigation or negotiating and entering into a settlement with the parties to remedy any competitive concerns, or to take legal action to block the merger in federal court or through the FTC's administrative process.[5] However, for proposed transactions in the pharmaceutical agency, given the particular nature of the products at issue, and the extremely broad nature of a Second Request, it is not uncommon for parties to choose not to substantially comply with the request and instead provide the FTC with more targeted information about the products at issue in order to either attempt to resolve the agency's concerns or negotiate a remedy in the most efficient way possible. If the parties agree to a settlement (typically a divestiture) to alleviate any FTC concerns about harm to competition from the proposed merger, the

4 See FTC, Merger Review, available at www.ftc.gov/news-events/media-resources/mergers-and-competition/merger-review.

5 id.

parties and the FTC staff will work with the FTC Compliance Division to draft a settlement agreement.[6] The settlement must be approved by the directors of the Bureau of Competition and the Bureau of Economics, and ultimately by a vote of the full Commission.

The FTC's antitrust review focuses on the potential harm to competition as a result of the proposed merger. In analysing the effect of a merger on competition in a particular industry, the FTC will determine the relevant geographic market and the relevant product market.[7] In the pharmaceutical drug industry, the relevant geographic market is generally the United States. FDA regulatory requirements govern the prescription drug approval process, and once a product is FDA-approved, it can generally be marketed across the United States without restraint from state regulations.

To determine the relevant product market, the FTC will examine how different products interact with each other in terms of price and substitutability. For transactions involving prescription drugs, the agency will evaluate how certain drugs are prescribed to and used by patients, working with both healthcare providers and physicians to determine which pharmaceutical products are interchangeable for treating particular conditions. The FTC will also examine whether two particular drugs are used in the same way. For example, two branded drugs in the same general therapeutic category but with different product attributes and labelling may be used by patients similarly, such that pricing decisions for each drug closely affect the other. In this case, the drugs would be likely to be considered as part of the same product market. By contrast, two branded products in the same general therapeutic category could be aimed at different types of patients, or have different side effects for particular patients, and could thus be considered part of two separate product markets. Products may also be distinguished based on the mechanisms for their use or the means by which they are administered. For example, the market for an injectable product may be distinguishable from the market for an oral medication aimed at treating the same condition.

Generally, the FTC views branded or innovative prescription drugs and generic prescription drugs as competing in two distinct product markets. Under the 1984 Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, generic prescription drugs that are bioequivalent to a branded version and that have the same labelling may be substituted by a pharmacist for patient use without specific permission from the prescriber. Under Hatch-Waxman, generic drugs may be launched in the market upon the expiration of the branded product's patent, or if before such expiration, with certification to the FDA that the generic version does not infringe the branded product's patent. When multiple generic versions of a particular branded drug enter the market, those generics will compete with each other on price. By contrast, the branded version of the same drug will typically stay priced at or above its pre-generic entry level to continue earning as much as possible from sales to patients and prescribers who prefer to use the branded product instead of moving to the generic version. Thus, when two merging companies each have a branded drug that treats the same condition, the FTC will carefully scrutinise the transaction. Similarly, mergers between companies that each have generic drugs that are substitutable

6 See Section III below for additional detail on the FTC remedial process.

7 See *Brown Shoe Co v. United States*, 370 US 294, 324 (1962) ('The "area of effective competition" must be determined by reference to a product market (the "line of commerce") and a geographic market (the "section of the country").'). See also US Department of Justice and the Federal Trade Commission, Horizontal Merger Guidelines at 7-8 (10 August 2010), available at www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

for the same branded drug will also be closely evaluated. But because of the different pricing strategies companies pursue for branded and generic drugs, a merger between a company with a branded product and a company with a substitutable generic typically draws less scrutiny, unless the relevant generic product will be or is the only generic substitute (or perhaps is one of only two) on the market.

As part of its review, the FTC will also consider whether each company also has products in development or pending FDA approval, commonly referred to as pipeline products, that may compete against the other party's pipeline or marketed products. By evaluating pipeline products in the antitrust review process, the FTC is able to assess a company's full portfolio of assets, including intellectual property and research and development efforts, rather than just its products currently on the market. The FTC has a stated goal of encouraging innovation in healthcare markets, and ensuring that merging companies continue to bring new or improved products to patients.[8] Evaluating the parties' pipeline products also relates to this goal, as the agency may tailor its review or structure an eventual settlement in a way designed to incentivise the parties to successfully bring the new product into the market.

Over the course of the FTC's investigation, it will determine whether the transaction is likely to harm competition through (1) unilateral effects or (2) coordinated effects. Under a theory of harm focusing on unilateral effects, the FTC will assess the level to which the products are substitutes for each other, and whether the elimination of competition as a result of the merger will allow the merged firm to unilaterally raise prices in the relevant markets. The more closely the parties compete, the more likely the merged firm will be able to raise prices, as the lost sales as a result of the merger are more likely to shift to the merged firm. Under a coordinated effects theory, the FTC will assess whether the merger is anticompetitive because it facilitates coordination among competitors, leading to collusion or other harmful results. If the FTC determines that a transaction is likely to harm competition based on either of these theories, the agency will require that the parties remedy this harm before the transaction is allowed to close.

III REMEDIES

If the FTC believes that the effect of the transaction 'may be substantially to lessen competition'[9] in a particular market (or markets), the FTC may seek remedial action such as pursuing a settlement or attempting to block the merger in court or through the agency's administrative process. FTC enforcement actions in the pharmaceutical sector typically result in settlement between the parties and the government, rather than litigation. These settlement agreements are referred to as 'consent decrees'. While the FTC evaluates each proposed remedy based on the facts of a particular case, prior consent decrees can provide insight into the typical structure and provisions of a divestiture involving pharmaceutical products.

The FTC's goal in crafting a remedy is to prevent or eliminate likely anticompetitive effects of a merger, and therefore is structured to maintain or restore any competition lost as a result of the merger. While the FTC has discretion in pursuing settlements in merger cases, the most common remedy in a pharmaceutical consent decree is a structural remedy, which typically involves divesting one of the parties' overlapping pharmaceutical products and its

8 See FTC, Competition in the Health Care Marketplace, available at www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

9 15 USC Section 18.

related assets. The FTC generally prefers the divestiture of assets that comprise a separate ongoing business. In the FTC's view, divesting an ongoing stand-alone business poses less risk that the acquired divested business will fail, by providing the buyer with the assets necessary to begin operations immediately.[10] Divestiture of an ongoing business also eliminates the difficulties of separating commingled assets between a seller and a purchaser competing in the same market.

The FTC must approve the buyer in any consent decree requiring a divesture. In most instances, the settlement will involve an up-front buyer, wherein the merging parties must identify a suitable buyer and negotiate a divestiture agreement before the parties can receive clearance from the FTC to close their proposed transaction. The assets to be divested, the proposed buyer and the negotiated divestiture agreement will be vetted by the FTC staff, and then must be examined and approved by a vote of the Commission. The parties must propose a buyer that is familiar with and committed to the relevant market, including current involvement in the same or adjacent markets and prior dealings with the same customers and suppliers, and that has the financial ability to acquire and maintain the divested assets.[11]

Typically, most pharmaceutical settlements provide for the appointment of an interim monitor, who is responsible for overseeing the transfer of the divestiture assets and the buyer's actions in connection with the new business. The monitor will make periodic reports to the FTC to provide information on the parties' compliance with the order and the buyers' progress in securing FDA approval related to the divested assets.[12] Many consent decrees will also require that the merged firm supply buyers with inputs or products for a specified period of time post-divestiture. These supply agreements can support the buyer's ability to immediately compete successfully in the market. Similarly, consent decrees may include transition services agreements, which require the merged firm to provide the buyer with back-office and other functions for a limited period of time until the buyer can perform the services on its own.

In addition to these general principles concerning divesture remedies, the FTC's experience with settlements in the pharmaceutical industry has led to certain patterns and expected practices for divestitures in this area. For example, the FTC has stated that the merging parties should expect to divest the 'easier to divest' product when possible, including products made at third-party manufacturing sites.[13] The parties should provide complete information to the proposed buyer, including any production problems or supply chain issues, and work with the buyer to develop a comprehensive technology transfer plan. The parties should identify specific employees that will oversee the transfer to the new manufacturing facility, and work with the appointed monitor to facilitate development of the technology transfer plan.[14] Finally, the buyer is expected to identify any necessary third-party contract manufacturers for the divested products that the buyer will not manufacture in its own facilities.

10 See FTC, The FTC's Merger Remedies 2006-2012 at 12, 21-22 (January 2017), available at www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.

11 id. at 24.

12 id. at 10.

13 id. at 36.

14 id. at 37.

IV RECENT DEVELOPMENTS

Antitrust review in the pharmaceutical sector has generally remained consistent with the transition from the Obama administration into the Trump administration, beginning in January 2017. This consistency is in contrast to other industries, where the new administration has shifted some direction in oversight and review. Recent FTC actions in mergers involving pharmaceutical products have generally followed the principles outlined in the sections above.

For example, in July 2017, Baxter International Inc and Claris Lifesciences Limited entered into a consent decree, agreeing to divest two types of generic pharmaceutical products – one an antifungal agent in saline intravenous bags called fluconazole, used to treat fungal and yeast infections, and the other a dextrose intravenous bag used as a short-term treatment for life-threatening heart failure called milrinone – as a condition of closing Baxter's $625 million acquisition of Claris's injectable drug business.[15] The FTC's complaint stated that the markets for fluconazole in saline intravenous bags would have been reduced from four to three suppliers as a result of the acquisition, which would 'likely . . . harm consumers through higher drug prices'.[16] Likewise, Baxter was one of three companies currently selling intravenous milrinone, while Claris was expected to enter the market once its pending application with the FDA was approved.[17] The FTC stated that in a market with three current suppliers, 'depriving consumers of a pending, fourth viable supplier' would likely keep prices at higher levels than they would be if the expected market entry had occurred.[18] Under the consent decree, Baxter and Claris agreed to divest Claris's rights to fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags to Renaissance Lakewood LLC.

Similarly, in July 2018, the FTC sought and obtained a settlement agreement in Amneal Pharmaceuticals LLC's $1.45 billion acquisition of a 75 per cent equity share in Impax Laboratories Inc. The FTC's press release regarding the settlement stated that, without a remedy, the acquisition would harm current or future competition in the markets for 10 different generic products. The FTC's complaint filed in connection with the settlement alleged that new entrants into the market for these products would not be sufficient to deter or counteract the anticompetitive effects of the acquisition, as drug development and FDA approval would take up to two years.[19] Under the terms of the settlement agreement, Impax divested its rights and assets to seven generic pharmaceuticals to ANI Pharmaceuticals, Inc. For the three remaining products, Impax divested its rights in generic pharmaceutical products that were co-owned or manufactured by other companies. Perrigo Company plc

15 See FTC, FTC Requires Baxter International and Claris Lifesciences to Divest 2 Types of Pharmaceutical Products as Condition of Baxter Acquiring Injectable Drugs Business from Claris (20 July 2017), available at www.ftc.gov/news-events/press-releases/2017/07/ftc-requires-baxter-international-claris-lifesciences-divest-2.

16 id.

17 id.

18 id.

19 See FTC, FTC Requires Generic Drug Marketers Amneal Pharmaceuticals LLC and Impax Laboratories Inc. to Divest Rights to 10 Generic Medications as Condition of Merger (27 April 2018), available at www.ftc.gov/news-events/press-releases/2018/04/ftc-requires-generic-drug-marketers-amneal-pharmaceuticals-llc.

acquired Impax's rights to two products that it had partnered with Impax to develop and manufacture, while G&W Laboratories acquired Impax's marketing rights to a product manufactured by G&W for Impax.[20]

The FTC's most recent consent decree requiring a divestiture of branded products was finalised in February 2017, when the agency approved a final order in connection with CH Boehringer Sohn AG's (Beohringer Ingleheim) $13.53 billion acquisition of Sanofi's animal health business.[21] The FTC stated that without the divestitures, the acquisition would have harmed competition in the US markets for five different types of vaccines for pets, such as canine, feline and rabies vaccines, and certain parasite control products for cattle and sheep.[22] The consent decree required Boehringer Ingelheim to divest its companion animal products, including the Fel-O-Vax and Fel-O-Guard cat vaccine product lines, to Eli Lilly and Company's Elanco Animal Health Division. The parasite control products, marketed under the name Cydectin, were divested to Bayer AG.[23]

Though these recent settlement agreements have followed expected patterns, there are some signals that FTC review and enforcement in the pharmaceutical sector may see some changes. At a February 2018 conference, Bruce Hoffman, then the Acting Director of the FTC's Bureau of Competition and now holding the same position on a non-interim basis, spoke about the FTC's shifting approach to structuring a remedy in transactions where the merging parties have an overlap between a branded and pipeline product. Mr Hoffman stated that in transactions where two merging companies have 'complex pharmaceutical products such as inhalants or injectables' that need to be divested, the FTC will require that the currently marketed branded product be divested instead of the pipeline product.[24] This approach reflects the FTC's view that divesting a pipeline product, where the divestiture buyer must navigate the final development and approval of the to-be marketed drug, places the risk of failure onto consumers. If the divested pipeline product fails to enter the market, consumers will not benefit from the lower drug prices that would result from an additional competitor in the market. By contrast, if the parties divest the product that is already successfully on the market and keep the pipeline product, the risk of the pipeline product's failure shifts to the merging parties rather than consumers.[25] This is also in keeping with the FTC's stated mission of encouraging innovation, as it incentivises the merged firm to continue channelling resources towards new pipeline products. Though Mr Hoffman's remarks focused on complex pharmaceutical products such as inhalants and injectables, these principles may also be applied to other types of products in the future.

20 See FTC, FTC Approves Final Order Imposing Conditions on Merger of Generic Drug Marketers Amneal Pharmaceuticals LLC and Impax Laboratories, Inc. (10 July 2018), available at www.ftc.gov/news-events/press-releases/2018/07/ftc-approves-final-order-imposing-conditions-merger-generic-drug.

21 See FTC, FTC Approves Final Order Preserving Competition in U.S. Markets for Animal Health Products (24 February 2017), available at www.ftc.gov/news-events/press-releases/2017/02/ftc-approves-final-order-preserving-competition-us-markets-animal.

22 See FTC, FTC Requires Divestitures as Condition to Proposed $13.53 Billion Deal between German Pharmaceutical Boehringer Ingelheim and Paris-Based Sanofi (28 December 2016), available at www.ftc.gov/news-events/press-releases/2016/12/ftc-requires-divestitures-condition-proposed-1353-billion-deal.

23 id.

24 D Bruce Hoffman, 'It Only Takes Two to Tango: Reflections on Six Months at the FTC', Remarks at GCR Live 7th Annual Antitrust Law Leaders Forum at 6 (2 February 2018), available at www.ftc.gov/system/files/documents/public_statements/1318363/hoffman_gcr_live_feb_2018_final.pdf.

25 id.

V CONCLUSION

Merger review in the US pharmaceutical industry has developed and followed steady patterns over time, based on the FTC's experience and understanding of the area. Parties pursuing a merger or acquisition can expect many of the FTC's standard merger review processes, as well as some pharmaceutical industry-specific nuances. The agency will examine the transaction for likely harm to competition, looking within the relevant geographic market of the United States and in the relevant product markets, which are generally distinct for generic and branded prescription drugs. Should the FTC identify such a likelihood of anticompetitive harm, the agency will likely pursue a settlement agreement with the parties involving the divestiture of products in the markets raising concern. The parties may look to the FTC's prior consent decrees with other companies to understand what such agreements generally entail, such as a preference that the parties divest a stand-alone ongoing business, the inclusion of a temporary supply agreement, or the appointment of a monitor to oversee the transfer of the business to an FTC-approved buyer. The FTC's recent actions in mergers involving pharmaceutical products have generally followed these principles, but there is some indication that the agency will continue to finesse its approach to evaluating transactions in this complex industry.

Appendix 1

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