THE MERGER CONTROL REVIEW

FOURTEENTH EDITION

Editor
Ilene Knable Gotts

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PREFACE

Pre-merger competition review has advanced significantly since its creation in 1976 in the United States. As this book evidences, today almost all competition authorities have a notification process in place – with most requiring pre-merger notification for transactions that meet certain prescribed minimum thresholds. Additional jurisdictions such as Malaysia are continuing to consider imposing mandatory pre-notification regimes, and in the meantime can assert some jurisdiction to review certain transactions under their conduct laws and for specific sectors (e.g., aviation, communications). The intended readership of this book comprises both in-house and outside counsel who may be involved in the competition review of cross-border transactions.

Given the ability of most competition agencies with pre-merger notification laws to delay, and even block, a transaction, it is imperative to take each jurisdiction – small or large, new or mature – seriously. For instance, the international business community had a wake-up call when, in 2009, China blocked the Coca-Cola Company's proposed acquisition of China Huiyuan Juice Group Limited and imposed conditions on four mergers involving non-China-domiciled firms. In *Phonak/ReSound* (a merger between a Swiss undertaking and a Danish undertaking, each with a German subsidiary), the German Federal Cartel Office blocked the entire merger, even though less than 10 per cent of each of the undertakings was attributable to Germany. In the United Kingdom, the Competition and Markets Authority (CMA) has effectively blocked transactions in which the parties question its authority. It is imperative, therefore, that counsel develop a comprehensive plan before, or immediately upon, execution of an agreement concerning where and when to file a notification with competition authorities regarding such a transaction. To this end, this book provides an overview of the process in 25 jurisdictions, as well as a discussion of recent decisions, strategic considerations and likely developments.

Some common threads in institutional design underlie most of the merger review mandates, although there are some outliers and nuances that necessitate careful consideration when advising a client on a particular transaction. Almost all jurisdictions vest exclusive authority to review transactions in one agency. The United States is now the major exception in this regard (China having consolidated its three antitrust agencies into one agency in 2018). Most jurisdictions provide for objective monetary size thresholds (e.g., the turnover of the parties, the size of the transaction) to determine whether a filing is required. Germany amended its law to ensure that it has the opportunity to review transactions in which, although the parties' turnovers do not reach the threshold, the value of the transaction is significant (e.g., social media, new economy, internet transactions). Other jurisdictions are also focused on ensuring that acquisitions involving smaller internet, online and data companies or, in other high-technology settings, a nascent competitor, do not escape review.

Newly adopted laws have tried to vest jurisdiction on these transactions by focusing on the 'value of the consideration' rather than turnover for acquisitions of nascent firms, particularly in the digital economy (e.g., in Austria and Germany). Some jurisdictions have also adopted a process to call in transactions that fall below the thresholds, but where the transaction may be of competitive significance. For instance, the Japan Federal Trade Commission (JFTC) has the ability to review and take action in non-reportable transactions (see discussion of *Google/Fitbit* in the International Merger Remedies and Japan chapters), and has developed guidelines for voluntary filings. Note that the actual monetary threshold levels can vary in specific jurisdictions over time. To provide the ability to review acquisitions of nascent but potentially important rivals, the European Commission (EC) has adopted potentially the most significant change in its rules: to use the referral process from Member States to vest jurisdiction in transactions that fall below its thresholds but that could have Community-wide significance. In one such matter, *Illumina/GRAIL*, the EC invited national competition authorities to request a referral of the transaction, even though it did not meet the review thresholds of the EU Merger Regulation or any national merger control rules (in fact, GRAIL had no sales at all in the European Union). At the time of writing, according to reports, the EC has since accepted Article 22 referral requests in three other cases (*Meta/Kustomer*, *Viasat/Inmarsat* and *Cochlear/Oticon Medical*), although in each of these the transaction triggered the national merger control thresholds in at least one EU Member State.

There are some jurisdictions that still use 'market share' indicia (e.g., Bosnia and Herzegovina, Colombia, Lithuania, Portugal, Spain, Ukraine and the United Kingdom). Most jurisdictions require that both parties have some turnover or nexus to their jurisdiction; however, there are some that take a more expansive view. For instance, in Poland, a notification may be required even though only one of the parties is present and, therefore, there may not be any effect on competition in Poland. Turkey recently issued a decision finding that a joint venture (JV) that produced no effect on Turkish markets was reportable because the JV's products 'could be' imported into Turkey. In Serbia, there is similarly no 'local' effect required. Germany also takes an expansive view by adopting as one of its thresholds a transaction of 'competitively significant influence'. Although a few merger notification jurisdictions remain 'voluntary' (e.g., Australia, Singapore, the United Kingdom and Venezuela), the vast majority impose mandatory notification requirements. Moreover, in Singapore, the transaction parties are to undertake a self-assessment of whether the transaction will meet certain levels and, if so, should notify the agency to avoid a potential challenge by the agency.

Although in most jurisdictions the focus of the competition agency is on competition issues, some jurisdictions have a broader mandate. For instance, the 'public interest' approach in South Africa expressly provides for consideration of employment matters, local enterprises and procurement, and for economic empowerment of the black population and its participation in the company. Many of the remedies imposed in South Africa have been in connection with these considerations. Notably, the current leadership at the US antitrust authorities have similarly suggested that their mandate under the antitrust laws is broader than the traditional focus on consumers and consumer welfare to include impact on labour, diversity and other considerations. It is unclear at this point how this shift will affect enforcement decisions and judicial challenges. Although a growing number of jurisdictions have separate regulations and processes for addressing foreign entity acquisitions when national security or specific industrial sectors are involved, in Romania, for example, competition law provides that the government can prohibit a merger if it determines that the merger could potentially affect national security.

Some jurisdictions are exempt from notification (e.g., Ecuador) or have special rules for the timing of bankrupt firms (e.g., Brazil, Switzerland and the Netherlands, where firms can implement before clearance if a waiver is obtained; Austria, India, Russia and the United States have shorter time frames). Also, in some jurisdictions, the law and precedent expressly recognise the consideration of the financial condition of the target and the failing firm doctrine (e.g., Canada, China and the United States). In Canada, for instance, the Competition Bureau explicitly permitted the *AIM/TMR* transaction to proceed on the basis of the failing firm defence. Similarly, the Netherlands has recently recognised the defence in a couple of hospital mergers. In a major matter in the United Kingdom, *Amazon/Deliveroo*, the CMA provisionally allowed the transaction to proceed owing to the target being a failing firm. This topic is likely to be an area to watch in other jurisdictions, particularly in some of the newer merger regimes.

The potential consequences for failing to file in jurisdictions with mandatory requirements vary. Almost all jurisdictions require that the notification process be concluded before completion (e.g., pre-merger, suspensory regimes), rather than permitting the transaction to close as long as notification is made before closing. Many of these jurisdictions can impose a significant fine for failure to notify before closing, even when the transaction raises no competition concerns (e.g., Austria, Cyprus, India, the Netherlands, Romania, Spain and Turkey). In France, for instance, the competition authority imposed a €4 million fine on Castel Frères for failure to notify its acquisition of part of the Patriarche group. In Ukraine and Romania, the competition authorities have focused their efforts on discovering consummated transactions that had not been notified and imposing fines on the parties. Chile's antitrust enforcer recommended a fine of US$3.8 million against two meat-packing companies, even though the parties had carved the Chilean business out of the closing. In 2021, Morocco similarly imposed a fine for failure to notify a transaction in excess of US$1 million.

Some jurisdictions impose strict time frames within which the parties must file their notification. For instance, Cyprus requires filing within one week of signing of the relevant documents and agreements; Serbia provides for 15 days after signing of the agreement; and Hungary, Ireland and Romania have a 30-calendar-day time limit for filing the notification that commences with entering into the agreement. Some jurisdictions that mandate filings within specified periods after execution of the agreement also have the authority to impose fines for late notifications (e.g., Bosnia and Herzegovina, Indonesia and Serbia). Most jurisdictions also have the ability to impose significant fines for failure to notify or for closing before the end of the waiting period, or both (e.g., Austria, Canada, China, Greece, Portugal, Ukraine and the United States). In Macedonia, the failure to file can result in a misdemeanour and a monetary fine of up to 10 per cent of worldwide turnover. In Belgium, the competition authority fined a party for late submission of information.

The United States and the EC both have a long history of focusing on interim conduct of the transaction parties, which is commonly referred to as gun-jumping, even fining companies that are found to be in violation. For example, the EC imposed a €124.5 million fine on Altice and, in 2023, fined Illumina €432 million for its closing of the *Grail* transaction. Other jurisdictions have become increasingly aggressive in the imposition of fines. Brazil, for instance, issued its first gun-jumping fine in 2014 and later issued guidelines on gun-jumping violations. Since then, Brazil has continued to be very active in investigating and imposing fines for gun-jumping activities. In addition, the sharing of competitively

sensitive information before approval appears to be considered an element of gun-jumping. Also, for the first time, France imposed a fine of €20 million on the notifying party for failure to implement commitments fully within the time frame imposed by the authority.

In most jurisdictions, a transaction that does not meet the pre-merger notification thresholds is not subject to review or challenge by the competition authority; however, in Canada – like the United States – the Competition Bureau can challenge mergers that were not required to be notified under the pre-merger statute, as well as challenge notified transactions within the first year of closing. In Korea, Microsoft initially filed a notification with the Korea Fair Trade Commission (KFTC), but when it faced difficulties and delays in Korea, the parties restructured the acquisition to render the transaction non-reportable in Korea and consummated the transaction; however, the KFTC continued its investigation as a post-consummation merger investigation and eventually obtained a consent order. This list of jurisdictions is illustrative rather than comprehensive and is consistent with the overarching concerns expressed above regarding catching transactions that may have fallen below the radar but are subsequently deemed problematic. In the same spirit, the EC has fined companies on the basis that the information provided at the outset was misleading (for instance, it fined Facebook €110 million for providing incorrect or misleading information during the *Facebook/WhatsApp* acquisition).

In almost all jurisdictions, very few transactions undergo a full investigation, although some require that the notification provide detailed information regarding the markets, competitors, competition, suppliers, customers and entry conditions. Most jurisdictions that have filing fees specify a flat fee or state in advance a schedule of fees based on the size of the transaction; however, some jurisdictions determine the fee after filing or provide different fees based on the complexity of the transaction.

Most jurisdictions more closely resemble the EC model than the United States model. In these jurisdictions, pre-filing consultations are more common (and even encouraged); parties can offer undertakings during the initial stage to resolve competitive concerns; and there is a set period during the second phase for providing additional information and for the agency to reach a decision. In Japan, however, the JFTC announced in June 2011 that it would abolish the prior consultation procedure option. When combined with the inability to 'stop the clock' on the review periods, counsel may find it more challenging in transactions involving multiple filings to avoid the potential for the entry of conflicting remedies or even a prohibition decision at the end of a JFTC review. Some jurisdictions, such as Croatia, are still aligning their threshold criteria and processes with the EC model. Even within the EC, there remain some jurisdictions that differ procedurally from the EC model. For instance, in Austria, the obligation to file can be triggered if only one of the involved undertakings has sales in Austria, as long as both parties satisfy a minimum global turnover and have a sizeable combined turnover in Austria. Finally, some jurisdictions have developed a fast-track process for transactions that are unlikely to raise antitrust concerns (e.g., because the parties' combined shares of potential relevant markets are all below a certain threshold or because of the size of the transaction). China and the EC are two such regimes in which the adoption of this fast-track process can make a significant difference to the review period.

The role of third parties also varies across jurisdictions. In some (e.g., Japan), there is no explicit right of intervention by third parties but the authorities can choose to allow it on a case-by-case basis. In contrast, in South Africa, registered trade unions or representatives of employees must be provided with a redacted copy of the merger notification from the outset and have the right to participate in merger hearings before the Competition Tribunal; the

Tribunal will typically also permit other third parties to participate. Bulgaria has announced a process by which transaction parties even consent to disclosure of their confidential information to third parties. In some jurisdictions (e.g., Australia, the EC and Germany), third parties may file an objection to a clearance decision. In other jurisdictions (including Canada, the EC and the United States), third parties (e.g., competitors) are required to provide information and data if requested by the antitrust authority. In Israel, a third party that did not comply with such a request was fined by the antitrust authority.

In almost all jurisdictions, once the authority approves the transaction, it cannot later challenge the transaction's legality. The United States is one significant outlier with no bar for subsequent challenge, even decades following the closing, if the transaction is later believed to have substantially lessened competition. Canada, in contrast, provides a more limited period of one year for challenging a notified transaction (see the recent *CSC/Complete* transaction). In Hong Kong, the authority has six months post-consummation to challenge a transaction. Norway is also a bit unusual in that the authority has the ability to mandate notification of a transaction for a period of up to three months following the transaction's consummation. In 'voluntary' jurisdictions, such as Australia and Singapore, the competition agency can investigate and challenge unnotified transactions.

In large cross-border transactions raising competition concerns, it is becoming the norm for the US, Canadian, Mexican, EC and UK authorities to work closely together during the investigative stages, and even in determining remedies, minimising the potential of arriving at diverging outcomes. The KFTC has stated that it will engage in even greater cooperation with foreign competition authorities, particularly those of China and Japan, which are similar to Korea in their industrial structure. Regional cooperation among some of the newer agencies has also become more common; for example, the Argentinian authority has worked with Brazil's competition authority, which, in turn, has worked with the Chilean authority. Competition authorities in Bosnia and Herzegovina, Bulgaria, Croatia, Macedonia, Montenegro, Serbia, Slovenia and Turkey similarly maintain close ties and cooperate on transactions. Taiwan is part of the Asia-Pacific Economic Cooperation forum, which shares a database. In transactions not requiring filings in multiple European jurisdictions, Member States often keep each other informed during the course of an investigation. In addition, transactions not meeting the EC threshold can nevertheless be referred to the EC in appropriate circumstances. The United States has signed cooperation agreements with a number of jurisdictions, including, most recently, Peru and India. China has consulted with the United States and the EC on some mergers and entered into a cooperation agreement with the United States authorities in 2011.

The impact of multi-jurisdictional cooperation is very evident. For instance, the transaction parties in *Applied Materials/Tokyo Electron* ultimately abandoned the transaction following the combined objections of several jurisdictions, including the United States, Europe and Korea. In *Office Depot/Staples*, the US Federal Trade Commission and the Canadian Competition Bureau cooperated and both jurisdictions brought suits to block the transaction (although the EC had also cooperated on this transaction, it ultimately accepted the undertakings offered by the parties). In the *GE/Alstom* transaction, the United States and the EC coordinated throughout, including at the remedies stage. Additionally, in the *Halliburton/Baker Hughes* transaction, the United States and the EC coordinated their investigations, with the United States suing to block the transaction while the EC's investigation continued. Also, in *Holcim/Lafarge*, the cooperation between the United States and Canada continued at the remedies stage, where both consents included assets in the other

jurisdiction's territory. The United States, Canada and Mexico coordinated closely in the review of the *Continental/Veyance* transaction. In fact, coordination among the jurisdictions in multinational transactions that raise competition issues is becoming the norm.

Although some jurisdictions have raised the size threshold at which filings are mandated (e.g., Austria), others have broadened the scope of their legislation to include, for instance, partial ownership interests. Some jurisdictions continue to have as their threshold test for pre-merger notification whether there is an acquisition of control. Many of these jurisdictions, however, will include, as a reportable situation, the creation of joint control, negative (e.g., veto) control rights to the extent that they may give rise to *de jure* or de facto control (e.g., Turkey), or a change from joint control to sole control (e.g., the EC and Lithuania). Minority holdings and concerns over 'creeping acquisitions', in which an industry may consolidate before the agencies become fully aware, have become the focus of many jurisdictions. Some jurisdictions will consider as reviewable acquisitions in which an interest of only 10 per cent or less is being acquired (e.g., Serbia for certain financial and insurance mergers), although most jurisdictions have somewhat higher thresholds (e.g., Korea sets the threshold at 15 per cent of a public company and otherwise at 20 per cent of a target; and Japan and Russia at any amount exceeding 20 per cent of the target). Others use as the benchmark the effect that the partial shareholding has on competition; Norway, for instance, can challenge a minority shareholding that creates or strengthens a significant restriction on competition. The United Kingdom also focuses on whether the minority shareholder has material influence (i.e., the ability to make or influence commercial policy) over the entity. Several agencies during the past few years have analysed partial ownership acquisitions on a stand-alone basis as well as in connection with JVs (e.g., Canada, China, Cyprus, Finland and Switzerland). Vertical mergers have also been the subject of review (and even resulted in some enforcement actions) in a number of jurisdictions (e.g., Belgium, Canada, China, Sweden and Taiwan). Portugal even viewed as an acquisition subject to notification the non-binding transfer of a customer base.

For transactions that raise competition issues, the need to plan and to coordinate among counsel has become particularly acute. Multi-jurisdictional cooperation facilitates the development of cross-border remedies packages that effectively address competitive concerns while permitting the transaction to proceed. The consents adopted by the United States and Canada in the *Holcim/Lafarge* merger exemplify such a cross-border package. As discussed in the 'International Merger Remedies' chapter, it is no longer prudent to focus merely on the larger mature authorities, with the expectation that other jurisdictions will follow their lead or defer to their review. In the current enforcement environment, obtaining the approval of jurisdictions such as Brazil and China can be as important as the approval of the EC or the United States. Moreover, the need to coordinate is particularly acute, to the extent that multiple agencies decide to impose conditions on the transaction. Although most jurisdictions indicate that structural remedies are preferable to behavioural conditions, a number of jurisdictions in the past few years have imposed a variety of behavioural remedies (e.g., China, the EC, France, Italy, Japan, the Netherlands, Norway, South Africa, Ukraine and Vietnam). This is particularly the case when non-compete or exclusive dealing relationships raise concerns (e.g., in Mexico and the United States). Some recent decisions have included as behavioural remedies pricing, sales tariffs and terms of sale conditions (e.g., Korea, Ukraine and Serbia), employee retrenchment (South Africa) and restrictions on bringing anti-dumping suits (e.g., Mexico). Many recent decisions have imposed behavioural remedies to strengthen the effectiveness of divestitures (e.g., Canada's decision in the *Loblaw/Shoppers*

transaction, China's Ministry of Commerce remedy in *Glencore/Xstrata* and France's decision in the *Numericable/SFR* transaction). It is important to note, however, that one of the areas flagged for change by the new leadership at the US antitrust authorities is the willingness to consider behavioural remedies, or, for that matter, any remedies, rather than bringing enforcement actions to challenge the transaction itself.

In many of the key enforcement regimes (e.g., the United States, Canada, China and the United Kingdom), we are at a potentially transformational point in competition policy enforcement; however, this book should provide a useful starting point in navigating cross-border transactions in this changing enforcement environment.

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Chapter 2

US MERGER CONTROL IN THE PHARMACEUTICAL SECTOR

Margaret T Segall and Nicole M Peles[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 agency that has jurisdiction over the relevant industry. The DOJ and the 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 or over-the-counter drugs (or both). 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 antitrust review accounts for the complexity of this highly regulated industry.

This chapter contains three main sections. First is 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. In Section III, we discuss merger remedies in the pharmaceutical sector and what parties can expect from an FTC consent decree. Section IV covers 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

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2 See Federal Trade Commission (FTC), 'Inside the Bureau of Competition' (May 2020), at 9 (https://www.ftc.gov/about-ftc/bureaus-offices/bureau-competition/inside-bureau-competition (accessed 10 July 2023)).

3 ibid., at 19.

minimum size-of-person thresholds, the transaction is HSR-reportable. As of 27 February 2023, the minimum size-of-transaction threshold is US$111.4 million. The minimum size-of-person thresholds are US$22.3 million and US$222.7 million in either annual sales or total assets, respectively. For transactions valued at less than US$111.4 million, no HSR filing is required. For transactions valued between US$111.4 million and US$445.5 million, HSR notification is required only if at least one party satisfies each of the size-of-person thresholds. For transactions valued above US$445.5 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, services or activities and, if necessary, either negotiating and approving a settlement to resolve any competitive concerns or bringing suit to block the transaction. 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 has filed its respective HSR forms, the FTC has 30 days to carry out its preliminary review. The parties may not close the transaction during this 30-day waiting period. During 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)[4] or simply allow the waiting period to expire without further action. Following early termination or the expiry 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 during the initial waiting period, it may issue a second request, which extends the timeline of the agency's review and allows the FTC to investigate a transaction more closely.[5] 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 it has 'substantially complied' with its 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.[6] However, for proposed transactions in the pharmaceutical

4 On 4 February 2021, the FTC and the Antitrust Division of the US Department of Justice (DOJ) announced a temporary suspension of early termination grants while the FTC 'reviews the processes and procedures used to grant early terminations'. See FTC, 'FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination' (4 February 2021) (www.ftc.gov/news-events/press-releases/2021/02/ftc-doj-temporarily-suspend-discretionary-practice-early (accessed 3 July 2023)). The agencies have not indicated if and when they expect to reinstate early termination.

5 See FTC, Merger Review (www.ftc.gov/news-events/media-resources/mergers-and-competition/merger-review (accessed 3 July 2023)).

6 id.

agency, given the particular nature of the products at issue, and the extremely broad nature of a second request, historically it has not been uncommon for parties to choose not to comply substantially with the request and instead provide the FTC with more targeted information about the products at issue 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 parties and the FTC staff will work with the FTC Compliance Division to draft a settlement agreement.[7] 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 geographical market, or markets, and the relevant product market, or markets.[8] In the pharmaceutical drug industry, the relevant geographical 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 or markets, 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 are 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 expiry of the branded product's patent, or if before the expiry date, 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

7 See Section III for additional detail about the FTC remedial process.

8 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 DOJ and FTC, 'Horizontal Merger Guidelines' (19 August 2010), at 7–8 (www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf (accessed 3 July 2023)).

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 for the same branded drug will also be closely evaluated. However, because of the different pricing strategies that 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 the products currently on the market. The FTC has stated goals of encouraging innovation in healthcare markets and ensuring that merging companies continue to bring new or improved products to patients.[9] 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 that incentivises the parties to successfully bring the new product onto the market.

During the course of the FTC's investigation, it will generally evaluate whether the transaction is likely to harm competition through either unilateral effects or 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. The FTC may also consider whether the transaction is likely to harm competition through conglomerate effects.[10] Conglomerate effects arise when the merging parties have neither horizontal nor vertical overlaps but could possibly harm competition through tactics such as tying and bundling of products or through reduced innovation incentives.[11] The FTC has rarely challenged mergers on the basis that competition is likely to be harmed through conglomerate effects. If the FTC determines that a transaction is likely to harm competition based on any of these theories, it will require that the parties remedy this harm before the transaction is allowed to close.

9 See FTC, 'Competition in the Health Care Marketplace' (www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care (accessed 3 July 2023)).

10 Organisation for Economic Co-operation and Development, 'Conglomerate effects of mergers – Note by the United States' (10 June 2020), at 2 (https://www.ftc.gov/system/files/attachments//us-submissions-oecd-2010-present-other-international-competition-fora/oecd-conglomerate_mergers_us_submission.pdf (accessed 3 July 2023)).

11 ibid., at 8–10.

III REMEDIES

If the FTC believes that the effect of the transaction 'may be substantially to lessen competition'[12] 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 historically have resulted in settlement between the parties and the government, rather than litigation. These settlement agreements are referred to as 'consent decrees'. Although 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. Although 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 related assets. The FTC generally requires 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.[13] 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 divestiture. 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 the 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.[14]

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 about the parties' compliance with the order and the buyers' progress in securing FDA approval regarding the divested assets.[15] Many consent decrees will also require that the merged firm supply buyers with inputs or products for a specified amount 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

12 15 U.S.C. Section 18.

13 See FTC, 'The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics' (January 2017), at 12, 21–22 (www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf (accessed 3 July 2023)).

14 ibid., at 24.

15 ibid., at 10.

transition services agreements, which require the merged firm to provide the buyer with back-office and other functions for a limited amount of time, until the buyer can perform the services on its own.

In addition to these general principles concerning divestiture remedies, the FTC's experience with settlements in the pharmaceutical industry has historically 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.[16] In early 2018, the FTC announced a shifting approach to structuring a remedy in transactions where the merging parties have an overlap between a branded and pipeline product: in transactions where two merging companies have 'complex pharmaceutical products such as inhalants or injectables' that need to be divested, the FTC would require that the currently marketed branded product be divested instead of the pipeline product.[17] 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.[18] 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. Although this announcement focused on complex pharmaceutical products such as inhalants and injectables, these principles now reflect the FTC's position on pharmaceutical products generally.

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.[19] 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.

During the Biden administration, the FTC has assumed a less favourable view of divestitures than in prior administrations. In 2021, the FTC announced that it would begin to require merging parties subject to a consent decree, including one requiring divestiture, to obtain prior approval before closing any future transaction affecting markets in which a violation was alleged.[20] In early 2023, the FTC announced that, moving forward, it will only

16 ibid., at 36.

17 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 (2 February 2018), at 6 (www.ftc.gov/system/files/documents/public_statements/1318363/hoffman_gcr_live_feb_2018_final.pdf (accessed 3 July 2023)).

18 id.

19 ibid., at 37.

20 FTC, 'Statement of the Commission on Use of Prior Approval Provisions in Merger Orders' (25 October 2021) (https://www.ftc.gov/system/files/documents/public_statements/1597894/p859900priorapprovalstatement.pdf (accessed 3 July 2023)).

support divestitures that allow the buyer to operate the divested assets quickly, independently and with the same incentives as the assets' original owner.[21] The FTC indicated that it would disfavour divestitures in which the merging parties propose to sell less than stand-alone business units that can successfully operate on their own and assets that require ongoing entanglements, such as supply agreements between the merged entity and the buyer.[22] The FTC also indicated that it will no longer engage in a protracted negotiation process with the merging parties and will instead set firm deadlines by which the merging parties must propose viable divestiture options.[23] These developments will present impediments to firms with overlapping products that plan to merge.

IV RECENT DEVELOPMENTS

While antitrust review in the pharmaceutical sector generally remained consistent with prior years for most of the Trump administration, mergers in the sector have faced significantly increased scrutiny in the past several years, and this scrutiny has only increased under the Biden administration.

There was significant M&A activity in the pharmaceutical sector during the final year of the Trump administration. Two of the major pharmaceutical deals announced in 2019–2020 were ultimately abandoned as a result of regulatory scrutiny.[24]

Several large pharmaceutical deals in 2019–2020 were allowed to proceed but the FTC required significant divestitures.[25] For these transactions, the two Democratic

21 Holly Vedova, 'Update from the FTC's Bureau of Competition', Remarks at 12th Annual GCR Live: Law Leaders Global Conference (3 February 2023), at 10 (https://www.ftc.gov/system/files/ftc_gov/pdf/vedova-gcr-law-leaders-global-conference.pdf (accessed 3 July 2023)).

22 ibid., at 11.

23 ibid., at 12.

24 See Novartis, 'Novartis announces mutual agreement to terminate sale of Sandoz US generic oral solids, dermatology portfolio to Aurobindo' (2 April 2020) (www.novartis.com/news/media-releases/novartis-announces-mutual-agreement-terminate-sale-sandoz-us-generic-oral-solids-dermatology-portfolio-aurobindo (accessed 3 July 2023)); FTC, 'Federal Trade Commission Closes Investigation of Johnson & Johnson's Proposed Acquisition of TachoSil from Takeda Pharmaceutical Company' (10 April 2020) (https://www.ftc.gov/news-events/news/press-releases/2020/04/federal-trade-commission-closes-investigation-johnson-johnsons-proposed-acquisition-tachosil-takeda (accessed 3 July 2023)).

25 See FTC, 'FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as a Condition of Acquisition' (15 November 2019) (www.ftc.gov/news-events/press-releases/2019/11/ftc-requires-bristol-myers-squibb-company-celgene-corporation (accessed 3 July 2023)); FTC, 'FTC Imposes Conditions on AbbVie Inc.'s Acquisition of Allergan plc' (5 May 2020) (www.ftc.gov/news-events/press-releases/2020/05/ftc-imposes-conditions-abbvie-incs-acquisition-allergan-plc (accessed 3 July 2023)); FTC, 'FTC Imposes Conditions on Combination of Pfizer Inc.'s Upjohn and Mylan N.V.' (30 October 2020) (www.ftc.gov/news-events/press-releases/2020/10/ftc-imposes-conditions-combination-pfizer-incs-upjohn-mylan-nv (accessed 3 July 2023)).

FTC commissioners – Rohit Chopra and Rebecca Kelly Slaughter – issued vocal dissents questioning both the proposed settlement agreements and the FTC's methods for reviewing pharmaceutical transactions more broadly.[26]

The dissenting statements by the Democratic commissioners in these matters regarding the FTC's overall approach indicate the high level of scrutiny that pharmaceutical mergers can be expected to receive under a now majority Democratic Commission in the Biden administration, in particular given the current FTC leadership's explicit scepticism about the effectiveness of divestiture remedies overall.[27] For example, in a public letter to Senator Elizabeth Warren, FTC chair Lina Khan wrote: 'While structural remedies generally have a stronger track record than behavioural remedies, studies show that divestitures, too, may prove inadequate in the face of an unlawful merger. In light of this, I believe the antitrust agencies should more frequently consider opposing problematic deals outright.'[28] In spite of this scepticism, some pharmaceutical deals have been cleared during the Biden administration.

For example, on 15 March 2021, Alexion Pharmaceuticals Inc disclosed that following informal discussions with the FTC, AstraZeneca plc had elected to withdraw and refile the notification and report form under the HSR to allow the FTC more time to review its US$39 billion acquisition of Alexion.[29] The transaction was cleared on 16 April 2021 without the issuance of a second request.[30]

26 See FTC, 'Dissenting Statement of Commissioner Rohit Chopra In the Matter of Bristol-Myers Squibb Company and Celgene Corporation' (15 November 2019) (www.ftc.gov/public-statements/2019/11/dissenting-statement-commissioner-rohit-chopra-matter-bristol-myers-squibb (accessed 3 July 2023)); FTC, 'Dissenting Statement of Commissioner Rebecca Kelly Slaughter In the Matter of Bristol-Myers Squibb Company and Celgene Corporation' (15 November 2019) (www.ftc.gov/public-statements/2019/11/statement-commissioner-rebecca-kelly-slaughter-matter-bristol-myers-squibb (accessed 3 July 2023)); FTC, 'Dissenting Statement of Commissioner Rohit Chopra In the Matter of AbbVie Inc. and Allergan plc' (5 May 2020) (www.ftc.gov/public-statements/2020/05/dissenting-statement-commissioner-rohit-chopra-matter-abbvie-inc-allergan (accessed 3 July 2023)); FTC, 'Dissenting Statement of Commissioner Rebecca Kelly Slaughter Regarding the Proposed Acquisition of Allergan plc by AbbVie Inc.' (5 May 2020) (www.ftc.gov/public-statements/2020/05/dissenting-statement-commissioner-rebecca-kelly-slaughter-regarding (accessed 3 July 2023)); FTC, 'Statement of Commissioner Rohit Chopra Joined by Commissioner Rebecca Kelly Slaughter In the Matter of Pfizer Inc. / Mylan N.V.' (30 October 2020) (www.ftc.gov/system/files/documents/public_statements/1582382/191_0182_pfizer-mylan_-_dissenting_statement_of_commrs_chopra_and_slaughter_1.pdf (accessed 3 July 2023)).

27 See 'FTC Chair Khan Shares Warren's Concerns About Giant Defense Industry Mergers' (12 August 2021) (www.warren.senate.gov/oversight/letters/new-ftc-chair-khan-shares-warrens-concerns-about-giant-defense-industry-mergers (accessed 3 July 2023)).

28 id.

29 See Alexion Pharmaceuticals, Inc., SEC Form 8-K (12 March 2021) (www.sec.gov/ix?doc=/Archives/edgar/data/899866/000114036121008493/nc10017928x20_8k.htm (accessed 3 July 2023)). A 'pull and refile' resets the statutory 30-day waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. §18a, and is a common tool to give the agency extra time to conclude its preliminary investigation to avoid (or streamline) any second request.

30 AstraZeneca, 'AstraZeneca receives US clearance of proposed acquisition of Alexion' (16 April 2021) (www.astrazeneca.com/content/astraz/media-centre/press-releases/2021/us-clearance-of-proposed-acquisition-of-alexion.html (accessed 3 July 2023)).

Likewise, on 29 October 2021, Merck withdrew and refiled its HSR form for its US$11.5 billion acquisition of Acceleron Pharma.[31] The applicable waiting period expired on 16 November 2021, without the issuance of a second request.[32] On 7 February 2022, Pfizer withdrew and refiled its HSR form for its US$6.7 billion acquisition of Arena Pharmaceuticals.[33] Pfizer completed the acquisition on 11 March 2022.[34]

On 16 March 2021, the FTC announced the launch of a multilateral working group (now called the Multilateral Pharmaceutical Merger Task Force) to establish a new approach to pharmaceutical mergers.[35] The Task Force, which was initiated by the FTC, will also include the Canadian Competition Bureau, the European Commission Directorate General for Competition, the UK's Competition and Markets Authority, the DOJ Antitrust Division and offices of US state attorneys general.[36] The FTC's press release announcing the Task Force indicates that its goal is to identify concrete and actionable steps to review and update the analysis of pharmaceutical mergers, which will ensure that FTC investigations include 'fresh approaches that fully analyse and address the varied competitive concerns' that pharmaceutical transactions raise.[37] Questions for the Task Force include the following:

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

On 11 May 2021, the Task Force issued a notice seeking public comment to inform its review.[38] On 31 May 2022, the agencies announced they would be holding a virtual

31 'Merck Announces Withdrawal and Refiling under the Hart-Scott-Rodino Act and Extension of Tender Offer to Acquire Acceleron Pharma Inc.' (16 April 2021) (www.merck.com/news/merck-announces-withdrawal-and-refiling-under-the-hart-scott-rodino-act-and-extension-of-tender-offer-to-acquire-acceleron-pharma-inc/ (accessed 3 July 2023)).

32 'Merck Completes Acquisition of Acceleron Pharma Inc.' (https://www.merck.com/news/merck-completes-acquisition-of-acceleron-pharma-inc/ (accessed 10 July 2023)).

33 Arena Pharmaceuticals, Inc., SEC Form 8-K (7 February 2022) (http://pdf.secdatabase.com/2553/0001080709-22-000003.pdf (accessed 10 July 2023)).

34 'Pfizer Completes Acquisition of Arena Pharmaceuticals' (11 March 2022) (www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-arena-pharmaceuticals (accessed 3 July 2023)).

35 FTC, 'FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers' (16 March 2021) (www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach (accessed 3 July 2023)).

36 id.

37 id.

38 FTC, 'Multilateral Pharmaceutical Merger Task Force Seeks Public Input' (11 May 2021) (www.ftc.gov/news-events/press-releases/2021/05/multilateral-pharmaceutical-merger-task-force-seeks-public-input (accessed 3 July 2023)).

workshop on pharmaceutical industry antitrust enforcement.[39] The workshop was held on 14 and 15 June 2022 and the FTC and DOJ Antitrust Division jointly issued a summary of the workshop on 1 June 2023.[40] Participants in the workshop emphasised the unique competitive dynamics of the pharmaceutical industry and proposed potential ideas for reforming the competition review process for pharmaceutical transactions. These wide-ranging proposals included, inter alia, (1) applying a presumption of harm to merger and acquisition activity involving two large originator firms (i.e., in the top decile of US sales), thereby shifting the burden to firms to show merger-specific efficiency gains that outweigh potential competitive harms, (2) abandoning the use of divestiture settlements in pharmaceutical merger challenges, (3) requiring commitments to maintain certain levels of research and development and patent output post-merger, and (4) examining the relationship between prior bad conduct and intent, and effects in pharmaceutical merger reviews.[41] It remains to be seen to what extent these proposals will be formalised and implemented in pharmaceutical merger reviews going forward.

On 9 July 2021, President Biden issued an Executive Order titled 'Promoting Competition in the American Economy'.[42] Among other topics, the Order asserted that the price of prescription drugs in the United States is too high and claimed that high drug prices have resulted from pharmaceutical companies' efforts to foreclose competition from generic competitors and biosimilars. The Order also pointed to over-concentration in prescription drug markets arising from pharmaceutical company mergers as a source of high prices for consumers. The Order noted that it is the policy of the Biden administration to employ federal antitrust laws to combat the excessive concentration and asserted that the administration may use its authority to challenge transactions whose prior consummation violates the antitrust laws, even if those transactions were approved by regulators when they were consummated. Likewise, the Order called for collaboration between the FTC and DOJ and the federal Department of Health and Human Services in preserving competition in markets for the sale of pharmaceuticals.[43]

On 10 November 2021, the FTC proposed a consent order in ANI Pharmaceuticals, Inc's US$210 million acquisition of Novitium Pharma LLC.[44] The order required ANI and Novitium to divest generic sulfamethoxazole-trimethoprim oral suspension (SMX-TMP) and dexamethasone tablets to Prasco LLC.[45] SMX-TMP oral suspension is an antibiotic that

39 See FTC, 'FTC and Justice Department to Hold Two-Day Virtual Public Workshop Re-examining Antitrust Enforcement in the Pharmaceutical Industry' (31 May 2022) (www.ftc.gov/news-events/news/press-releases/2022/05/ftc-justice-department-hold-two-day-virtual-public-workshop-re-examining-antitrust-enforcement (accessed 3 July 2023)).

40 See FTC, 'The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers – FTC-DOJ Workshop Summary' (1 June 2023) (https://www.ftc.gov/system/files/ftc_gov/pdf/Future%20of%20Pharma%20Workshop%20--%20Summary.pdf (accessed 3 July 2023)).

41 ibid., at 13–14.

42 See The White House, 'Executive Order on Promoting Competition in the American Economy' (9 July 2021) (www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/ (accessed 3 July 2023)).

43 id.

44 See FTC, 'FTC Requires Generic Drug Marketers ANI Pharmaceuticals, Inc. and Novitium Pharma LLC to Divest Rights and Assets to Two Generic Products as Condition of Merger' (10 November 2021) (www.ftc.gov/news-events/news/press-releases/2021/11/ftc-requires-generic-drug-marketers-ani-pharmaceuticals-inc-novitium-pharma-llc-divest-rights-assets (accessed 3 July 2023)).

45 id.

treats various bacterial infections, including of the ear and urinary tract, and bronchitis. The FTC's press release notes that at the time of the acquisition, ANI was a manufacturer of SMX-TMP and Novitium was well-positioned to enter the SMX-TMP market.[46] Dexamethasone is an oral steroid that treats inflammation associated with conditions such as arthritis, allergic reactions, skin disorders and breathing problems. Both ANI and Novitium sold dexamethasone. The FTC's complaint asserted that, absent a divestiture, ANI's acquisition of Novitium 'would likely harm future competition in U.S. markets for both of these generic products'.[47] The Commission vote was unanimous.[48]

On 19 April 2022, the FTC proposed a consent order in Hikma Pharmaceuticals PLC's US$375 million acquisition of Custopharm, Inc.[49] The FTC required Custopharm's parent to retain and transfer Custopharm's assets relating to the corticosteroid triamcinolone acetonide (TCA) to another subsidiary of Custopharm's parent, Long Grove Pharmaceuticals, LLC.[50] TCA is a topical ointment that treats a variety of skin conditions, including eczema, dermatitis, allergies and rashes.[51] Custopharm was an existing manufacturer of TCA, whereas Hikma had a TCA product in its generic pipeline. In its complaint, the FTC alleged that, absent the requirement, the acquisition was likely to harm competition because 'Hikma likely would have stopped developing its injectable TCA product, forestalling the increased price competition it would have brought to the market'.[52]

A small number of public pharmaceutical transactions closed in the second half of 2022 without any apparent second request review. On 17 August 2022, Bristol Myers Squibb completed a US$4.1 billion acquisition of Turning Point Therapeutics, Inc, purchasing repotrectinib, a next-generation cancer drug.[53] On 3 October 2022, Pfizer, Inc completed a US$11.6 billion acquisition of Biohaven Pharmaceutical Holding Company Ltd, purchasing the acute migraine treatments rimegepant and zavegepant.[54] On 5 October 2022, Pfizer completed a US$5.4 billion acquisition of Global Blood Therapeutics, Inc, purchasing a portfolio and pipeline of drugs that treat sickle cell disease.[55] There have not been any

46 id.

47 id.

48 id.

49 See FTC, 'Federal Trade Commission Preserves Competition for Development and Marketing of Steroid Injectable Drug' (19 April 2022) (www.ftc.gov/news-events/news/press-releases/2022/04/federal-trade-commission-preserves-competition-development-marketing-steroid-injectable-drug (accessed 3 July 2023)).

50 id.

51 id.

52 id.

53 See Bristol Myers Squibb, 'Bristol Myers Squibb Completes Acquisition of Turning Point Therapeutics, Expanding Precision Oncology Portfolio' (17 August 2022) (https://news.bms.com/news/details/2022/Bristol-Myers-Squibb-Completes-Acquisition-of-Turning-Point-Therapeutics-Expanding-Precision-Oncology-Portfolio/default.aspx (accessed 3 July 2023)).

54 See Pfizer, 'Pfizer Completes Acquisition of Biohaven Pharmaceuticals' (3 October 2022) (https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-biohaven-pharmaceuticals (accessed 3 July 2023)).

55 See Pfizer, 'Pfizer Completes Acquisition of Global Blood Therapeutics' (5 October 2022) (https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-global-blood-therapeutics (accessed 3 July 2023)).

publicly announced in-depth investigations of pharmaceutical transactions ending either in clearance or a consent decree since the announcement of the consent decree permitting Hikma Pharmaceuticals plc to acquire Custopharm, Inc on 14 July 2022.[56]

On 16 May 2023, the FTC filed suit to block Amgen, Inc's US$30 billion acquisition of Horizon Therapeutics plc.[57] In its complaint, the FTC alleges that the transaction would enable Amgen to engage in cross-market bundling by offering rebates on its existing drugs to insurance companies and pharmacy benefit managers in exchange for preferential treatment of Horizon's drugs Tepezza (used to treat thyroid eye disease) and Krystexxa (used to treat chronic refractory gout).[58] This conduct, the FTC argues, would harm competition by raising Tepezza and Krystexxa rivals' barriers to entry if and when they eventually gain FDA approval because these smaller rivals would not be able to match the rebates Amgen could offer.[59] Amgen had offered a commitment not to engage in bundling with respect to Tepezza and Krystexxa, but the FTC rejected this proposal and is seeking a preliminary injunction to block the deal.[60]

V CONCLUSION

Merger review in the US pharmaceutical industry has generally developed and followed steady patterns over time, though recently has seen an increasing level of scrutiny by the FTC, which has initiated a sweeping evaluation of its approach to analysing transactions in the pharmaceutical industry. 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 geographical market of the United States and in the relevant product markets, which are generally distinct for generic and branded prescription drugs, and potentially for broader or more novel theories of anticompetitive harm relating to innovation or other activities by the merging parties. Should the FTC identify such a likelihood of anticompetitive harm, it may 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 these agreements generally entail, such as a preference that the parties divest a stand-alone ongoing business, the inclusion

56 See FTC, 'FTC Approves Final Order Preserving Competition for Development and Marketing of Steroid Injectable Drug' (14 July 2022) (https://www.ftc.gov/news-events/news/press-releases/2022/07/ftc-approves-final-order-preserving-competition-development-marketing-steroid-injectable-drug (accessed 3 July 2023)).

57 See FTC, 'FTC Sues to Block Biopharmaceutical Giant Amgen from Acquisition That Would Entrench Monopoly Drugs Used to Treat Two Serious Illnesses' (16 May 2023) (https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-sues-block-biopharmaceutical-giant-amgen-acquisition-would-entrench-monopoly-drugs-used-treat (accessed 3 July 2023)).

58 id.

59 id.

60 See Amgen, 'Amgen Responds to FTC Action re: Proposed Acquisition of Horizon Therapeutics' (16 May 2023) (https://www.amgen.com/newsroom/press-releases/2023/05/amgen-responds-to-ftc-action-re-proposed-acquisition-of-horizon-therapeutics (accessed 3 July 2023)).

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. However, the dissenting statements by Commissioners Chopra and Slaughter at the end of the prior administration indicate that, under the Biden administration, the agency will take a broader approach to evaluating any potential anticompetitive issues and effects for transactions in this complex industry. Additionally, the scrutiny placed on both the merging parties and divestiture buyers since the end of the prior administration, as well as the public statements and limited number of consent decrees that we have seen under the current Biden administration, indicate a very stringent approach to potential remedies. As a result, parties should be prepared for increased scrutiny and potential difficulties in getting a consent decree approved under a Democratic-majority FTC.