THE GUIDE TO LIFE SCIENCES

Editors
Ingrid Vandenborre and Caroline Janssens

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Publisher's Note

One of the unexpected side-effects of the covid-19 pandemic is how the hunt for both vaccines and treatments has pushed the life sciences industry centre stage, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. As Ingrid Vandenborre and Caroline Janssens point out in their introduction, there has been growing regulatory attention paid to mergers in this innovative space and increasing intervention by antitrust agencies in a range of practices particular to the biopharma sector. Practical and timely guidance for both practitioners and enforcers trying to navigate this fast-moving environment is thus critical.

The first edition of *The Guide to Life Sciences* – published by Global Competition Review – provides exactly this detailed analysis. It examines both the current state of law and the direction of travel for those jurisdictions with the most impactful life sciences industries. The Guide draws on the expertise and experience of distinguished practitioners globally, and brings together unparalleled proficiency in the field to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

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Introduction

Ingrid Vandenborre and Caroline Janssens[1]

Antitrust agencies around the world have been highly active in recent years, examining a range of practices, including alleged denigration of rivals' products, price increases, biosimilar entry, delayed entry of generic medicines, collaboration agreements and local regulatory/procurement practices. There is also growing attention to mergers, especially in dynamic, innovation-driven areas. While many of the concerns are similar in most jurisdictions, enforcers have addressed those specific to the functioning of their local markets and antitrust principles. This first edition of Global Competition Review's *Guide to Life Sciences* explores how enforcers have approached these practices and where key jurisdictions diverge or converge in their analysis.

Spending on pharmaceuticals constitutes a significant share of government spending on healthcare. This has driven increased regulatory focus on pharmaceutical pricing, including from competition authorities. While competition authorities in the European Union and the United Kingdom have historically been reluctant to intervene, the pharmaceutical sector has seen mounting regulatory interest in alleged excessive pricing practices in recent years. Even with economists highlighting the complexities and shortcomings around the enforcement of exploitative abuses of companies in a dominant position through excessive pricing, antitrust scrutiny of pharmaceutical pricing is expected to continue. By contrast, while we have seen a recent push from academics in the United States to recognise high (excessive) prices of pharmaceuticals as an antitrust violation, US courts have not yet recognised these claims.

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1 Ingrid Vandenborre is a partner and Caroline Janssens is a senior professional support lawyer at Skadden, Arps, Slate, Meagher & Flom LLP.

Biosimilars, and more generally biological medicines, have received growing attention from competition authorities across Europe. Recent antitrust investigations in the EU and the UK have examined how commercial practices adopted by incumbent suppliers may hinder biosimilar competition. However, the inherent features of biologicals, such as high costs and longer approval times, raise fundamental challenges in increasing biosimilar competition.

Product denigration cases in life sciences have been rare in the EU and around the world, and in most of them the denigration behaviour was combined with other infringements such as abuse of patent procedures or product hopping. There has since been an abundance of similar investigations at national level, with France leading the way, where cases have expanded the scope of the conduct to include product denigration and the provision of unsubstantiated, but not necessarily incorrect, information to consumers and other parties concerning either the company's own products or competing products.

Cooperative agreements have always played an important role in the pharmaceutical industry with companies partnering from early stage research and development through to late-stage commercialisation. The covid-19 pandemic has been an opportunity for the industry to demonstrate the benefits that expeditious and flexible cooperation can bring, and competition authorities have also recognised this. Beyond the pandemic, the pharmaceutical industry is facing increasing pressure to enhance affordable access to new medicines. In that context, cooperation agreements will remain of central importance to pharmaceutical companies, perhaps increasingly so.

With regard to merger control, clearance processes for some pharmaceutical transactions are expected to become more uncertain. This is due to several procedural developments in many countries designed to broaden jurisdiction over acquisitions by incumbents of nascent competitors that could play a significant competitive role in the market in the future ('killer acquisitions'), coupled with flexible and creative notification requirements and new theories of harm. The Multilateral Pharmaceutical Merger Task Force (a working group comprised of the US Federal Trade Commission (FTC), the Canadian Competition Bureau, the European Commission (EC) Directorate General for Competition, the UK's Competition and Markets Authority (CMA), the US Department of Justice Antitrust Division and offices of state attorneys general) can play an important role in brokering alignment in analysis between key jurisdictions.

Competition authorities in Europe, and in particular the EC, have historically been very active in antitrust enforcement and merger control review in the pharmaceutical sector. Consistent with its focus on innovation, the EC has significantly increased its scrutiny in recent years and is expected to continue

doing so, including, as we have seen, by way of expanding jurisdictional scope of review. At Member State level, France has been leading the way on enforcement of product denigration, while Germany and Austria have increased their scrutiny of innovation-driven markets with the introduction of alternative transaction value thresholds in 2017, designed to capture high-value/low-revenue deals.

Italy has been a pioneer in antitrust enforcement in life sciences, with landmark cases on excessive pricing and product denigration influencing the EC's decisional practice. The Italian Competition Authority is likely to continue its enforcement efforts in this area in the future. In contrast, the activity of the Authority in merger control in recent years has been limited.

In the Netherlands, the focus has been on price levels, with the Authority for Consumers and Markets making important contributions to the debate on excessive pricing both through case practice and working papers.

In the UK, the CMA is expected to continue to regard the life sciences sector as an enforcement priority. With regard to merger control, recent cases have illustrated the CMA's willingness to push the limits of jurisdictional rules and intervene in deals in dynamic, innovation-driven sectors where target companies have limited (or no) revenues or direct activity in the UK. In addition, Brexit has created heightened risks of parallel conduct investigations and merger reviews in the EU and UK.

To date, the life sciences sector has not raised major competition law issues in Switzerland, under neither the cartels, abuse of dominance nor merger control rules. It remains to be seen whether recent and ongoing regulatory changes, as well as mutual market access concerns with the EU, will lead to a different competitive environment in the near future.

In the US, recent merger enforcement in the pharmaceutical sector continues to follow traditional principles and reasoning. However, it is increasingly likely that the FTC's enforcement actions will reflect more aggressive theories of harm. Recent behavioural enforcement has largely consisted of pay-for-delay litigation and continuing prosecution of price-fixing charges against generic manufacturers. However, the FTC has given strong indications that it has competitive concerns with fees and rebates paid by pharmaceutical manufacturers to pharmacy benefit managers, which is likely to lead to new fronts of enforcement.

In Australia, the life sciences sector is not currently identified as a priority area for Australian Competition and Consumer Commission (ACCC) enforcement. However, there have been some important regulatory developments affecting the sector, such as the repeal of a safe harbour for intellectual property assignments or licensing arrangements, and the ACCC has also taken some significant cases

against companies in this sector in recent years. Lastly, in Brazil, the health sector is under close scrutiny from the Brazilian antitrust authorities, and this is not expected to change in the near future.

CHAPTER 16

United States: FTC Looks Set to Open up New Enforcement Front

Arman Oruc, Andrew Lacy, Elliot Silver and Brady Cummins[1]

Recent merger enforcement in the pharmaceutical space continues to follow traditional principles and modes of analysis. However, with a new 3-to-2 Democratic majority, it is increasingly likely that the Federal Trade Commission's (FTC) enforcement actions will reflect more aggressive theories that were previously advocated only in dissenting statements.

Recent behavioural enforcement has largely consisted of pay-for-delay litigation and continuing prosecution of price-fixing charges against generic manufacturers. However, the FTC seems poised to open a new front of enforcement as it has given strong indications that it has competitive concerns with fees and rebates paid by pharmaceutical manufacturers to pharmacy benefit managers and is looking to take related enforcement action in the near future.

Recent regulatory developments

The 'old world' – big 2019–2020 deals

The FTC has traditionally assessed mergers in the pharmaceutical space using a well-established analytical framework based on market shares and market concentration, harmonising closely with the Horizontal and Vertical Merger Guidelines. The outcomes of three merger reviews late in the Trump administration (*Roche/Spark*, *Bristol-Myers Squibb/Celgene* and *AbbVie/Allergan*) were typical of the FTC's historical approach. However, dissenting commissioner statements in these cases foreshadow a potential shift in enforcement priorities and approach

1 Arman Oruc and Andrew Lacy are partners, Elliot Silver is counsel and Brady Cummins is an associate at Goodwin Procter LLP.

under the recently established Democratic majority at the FTC. Arising from these policy priorities, the FTC and the Department of Justice (DOJ), along with US offices of state attorneys general, Canada, EU and UK antitrust/competition agencies, launched the Multilateral Pharmaceutical Merger Task Force (the Task Force) in March 2021. The expressed mission of the Task Force is to build a new approach to pharmaceutical mergers and analyse and address the varied competitive concerns that these mergers and acquisitions raise.

Roche/Spark

In *Roche/Spark*,[2] the FTC voted unanimously to close its 10-month investigation without requiring a remedy. According to the FTC's statement, the key issue in the investigation was the overlap between Roche's existing haemophilia A product and Spark's pipeline product in the same space. Roche's existing product, Hemlibra, was a monoclonal antibody that prevented or reduced the frequency of bleeding episodes in haemophilia A patients. Spark had a pipeline product in a different mechanism of action or treatment class – an experimental gene therapy – that, according to the FTC, 'ha[d] the potential to significantly improve the treatment of, and possibly even cure, hemophilia A, eliminating the need for additional treatment'.[3]

In finding that Roche would not have an incentive to delay or terminate the development of Spark's offering, the FTC highlighted that there were a number of other existing types of treatments of haemophilia A in addition to monoclonal antibodies and gene therapies and that Spark was just one of 'several companies currently developing a gene therapy treatment for hemophilia A'.[4]

In its closing statement, the FTC articulated its overall investigatory priorities – all of which were consistent with previous investigations and enforcement actions – stating that it 'strives to closely scrutinize incumbents' acquisitions of current, potential and nascent competitors, particularly where the incumbent has market power' and that it 'will seek to block or require divestitures in transactions

2 Federal Trade Commission (FTC), 'Federal Trade Commission Closes Investigation of Roche Holding AG's Proposed Acquisition of Spark Therapeutics, Inc.', 16 December 2019, www.ftc.gov/news-events/news/press-releases/2019/12/federal-trade-commission-closes-investigation-roche-holding-ags-proposed-acquisition-spark.

3 FTC, 'Statement of the Federal Trade Commission In Re Roche Holding/Spark Therapeutics', 16 December 2019, www.ftc.gov/system/files/documents/public_statements/1558049/1910086_roche-spark_commission_statement_12-16-19.pdf, at p. 1.

4 ibid.

where such acquisitions diminish competition and harm consumers'.[5] Although the FTC's investigation in *Roche/Spark* showed a heightened interest in a transaction's impact on innovation and a willingness to look for that impact across treatment types, the FTC emphasised that its ultimate determinations would continue to be 'highly fact-specific' and that, in this particular case, '[t]he evidence . . . did not indicate that Roche would have the incentive to delay or terminate Spark's developmental effort . . . , or that the acquisition would affect Roche's incentives regarding Hemlibra'.[6]

Bristol-Myers Squibb/Celgene

The FTC's 2019 review of *Bristol-Myers Squibb/Celgene*[7] also involved the application of traditional merger review principles. In that matter, the FTC required the parties to divest Celgene's Otezla, the leading oral treatment for moderate-to-severe psoriasis in the United States. At that time, Bristol-Myers Squibb (BMS) had in its pipeline an orally administered psoriasis treatment in development. While the FTC identified other competitors in the space, it concluded that several were 'older oral generic products' with inferior efficacy and safety profiles compared to Celgene's pipeline asset. As a result, the FTC found that BMS would likely become the number two player behind Celgene's market-leading product upon Food and Drug Administration (FDA) approval.[8]

Commissioner Wilson's statement in support of the divestiture emphasised that the investigation closely aligned with traditional merger review principles:

> *Staff conducted the investigation of this proposed transaction in the same careful manner that all pharmaceutical transactions are investigated. The investigation examined the likely competition between and among all of BMS and Celgene's current products and those now in development. The investigation identified a likely harm to innovation involving oral products to treat moderate-to-severe psoriasis; the identified overlap includes a product that is still in development by BMS.*[9]

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5 ibid.

6 ibid.

7 FTC, *In the Matter of Bristol-Myers Squibb Company and Celgene Corporation*, 12 November 2021, www.ftc.gov/legal-library/browse/cases-proceedings/191-0061-bristol-myers-squibb-company-celgene-corporation-matter.

8 'Celgene is currently the market leader and BMS would likely be the next entrant into the market.' Analysis of Agreement Containing Consent Orders to Aid Public Comment.

9 Statement of Commissioner Christine S Wilson, 15 November 2019, www.ftc.gov/system/files/documents/public_statements/1554278/bms-celgene_-_wilson_statement.pdf, at footnote 2.

In addition to assessing competition between individual products, the FTC investigated whether the transaction would have an impact on innovation competition in the broader oncology space. Staff concluded (and a majority of the FTC agreed) that 'reduced innovation competition was unlikely'.[10] In support of this finding, the FTC found that '[n]o fewer than 711 companies are conducting late-stage research and development in oncology'.[11]

As the FTC approved the *BMS/Celgene* consent on party lines, Democratic commissioners Slaughter and Chopra took the opportunity to issue sweeping dissents identifying their issues with the outcome in that specific matter, as well as broader concerns about what they viewed as the FTC's overly permissive approach to pharmaceutical mergers more generally. They wove into these dissents their observations about macroeconomic trends and the potential deleterious impact that mergers were having on entire industries.

In her *BMS/Celgene* dissent, Commissioner Slaughter raised the alarm that pharmaceutical prices have been rising and mergers have been happening at a 'high pace', and she cited research that mergers might be slowing the pace of pharmaceutical innovation.[12] She argued that the FTC's approach of identifying horizontal overlaps is, in general, 'too narrow', and recommended instead that the FTC 'take a more expansive approach to analyzing the full range of competitive consequences of pharmaceutical mergers'.[13]

Commissioner Chopra's dissent struck a similar tone, stating that a more intensive, wider-ranging investigation was warranted beyond 'the status quo approach'. He pointed to several facts that he argued were cause for concern. For one, he pointed to the sheer size of the transaction – US$74 billion – as an indicator of potentially significant implications for patients and inventors.[14] He also found it concerning that the parties were motivated by financial and tax incentives, rather than a 'genuine drive for greater discovery of life-saving medications' and that the transaction was 'without clear benefits to patients or the public'.[15] Echoing recently developed theories on common ownership, Commissioner Chopra

10 id. at p. 1.

11 id. at footnote 2.

12 Dissenting Statement of Commissioner Rebecca Kelly Slaughter, 15 November 2019, www.ftc.gov/system/files/documents/public_statements/1554283/17_-_final_rks_bms-celgene_statement.pdf, at p. 2.

13 ibid.

14 Dissenting Statement of Commissioner Rohit Chopra, 15 November 2019, www.ftc.gov/system/files/documents/public_statements/1554293/dissenting_statement_of_commissioner_chopra_in_the_matter_of_bristol-myers-celgene_1910061.pdf, at p. 1.

15 id. at p. 2.

observed that the significant overlap between the two parties' shareholder bases (100 of BMS' largest shareholders had a stake in Celgene) may distort incentives of the combined company moving forward.[16] Finally, he cited Celgene's history of receiving anticompetitive complaints from market participants.[17]

More broadly, he stated that he was 'deeply skeptical that [the FTC's traditional] approach' (meaning 'an examination of whether there are any product overlaps between the merging corporations, or where there may be clear-cut incentives to foreclose rivals with the ability to compete') 'can unearth the complete set of harms to patients and innovation'.[18] Commissioner Chopra advocated that the FTC now consider, for example, whether the merger will facilitate a capital structure that magnifies incentives to engage in anticompetitive conduct or abuse of intellectual property, or whether it might deter in the first instance the formation of biotechnology firms that often fuel innovation.[19]

AbbVie/Allergan

The FTC again followed what appeared to be a well-accepted approach in its investigation of the *AbbVie/Allergan*[20] transaction and required divestitures of two of the parties' products: Interleukin-23 (IL-23) inhibitors, a drug class for treating moderate-to-severe ulcerative colitis and moderate-to-severe Crohn's disease; and treatments for exocrine pancreatic insufficiency (EPI). In both instances, the FTC concluded that the parties were two of the only four companies with products on the market or in development. Accordingly, the agency required a divestiture of Allergan's rights and assets related to its pipeline IL-23 inhibitor to AstraZeneca, which originally developed the drug and licensed it to Allergan, and the divestiture of Allergan's EPI product to Nestlé.

The vote to accept the consent decree was split along party lines, with the three Republican commissioners voting to accept. The approach adopted by the three Republican commissioners again reflected past practice (i.e., identifying overlapping products, both existing and pipeline, and requiring divestitures where the parties were two of a limited set of suppliers).

16 id. at footnote 7.
17 id. at footnote 8.
18 id. at p. 3.
19 ibid.
20 FTC, *In the Matter of AbbVie Inc. and Allergan plc*, 12 May 2020, www.ftc.gov/legal-library/browse/cases-proceedings/191-0169-abbvie-inc-allergan-plc-matter.

The two Democrat commissioners voted to not accept and issued dissenting statements arguing the insufficiency of the remedy. Commissioner Chopra's dissent in that matter specifically took aim at divestitures, including both the divestiture buyers in the transaction at issue, as well as the prudence of divestiture remedies and the process by which the FTC and the parties arrive at them.

With respect to the divestiture buyers in the transaction at issue, Commissioner Chopra criticised Nestlé as an unsuitable divestiture buyer of the EPI product because it was not 'a drug company'. He argued:

> *The Commission is too confident that Nestlé can cure this merger. Nestlé is not a pharmaceutical company. Its core focus is on food, beverages, and other grocery store items. While it has a nutrition subsidiary, this line of business does not match the capability and capacity of Allergan, which currently owns the rights to drugs that treat patients with serious pancreatic conditions. In addition, Nestlé has a checkered record in its past experiments with pharmaceuticals. If this new venture into pharmaceuticals does not succeed, it will not have a meaningful impact on Nestlé's financial results.*[21]

He also disapproved of the other divestiture buyer, AstraZeneca. While AstraZeneca was a pharmaceutical company, he had concerns that the divestiture constituted a 'windfall' for AstraZeneca, which was 'without skin-in-the-game' and would 'pay nothing for a valuable drug development project and is free to re-license the business to another company'. He also thought AstraZeneca was unsuitable because it was unclear 'where this project falls in AstraZeneca's development priorities and whether the company is committed to the project over the long-term',[22] thus increasing the risk that competition would not be restored by the divestiture.

In addition to specific concerns about the specific divestiture buyers, Commissioner Chopra took the opportunity to express broader scepticism about divestitures as an adequate remedy for transactions that raise competitive concerns. First, he lamented that the FTC's evaluation of divestitures was often superficial and lacked a careful assessment of divestiture buyers. Commissioner Chopra called for examinations that would 'more closely resemble how a lender, insurer, or equity investor might assess a corporate entity's likelihood of success'.[23] Second,

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21 Dissenting Statement of Commissioner Rohit Chopra, 5 May 2020, www.ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf, at p. 2.

22 ibid.

23 id., at p. 7.

he believed that, for self-interested reasons, merging parties were most likely to choose as divestiture buyers companies they viewed as weak competitors. Given that these buyers would immediately become their competitor, merging parties 'have an incentive to [] consider who is likely to be the weakest buyer and the easiest to dominate once the buyer takes full ownership of the divested product'.

Commissioner Chopra's *AbbVie/Allergan* dissent signalled a desire for more scepticism of proposed divestiture buyers that would seem to shift the burden to the parties involved to demonstrate to almost a near certainty that the divestiture buyer would replace current competition. Additionally, Commissioner Chopra's criticism of the parties' role in proposing divestiture buyers suggests the potential for more hands-on involvement by the FTC in divestiture sale processes.

Merger enforcement under the new Biden administration

Recent merger enforcement continues to closely follow traditional approach

Despite the aggressive rhetoric in dissents and speeches, the change to Democratic leadership and a majority-Democratic FTC has yet to result in more enforcement. A little under a year and a half into the new administration, there is a sense that otherwise 'easy' transactions might be getting more scrutiny during the Hart-Scott-Rodino Act (HSR) waiting period, but recent enforcement actions have focused on deals that likely would have been reviewed in a similar way in prior administrations. So far, there has not been a challenge to any transaction involving a 'big pharma' acquisition or licence of any innovative biotech companies or any signs of a new approach to reviews of pharmaceutical mergers.[24] Recent enforcement actions have been in generics and dialysis clinics, two areas that have been in the FTC's cross hairs for a long time.

Hikma/Custopharm

On 18 April 2022, the FTC unanimously approved a final order requiring that Water Street Healthcare Partners divest the injectable triamcinolone acetonide (TCA) – a generic injectable corticosteroid – product of its portfolio company Custopharm to another portfolio company, Long Grove Pharmaceuticals, as a

24 At the time of writing, the FTC is investigating CSL's acquisition of Vifor.

condition of the sale of Custopharm to Hikma Pharmaceuticals.[25] The consent decree highlights the agency's emphasis on potential competition between the merging parties.

Pursuant to a September 2021 merger agreement, Hikma proposed to acquire Custopharm in a transaction valued at approximately US$375 million. There were only two incumbent generic injectable TCA corticosteroids on the market, from Amneal Biosciences and Teva Pharmaceutical Industries. The merging parties each had pipeline products and, in fact, Custopharm received FDA approval to market its injectable TCA product during the HSR review, on 19 January 2022. According to the FTC, Hikma had a pipeline product that it expected to launch in the near future. The FTC expressed concern that the transaction would reduce competition by eliminating the potential fourth generic competitor.

The consent decree required that for a 10-year period, Hikma would not acquire any rights or interests in TCA products or assets, or rights or interests in the therapeutical equivalent or biosimilar of TCA products without the prior affirmative approval of the FTC even if the transaction is not reportable under HSR. The proposed order also required Water Street and Long Grove to operate and maintain in the normal course of business and not sell or dispose of the TCA assets for a period of four years.

ANI/Novitium

In another transaction involving generics, on 12 January 2022 the FTC approved a final order regarding ANI Pharmaceuticals' (ANI) US$210 million acquisition of Novitium Pharma.[26] The FTC order required, among other things, divestitures of a generic sulfamethoxazole-trimethoprim (SMX-TMP) oral suspension and generic dexamethasone tablets.[27] While the divestitures are the latest in a long line of FTC actions in the pharmaceutical industry, there are a few notable elements of the FTC's analysis that reflect a more aggressive enforcement approach.

With respect to the substantive analysis, for dexamethasone, the transaction featured a pipeline-pipeline overlap in the 4mg strength. The FTC Analysis to Aid Public Comment acknowledges at least four other players in the space,

25 FTC, *In the Matter of Hikma Pharmaceuticals et al.*, 14 July 2022, www.ftc.gov/legal-library/browse/cases-proceedings/2210001-hikma-pharmaceuticalscustopharm.

26 FTC, *In the Matter of ANI/Novitium*, 12 January 2022, www.ftc.gov/legal-library/browse/cases-proceedings/211-0101-aninovitium-matter.

27 Decision and Order, *In the Matter of ANI/Novitium*, www.ftc.gov/system/files/documents/cases/ani_novitium_do_4_2021.10.25.pdf.

including two marketed products and a 'limited number' of other pipeline products.[28] Despite being no worse than a 5-to-4 ratio, the FTC still sought a divestiture.

For SMX-TMP, where the parties held current and pipeline products, respectively, the FTC conceded that there were four other companies currently offering the product in the market and at least one other supplier capable of entering in the near future. Despite this somewhat crowded competitive landscape, the FTC required a divestiture.

In both instances, the FTC's rationale for divestitures does not appear to have been based primarily on the strict 'nose-counting' it has used in recent pharmaceutical transactions.[29] It showed a willingness to either discount present competitors (e.g., by noting manufacturing issues) or credit the likelihood of entry, particularly by the parties. On the latter point, a touchstone in both divestitures appears to be the FTC's finding that prices in human pharmaceutical markets 'decrease incrementally within the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.'[30] This observation is particularly meaningful with respect to pipeline products. Carried to its logical end, it can support a finding that the elimination of any potential entrant deprives the market of meaningful price competition. The FTC's order here serves as a reminder of how carefully the FTC will scrutinise transactions involving pipeline products or potential competitors and what it may use as a starting point for these analyses.

In addition to these traditional divestiture remedies, the FTC also required that the parties submit to prior approval for future transactions in a product category in which the parties did not compete, specifically one where ANI was present and Novitium had an unexecuted option to acquire a competing drug

28 Analysis to Aid Public Comment, *ANI/Novitium*, 12 May 2020, www.ftc.gov/system/files/documents/cases/2110101c4754aninovitiumaapc.pdf.

29 See, e.g., *In the Matter of Pfizer, Inc., et al* (divestitures in 5-to-4, 4-to-3 and 3-to-2 product markets), October 2020; *In the Matter of AbbVie Inc. and Allergan plc* (divestitures in a 4-to-3 product market), May 2020; and *In the Matter of Impact Laboratories, Inc. et al.* (divestiture in a 4-to-3 product market), April 2015.

30 FTC Analysis at p. 3. A similar observation appeared in the October 2020 order regarding Pfizer's proposed spin-off of its Upjohn business and combination with Mylan (at p. 1). In these and other instances, it is notable that the products at issue were generic pharmaceuticals. There is extensive literature supporting the proposition cited by the FTC here – that the entry of additional generic players has price effects.

from another company.[31] The order is notable in this regard for its willingness to reach beyond product areas where the FTC has found a substantial lessening of competition.

Looking ahead, companies pursuing deals in the life sciences space should expect the FTC to take a similarly broad look at the merging parties' portfolios. Parties must also prepare for departures from precedent, including with respect to the number of existing (or pipeline) competitors necessary to provide meaningful competition post-merger.

FTC enforcement actions in adjacent industries applicable to life sciences

Nascent and vertical competition concerns

Recent FTC enforcement action in adjacent industries demonstrates that the agency will aggressively investigate and potentially challenge transactions that eliminate nascent competition or present vertical concerns, or both. For example, the FTC is currently litigating to unwind Illumina's acquisition of Grail, alleging that the acquisition gives Illumina the ability and incentive to snuff out Grail's nascent competitors by cutting off supply of Illumina's next-generation DNA sequencing products and consumables, which the FTC alleges are necessary inputs for the development of competing multi-cancer early detection tests.[32]

In *Medtronic/Intersect*, the FTC required a divestiture to clear the transaction due to nascent competition concerns.[33] According to the FTC, Medtronic had a dominant position in ear, nose and throat (ENT) navigation systems and was one of only four makers of balloon sinus dilation products.[34] Despite a very recent

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31 The FTC order also provides for prior approval over future transactions in the divested product areas. The FTC's prior approval policy requires that parties secure the FTC's approval (rather than just Hart-Scott-Rodino (HSR) clearance) before closing any future transaction in an identified relevant market. The FTC concedes that an investigation under a prior approval provision 'is much different than a similar investigation' under the HSR Act, and will not afford parties the due process and timing afforded under the HSR process.

32 Complaint, *In the Matter of Illumina, Inc., and GRAIL, Inc.*, Docket No. 9401, 13 March 2021, www.ftc.gov/system/files/documents/cases/redacted_administrative_part_3_complaint_redacted.pdf.

33 Fiagon, 'Hemostasis Closes Acquisition of Fiagon Medical Technologies', 13 May 2022, www.fiagon.com/ous/company/news/87-hemostasis-closes-acquisition-of-fiagon-medical-technologies; Fierce BioTech, 'Medtronic makes FTC-mandated sale to close Intersect ENT deal and scores FDA nod to boot', 13 May 2022, www.fiercebiotech.com/medtech/medtronic-takes-ftc-mandated-route-close-intersect-ent-buy-and-scores-fda-nod-boot.

34 Complaint, *In the Matter of Medtronic plc*, Docket No. C-4763, 7 May 2022, paragraph 7, www.ftc.gov/system/files/ftc_gov/pdf/2110184%20C4763MedtronicComplaint.pdf.

launch and a small amount of sales, the FTC alleged that Intersect's subsidiary Fiagon was a nascent, innovative competitor to Medtronic for ENT devices, specifically for ENT navigation systems and balloon sinus dilation products.[35]

Expansion of consent decree requirements

In the more than 25 years following the FTC's 1995 policy statement limiting the use of future prior approval and prior notice provisions in consent orders, the FTC has required these provisions only in select cases and has limited the scope of these provisions to the product and geographic markets relevant to the competitive concerns in the transaction being investigated.[36] The FTC withdrew the 1997 policy statement in July 2021,[37] and issued new guidance that it was returning 'to its prior practice of routinely requiring merging parties subject to a Commission order to obtain prior approval from the FTC before closing any future transaction affecting each relevant market for which a violation was alleged'.[38] The FTC's new policy statement also signalled that it would seek to expand the scope of prior approval provisions, stating that '[i]n some situations . . . the Commission may decide to seek a prior approval provision that covers product and geographic markets beyond just the relevant product and geographic markets affected by the merger'.[39]

The FTC implemented the latter policy in two recent mergers in the healthcare space. In its October 2021 consent order regarding DaVita's acquisition of dialysis clinics from the University of Utah, the FTC required divestitures of three dialysis clinics in the Provo, Utah area. It also included a provision requiring DaVita to obtain prior approval for any acquisition of a dialysis clinic in the state

35 ibid.

36 In 2020, seven FTC orders included prior notice provisions and one included a prior approval provision.

37 FTC, 'FTC Rescinds 1995 Policy Statement that Limited the Agency's Ability to Deter Problematic Mergers', 21 July 2021, at www.ftc.gov/news-events/news/press-releases/2021/07/ftc-rescinds-1995-policy-statement-limited-agencys-ability-deter-problematic-mergers.

38 FTC, 'Statement of the Commission on Use of Prior Approval Provisions in Merger Orders', at www.ftc.gov/system/files/documents/public_statements/1597894/p859900priorapprovalstatement.pdf.

39 ibid.

of Utah for 10 years. As the FTC highlighted, this state-wide prior approval provision 'extends the coverage of the prior approval beyond the markets directly impacted by this merger'.[40]

The FTC imposed similar state-wide prior approval provisions along with a nationwide prior notice provision in the *JAB/Sage* consent order. The transaction involved private equity firm JAB's acquisition of Sage Veterinary Partners, a business that operates 'specialty and emergency veterinary clinics'.[41] The consent order required divestitures of six clinics in three local markets defined as the areas in and around Austin, San Francisco and East Bay. Despite these local market definitions, the consent order's prior approval provision was state-wide, covering future acquisitions anywhere in Texas and California if the target clinic is within 25 miles of a JAB clinic. The prior notice provision was even broader, requiring prior notice for future acquisitions nationwide if the target is proximate to a JAB clinic.[42] Chair Khan recognised the novelty of the latter, touting it as 'the first of its kind in a[n] FTC order'.[43]

Recent behavioural and price-fixing enforcement

Pharmacy benefit managers scrutiny

The FTC has signalled plans for increased scrutiny of relationships between pharmaceutical manufacturers and pharmacy benefit managers (PBMs). In June 2022, the FTC voted unanimously in favour of an enforcement policy statement that it intends to closely scrutinise 'rebates and fees paid by drug manufacturers to PBMs to favor high cost drugs' that may 'shift costs and misalign incentives in a

40 FTC, 'FTC Imposes Strict Limits on DaVita, Inc.'s Future Mergers Following Proposed Acquisition of Utah Dialysis Clinics', 25 October 2021, at www.ftc.gov/news-events/news/press-releases/2021/10/ftc-imposes-strict-limits-davita-incs-future-mergers-following-proposed-acquisition-utah-dialysis.

41 FTC, 'Analysis Of Agreement Containing Consent Orders to Aid Public Comment, In the Matter of JAB Consumer Partners SCA SICAR, National Veterinary Associates, Inc., and SAGE Veterinary Partners, LLC, 13 June 2022, www.ftc.gov/system/files/ftc_gov/pdf/2110140C4766NVASAGEAAPC.pdf.

42 id. at p. 4.

43 'Statement of Chair Lina M Khan, Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M Bedoya Regarding JAB Consumer Fund/SAGE Veterinary Partners', 13 June 2022, www.ftc.gov/system/files/ftc_gov/pdf/2022.06.13%20-%20Statement%20of%20Chair%20Lina%20M.%20Khan%20Regarding%20NVA-Sage%20-%20new.pdf.

way that ultimately increases patients' costs and stifles competition from lower-cost drugs, especially when generics and biosimilars are excluded or disfavored on formularies'.[44]

According to the statement, 'Health plans, usually through PBMs, use formularies to define which drugs are covered. Drug manufacturers commonly pay PBMs and other intermediaries rebates and fees to have their drugs included on formularies or placed on preferred formulary tiers. Some rebates and fees are conditioned on the sales volume of specific drugs or the exclusion of competing drug products from the same formulary tier.' The FTC's concern is that, 'these rebate and fee agreements may incentivize PBMs and other intermediaries to steer patients to higher-cost drugs over less expensive alternatives. This practice could lead to increased costs for both patients and payers, including increased out-of-pocket costs at the point of sale. It may also insulate more expensive drugs from competing with less expensive alternatives.' The FTC warned that it could take action against these rebate arrangements under Section 1 or 2 of the Sherman Act, Section 3 of the Clayton Act or Section 2(c) of the Robinson Patman Act.

The FTC's policy statement came just days after it announced that it was launching an inquiry into the impact of vertically integrated PBMs on the access and affordability of medicine.[45] The FTC, which voted unanimously to launch the inquiry, identified several practices that will be under scrutiny:

- fees and clawbacks charged to unaffiliated pharmacies;
- methods to steer patients towards PBM-owned pharmacies;
- potentially unfair audits of independent pharmacies;
- complicated and opaque methods to determine pharmacy reimbursement;
- the prevalence of prior authorisations and other administrative restrictions;
- the use of 'specialty drug lists' and surrounding 'specialty drug policies'; and
- the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

44 FTC, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, 7 June 2022, www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.

45 ibid.

Pay-for-delay post Activis

Since the Supreme Court's 2013 decision in *FTC v. Activis, Inc*,[46] pay-for-delay agreements, under which a drug patentee agrees to pay a generic drug manufacturer to stay out of a market, have been an area of focus of the FTC. Two of the more high-profile cases that have been litigated in this area are two separate FTC cases involving agreements between Endo and Impax related to Endo's brand name oxymorphone drug, Opana ER.

In the first, the FTC brought an administrative complaint charging Impax and Endo with illegally agreeing in 2010 that Impax would not launch its generic version of Opana ER until January 2013 in exchange for a payment by Endo of more than US$112 million.[47] On 18 May 2018, the FTC administrative law judge (ALJ) dismissed the charges, finding that 'the magnitude and extent of any anticompetitive harm is largely theoretical, based on an inference that, absent the Challenged Agreement, Impax's entry date, and therefore generic competition, would have been earlier than January 2013. The evidence shows that such earlier entry was unlikely.'[48] The ALJ therefore concluded that the pro-competitive benefits of the agreement outweighed the anticompetitive harm.[49]

On 28 March 2019, however, the FTC overturned the ALJ's ruling,[50] and on 23 April 2021, the Fifth Circuit upheld the FTC's finding.[51] 'There was more than enough evidence to support th[e] unanimous view of the Commissioners . . . that a less restrictive alternative was viable,' Judge Gregg Costa wrote in the Fifth Circuit's opinion.[52]

On 25 January 2021, the FTC sued Endo and Impax again, alleging that a 2017 agreement between the two companies violated Sherman Act Sections 1 and 2 by eliminating competition in the market for oxymorphone extended release (ER).[53] The complaint focused on an agreement that Endo and Impax formed after the

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46 *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

47 FTC, Complaint, *In the Matter of Impax Laboratories, Inc.*, 23 January 2017, www.ftc.gov/system/files/documents/cases/docket_no_9373_impax_part_3_administrative_complaint_redacted_public_version_1-23-17.pdf.

48 id. at 7.

49 ibid.

50 FTC, Opinion of the Commission, *In the Matter of Impax Laboratories, Inc.*, 28 March 2019, www.ftc.gov/system/files/documents/cases/d09373_impax_laboratories_opinion_of_the_commission_-_public_redacted_version_redacted_0.pdf.

51 *Impax Laboratories, Inc. v. Federal Trade Commission*, No. 19-60394 (5th Cir. 2021).

52 id. at 25.

53 FTC, Complaint for Injunctive and Other Equitable Relief, Case No. 1:21-cv-217-RCL, 25 January 2021.

FDA removed Endo's Opana ER drug from the market in 2017.[54] The FTC alleged that, instead of preparing a new drug to replace its unmarketable Opana ER, Endo signed an agreement with Impax in August 2017 whereby Impax would pay Endo to not re-enter the oxymorphone market.[55] Impax was the only supplier of the drug at that time.[56]

On 24 March 2022, a DC district court dismissed the case.[57] The court agreed that the FTC had plausibly alleged that the defendants entered an exclusive licensing agreement and created a patent monopoly.[58] However, the court found that the FTC did not plausibly allege anticompetitive activity, insofar as the agreement was protected by patent law.[59] Endo had a valid patent and therefore a right to exclude and thus maintain a monopoly and charge supra-competitive prices.[60] The right also permitted Endo to license this patent to another company, which it did to Impax, instead of competing itself in the oxymorphone ER market.[61] In short, according to the court, the Patent Act protects a patent holder from antitrust liability where it licenses its lawful monopoly to another competitor.[62]

Generic drug price-fixing

Over the past five years, the DOJ has charged a number of generic drug manufacturers with price-fixing. These charges stem from investigations stretching back to the Obama administration. The first federal charges from this probe came in 2016 against two Heritage Pharmaceuticals executives,[63] and then, from mid-2019 to August 2021, the DOJ brought price-fixing charges against eight generic drug manufacturers related to various generic drugs: Heritage, Rising, Ara Aprahamian, Taro, Sandoz, Apotex, Glenmark and Teva. Most of the companies charged have settled the DOJ charges, with Taro, Sandoz and Apotex

54 id. at 2.

55 ibid. The August 2017 agreement between Endo and Impax was a settlement of a breach of contract case.

56 ibid.

57 *FTC v. Endo Pharms. Inc.*, 2022 U.S. Dist. Lexis 61052, *4 (D.D.C. 24 March 2022).

58 id. at *18–*21.

59 id. at *21.

60 id. at *22–*25.

61 id. at *25.

62 ibid.

63 Department of Justice (DOJ), 'Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies', 14 December 2016, www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer.

agreeing in October 2021 to pay a combined US$447 million in penalties.[64] As at the time of writing, Glenmark and Teva are litigating the charges in the Eastern District of Pennsylvania.[65]

Outlook

With respect to merger enforcement in life sciences moving forward, although enforcement actions to date have followed traditional principles, statements from FTC leadership and enforcement actions in adjacent sectors signal that the agency is likely to take a broader approach to identifying potential competition concerns. With a new 3-2 Democratic party majority at the FTC, parties to life sciences transactions can expect that the agency will pursue more aggressive enforcement generally, while testing theories of competitive harm beyond traditional structural analysis/nose-counting, including vertical and nascent competition concerns. Merging parties should also anticipate that consent orders going forward will include prior notice or approval provisions, or both, in divested product areas and possibly others. Buyers, in particular, may consider factoring the potential for these remedies into antitrust provisions.

On the behavioural side, drug manufacturers should be aware of the FTC's intention to broadly scrutinise fees and rebates paid to PBMs. Documentation related to these fees should clearly reflect pro-competitive purposes. Parties must also continue to carefully consider risks and implications of agreements that may in any way prohibit or delay generic entry. Additionally, drug manufacturers should use caution in their interactions with their competitors, given antitrust enforcer focus on potential unlawful agreements between competitors, as evidenced by price-fixing investigations and charges brought in the generic pharmaceutical sector.

64 DOJ, 'Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs', 1 October 2021, www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

65 Second Superseding Indictment, *United States of America v. Teva Pharmaceuticals USA, Inc. and Glenmark Pharmaceuticals Inc.*, USA, Case No. 2:20-cr-00200, 25 August 2020, www.justice.gov/atr/case-document/file/1316996/download.

The covid-19 pandemic – and the amount of public money that governments are spending on healthcare – has thrust the life sciences industry into the international spotlight, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. The first edition of *The Guide to Life Sciences* – edited by Ingrid Vandenborre and Caroline Janssens – provides practical and timely guidance for both practitioners and enforcers trying to navigate this high-stakes environment. The Guide draws on the wisdom and expertise of distinguished practitioners globally to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

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