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.

Contents

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 6

Merger Control: Substantive Issues

Maria Raptis, Michael Frese, Julia Zhu and Marta Navarro Hernández[1]

Introduction

As the ability for competition authorities to review pharmaceutical deals is increasing,[2] there is growing attention as to whether the existing toolbox for review suffices. Against this backdrop, several authorities in North America and Europe have launched the Multilateral Pharmaceutical Merger Task Force (the Task Force).[3] The Task Force builds upon existing relationships between these authorities to update their approaches to analysing the effects of pharmaceutical mergers.

On 11 May 2021, the Task Force issued a notice seeking public comment on how best to update its approaches to pharmaceutical mergers.[4] The Task Force has been evaluating the sufficiency of existing theories of harm, legal standards and remedies. This chapter takes stock of recent developments in these areas in the EU, US and Asia-Pacific (APAC).

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1 Maria Raptis is a partner and Michael Frese, Julia Zhu and Marta Navarro Hernández are associates at Skadden, Arps, Slate, Meagher & Flom LLP. The authors wish to thank Ingrid Vandenborre, Andrew Foster, Cedric Nys and Hayley May for their helpful comments.

2 The expanding jurisdiction for authorities to review (pharmaceutical) deals is most clearly visible in Europe, where several countries have recently introduced (e.g., Germany and Austria) or are applying (e.g., the UK) flexible thresholds for merger review. Similarly, since March 2021, the European Commission (EC) encourages EU Member States to refer certain types of transactions for review even if no national filing thresholds are met. The EU General Court recently confirmed that the EC has jurisdiction to review these transactions. See Judgment of the General Court, 13 July 2022, *Illumina v. Commission*, Case T-227/21. The US authorities have also been creative in increasing their merger review role, as the *Hikma* case (discussed below) shows.

3 www.ftc.gov/system/files/attachments/press-releases/multilateral-pharmaceutical-merger-task-force-seeks-public-input/final_ftc_notice_for_multilateral_pharmaceutical_merger_task_force.pdf.

4 ibid.

Theories of harm

Traditionally, competition authorities have focused their attention in pharmaceutical mergers on unilateral effects. However, authorities are increasingly considering broader innovation effects, conglomerate effects and coordinated effects in their assessments.

Recent developments in the EU

Unilateral effects

In the EU, the European Commission (EC) takes a strict approach to horizontal overlaps. This is also reflected in the more recent cases. Modest share increments and even overlaps based on non-marketed pipeline may give rise to EC intervention.

In *GSK/Pfizer Consumer Healthcare Business*,[5] the EC found that the transaction would reinforce GSK's leading position, given its high market shares pre-transaction and the advantages of a distant leadership position in topical pain management products,[6] notwithstanding the fact that the increase in shares was less than 5 per cent. The EC focused on the risk of prices increasing via the reduction of rebates granted to pharmacies, which would eventually be passed on to end-consumers. The EC considered that the market was characterised by high barriers to entry or expansion, notably because of a strong brand awareness,[7] combined with a lack of other stronger brands[8] and the role that wholesalers played.[9] The fact that the products in question were based on off-patent, generic molecules was considered but ultimately not decisive.[10]

In *J&J/Tachosil*,[11] the EC found that despite the lack of overlap with J&J's products in the European Economic Area (EEA), the transaction would remove the best placed potential entrant in the market for the supply of dual haemostatic patches for the most problematic bleeding situations, where Tachosil was found to be dominant. Specifically, the EC's preliminary investigation indicated that

5 See EC decision of 10 July 2019, *GSK/Pfizer Consumer Healthcare Business*, M.9274.

6 The involved products concerned a patch that generated heat and a medical ointment/cream to treat muscle pain.

7 See EC decision of 10 July 2019, *GSK/Pfizer Consumer Healthcare Business*, M.9274, paragraph 3.1.2.3.

8 id., paragraph 3.1.3.3.

9 id., recital 288.

10 id., recital 204.

11 See EC Press Release of 25 March 2020, 'Commission opens in-depth investigation into proposed acquisition of Tachosil by Johnson & Johnson', available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_529.

in the absence of the transaction, J&J would have strong incentives to enter the market as it already sold a haemostatic patch outside the EEA, and it was unlikely that timely and credible entry from other players would take place.

In *Takeda/Shire*,[12] the EC assessed the overlap between Takeda's leading biological treatment for inflammatory bowel disease (IBD), which was the only such product available in the EEA at the time, and Shire's pipeline biological product to treat IBD, which was expected to launch before Takeda's treatment lost exclusivity. The EC was concerned that post-transaction, Takeda would stop developing Shire's new treatment, which would lead to a loss of innovation and potential future competition.

In *Pfizer/Hospira*,[13] Hospira had introduced the first biosimilar version of infliximab (under the brand name Inflectra) to treat autoimmune diseases such as rheumatoid arthritis and Crohn's disease, competing with the originator product, Remicade. The same product as Inflectra was also sold in parallel by Celltrion (the manufacturer of Inflectra) under the brand name Remsima, and the next biosimilar infliximab products likely to enter the market were considered to be those of Pfizer and Samsung Bioepis, which were both in Phase III clinical trials. The EC identified resistance to switching stable patients under Remicade treatment to its biosimilar copies. Therefore, the EC considered the original Remicade product to be only a distant competitor to infliximab biosimilars and concluded that Hospira's Inflectra was mainly constrained by Pfizer's pipeline biosimilar. The EC was concerned about the potential loss of imminent competition.

Innovation effects

As illustrated by *Takeda/Shire* and *Pfizer/Hospira*, innovation effects have become front and centre in the EC's unilateral effects analysis. Increasingly, the EC looks at risks of discontinuation, delay or redirection of overlapping lines of research and early pipeline products, and structural reduction of incentives and ability to achieve the same level of innovation. The EC not only looks at (pipeline) overlaps with actual marketed products, it also assesses pure pipeline-to-pipeline overlaps and even loss of innovation competition. The distinction between unilateral effects and innovation effects is gradual.

12 See EC decision of 20 November 2019, *Takeda/Shire*, M.8955.

13 See EC decision of 4 August 2015, *Pfizer/Hospira*, M.7559.

In *Novartis/GlaxoSmithKline Oncology Business*,[14] the EC focused in particular on innovative drugs for the treatment of advanced cancers and the impact on future treatments. GSK and Novartis were considered direct competitors in the development and commercialisation of cancer treatments B-Raf and MEK inhibitors. The EC raised concerns that, post-merger, only two companies would be developing and marketing both B-Raf and MEK inhibitors, and that there would be a reduction of competition on innovation, with the expected abandonment of Novartis' broader clinical trial programme for its B-Raf and MEK inhibitors.

In *J&J/Actelion*,[15] the EC raised issues in relation to overlaps of Phase II pipeline products. The EC's concerns focused on the development of the parties' overlapping development programmes for insomnia drugs. The market investigation indicated that these pipeline products could constitute a significant improvement over the existing standards of care, that there were no competing pipeline products in the EEA based on the same novel mechanisms, and that the merging parties' products were expected to be higher priced than competing drugs. For these reasons, the EC considered that merging these overlapping pipelines would reduce innovation competition, stemming from a possible discontinuation, delay or redirection of one of the two pipelines. Although J&J's pipeline product was co-developed with an independent third party, the EC concluded that J&J would have had the ability to negatively impact product launch. J&J held the patent rights and know-how, whereas the third party had an exclusive licence to sell in the EEA.

Conglomerate effects

Although traditionally focused on unilateral effects, the EC also analyses conglomerate effects. This is particularly the case in the over-the-counter (OTC) segment. The merging parties' enlarged portfolio may give rise to concerns about the ability to monopolise shelf space at retail level; for example, by offering a full range of complementary OTC products. Cases in which this played a role are the aforementioned *GSK/Pfizer Consumer Healthcare Business* case and *Teva/Allergan Generics*.[16] In the latter case, the EC assessed whether the combination of the parties' generics activities would affect competition beyond the markets for the individual molecules. Following the market investigation, the EC found that in Iceland, Ireland and the UK, where the merging parties were

14 See EC decision of 28 January 2015, *Novartis/GlaxoSmithKline Oncology Business*, M.7275.

15 See EC decision of 9 June 2017, *J&J/Actelion*, M.8401.

16 See EC decision of 10 March 2016, *Teva/Allergan Generics*, M.7746.

the two largest generics suppliers, the remaining players would have been unable to compete effectively with the merged entity due to the prevalent distribution models and the structure of the national generics market.

Conglomerate effects analysis is also relevant in the area of medical devices. For example, in *Siemens Healthineers/Varian*,[17] the EC's concerns related to the merged entity's ability and incentive to foreclose rivals through the degradation of the interoperability between Siemens Healthineers' imaging solutions and third-party solutions, as well as between Varian's radiotherapy solutions and third-party medical imaging solutions. The EC clearance decision was contingent on the condition that the companies make their medical imaging and radiotherapy devices interoperable with rival products.

Coordinated effects

Coordinated effects have not been a major concern of the EC in pharmaceutical cases. The absence of coordinated effects cases in the EC's pharmaceutical merger control practice may be explained in part by the fact that innovation-intensive markets are less stable, as a result of which collusion is more difficult to sustain and thus less likely to occur.

Recent developments in the US

The US Federal Trade Commission (FTC) considers a wide array of theories of harm. Traditionally, the focus of the FTC's analysis has been on whether the transaction will enhance market power simply by eliminating existing competition between the merging parties, either by creating a unilateral incentive to raise prices or otherwise harm consumers (i.e., unilateral effects) or, more rarely, by increasing the risk of coordinated behaviour among competitors (i.e., coordinated effects). The FTC also examines whether a transaction creates an incentive to cease or delay development of pipeline products or otherwise take steps to maintain a competitive advantage in the specific product area. There are numerous FTC enforcement actions predicated on a 'potential competition' theory of harm.

More recently, the FTC's traditional approach to pharmaceutical transactions has faced increased scrutiny about whether it fully captures all potential anti-competitive effects, and current FTC leadership appears to be considering new approaches to evaluating harm, including how mergers may result in harm to innovation even in the absence of specific overlaps or harm from cross-portfolio contracting.

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17 See EC decision of 31 March 2021, *Siemens Healthineers/Varian Medical Systems*, M.9945.

Innovation effects

The FTC's application of true innovation effects – harm to a market consisting of research and development (R&D) in a targeted area – has been rare. Rather, the FTC has almost exclusively concerned itself with either existing products or products contemplated in the merging firms' pipelines (i.e., potential competition mergers). In potential competition cases, the FTC's historic practice has typically been to evaluate only more advanced pipeline products (i.e., Phase III) and take action when the merging parties are among a handful of products on the market or in late-stage development and few other firms are likely to enter in the foreseeable future.

More recently, the FTC has been examining overlaps between the merging parties' early stage pipeline with more frequency. In *Roche/Spark*,[18] the key issue in the FTC investigation was the overlap between Roche's existing haemophilia A product and Spark's novel gene therapy in Phase II development for haemophilia A. Roche's existing product was a monoclonal antibody that prevented or reduced the frequency of bleeding episodes in haemophilia A patients, whereas Spark's pipeline product was a different mechanism of action: an experimental gene therapy that, according to the FTC, had the potential to significantly improve the treatment of haemophilia A and possibly even cure the disease. Ultimately, the FTC voted unanimously to close its 10-month investigation of the deal without requiring a remedy, noting that Roche would not have an incentive to delay or terminate the development of Spark's programme because of the number of other companies developing similar gene therapy treatments.

Critics have noted that extending the potential competition framework to early stage pipeline products stretches merger analysis to periods in which the 'but-for' world become too speculative to predict with any accuracy, risking over-enforcement. Nevertheless, experts expect the FTC to continue its trend of evaluating earlier stage pipeline products.

FTC leadership has also recently signalled a willingness to pursue theories of harm to innovation markets (i.e., R&D directed towards new or improved products or processes and the close substitutes for that R&D). The only example of the FTC's regulation of mergers based on innovation effects is *Ciba-Geigy/Sandoz*,[19] a decades-old case where the FTC argued that the firms' combined position in

18 Statement of the Federal Trade Commission, *In Re Roche Holding/Spark Therapeutics*, Commission Matter No. 1910086, 16 December 2019.

19 *In the Matter of Ciba-Geigy Limited, Ciba-Geigy Corporation, Chiron Corporation, Sandoz Ltd, Sandoz Corporation, and Novartis AG*, File No. 961-0055, Docket No. C- 3725 (1997).

gene therapy research was so dominant that other firms doing research in the area would have to license or otherwise contract with one of the merging parties to commercialise their own research efforts and that combining the two programmes would reduce research in the area. A consent order required the newly combined company, Novartis, to grant non-exclusive licences to third parties before the deal would be approved.

Although the FTC has not come close to challenging a transaction on pure innovation grounds recently, in *Pfizer/Mylan*,[20] dissenting Commissioner Rohit Chopra called on the FTC to 'dramatically increase rigor and supervision of innovation merger investigations'.

Conglomerate effects

Although the US authorities have traditionally been focused on unilateral effects and potential competition theories of harm, the launch of the Task Force shows that there is concern that the traditional approach does not address all potential harms resulting from pharmaceutical mergers (e.g., mergers resulting in expanded drug portfolios).

Recent developments in APAC

APAC regulators have exhibited a strong preference for aligning their substantive review with mature jurisdictions such as the EU and the US and often request waivers to exchange opinions with the EC, the US Department of Justice, the FTC and, increasingly, the UK Competition and Markets Authority.[21] Unilateral effects remain the APAC regulators' primary focus when reviewing mergers in the pharmaceutical sector.

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20 *In the Matter of Pfizer Inc, Upjohn Inc, Viatris Inc, Mylan NV, Utah Acquisition Sub Inc*, File No. 191-1082, Docket No. C-4727 (2019).

21 For example, the Chinese regulator noted in the *Abbott/St. Jude Medical* (2016) decision that it exchanged views with the US and the EU regulators, available at http://english.mofcom.gov.cn/article/newsrelease/significantnews/201701/20170102496993.shtml; and Australia and New Zealand are among the 'Five Eyes' nations, together with the US, UK and Canada, who agreed to meet regularly to develop and share intelligence to detect and investigate suspected anticompetitive behaviour and collusion, using existing international cooperation tools, available at https://content.mlex.com/#/content/1360342?referrer=search_linkclick.

Innovation effects are also carefully assessed by the APAC regulators in pharmaceutical mergers, especially when there is international consensus reached in other jurisdictions.[22] As an illustration, in China, in *Becton Dickinson/Bard*,[23] the Chinese regulator focused on Becton Dickinson's ongoing R&D project that would potentially challenge Bard's technology and its incumbent market position for years. The decision noted that the concentration may decrease the innovation level of the ongoing project and cause delay in the introduction of new products, thus resulting in a suppression of technology development in the core needle biopsy device market in China. Innovation concerns in the same vein were raised in Japan in *Takeda/Shire*,[24] where the Japan Fair Trade Commission (JFTC) assessed not only the market impact by the existing products as a result of the transaction, but also the pipeline biological product that would introduce a new IBD treatment and potentially compete in the market after its launch.

Relatedly, the South Korean regulator amended its merger review guidelines in 2019, introducing 'innovation markets' in industries in which innovative activities such as R&D are so essential for (continuous) competition that those innovative activities themselves may form a relevant market separately.

However, even though most APAC regulators typically would not raise novel antitrust theories, industrial policies tend to play a bigger role in certain APAC jurisdictions. For instance, according to the Anti-Monopoly Law in China, the Chinese regulator is mandated to take into account the merger's impact on the nation's economic growth. This means that in practice, when the parties' combined market share reaches 30 per cent – notwithstanding the insignificant share increment and other supporting evidence – the Chinese regulator would find adequate legal basis to justify its theory of harm stemming from industrial policies to protect domestic interests.

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22 For example, in China, to assess the 'impact on market access and technological innovation', the Interim Provisions on Review of Concentration of Undertakings 2020 (article 27.2) require the regulator to consider the impact of the concentration on aspects including the driving force of technological innovation, the investment in research and development (R&D) and utilisation of technologies, and the integration of technical resources.

23 See the decision of the Ministry of Commerce in China (the previous Chinese merger regulator) of 27 December 2017, *Becton Dickinson/Bard*, available at http://fldj.mofcom.gov.cn/article/ztxx/201712/20171202691390.shtml.

24 The Japan Fair Trade Commission (JFTC) decision on Takeda Pharmaceutical Company Limited's acquisition of Shire Plc in 2018. See a decision summary by the Organisation for Economic Co-operation and Development (OECD), available at https://one.oecd.org/document/DAF/COMP/WD(2020)18/en/pdf.

Legal standards for identifying competition issues

Most authorities apply a predictable but flexible framework for assessing potential concerns.

Recent developments in the EU

Identifying unilateral effects

The EC applies a detailed but flexible framework to identify unilateral effects. It looks at each level in the production chain[25] and focuses on closeness of substitution. Market definition plays a key role in the assessment.

In cases involving finished dose pharmaceuticals (FDPs), substitution is normally assessed on the basis of the Anatomical Therapeutic Chemical (ATC) classification devised by the European Pharmaceutical Marketing Research Association. There are four ATC levels. ATC4 is the most granular level. ATC3 (specific therapeutic indications) is typically the starting point for defining the relevant product market.[26] However, in several cases, the EC has used the ATC4 level (distinct modes of action within certain ATC3 groups), the molecule level or group of molecules level, or even an alternative classification system altogether, as a starting point for market definition.[27] The EC may deviate from its starting point market depending on the feedback from the market investigation. Geographic markets are defined nationally.

25 The production chain is split into active pharmaceutical ingredient (API) production, outlicensing of marketing authorisation dossiers, contract manufacturing of finished dose pharmaceutical (FDP) and FDP production. API production markets span the European Economic Area (EEA) at least, and are possibly global. In-house API production for captive use is not considered. See EC decision of 28 January 2015, *Mylan/Abbott*, M.7379, paragraph 457 et seq.

26 See EC decision of 22 April 2020, *Mylan/Upjohn*, M.9517, recitals 13–18; EC decision of 10 July 2019, *GSK/Pfizer Consumer Healthcare Business*, M.9274.

27 For example, in EC decision of 28 January 2015, *Mylan/Abbott*, M.7379, paragraph 45, the EC applied the Vaughan-Williams Classification. The EC has also defined markets based on the decease or the type of treatment; see EC decision of 10 June 2020, *AbbVie/Allergan*, M.9461, paragraphs 9–10. See further EC decisions of 10 July 2019, *GSK/Pfizer Consumer Healthcare Business*, M.9274, recital 15; and of 28 January 2015, *Novartis/GSK Oncology*, M.7275, recitals 207 and 216; and *Mylan/Abbott*, M.7379, paragraph 12.

Markets for pipeline drugs are typically wider in a geographic sense (at least EEA) and generics competition is typically assessed on a narrower market in a therapeutic sense (molecule level, possibly by pharmaceutical form).[28] The EC will normally only consider pipeline products that are around two years from possible market entry.[29]

In cases where many potential overlaps need to be assessed, the EC has developed a practice of applying a system of filters aimed at determining the group of markets where concerns are most likely and on which it focuses its analysis.[30]

For marketed pharmaceuticals, the filters are based on: the combined share (below or above 35 per cent); the share increment (below or above 1 per cent); whether the party with the lowest share is a recent entrant; and the number of independent competing suppliers (more than one or not).[31]

For pipeline pharmaceuticals, the filters are based on: pre-existing combined share (below or above 35 per cent); pre-existing single firm share (below or above 35 per cent); whether one of the merged firms is the originator; whether there is a pipeline overlap; and the number of independent competing companies (more than two or not).[32]

In assessing potential issues on the (filtered) overlap markets, the EC typically considers distinctions between: patented and generic pharmaceuticals (branded and unbranded); prescription drugs and OTC drugs; and different galenic forms (form, route of administration). Differences between overlap products across these dimensions make competition issues less likely. For example, the fact that the price of a prescription drug is regulated limits the risk of competition issues even if combined shares are significant.[33] There are numerous additional considerations that are brought to bear in assessing overlap markets (e.g., market size, market growth or decline, nature of demand (e.g., tender-based) and capabilities of third-party competitors).[34]

With respect to biopharmaceuticals and biosimilars, the EC takes a more flexible approach when it comes to closeness of substitution.[35] While the originator product and its biosimilar versions are not necessarily considered as interchangeable

28 See EC decision of 10 March 2016, *Teva/Allergan Generics*, M.7746.
29 See EC decision of 28 January 2015, *Mylan/Abbott*, M.7379, paragraph 450.
30 id., paragraph 32.
31 See EC decision of 10 March 2016, *Teva/Allergan Generics*, M.7746, paragraph 58.
32 id., paragraph 62.
33 See EC decision of 28 January 2015, *Mylan/Abbott*, M.7379, paragraphs 51, 65, 70, 75, 88.
34 ibid., where many of these factors were considered.
35 See EC decision of 03 August 2010, *Teva/Ratiopharm*, M.5865.

by prescribers or purchasing institutions, there are situations in which the originator drug and its biosimilar version can be in close competition (in particular, for newly diagnosed patients). Interchangeability is assessed by: whether the originator and its registered biosimilar compete for the same tenders; whether healthcare practitioners confirm that they can be used interchangeably; and whether entry of the biosimilar impacts the prices or sales volumes of originators.

Identifying innovation effects

The EC assesses innovation effects based on a three-layer competitive assessment.[36]

The first layer consists of identifying any loss of potential competition. To do so, the EC assesses two types of overlaps: first, overlaps between the parties' existing (marketed) and pipeline products at advanced stages of development on the one hand, and second, overlaps between the parties' pipeline products at advanced stages of development. For pharmaceutical products, in principle the EC considers programmes in Phases II and III of clinical trials as being at an advanced stage of development. As discussed above, this first layer has become part of traditional unilateral effects analysis.

The second layer consists of analysing innovation competition in relation to the parties' ongoing pipeline products by assessing the significant loss of innovation competition resulting from the discontinuation, delay or redirection of the overlapping pipelines, including early stage pipelines.

The third layer looks at innovation competition in relation to the capability to innovate in certain innovation spaces, by assessing the risk of a significant loss of innovation competition resulting from a structural reduction of the overall level of innovation.

When R&D activities are assessed in terms of importance for future markets, the product market definition can be less clearly defined than for marketed products, reflecting the intrinsic uncertainty in analysing products that do not exist yet.[37]

Identifying conglomerate effects

The EC also recognises that competition may not always or only take place on a product-by-product basis but may be based on a portfolio of products, such as when pharmaceutical companies compete with wholesalers to supply pharmacies.[38]

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36 See EC decision of 10 June 2020, *AbbVie/Allergan*, M.9461, recital 19.

37 See EC decision of 28 January 2015, *Novartis/GSK Oncology*, Case M.7275, recital 26.

38 See EC decision of 10 March 2016, *Teva/Allergan Generics*, M.7746, paragraph 47.

The EC has recognised that two companies can compete both on the marketing of individual molecules and on the wholesale of generic pharmaceuticals. For example, in *Teva/Allergan*, the EC was concerned that Teva and Allergan were the only two generics manufacturers with a portfolio broad enough to be able to sell directly to UK pharmacies, without going through a wholesaler, offering competitive discount schemes.

Identifying coordinated effects

Coordinated effects have not raised any concerns to date but have been considered. There is an existing framework to assess coordinated effects. For example, in *J&J/Synthes*,[39] concerning orthopaedic medical devices, the EC did not find any evidence that would support a theory of harm based on coordinated effects:

> *In particular, the (i) purchasing patterns in the market, (ii) the heterogeneity of products (differentiated product markets), (iii) a lack of transparency as regards market shares, contracts won and prices, (iv) the fact that a number of credible competitors are remaining, (v) strong evidence of recent entry, and finally (vi) the absence of any indication of past coordination speak against such a theory.*[40]

Although the EC has not ruled out that it might be a factor in its assessment, to date issues relating to past anticompetitive conduct have not been decisive in a merger decision.

Recent developments in the US

As in the EU, market definition plays a key role in the FTC's analysis of pharmaceutical transactions, and while the agency's analysis is not always obviously consistent, there are several defining principles. First, because of the existence of country-specific intellectual property (IP) rights and Food and Drug Administration regulatory requirements, only companies authorised to manufacture and distribute products in the US market are considered participants in the relevant market. Moreover, the FTC defines product markets narrowly in the pharmaceutical space and has looked at the following factors to determine the precise scope:

- the disease or condition that the product treats;
- the active ingredient or chemical compound;

39 See EC decision of 18 April 2012, *Johnson & Johnson/Synthes*, M.6266.

40 id., paragraph 38.

- the method of delivery and dosage strength or frequency;
- whether the drug is branded or generic; and
- any differences in addressable patient populations, contraindications or other special factors.

Recent developments in APAC

The Chinese regulator published the Antitrust Guidelines for the API Industry in November 2021, which state that the type of active pharmaceutical ingredient (API) should typically form the starting point of its market definition analysis. Nevertheless, on a case-by-case basis, the needle could move in both directions for either defining the market more narrowly by segmenting within a type of API or more broadly by grouping several types of API in the same market.[41]

Other jurisdictions, such as Japan and India, have exhibited a preference of following the ATC levels. Largely aligned with the EC's approach, the Japanese regulator generally would begin to approach the product market of medical drugs at ATC3 or ATC4, or both, and further assess the substitutability based on opinions of medical institutions and doctors. There are also circumstances where the JFTC would deviate from the ATC classification, which would usually involve new types of drugs. For example, in *Novartis/GlaxoSmithKline*,[42] the JFTC defined the markets independently from the ATC code for pipeline drugs.

The geographic markets are typically defined as national for pharmaceuticals and medical devices due to varying local regulations.[43]

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41 China's Antitrust Guidelines for the API Industry, article 4.1. For substitution analysis, it provides some aspects to consider: a demand substitution analysis will consider factors such as product characteristics, quality standards, usages and price, while a supply substitution analysis can be conducted based on factors such as market entry, production capacity, production facility renovation and technology barriers.

42 See the JFTC's decision on the transfer of business from GlaxoSmithKline KK to Novartis International AG in 2014 (Case 4 of the Major Business Combination Cases in Fiscal Year 2014, available at www.jftc.go.jp/en/policy_enforcement/mergers/index_files/MajorBusinessCombinationCasesFY2014.pdf).

43 See, e.g., in China, the Chinese regulator considered the registry and licensing requirements for certain medical devices in *Abbott/St. Jude Medical* (2016) and *Becton Dickinson/Bard* (2017); and in Japan, the JFTC defined a local Japanese market in *Takeda/Shire* (2018), considering the same pricing throughout Japan and the regulatory approval required in Japan for launching new pharmaceutical products (see a decision summary in 'Start-ups, killer acquisitions and merger control – Note by Japan', OECD Competition Committee, 11 June 2020, available at https://one.oecd.org/document/DAF/COMP/WD(2020)18/en/pdf).

Market shares are still the primary factor considered by APAC regulators in assessing unilateral effects, but high shares that ordinarily may lead to concerns may be alleviated by local price regulations. For example, in *Sun/Ranbaxy*,[44] the Indian regulator assessed 51 molecules in total for potential competition concerns, out of which it determined that seven were likely to result in an appreciable adverse effect on competition. However, no harm was determined with respect to four of the formulations, despite the combined shares of up to 95 per cent, owing to the fact that they were covered in India's National List of Essential Medicines 2015 and were subject to price control. Other factors taken into account include technical capabilities (IP or know-how), customer recognition or brand loyalty and business history or experience in the industry, as well as the administrative cost to comply with local regulations as part of the overall entry barriers.

Remedies

Although remedies in pharmaceutical mergers are typically very predictable and therefore offered early in the review process, the new trends in merger review could also complicate remedy discussions.

Recent developments in the EU

The EC has adopted a now well-established and predictable approach to address concerns in pharmaceutical mergers. In cases involving FDPs, to eliminate the full overlap between the parties, the EC generally requests the divestiture of the entire product range sold under the overlapping brand, including the rights and assets[45] required to commercialise the product, previous and ongoing R&D projects related to the brand and the necessary safeguards to ensure the viability of the divestment business (including transitional support for up to five years). Importantly, the EC also generally requires that the divestment business is acquired by an upfront buyer with experience in the supply of healthcare products, an established presence, an ability to innovate and access to distribution channels

44 See the Competition Commission of India's decision in *Sun Pharmaceutical Industries Limited/Ranbaxy Laboratories Limited*, C-2014/05/170.

45 These include the applicable contracts, marketing authorisations, brands, customer lists and key personnel.

in the relevant countries, particularly in relation to OTC products.[46] The parties are generally free to decide whether to divest the target's or the acquirer's overlap business, and may also decide to divest the pipeline business.[47]

In cases involving pipeline drugs, the EC addresses potential harms to innovation by requiring the divestment of late and early stage pipeline drugs.[48] In these cases, the EC typically expects: the additional requirement of transferring all related pipeline assets and rights to ensure that development of the drug is no longer controlled by the undertaking concerned;[49] transitional support to ensure completion of clinical studies trialling these drugs; and a commitment to develop and commercialise the related clinical research.[50]

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46 See EC decisions of 4 August 2015, *Pfizer/Hospira*, M.7559; of 10 July 2019, *GSK/Pfizer Consumer Healthcare Business*, M.9274; of 22 April 2020, *Mylan/Upjohn*, M.9517; and of 8 June 2020, *Elanco Animal Health/Bayer Animal Health Division*, M.9554.

47 Parties typically propose which overlapped product to divest, which can be either the acquirer's or the target's product. For example, in *GSK/Pfizer Consumer Healthcare Business*, the parties proposed to divest Pfizer's topical pain management business. Similarly, in *Takeda/Shire*, Takeda offered to divest Shire's pipeline product. In *Pfizer/Hospira*, the companies offered Pfizer's infliximab biosimilar. In *Novartis/GSK Oncology*, the transaction was cleared after a commitment to divest two of Novartis' cancer treatments.

48 See EC decision of 20 November 2019, *Takeda/Shire*, M.8955. The EC raised concerns over the potential competition between products Allergan and Abbvie were developing and the likelihood of one of them being discontinued. The EC accepted that the parties divest the product that was still at an early stage of development (no planned trials at the moment of the transaction), while letting the parties keep the product that was already in Phase III, but required the divestment package to include the necessary transitional support.

49 See EC decision of 9 June 2017, *Johnson & Johnson/Actelion*, M.8401.

50 See EC decision of 28 January 2015, *Novartis/GlaxoSmithKline Oncology Business*, M.7275. Here, the divestment presented the challenge that one of the divested products was owned by a third party, so remedies needed to ensure cooperation between the third-party licensor and the suitable third-party partner. Novartis committed to both return the licensed product and to divest its own product to the concerned third party. The latter would negotiate appropriate agreements with another partner to develop and commercialise the two products. The EC had to approve both the partner and the partnership agreement as the success of the development of the two drugs critically depended on the partner's skill set, resources, motivation and experience in developing oncology products. Should the third-party licensor fail to find a suitable partner within the prescribed deadline, the commitments provided that the rights over the two products would then be sold to a suitable purchaser by a divestiture trustee. See, also, EC decision of 4 August 2015, *Pfizer/Hospira*, M.7559, where the EC requested the divestment package to include Pfizer's infliximab biosimilar pipeline product, which, at the time of the transaction, was undergoing a Phase III clinical trial, and that as part of the remedy, the purchaser has the

The EC's predictable assessment framework for addressing concerns and the overall will from merging parties to cooperate has resulted in most cases being cleared in Phase I, including based on fix-it-first remedies.[51] But recent cases show that remedies may become increasingly complex.

In *J&J/Actelion*,[52] the EC was concerned with any remaining structural links. In this transaction, the parties proposed to carve-out Actelion's insomnia pipeline product into a newly created company, Idorsia. The EC considered that the merged entity would still have the ability to negatively impact the launch of Idorsia's competing insomnia pipeline product, given a long-term loan, a credit facility and access to IP rights linking the two firms, and therefore found these remedies insufficient. J&J also held a minority shareholding in Idorsia and could potentially appoint one or two board members. In the accepted commitments, J&J offered remedies to ensure that it could not influence Idorsia's strategic decisions nor acquire commercially sensitive information on its insomnia medicine in development by proposing to limit its shareholding below 10 per cent (or up to 16 per cent provided that J&J was not the largest shareholder) and not nominate any board member, thereby strongly reducing the structural and economic links and removing incentives that could negatively influence the development of its insomnia research programme.[53]

To address concerns raised from potential portfolio effects in conglomerate mergers, the EC has accepted complex remedies that addressed the overall ('big picture') impact of the transaction. In *Teva/Allergan Generics*, the EC required the divestment package to include non-overlapping, non-problematic molecules (both marketed and pipeline generics) to allow the purchaser to have the necessary scale and scope to compete effectively with the merged entity post-transaction.[54]

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option to request the necessary arrangements for the supply of the pipeline drug, including reasonable clinical development assistance and support with market approvals and post-authorisation procedures.

51 See EC decision of 9 November 2016, *Boehringer Ingelheim/Sanofi Animal Health Business*, M.7917. In *Pfizer/Hospira*, the parties initiated remedies discussions with the EC in pre-notification. This allowed the EC to review and assess the adequacy of the proposed remedies and potential purchaser and discuss improvements in the context of pre-notification. The parties submitted the remedy package together with the notification of the transaction, which allowed for some additional time to market test it in Phase I (EC decision of 4 August 2015, *Pfizer/Hospira*, M.7559).

52 EC decision of 9 June 2017, *J&J/Actelion*, M.8401.

53 This was done by granting Minerva Neurosciences new rights over the global development and waiving its royalty rights on Minerva's sales in the EEA.

54 See EC decision of 10 March 2016, *Teva/Allergan Generics*, M.7746. See, also, EC decision of 20 July 2016, *Mylan/Meda*, M.7975, in which the market test confirmed that generic

In relation to covid-19, it is noteworthy that the EC has adapted to the circumstances when adopting remedies. For instance, in *Mylan/Upjohn*, the EC acknowledged that the covid-19 outbreak had disrupted the usual course of business in the pharmaceutical sector and accepted not to require an upfront buyer and rather set legally binding agreements setting out the material terms of the divestment.[55]

Recent developments in the US

FTC enforcement actions in the pharmaceutical sector have historically resulted in settlement between the parties and the government, rather than in litigation to block the merger in court. As part of its traditional approach to remedies in this space, in almost all cases the FTC has required divestitures that allow for the buyer to become fully operational quickly and an upfront buyer vetted by the FTC for its financial capability to acquire and maintain the assets and experience in the relevant area. In practice, this means that the divestiture must include all assets necessary to maintain the viability of the relevant product, including any relevant IP, confidential information, access to employees needed to continue development and even transition services that require the merged firm to provide the buyer with supply or other functions for a limited period until the buyer can independently compete successfully in the market. Often, the FTC will appoint a monitor to oversee the transfer of the divestiture assets.

Currently, there is greater scepticism that divestitures have successfully resolved competitive concerns, and regulators have signalled a tougher approach to remedies in general. In *AbbVie/Allergan*,[56] the Commission required remedies involving two of the parties' pharmaceutical products, in both instances concluding that the merging parties were two of only four companies with products on the market or in development. The Commission followed its well-established approach of

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suppliers compete using their entire portfolio when negotiating with pharmacies and wholesale customers, so the purchasers had to be well-established in the marketing of generic pharmaceutical products, with a significant product portfolio and an existing distribution and sales footprint in the relevant countries.

55 See EC decision of 22 April 2020, *Mylan/Upjohn*, M.9517. See, also, EC decision of 20 November 2018, *Takeda/Shire*, M.8955, where the EC agreed to entirely waive remedies due to the increase in the drug's development costs because companies struggled to recruit patients for Phase III clinical trials due to covid-19 restrictions and the publishing of an independent study on the pipeline drug showing abnormal infant death rates. No measure appeared capable of restoring the pipeline drug's initial timeline and it would no longer be able to launch before the overlapping drug lost exclusivity.

56 *In the Matter of AbbVie Inc and Allergan plc*, File No. 191-0169 (2020).

requiring divestitures; however, the vote to accept the consent decree was split. Dissenting Commissioner Chopra criticised one of the divestiture buyers, Nestle, due to its lack of experience as a pharmaceutical company, but took broader aim at the FTC's remedies process as inadequate to resolve competition issues.

The most significant development in remedies relates to the FTC's new policy of requiring parties to a consent decree to seek the FTC's prior review and approval before making certain future acquisitions. For example, the FTC recently unanimously approved an order requiring Water Street HealthCare Partners to divest injectable triamcinolone acetonide, a generic injectable corticosteroid, as a condition of the sale of its portfolio company Custopharm to Hikma Pharmaceuticals. The consent decree requires that Hikma not acquire any rights or interest in triamcinolone without the prior affirmative approval of the Commission, even if the transaction is not reportable under the Hart-Scott-Rodino Act. The proposed order also requires the divestiture buyer to maintain and not sell or dispose of the triamcinolone assets for a period of four years. To date, prior approval provisions have generally been applied narrowly to the market covered by the decree.

Recent developments in APAC

Similar to the practice in the EU and the US, the remedies imposed by the APAC regulators for pharmaceutical mergers are largely structural (i.e., to divest one party's business relating to the products with anticompetitive concerns to ensure effective competition in the market).[57] For China, this is somewhat out of character with the regulator's ordinary approach to remedies, especially for mergers in sensitive industries such as the semiconductor sector, which tends to be far more flexible and open to behavioural conditions in response to stakeholders' opinions or industry policy concerns.[58] To date, the Chinese regulator has not shown a particular inclination towards licensing requirements or commitments with regard to pharmaceutical assets.

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57 See, e.g., in *China, Abbott/St. Jude Medical* (2016) and *Becton Dickinson/Bard* (2017); and in Australia, *Mylan NV/Upjohn Inc* (2020) and *Elanco Animal Health/Bayer Animal Health Division* (2020).

58 The Chinese regulator is explicitly granted the power to consider the 'impact on the development of national economy' under Article 27 of the original Anti-Monopoly Law 2008 and Article 33 of the amended Anti-Monopoly Law 2022. Therefore, the Chinese regulator will solicit opinions from key Chinese stakeholders, which, in many cases, has led to behavioural remedies to protect domestic interests. Typical remedies include pricing, output commitment, secured supply, no tying or bundling and interoperability.

The scope of divestiture typically covers tangible assets (including inventory and facilities) and intangible assets (including IP and know-how), equity, key personnel, key customer and supplier contracts, customer records and administrative approvals and licences.[59] The divestiture buyer's independence and its capabilities to operate the divestment business competitively are key considerations for the APAC regulators' approval, and in some cases the regulators may require an upfront buyer approval before approving the main transaction.[60]

To address innovation effects, relevant pipeline products and R&D projects may become part of the divestment assets. For example, in *Becton Dickinson/Bard* in China, assets and information regarding ongoing R&D projects were also divested.[61] Similarly, in *Elanco Animal Health/Bayer Animal Health Division*,[62] the New Zealand regulator required Elanco to divest certain parts of the business so that the buyer could continue developing the pipeline products that may become competitive alternatives to Bayer's products in the absence of the merger.

The APAC regulators have also required additional remedies to divestitures for pharmaceutical mergers. As a unique feature in China, the regulator has ordered a hold-separate remedy to avoid loss of a competitive alternative.[63] In Japan, typical remedies in addition to divestitures include accessibility to essential facilities by competitors, no discriminatory treatment, no tying or bundling

59 See, e.g., *Abbott/St. Jude Medical* (2016) in China; and *Mylan NV/Upjohn Inc* (2020) and *Elanco Animal Health/Bayer Animal Health Division* (2020) in Australia.

60 See, e.g., *Becton Dickinson/Bard* (2017) in China. In *Abbott/St. Jude Medical* (2016), the Chinese regulator required upfront buyer approval as a condition to approve the main transaction. In Australia, the Australian Competition and Consumer Commission sets largely similar requirements and approval processes for determining divestiture buyers, where it will also review the sale and purchase agreement for the divested business.

61 The divestiture of the R&D project specifically covers the following: tangible assets, non-exclusive licensing of relevant know-how and trade secrets, a transitional service agreement and training for the buyer's relevant staff.

62 See the New Zealand regulator's *Elanco Animal Health/Bayer Animal Health Division* decision (2020), in which the regulator agreed that Elanco's divestment of the Osurnia brand business would avoid the removal of a close competitor to Bayer's pipeline product in the otitis treatment market, available at https://comcom.govt.nz/__data/assets/pdf_file/0015/236031/2020-NZCC-14-Elanco-Animal-Health-Inc-and-Bayer-AGs-animal-health-business-Clearance-determination-9-July-2020.pdf.

63 See, e.g., *ZGBH/Royal DSM JV* (2019), in which the Chinese regulator required the parties to remain independent in running the relevant overlapping businesses and to keep the joint venture independent from the parties (except for certain agreed necessary support). Specifically, the parties were to be held separate in terms of personnel, business management and operations, supply terms and confidential information, offices and facilities, information systems and others.

and firewalls to protect competitors' sensitive information.[64] In Singapore, the regulator has required remedies including supplying products to competitors at fair, reasonable and non-discriminatory prices, not locking in customers on an exclusive basis, guaranteeing customers' freedom to terminate contracts without cause, and maintaining the same prices and other transaction terms with certain customers.[65] In India, in multiple cases the regulator has also required the parties to shorten the term of non-compete clauses to three to four years, so that they would not unreasonably hinder entry into the market.[66]

Outlook

After years of relative stability and predictability, clearances processes for pharmaceutical deals are expected to become more uncertain. This is due to flexible and creative notification requirements, coupled with new theories of harm. The Task Force can play an important role in brokering alignment between key jurisdictions, which could help pharmaceutical companies anticipate whether a planned transaction will raise issues.

That said, most transactions will continue to benefit from the tried and tested approach that has worked so well for pharmaceutical companies and antitrust authorities, resulting in early remedy offers and very few blocked deals.

64 See, e.g., *M3/Ultmarc* (2019) in Japan.

65 See *Pathology Asia Holdings Pte Ltd/Innovative Diagnostic Private Limited and Quest Laboratories Pte Ltd* (2019) in Singapore.

66 See, e.g., *Hospira/Orchid* (2009) in India.

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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