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Recent Developments in the Analysis of Life Sciences Mergers

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1. Introduction

Pharmaceutical deals have the attention of competition regulators globally. The European Commission ("EC") recently noted in its Report on Competition Enforcement in the Pharmaceutical Sector (2018-2022) that it "*now actively monitors pharmaceutical transactions to identify concentrations that fall below the EU's and Member States' notification thresholds but nonetheless merit review by the Commission to ensure that they do not harm effective competition*."[2] In the U.S., health care remains an enforcement priority, and the new Horizontal Merger Guidelines provide regulators with an expanded toolkit for investigating mergers, including in the pharmaceutical sector (although this toolkit has yet to be applied under the current administration). Similarly, in the rest of the world, China reaffirmed its commitment to strengthening antitrust regulation to ensure the security of drug supplies for people's livelihood in an official announcement made in August 2025.[3] India also introduced a new transaction value-based threshold in 2024 in part to capture killer acquisitions in the pharmaceutical sector.

At the same time, the review paradigm is shifting. Transactions in the pharmaceutical space have long benefitted from tried and tested approaches from competition authorities, resulting in early remedy offers and very few blocked deals. But after years of relative stability and predictability, clearances processes for pharmaceutical deals have become more uncertain in recent years. This is due to less predictable notification requirements and new theories of harm.

Against this background, this article discusses the lay of the land in terms of theories of harm and remedies in pharmaceutical mergers in the EU, U.S., and APAC regions.

2. Theories of Harm

Pharmaceutical mergers have traditionally been assessed based on unilateral effects, i.e. the loss of competition between the merging parties. But recent case practice in the EU, U.S., and APAC region shows that competition authorities have broadened their purview to also examine additional

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[2] See Report on Competition Enforcement in the Pharmaceutical Sector (2018-2022), available at: https://op.europa.eu/en/publication-detail/-/publication/8aeb6cf3-bc34-11ee-b164-01aa75ed71a1/language-en/format-PDF/source-search. The EU General Court endorsed the EC's approach in Case T-227/21 *Illumina v. Commission*, but this judgment is currently being appealed before the EU Court of Justice. In its Opinion of 21 March 2024, Advocate General Nicholas Emiliou disagreed with the General Court. The U.S. authorities have also been creative in increasing their merger review role, as the *Hikma* case (discussed below) shows.

[3] See SAMR's website at https://www.samr.gov.cn/xw/sj/art/2025/art_dc9ef27b06ee44f7ab2b274ac7e12e17.html.

theories of harm, such as wider innovation impact and non-horizontal effects.

(a) Theories of Harm in the EU

(i) Unilateral Effects

Within the EU, the EC is strict in evaluating horizontal overlaps in pharmaceutical mergers. Even minor increases in market share or overlaps involving products still in development may requires remedies.[4]

GSK/Pfizer Consumer Healthcare Business[5] is a case in point. The EC found that the transaction would bolster GSK's leading position in the market for topical pain management products, despite the market share increase being less than 5 percent. The EC's concerns centered on the potential for higher prices due to reduced rebates for pharmacies, which could ultimately impact consumers. The fact that the products were based on off-patent, generic molecules was considered but did not sway the EC. The EC highlighted significant barriers to entry, such as strong brand recognition and a lack of robust competing brands, as well as the influential role of wholesalers.

Similarly, in *Cooper/Viatris (European OTC Business)*, [6] the EC assessed the overlap between Viatris' OTC pharmaceutical products for personal hygiene and the OTC, consumer health and consumer products offered by Cooper and other CVC portfolio companies. [7] Given the high combined market shares as well as high concentration levels in the affected markets, the EC was concerned that the transaction would have reduced competition in the markets for certain pharmaceutical products. The EC also found that post-merger there would not be sufficient potential competitors to exert sufficient competitive pressure on the merged entity. Conversely, in *ICG/Holding Uriach/Uriach/Ineldea*, [8] concerning OTC non-medicated products and consumer healthcare products and combined shares in excess of 30 percent, the EC noted that the increment from the transaction was minimal and that significant competitors remained in all affected markets.

In *J&J/TachoSil,* the EC concluded that despite the lack of overlap with J&J's marketed products in the EEA, the deal would eliminate the most likely new entrant into the market for dual haemostatic patches used in severe bleeding situations, where TachoSil held a dominant position.[9] The investigation suggested that, absent the merger, J&J would have had strong incentives to enter the market, given its experience with similar products outside the EEA, and that other competitors were

[4] To date, coordinated effects have not been a major concern for the EC in pharmaceutical mergers.

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

[6] EC Decision of 26 June 2024, *Cooper/Viatris (European OTC Business)*, M.11383.

[7] Cooper is ultimately owned by CVC Capital Partners and, together with several CVC portfolio companies, manufactures and distributes OTC, consumer health and consumer self-care products.

[8] See EC Decision of 15 July 2024, *ICG/Holding Uriach/Uriach/Ineldea*, M.11532.

[9] 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

unlikely to enter in a timely or credible manner.

Similarly, in *Takeda/Shire*, [10] the EC examined the overlap between Takeda's leading biologic inflammatory bowel disease, which was the only available treatment in the EEA at the time, and Shire's pipeline biologic product to treat the same disease, which was expected to launch before Takeda's product lost exclusivity. The EC was concerned that the merger could result in Takeda discontinuing Shire's new treatment, leading to a reduction of innovation and future competition.

In *Pfizer/Hospira,* the EC was concerned about the loss of competition between Hospira's infliximab biosimilar (Inflectra), and Pfizer's pipeline infliximab biosimilar, in circumstances where there was an originator product on the market, in addition to one other infliximab biosimilar (by Celltrion, which was identical to Hospira's biosimilar), one other biosimilar in Phase III clinical trials (by Samsung Bioepis), and two early stage biosimilars.[11] The EC's concerns were driven by the potential loss of imminent competition between the parties' biosimilars, e.g. because the originator product was only a distant competitor for certain indications and some of the other pipeline products were early stage.

(ii) Innovation Effects

The EC is increasingly assessing the impact of mergers on innovation, i.e. the risk of discontinuation, delay, or redirection of R&D projects. The EC's review extends beyond late stage pipeline overlaps and include early-stage R&D and even to the broader competitive landscape for innovation.

Innovation effects were central in *Novartis/GlaxoSmithKline Oncology Business*,[12] concerning innovative drugs for the treatment of advanced cancers. GSK and Novartis were considered direct competitors in the development and commercialization of cancer treatments B-Raf and MEK inhibitors. The EC found that post-merger there would only be two companies developing and marketing both B-Raf and MEK inhibitors. It was concerned that there would be a reduction of competition on innovation, with the expected abandonment of Novartis' broader clinical trial program for its B-Raf and MEK inhibitors.

The effects on innovation was also a key consideration in *BMS/Celgene*, [13] but resulting in a different outcome. The EC noted that the pharmaceutical R&D landscape in the relevant therapeutic areas was highly competitive, with numerous large and small companies, academic institutions, and research organizations active in late-stage and early-stage development. The EC also considered that the likelihood of the merged entity discontinuing or delaying pipeline projects was low, given the commercial incentives to pursue promising assets and the public commitments made to investors.

[10] See EC Decision of 20 November 2019, *Takeda/Shire*, M.8955.

[11] See EC Decision of 4 August 2015, *Pfizer/Hospira*, M.7559.

[12] See EC Decision of 28 January 2015, *Novartis/GlaxoSmithKline Oncology Business,* M.7275.

[13] See EC Decision of 29 July 2019, *BMS/Celgene,* M.9294.

In *J&J/Actelion*,[14] the EC raised concerns over the overlapping Phase II development programs for insomnia drugs. The EC concluded that the merger could reduce innovation competition by increasing the risk of discontinuation or delay of one of the pipelines as there were no competing pipeline products in the EEA based on the same novel mechanisms. Despite the fact that a third party was involved in the co-development of J&J's pipeline product, 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 license to sell in the EEA.

Concerns around the reduction of innovation also drove the EC decision in *Illumina/GRAIL.* The EC blocked this deal over concerns that the deal would stifle innovation and reduce choice in the emerging market for blood-based early cancer detection tests.[15] The EC argued that protecting ongoing innovation competition was essential to ensure a variety of future products with different features and price points. It found that "*GRAIL and its rivals were engaged in an innovation race to develop and commercialize early cancer detection tests. While there was still uncertainty about the exact results of this innovation race and the future of the market for early cancer detection tests, protecting the current innovation competition was crucial to ensure that early cancer detection tests with different features and price points will come to the market*."[16] The EC's prohibition was later annulled by the European Court of Justice ("ECJ") on jurisdictional grounds.[17]

(iii) Non-horizontal Effects

While the EC's primary focus has been on unilateral and innovation effects, it also considers non-horizontal effects.

In the OTC segment, mergers that result in a broader product portfolio may raise concerns about the ability to dominate retail shelf space, e.g. by offering a full range of complementary OTC products. This was evident in cases such as *GSK/Pfizer Consumer Healthcare Business* and *Teva/Allergan Generics*,[18] where the EC examined whether the combined portfolios would enable the parties to outcompete rivals beyond individual product markets. In *Teva/Allergan Generics*, the EC found that in Iceland, Ireland, and the UK, where the merging parties were the two largest generics suppliers, the remaining players would have been unable to compete effectively with the merged entity due to the

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[14] See EC Decision of 9 June 2017, *J&J/Actelion,* M.8401.

[15] See EC press release of 6 September 2022, 'Commission prohibits acquisition of GRAIL by Illumina', available at: https://ec.europa.eu/commission/presscorner/detail/es/ip_22_5364.

[16] *Id*.

[17] The deal was not notifiable in the EU because it fell below the EC and national notification thresholds, but was examined by the EC upon request from a number of Member States using the Article 22 of Regulation No 139/200 referral mechanism. The EC decision was annulled by the ECJ on the grounds that the EC lacked the authority under Article 22 of Regulation No 139/2004 to review the deal. Joined Cases C-611/22 P and C-625/22 P, *Illumina v. Commission*.

[18] See EC Decision of 10 March 2016, *Teva/Allergan Generics*, M.7746.

prevalent distribution models and the structure of the national generics market.

In the medical devices sector, non-horizontal effects have also been relevant. For example, in *Siemens Healthineers/Varian*, the EC's approval was conditional on the companies ensuring interoperability between their imaging and radiotherapy solutions and those of third parties, to prevent foreclosure of competitors.[19]

Most recently, in *Novo Holdings/Novo Nordisk/Catalent*, [20] the EC examined the vertical relationships between Novo Nordisk, a developer of GLP-1 receptor agonists for diabetes and obesity, with Catalent, a contract development and manufacturing organization ("CDMO") specializing in sterile fill-finish services for injectable pharmaceuticals. The EC assessed whether the transaction could result in input foreclosure, particularly given the surging demand for GLP-1 products. The EC's market investigation found that (i) there was significant alternative capacity available from other CDMOs; (ii) most of Catalent's relevant capacity was already committed to Novo Nordisk under pre-existing contracts; and (iii) rival pharmaceutical companies had limited reliance on Catalent for their own GLP-1 or anti-obesity products.

(b) Theories of Harm in the U.S.

The U.S. Federal Trade Commission ("FTC"), the U.S. antitrust agency which investigates pharmaceutical mergers, traditionally focuses its analysis on unilateral effects theories (i.e. whether a transaction will create an incentive for the merged firm to raise prices or otherwise harm consumers due to increased market power from elimination of competition between the parties to the transaction), as well as, to a lesser extent, coordinated effects (i.e. whether a transaction will increase the risk of coordination among competitors). The FTC has also focused on potential competition theories, i.e. whether a transaction incentivizes the merged firm to cease or delay development of pipeline products or take other steps to maintain a competitive advantage by inhibiting product innovation.

The FTC has historically defined pharmaceutical product markets using the following factors: (i) approved indication, or in the case of pipeline products the indication(s) for which the product is being investigated; (ii) active ingredient and mechanism of action: (iii) how the drug is administered to patients, including route of administration, dosage, strength, frequency, line of treatment, and setting; (iv) whether the drug is branded or generic; and (v) other factors such as patient demographics. Because drugs must be approved by the Food and Drug Administration ("FDA") prior to being marketed in the U.S., and due to U.S.-specific intellectual property rights, the FTC will only consider companies formally approved to manufacture and market products in the U.S. as market participants for the purposes of assessing competition.

While no pharmaceutical mergers have been challenged under the current administration,

[19] See EC Decision of 31 March 2021, *Siemens Healthineers/Varian Medical Systems,* M.9945.

[20] See EC Decision of 6 December 2024, *Novo Holdings/Novo Nordisk/Catalent*, M.11486.

current leadership at the FTC and Department of Justice ("DOJ") did confirm that revised merger guidelines developed by prior agency leadership will remain in effect. The 2023 Horizontal Merger Guidelines include several novel theories of harm, including effects on competition from serial acquisitions, increasing concentration, entrenching dominance or expanding dominance from one market into a related market, as well as effects on labor (e.g. wages, wage growth, benefits, working conditions). Several of these theories examine competitive effects regardless of specific overlaps and even if one merging firm is not present in a market at issue. [21] This embrace of novel theories is aligned with statements by FTC and DOJ leadership, which argue that the consumer welfare standard that has served as the foundation for antitrust analysis in the U.S. must also consider competitive effects beyond price and output. However, this paradigm shift has yet to be evidenced in a formal merger challenge in the healthcare space.

As an illustrative example, in its first merger challenge, current FTC leadership sued to block a merger involving medical device coatings — private equity firm GTCR's acquisition of Surmodics. In that case, FTC's merger challenge is based on traditional, unilateral-effects-based theories of harm in the market for hydrophilic coatings for medical devices, alleging that elimination of competition between the parties will remove "*a key driver of quality, competitive pricing, and innovation to the detriment of OEMs and patients*." [22] Specifically, FTC alleged that the transaction will "*combine the two largest manufacturers of critical medical device coatings*" creating "*a combined company controlling more than 50% of the market for outsourced hydrophilic coatings . . . often used by medical device manufacturers and are applied to lifesaving medical devices such as catheters and guidewires.*" [23] While novel theories were not alleged in the complaint, former FTC Commissioners Rebecca Slaughter and Alvaro Bedoya noted in a statement that the case "*challenges a transaction that is part of a widespread and problematic playbook in our economy: a private equity giant establishes a position in a market then acquires competing businesses as part of a consolidation strategy*." [24] The former Commissioners went on to note that "*[t]his type of consolidation playbook is prevalent and is particularly concerning when it is executed in healthcare markets, where not just money but lives are on the line*."[25]

(i) Innovation Effects

The FTC has traditionally focused on merging parties' existing marketed or pipeline products. When analyzing potential competition, FTC has historically investigated whether the merging parties are two of a few manufacturers of marketed

[21] See 2023 DOJ and FTC Merger Guidelines.

[22] See https://www.ftc.gov/system/files/ftc_gov/pdf/d9440_part_3_complaint_public_redacted.pdf.

[23] See https://www.ftc.gov/legal-library/browse/cases-proceedings/241-0095-gtcr-bc-holdings-llc-surmodics-inc-matter.

[24] See https://www.ftc.gov/system/files/ftc_gov/pdf/Slaughter-Bedoya-Statement-GTCR-Surmodics.pdf.

[25] *Id*.

or late-stage (i.e. Phase III) drugs, with minimal to no likely entrants in the near future.

Prior FTC leadership did expand its analysis of innovation effects to more speculative and earlier-stage pipeline products. For example, in *Roche/Spark*, FTC investigated the overlap between Roche's marketed monoclonal antibody targeting hemophilia A and a novel Phase II gene therapy for the same indication in development by Spark.[26] The FTC ultimately closed its investigation after ten months without a remedy, citing the quantity of other drug companies developing gene therapy treatments similar to Spark's product. Similarly, in *Sanofi/Maze*, the FTC sued to block an agreement which would give Sanofi an exclusive license to a Phase II drug targeting Pompe disease in development by Maze.[27] FTC alleged that the licensing agreement would eliminate Maze as a potential threat to Sanofi's alleged monopoly for Pompe disease treatments, and the parties ultimately abandoned the transaction.

(ii) Non-horizontal Effects

The FTC, and DOJ for that matter, have not traditionally assessed conglomerate or portfolio effects theories. As stated above, while current FTC leadership has not sued to block any pharmaceutical mergers, its first merger challenge, *GTCR/Surmodics*, focuses on traditional unilateral effects theories. Under prior FTC leadership, however, the FTC sued to enjoin *Amgen/Horizon*, alleging that the merger would allow Amgen to obtain favorable placement on pharmacy benefit manager formularies, by providing bundled discounts with its own blockbuster drugs, which would disadvantage future competitors and keep consumer prices high.[28] Notably, Amgen and Horizon did not have any overlapping marketed, or even pipeline, products. Ultimately, the litigation settled, with Amgen agreeing not to bundle Horizon's products with its existing portfolio and to "*seek FTC approval if it seeks to acquire any pre-commercial products that have completed FDA clinical trials to treat either thyroid eye disease or chronic refractory gout.*"[29]

(c) Theories of Harm in APAC

APAC regulators have exhibited a strong preference for aligning their substantive review with mature jurisdictions such as the U.S., the EU, and the UK – especially for Commonwealth jurisdictions such as Australia – and indeed, often request waivers to exchange opinions with the DOJ/FTC, the EC, and more commonly the UK Competition and Markets Authority.[30]

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

[27] See https://www.ftc.gov/news-events/news/press-releases/2023/12/statement-regarding-termination-sanofis-proposed-acquisition-maze-therapeutics-pompe-disease-drug.

[28] See https://www.ftc.gov/system/files/ftc_gov/pdf/2310037amgenhorizoncomplainttropi.pdf.

[29] See https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-approves-final-order-settling-horizon-therapeutics-acquisition-challenge.

[30] See e.g. the Chinese regulator noted in the *Abbott/St. Jude Medical (2016)* decision that it *(cont'd)*

The pharmaceutical sector has been an area of attention for several APAC regulators as a key area of public interest, with concerns, e.g. that price increases (including for the active pharmaceutical ingredients ("API")) would eventually be passed on to end-customers. The Chinese regulator, the State Administration for Market Regulation ("SAMR"), has been active in enforcement activities involving pharmaceutical companies over the past five years. [31] Regulators in other jurisdictions such as Japan and South Korea also prioritize the pharmaceutical sector in their recent antitrust regulation and enforcement.[32]

Unilateral effects remain the APAC regulators' primary focus when reviewing mergers in the pharmaceutical sector.

However, innovation effects are also carefully assessed by many APAC regulators, especially when there is international consensus reached in other jurisdictions. For

exchanged views with the U.S. 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 U.S., UK, and Canada, who agreed to meet regularly to develop and share intelligence to detect and investigate suspected anticompetitive behavior and collusion, using existing international cooperation tools (available at: https://content.mlex.com/#/content/1360342?referrer=search_linkclick). The Korean regulator also created a new review division (i.e. the International M&A Division) focusing on foreign transactions in December 2022, through which the regulator intended to "boost its network with competition authorities abroad."

[31] In the first half of 2025, SAMR and its local offices imposed collective fines of EUR 74 million (CNY 623 million) in five investigations against pharmaceutical companies and relevant individuals (see SAMR's website at: https://www.samr.gov.cn/xw/sj/art/2025/art_dc9ef27b06ee44f7ab2b274ac7e12e17.html). Relevant violations include abusive conducts such as excessive pricing and forcing unreasonable transaction conditions, as well as horizontal monopoly agreements and Resale Price Maintenance. *Shanghai No.1 Biochemical & Pharmaceutical and others* in December 2023 was the highest penalty levied so far, of EUR 140 million (CNY 1.2 billion) against four companies for abusing their dominance to sell injectable Polymyxin B sulphate at unfairly high prices (available at: https://www.samr.gov.cn/zt/qhfldzf/art/2023/art_d8b4075b8ccf4a22accb1af35aad2d5e.html).

[32] See e.g. in February 2025, the Japan Fair Trade Commission ("JFTC") ended its investigation against the leading hematology analyzer company Sysmex after raiding the company in 2024, accepting its commitment to ceasing tie-in sales of reagents and analyzers (available at: https://www.jftc.go.jp/en/pressreleases/yearly-2025/February/250213.html). In March 2023, the JFTC penalized five pharmaceutical wholesalers as they "*substantially restrained competition in the field of […]pharmaceutical procurement, contrary to the public interest*" via bid rigging from 2016 to 2019 (see https://www.jftc.go.jp/en/pressreleases/yearly-2023/March/230324.html). In August 2025, the Korean Supreme Court confirmed the antitrust regulator's fine of EUR 25 million (KRW 40.9 billion) in 2023 against 32 pharmaceutical companies for bid rigging involving essential vaccines (available at: https://www.mlex.com/mlex/antitrust/articles/2379020/korea-vaccine-sales-fails-to-overturn-kftc-sanctions-for-bid-rigging).

example, SAMR[33] will typically consider the impact on innovation and products in the R&D stage in its assessment, as evidenced by recent decisions and the Antitrust Guidelines for the Pharmaceutical Industry effective on January 24, 2025.[34] SAMR's Guidelines for the Review of Horizontal Mergers effective on December 10, 2024 also highlight the importance of technological developments and innovations (e.g. less R&D investment and innovative efforts) when evaluating mergers involving a potential market entrant.[35] As an illustration, in China, the investigation of *Becton Dickinson/Bard*[36] 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.*[37] 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 biologic product which will introduce a new IBD treatment and potentially compete in the market after its launch. The regulator in India, the Competition Commission of India ("CCI"), took the same approach in *Sekhmet/Optimus* to assess the overlap in an API product that was still under development and had not been commercially launched by one party.[38]

Relatedly, already since 2019, the South Korean regulator applies the notion of "innovation markets" in industries where innovative activities such as R&D are so essential for (continuous) competition that those activities may form a distinct relevant market. In China, SAMR's Antitrust Guidelines for the Pharmaceutical Industry also recognize R&D as a possible form of relevant product market when a business is specifically focused on this stage of the

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33 Before 2018, merger review was carried out by the Ministry of Commerce.

34 In China, to assess the "impact on market access and technological innovation", the Provisions on Review of Concentration of Undertakings 2023 (Article 34.2), requires the regulator to consider the impact of the concentration on aspects including the driving force and capability of technological innovation, the investment in R&D and utilization of technologies, and the integration of technical resources. This is further confirmed by SAMR's new 2025 Antitrust Guidelines for the Pharmaceutical Industry (Articles 35(3)). SAMR also expressly proposed to account for drugs in the R&D stage when assessing potential competitors (Articles 32).

35 SAMR's Guidelines for the Review of Horizontal Mergers (2024), Article 42 and Article 61.

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

37 The JFTC's decision on Takeda Pharmaceutical Company Limited's acquisition of Shire Plc in 2018. See a decision summary by OECD available at: https://one.oecd.org/document/DAF/COMP/WD(2020)18/en/pdf.

38 See the CCI's decision *Sekhmet Pharmaventures Private Limited/Optimus Drugs Private Limited* (*Sekhmet/Optimus*), C-2022/06/943 (available at: https://www.cci.gov.in/search-filter-details/4596).

pharmaceutical supply chain.[39] Notably, the guidelines recognize that patent licensing involving pharmaceuticals, including pipeline products, may constitute a notifiable concentration that requires careful market definition and merits analysis.[40] Different from the U.S. approach which only requires merger notifications for "exclusive" transfers of all of the commercially significant rights to a patent,[41] exclusivity is not a prerequisite to trigger a filing in China, meaning more IP related transactions, such as the common license-in and license-out transactions in the pharmaceutical industry, may be subject to merger review in China, subject to a case-by-case assessment.[42]

While most APAC regulators will typically focus on established antitrust theories, industrial policies tend to play a bigger role in certain APAC jurisdictions. For instance, according to the Anti-Monopoly Law in China, SAMR 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 percent — regardless of the minimal increase in market share or other supporting evidence — SAMR may find sufficient legal grounds to support a theory of harm based on industrial policies aimed at protecting domestic interests. The 2025 Antitrust Guidelines for the Pharmaceutical Industry also reiterate the importance of economic growth and public interest, as well as consumer benefits, in SAMR's substantive analysis.[43] The U.S.-China geopolitics also cast another layer of uncertainty, e.g. the proposed U.S. BIOSECURE Act targets biotechnology suppliers related to China and other countries of national security concerns.[44] It remains to be seen whether transactions in the life science sector will be subject to increasing scrutiny in China packaged in broad and innovative theories of harm.

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39 SAMR's 2025 Antitrust Guidelines for the Pharmaceutical Industry, Article 6.

40 In China, according to Article 33 of SAMR's 2025 Antitrust Guidelines for the Pharmaceutical Industry, a transaction involving pharmaceutical IP rights, such as IP licensing, may be deemed as a concentration of undertakings, if one party obtains the control over or is able to exert decisive influence on another party through this transaction.

41 *See* 15 U.S.C. 18a(d), § 801.2(g) and § 801.1(o).

42 In China, the IP Antitrust Guidelines in 2019 (Article 20) set forth the factors to assess whether an IP-related transaction may constitute a concentration: 1) whether the IP rights constitute an independent business, 2) whether the IP rights generate an independent and quantifiable stream of revenues, and 3) the approach and term of licensing.

43 SAMR's 2025 Antitrust Guidelines for the Pharmaceutical Industry, Article 35(4) and (5).

44 The draft BIOSECURE Act proposed to prohibit the U.S. government from engaging in contracts, grants and loans with the biotechnology providers connected to certain foreign adversaries. The 2024 version failed to be passed. In July 2025, Senators submitted a potential "Amendment" to the Senate's version of the National Defense Authorization Act (NDAA) for the upcoming fiscal year. See the latest "Amendment" in July 2025 here: https://www.congress.gov/amendment/119th-congress/senate-amendment/3236/text.

3. Remedies

While remedies in pharmaceutical mergers are generally quite foreseeable and are often proposed early in the review process, the rise of more complex theories of harm could make remedy negotiations more complex.

(a) Remedies in the EU

To address unilateral effects involving finished dose pharmaceuticals, the EC typically requires the divestiture of the entire overlapping product line, including all rights and assets necessary for commercialization.[45] This encompasses R&D projects related to the products, as well as measures to ensure the divested business remains viable, such as transitional support. The EC also generally requires an upfront buyer[46] with experience in the supply of healthcare products, with proven experience, innovative capacity, and access to relevant distribution channels, especially for OTC products.[47] The merging parties generally have the flexibility to choose whether to divest the acquirer's or the target's overlapping business, and may also opt to divest pipeline assets.

The EC addresses innovation concerns by expecting the divestiture of both late-stage and early-stage pipeline products.[48] The divestment package in these cases must include all associated assets and rights, ensuring that the development of the drug is no longer under the control of the merging entity.[49] Transitional support is also required to facilitate the completion of clinical trials, and the commitment to continue the development and commercialization of the relevant research.[50]

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[45] These include the applicable contracts, marketing authorizations, brands, customer lists, key personnel, etc. See, e.g. EC Decision of 26 June 2024, *Cooper/Viatris (European OTC Business)*, M.11383, where the EC accepted that the Parties divest rights, title and interests in its products, including the right to develop and manufacture the product, and to sell or/and market it in any form at the option of the purchaser.

[46] The EC has also demonstrated flexibility in response to extraordinary circumstances. During the COVID-19 pandemic, for example, in *Mylan/Upjohn*, the EC recognized the disruption to normal business operations and allowed for legally binding agreements on the terms of divestment instead of requiring an upfront buyer. See EC Decision of 22 April 2020, *Mylan/Upjohn*, M.9517.

[47] See EC Decision of 26 June 2024, *Cooper/Viatris (European OTC Business)*, M.11383, para. 333; 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.

[48] See EC Decision of 10 January 2020, *AbbVie/Allergan,* M. M.9461. As noted, 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 which was still at an early stage of development (no planned trials yet 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

(cont'd)

This tried and tested approach is well-understood by merging parties and has led to early resolution of most pharmaceutical merger inquiries, often with "fix-it-first" remedies.[51] However, recent cases indicate that remedy packages are becoming more complex.

For example, in *J&J/Actelion*, the EC was concerned about residual structural links. The parties proposed to carve out Actelion's insomnia pipeline product into a new company, Idorsia, but the EC found that J&J's ongoing financial (long-term loan) and intellectual property ties to Idorsia could have allowed it to influence the development of the competing product. J&J also held a minority shareholding in Idorsia and could potentially appoint one or two board members. To address these concerns, J&J committed to reduce its shareholding in Idorsia below 10 percent (or up to 16 percent provided it was not the largest shareholder) and to refrain from appointing any board members, thereby minimizing its ability to affect Idorsia's strategic decisions or access sensitive information.[52]

In cases involving non-horizontal effects, other remedies are required. In *Teva/Allergan Generics,* the divestiture package included not only overlapping products but also non-overlapping and pipeline generics, ensuring the buyer would have sufficient scale and scope to compete effectively post-merger.[53]

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 commercialize 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 skillset, 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 was undergoing, at the time of transaction, a Phase 3 clinical trial, and that as part of the remedy, the Purchaser has the 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-authorization 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 already 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] This was done by granting Minerva Neurosciences, with which the insomnia research program was being co-developed, new rights over the global development and waiving its royalty rights on Minerva's sales in the EEA.

[53] See EC Decisions of 10 March 2016, *Teva/Allergan Generics*, M.7746. See also, EC Decision of 20 July 2016, *Mylan/Meda*, M.7975, where the market test confirmed that generic suppliers compete using their entire portfolio when negotiating with pharmacies and wholesale customers, so the purchaser(s) 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.

Behavioral remedies are more difficult to get accepted. In *Illumina/GRAIL*, Illumina's offer to license patents and provide standardized supply contracts to GRAIL's rivals was considered inadequate. The EC was concerned that this would not fully eliminate the risk of foreclosure or address all possible strategies Illumina could use to disadvantage competitors, such as degrading the technical support to GRAIL rivals.[54] The EC also found the proposed commitments too complex to monitor effectively.

(b) Remedies in the U.S.

The FTC has rarely litigated to block a pharmaceutical merger in court, with most pharmaceutical enforcement actions culminating in a settlement requiring divestitures to a competitively and financially acceptable buyer, as determined by the FTC. The buyer must be in a position to compete with the merged firm in short order, with limited reliance on the merged firm to successfully and independently compete. Thus, the divestiture must include everything required for a buyer to be fully operational and maintain the divested product, such as manufacturing facilities, research and development capabilities, intellectual property, technology and know-how, and access to personnel. The FTC will often also appoint a monitoring trustee to oversee the divestiture.

While prior agency leadership expressed skepticism about the sufficiency of divestitures, and particularly conduct remedies, to restore competition, prior FTC leadership did enter into a behavioral remedy in *Amgen/Horizon*, with Amgen agreeing not to bundle Horizon's products with its existing portfolio and to seek FTC approval for certain acquisitions. Prior leadership also reinstated the inclusion of review and approval provisions in consent decrees, requiring merged firms to seek FTC approval for future transactions in the market covered by the decree.

Current agency leadership has expressed more openness to structural remedies, with FTC Chairman Andrew Ferguson stating that the Commission "*must be open to settling merger cases*" but "*should accept settlements in merger cases only when it is confident that the settlement will protect competition in the relevant market to the same extent that successful litigation would*."[55] Chairman Ferguson went on to state that the FTC should accept a structural remedy only if it "*involves the sale of a standalone or discrete business, or something very close to it, along with all tangible and intangible assets necessary (1) to make that line of business viable, (2) to give the divestiture buyer the incentive and ability to compete vigorously against the merged firm, and (3) to eliminate to the to the extent possible any ongoing entanglements between the divested business and the merged firm" and "must also be confident that the divestiture buyer has the resources and experience necessary to make that standalone business*

[54] See EC press release of 6 September 2022, 'Commission prohibits acquisition of GRAIL by Illumina', available at: https://ec.europa.eu/commission/presscorner/detail/es/ip_22_5364. The ECJ has nevertheless annulled the EC decision in Joined Cases C-611/22 P and C-625/22 P, *Illumina v. Commission*, on 3 September 2024, on the basis that the EC lacked jurisdiction.

[55] See https://www.ftc.gov/system/files/ftc_gov/pdf/synopsys-ansys-ferguson-statement-joined-by-holyoak-meador.pdf.

competitive in the market." [56] Chairman Ferguson cautioned against behavioral remedies, which "*are often difficult or impossible for the Commission to enforce effectively and can lock the Commission into the status of a monitor . . . rather than a guardian of competition.*" [57]

In *GTCR/Surmodics*, for example, a key issue is whether the proposed divestiture of a portion of GTCR portfolio company Biocoat's hydrophilic coating business to Integer is sufficient to restore competition. At trial, the FTC argued that it could take as long as a year for the divested assets to begin operating at a capacity that would make Integer a viable competitor, and until then Integer would need to rely on Biocoat. The FTC also argued that Integer would not be receiving a manufacturing plant, but that this would be required for it to restore competition lost by GTCR owning both Surmodics and the unsold portion of Biocoat.

(c) Remedies in APAC

Similar to the EU and the U.S., pharmaceutical merger remedies in the APAC region are largely structural, *i.e.* divestments of one party's business relating to the products with anticompetitive concerns to ensure effective competition in the market.[58] For China, this is somewhat out of character with SAMR's ordinary approach to remedies, especially for mergers in sensitive industries like semiconductors, which tends to be far more flexible and open to behavioral conditions in response to stakeholders' opinions or industry policy concerns.[59]

China took the rare step of ordering the unwinding of the *Wuhan Yongtong Pharma/Shandong Huatai Pharma* merger in July 2025 — a vertical merger between two domestic pharmaceutical companies completed years earlier. Although the deal fell below notification thresholds, SAMR intervened over concerns of input foreclosure, highlighting the buyer's dominance in the upstream API market and pointing to both the incentive and actual increases in market share and prices for downstream injection products post-merger. Because SAMR does not have a statutory tool to impose structural remedies outside a merger review context, instead, it elected to use its merger review authority to impose a structural fix that required the merged entity to unwind the transaction and divest the related businesses and exclusive contracts. This case is remarkable and unique — though the decision appears to have been limited to the deal's specific facts and should not impact most global deals.

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[56] *Id*.

[57] *Id*.

[58] See, e.g. in China, *Simcere/Beijing Tobishi (2023)*, *Abbott/St. Jude Medical (2016)*, *Becton Dickinson/Bard (2017)*; and in Australia, *Mylan N.V./Upjohn Inc. (2020)*, and *Elanco Animal Health/Bayer Animal Health Division (2020)*, *Zoetis Inc./Jurox Pty Ltd (2022), Integral Diagnostics/Capitol Health (2024), and BXJB II Holding KK/I'rom Group Co (2024)*.

[59] SAMR is explicitly granted the power to consider the "impact on the development of national economy" under Article 33 of the amended Anti-Monopoly Law 2022 (which is the same as Article 27 of the original Anti-Monopoly Law 2008). Therefore, SAMR will solicit opinions from key Chinese stakeholders, which in many cases, led to behavioral remedies to protect domestic interests. The typical ones include pricing, output commitment, secured supply, no tying and bundling and interoperability.

The scope of divestiture typically covers tangible assets (including inventory, facilities and others) and intangible assets (including IPs, knowhow, and data), equity, key personnel, key customer and supplier contracts, customer records, and administrative approvals and licenses.[60] 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.[61]

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.[62] SAMR's 2025 Antitrust Guidelines for the Pharmaceutical Industry also call out ongoing R&D projects, and relevant R&D platforms, data and core teams, as part of the potential divestment scope.[63] Similarly in *Elanco Animal Health/Bayer Animal Health Division,*[64] the New Zealand regulator required Elanco to divest one of its businesses so that the buyer can continue developing the pipeline products which may become a competitive alternative to Bayer's products.

The APAC regulators have also required other remedies than divestitures for pharmaceutical mergers. As a unique feature in China, SAMR has ordered a hold-separate remedy to avoid loss of a competitive alternative. For example, in *ZGBH/Royal DSM JV (2019)*, SAMR 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).[65] However, SAMR so far has not shown a particular inclination towards licensing requirements or commitments with regard to pharmaceutical assets in horizontal mergers. Behavioral

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

61 See e.g. *Becton Dickinson/Bard (2017)* in China. In *Abbott/St. Jude Medical (2016)*, the Ministry of Commerce (the ex-Chinese merger regulator) required upfront buyer approval as a condition to approve the main transaction. In Australia, the ACCC sets largely similar requirements and approval process for determining divestiture buyers, where the ACCC will also review the sales/purchase agreement regarding the divested business.

62 The divestiture of the R&D project specifically covers the followings: tangible assets, non-exclusive licensing of relevant knowhow and trade secrets, a transitional service agreement, and trainings to relevant staff at the buyer.

63 SAMR's 2025 Antitrust Guidelines for the Pharmaceutical Industry, Article 36.

64 See the New Zealand regulator's *Elanco Animal Health/Bayer Animal Health Division (2020)* decision, where 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).

65 Specifically, in *ZGBH/Royal DSM JV (2019)*, SAMR required that the parties should be held separate in terms of personnel, business management and operations, supply terms and confidential information, offices and facilities, information systems, and others.

remedies are also a common tool deployed to address concerns in vertical cases.[66] In Japan, typical remedies in addition to divestitures include accessibility to essential facilities by competitors, no discriminatory treatment, no tying or bundling, and firewalls to protect competitors' competitive information.[67] The JFTC recently accepted behavioral remedies in *Shionogi/Torii Pharmaceutical (2025)* — a horizontal merger between two domestic pharmaceutical companies — requiring one party to terminate exclusive licensing and provide handover assistance to enable a new licensee to compete with the merged company.[68] In Singapore, the CCCS 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.[69] In India, the regulator has also in multiple cases 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.[70]

4. Outlook

In the EU, the EC's focus on innovation and resilience is likely to influence but not materially change the substantive assessment of mergers in the life sciences sector. Commissioner Ribera has emphasized the importance of innovation effects in merger control, consistent with EC case precedent.[71] In fact, the pending revision of the Horizontal and Non-Horizontal Merger Guidelines is expected to codify recent enforcement practice in life sciences mergers, in particular by formalizing the focus on innovation effects. Addressing the perceived threat of killer

[66] For example, in *Simcere/Beijing Tobishi (2023)*, SAMR imposed a set of behavioral conditions in addition to the divestiture to address the input foreclosure concern on the upstream market. These conditions include terminating the exclusive supply agreement on the upstream market, guaranteeing supplies and lowering the pricing for the downstream products. In *Wuhan Yongtong Pharma/Shandong Huatai Pharma (2025)*, SAMR also imposed a behavioral remedy requiring the buyer to end its exclusive upstream API sales agreement, to further address the dominance in the upstream.

SAMR's 2025 Antitrust Guidelines for the Pharmaceutical Industry (Article 36) also highlight the flexible deployment of behavioral and structural remedies. Typical behavioral remedies in pharmaceutical transactions include continuing R&D projects and investments, licensing key technologies, terminating exclusivity agreements, maintaining independent operations, providing access to R&D platforms, sharing R&D data, guaranteeing supplies, and lowering pricing.

[67] See e.g. *M3/Ultmarc (2019)* in Japan.

[68] See the JFTC's decision *Shionogi/Torii Pharmaceutical (2025)* (see local counsel's summary at https://www.amt-law.com/asset/pdf/bulletins20_pdf/250630.pdf, page 6).

[69] See the CCCS's decision of *Pathology Asia Holdings Pte. Ltd./Innovative Diagnostic Private Limited and Quest Laboratories Pte Ltd (2019)*.

[70] See e.g. *Hospira/Orchid (2009)* in India.

[71] Remarks by Executive Vice-President Teresa Ribera at 52nd Annual Conference on International Antitrust Law and Policy, and Antitrust Economics at Fordham Law School (September 19, 2025).

acquisitions is anticipated to constitute another central element of the forthcoming Guidelines, with clear implications for life sciences mergers. The EC's consultation documents for the Guidelines emphasize that mergers "*may increase the ability of the merged firm to innovate but also harm innovation competition*" and that "*[i]t is important that the framework for merger assessments enables the Commission to adequately assess both elements, the positive and the negative impact on innovation.*" [72] It remains to be seen to what extent the new Guidelines will accommodate efficiency defenses.

In the U.S., the 2023 Horizontal Guidelines have continued in force despite the change in administration, with FTC Commissioner Ferguson stating that "*guidelines work best when there's some stability.*"[73] However, the novel theories formalized in those Guidelines have yet to be applied under the current administration. In particular, without any recent challenges to pharmaceutical mergers as a reference, it is yet to be seen whether the traditional framework used to evaluate mergers by the U.S. FTC will continue to guide merger analysis in the pharmaceutical space, or if the deviations from that traditional framework evidenced in the prior administration's merger challenges will continue into the future.

China has also ramped up antitrust scrutiny of pharmaceutical mergers, including those below notification thresholds, armed with multiple guidelines including new guidelines for the pharmaceutical industry and for horizontal mergers, as well as incoming guidelines for non-horizontal mergers. While the recent unwinding order should not have chilling effect on global dealmakers, the new guidelines signal that the agencies will continue to pursue an aggressive merger enforcement agenda, meaning that more transactions will likely receive scrutiny, and extended investigations will become more commonplace and burdensome.

[72] See Topic 7 (Innovation and other dynamic elements in merger control) of the EC's In-Depth Consultation.

[73] https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-memo-re-merger-guidelines.pdf.