

The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers

FTC-DOJ Workshop Summary

Preface

This document summarizes the June 2022 FTC-DOJ Future of Pharmaceuticals workshop.¹ It concisely describes each speaker’s remarks, generally in the order they were made during the workshop. The goal is to provide a brief overview of what participants said during the (1) introduction, (2) opening remarks, and (3) panel discussions. There is also a brief concluding statement and an appendix of ideas. For additional details see the workshop webpage, which includes transcripts and video recordings of the event.²

I. Introduction

The Federal Trade Commission (“FTC”) and the U.S. Department of Justice (“DOJ”) Antitrust Division hosted a two-day virtual workshop on June 14–15, 2022 entitled, “The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers.” The workshop explored new approaches to enforcing the antitrust laws in regard to mergers and acquisitions in the pharmaceutical industry. The workshop was the culmination of the Multilateral Pharmaceutical Merger Task Force (“Task Force”), an effort launched in March 2021 by the FTC, DOJ, offices of multiple state Attorneys General, Competition Bureau Canada, the European Commission (“EC”) Directorate-General for Competition, and the U.K. Competition and Markets Authority (“CMA”).

The workshop featured introductory remarks by FTC Chair Lina M. Khan and DOJ Assistant Attorney General for the Antitrust Division Jonathan Kanter, as well as a keynote address delivered by FTC Commissioner Rebecca Kelly Slaughter. Plenary sessions discussed market concentration in the pharmaceutical sector, merger remedies, innovation aspects of pharmaceutical mergers, and the intersection between conduct by pharmaceutical companies and merger analysis.

II. Opening Remarks

FTC Chair Khan emphasized the life and death stakes of creating the right competitive conditions in the pharmaceutical sector. Chair Khan noted the importance of ensuring that companies are incentivized to innovate and to make their pharmaceutical products available at affordable prices. She expressed concern that the median list price for new drugs has been increasing in recent years, that “killer” acquisitions shut down potential competitors, and that lawsuits have been alleging illegal bundling and tying practices in the industry. The Chair wants to learn more about what factors should specifically be considered in analyzing pharmaceutical

¹ FTC, The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers (June 14–15, 2022), <https://www.ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers>.

² *See id.* (Transcripts and Video).

mergers—beyond traditional concerns around horizontal overlaps—and how remedies, potential innovation, and prior bad acts might be incorporated into merger analysis.

Assistant Attorney General Kanter noted the value of understanding how competitive healthcare markets give patients access to medicine at affordable prices. He discussed the importance of competition not just in medicines that exist today, but also for solving problems for the future. He also stressed that it is essential to the livelihood of the nation for antitrust enforcers to act when mergers or other kinds of anticompetitive conduct harm the innovative process.

Commissioner Slaughter highlighted the importance of pharmaceuticals in the daily lives of millions of people to treat deadly and serious illnesses, manage chronic diseases and conditions, and provide preventative care. She emphasized that a competitively vibrant market is important to protect access to existing drugs and promote new innovations. The Commissioner cited the FTC’s case against Martin Shkreli as an example of the pharmaceutical industry’s particularly checkered legacy of anticompetitive conduct.³ The Commissioner said that enforcement should not be limited to existing and pipeline products. Rather, enforcement should also encompass competition to innovate, which can include competition to bring new drugs to market. More broadly, competition to innovate can also include how clinical trials are conducted or how drugs are delivered. In addition, the Commissioner noted that the Task Force had provided participants the time and space to jointly learn about, contemplate, and discuss each other’s concerns and challenges outside the context of specific cases, which has further strengthened cooperation.

III. Concentration Levels in the Pharmaceutical Sector

The first panel focused on concentration in the pharmaceutical sector. Thomas DeMatteo, Counsel to the Assistant Attorney General, introduced three panelists and moderated the subsequent discussion.

Patricia Danzon, Professor of Health Care Management at the Wharton School of the University of Pennsylvania, addressed the role of firm size in pharmaceutical merger analysis. Danzon stated that standard merger review examines whether a merger increases dominance in individual product markets, with divestiture of overlapping products as the standard remedy. Danzon found, however, this standard analysis ignored complex customers in pharmaceutical markets, and cross-market effects due to firm size. Danzon emphasized that portfolio-wide effects matter when dealing with payers and physician customers in pharmaceutical markets, and that payer and provider organizations as well as reimbursement rules determine the size advantages of supplier drug firms. According to her, the role of payers and physician customers differs across markets and types of drugs. Danzon argued that the advantages of size are greatest for originator firms producing on-patent branded drugs in the United States, as compared to these same originator firms in European markets, or the generic pharmaceutical sector.

Danzon stated that merger and acquisition activity, not research and development excellence, accounts for the persistence of many of the same firms in the top twenty pharmaceutical companies. Danzon found that very small firms originate seventy percent of new

³ See FTC, Vyera Pharms., LLC (last updated Jan. 14, 2022), <https://www.ftc.gov/legal-library/browse/cases-proceedings/161-0001-vyera-pharmaceuticals-llc>.

active substances and finds no evidence that firm size increases research and development activity. Instead, firm size enabled by merger and acquisition activity may provide advantages in contracting, marketing, financing, and regulatory activities. But large firm acquisitions of other large firms yield no merger-specific savings, according to her research.

According to Danzon, large pharmaceutical firms that have a large product portfolio, or “must-have” or “blockbuster” products have leverage with pharmaceutical benefit managers (“PBMs”) and can engage in a cross-market strategy of leveraging certain major products to achieve preferred status for all their products. This bundling strategy limits or blocks access for the products of small companies, potentially benefitting incumbents and harming consumers and competition without necessarily resulting in price increases. Danzon allowed that there may be some real economies of scale or scope associated with the marketing of larger drug portfolios, but concluded that any savings are captured by pharmaceutical firms and physicians and not consumers. She further noted that the role of insurance blunts consumer price sensitivity and firm incentives to compete on price.

Danzon recommended applying a presumption of harm to merger and acquisition activity involving two large originator firms (i.e., in the top decile of U.S. sales), which would shift the burden to firms to show merger-specific efficiency gains that outweigh potential competitive harms. Danzon further recommended applying heightened scrutiny to combinations involving large and mid-size firms or two mid-size firms (i.e., in the second decile of U.S. sales), especially if either firm has a must-have or blockbuster product that increases the risk of anticompetitive bundling or cross-market leverage. Danzon found that standard market analysis is sufficient for smaller firms but recommended applying extra scrutiny if a must-have or blockbuster product is involved. Danzon stated that preempting potentially harmful large mergers should supplement remedies that in theory can address anticompetitive conduct directly, but which in practice are weak in pharmaceutical contexts characterized by confidential contracting. She also recommended asking merging firms to provide evidence of real merger-specific efficiency savings and looking into their past conduct involving contracting with PBMs.

Diana Moss, President of the American Antitrust Institute, then recommended rethinking merger remedies involving divestitures. According to Moss, numerous research studies show a strong connection between high market concentration and high and rising drug prices. Moss also stressed the importance of looking at pharmaceuticals in the context of the bigger supply chain, which includes dominant players and oligopolies having significant bargaining power. She argued that the goal of obtaining bargaining power in the supply chain creates incentives to engage in merger and acquisition activity to become a bigger, better, and more powerful bargainer, resulting in a very bottlenecked supply chain in pharmaceuticals.

According to Moss, FTC merger challenges typically involve highly concentrated markets where the merger-induced concentration was significant even though a common theme of acquisitions is eliminating small rivals with asset purchases often made by serial acquirers.⁴

⁴ See Diana L. Moss, *From Competition to Conspiracy: Assessing the Federal Trade Commission’s Merger Policy in the Pharmaceutical Sector* (Sept. 3, 2020) (American Antitrust Institute White Paper), https://www.antitrustinstitute.org/wp-content/uploads/2020/09/AAI_PharmaReport2020_9-11-20.pdf (analyzing pharmaceutical mergers challenged by the FTC between 1994–2020).

The result is a shrinking group of very powerful drug manufacturers.⁵ Moss further noted the existence of antitrust litigation, including those involving alleged generic price-fixing conspiracies, against many pharmaceutical companies. She also expressed concern about monopolization, pay-for-delay tactics, product hopping, deceptive practices, and sham petitioning in the pharmaceutical industry.

Moss suggested abandoning the use of divestiture settlements in merger challenges, more closely scrutinizing divestitures, and utilizing prior approval requirements. If a company has a history of antitrust violations, especially criminal violations, the firm should not be considered a candidate for purchasing divested assets. Moss also suggested discouraging additional mergers and acquisitions by pharmaceutical companies having deep records of past merger and acquisition activity and past purchases of divested assets, who are also defendants in cases.

Rena Conti, Associate Professor at Boston University Questrom School of Business, closed out the first panel and spoke on competition and transparency across the generic drug market and PBMs. She found that approximately 50 percent of all generic drug markets are dominated by either monopoly or duopoly suppliers, when controlling for volume. She also noted that generic competition is in a steady state, after entry has occurred, and generates only limited revenue. This high concentration in a steady-state environment can result in bad outcomes for consumers and payers, including price inflation, drug shortages, and quality lapses, among many important generics, and not just outliers. She also questioned whether monopoly and oligopoly supply in the generic market, combined with monopsony purchasing by PBMs, is actually keeping prices lower than they otherwise would be.

Focusing next on transparency, Conti discussed her findings that manufacturers of excipients (i.e., inactive substances in a drug) are also highly concentrated, and this fact is sometimes unrecognized until bad behavior is revealed. Conti stated that her research using Food and Drug Administration (“FDA”) data has found that fill and finish manufacturers tend to be located domestically, while Active Pharmaceutical Ingredient (“API”) manufacturers are overwhelmingly located in India, China, and Europe. She noted that this situation can make it challenging for regulators to assess both conduct and the quality of products coming into the U.S. market. According to Conti, the fill and finish sites and the API manufacturers are both increasingly concentrated overseas. Yet, it is critically important to understand who is making the products and the market structure in order to determine whether a merger might shift that market structure. Thus, Conti noted that simple competitor counting is insufficient to assess competition in product markets and stressed the need for greater transparency into the U.S. supply chain. Increased transparency into the U.S. prescription drug supply chain, including on the relationship between PBMs and generics, would support competitive and resilient general drug markets.

IV. Broken Fixes? Remedies in Pharmaceutical Mergers

The second panel discussed historical merger remedy practices, particularly divestiture, and possible alternatives. Panelists considered different, new, and underutilized remedy practices to address concerns about the effectiveness of remedies. Malinda Lee, Deputy Attorney General

⁵ *See id.*

with the Healthcare Rights and Access Section’s Competition Unit in the California Attorney General’s Office, moderated the discussion.

Robin Feldman, Professor of Law at UC Hastings Law, presented her views on merger remedies in the context of increased consolidation in the pharmaceutical industry. Feldman described the bulk of current consolidation since 2010 as consisting of large firms acquiring smaller firms to bolster their innovation portfolios, with the larger firms then being responsible for later stage clinical trials and regulatory approval. Feldman’s examination of seventeen FTC pharmaceutical merger enforcement cases between 2008–18 involving fifty-six pipeline product divestitures has preliminarily found that only 36 percent of those products have an active marketing license today.⁶ Feldman suggested that regulators adopt a robust “second look” policy of post-merger review to ensure that past decisions had the intended result and to improve future evaluations. Feldman further suggested that regulators consider the power of volume across markets, and the impact of repeated small mergers and acquisitions of startup firms. She also noted problems with evergreening strategies like product hopping, which merely seek to shift the market to existing drugs with only minor modifications and suggested imposing conduct remedies to prohibit such evergreening behavior. She suggested that regulators seek divestiture of existing drug products, rather than pipeline drug products. Feldman stated that merger tools should consider interactive effects—examining PBM consolidation together with the consolidation of large pharmaceutical companies, for example—and cautioned against focusing too much on an individual transaction in an individual market.

Barak Richman, Professor of Law at Duke University School of Law, similarly emphasized the importance of understanding the role of PBMs as intermediaries in the pharmaceutical distribution system. Richman emphasized that manufacturers are not competing for consumers, but rather are competing for space in the formularies of PBMs. He recommended developing a two-part purchasing analysis to account for the role of intermediaries, like the approach the FTC pioneered to evaluate hospital mergers and the intermediary role of insurance. A more realistic understanding of the marketplace and its institutional complexity would thus enable a better understanding of a merger’s potential competitive harm and the potential benefits of certain remedies.

Richman stated that mergers exacerbate all negative conduct, and therefore conduct remedies should be disfavored. He further questioned whether enforcers should approve a merger at all, precisely because of these exacerbation effects. In addition, even when independent monitors are charged with ensuring compliance with conduct remedies, he opined that there is still reason to remain skeptical: while monitors are instructed to detect certain kinds of behavior, they are rarely ever charged with monitoring for anticompetitive conduct overall in a market. Richman also suggested that the right structural modeling, with reliable equations, could predict which firms might be incentivized to engage in anticompetitive conduct post-merger.

Arti Rai, Professor of Law at Duke University School of Law, highlighted two potential anti-innovation effects that can arise in the context of mergers and acquisitions. One effect is that when a large, well-established firm acquires another firm with an overlapping pipeline asset, the

⁶ Robin Feldman, *Pharmaceutical Pipeline Divestitures Study: Preliminary Results* (2021) (UC Hastings Research Paper Forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3861975.

merged firm will have a reduced incentive to continue developing the pipeline product because it will compete with the existing marketed product. Rai suggested there are many problems with divestiture as a remedy in this scenario, including the complexity of manufacturing complex drugs, which she views as a barrier to entry for a less-established firm or a less-skilled divestiture buyer. Rai argued that another potential effect is the reduced incentive to do research and development, particularly risky early-stage research and development, even when there is no particular potential for horizontal product overlap. Rai further expressed concern that reductions in research and development might be presented as a claimed efficiency.

To address these anti-innovation effects, Rai suggested that the remedy might include the ongoing monitoring of research and development levels and patent output after a merger. Another possible remedy would require a commitment to maintain certain levels of research and development and patent output post-merger. Rai suggested that monitoring certain bright-line criteria relating to inputs may be helpful, but at the same time also recognized that inputs do not necessarily mechanically equate to product outputs.

Youenn Beaudouin, Case Handler at the EC Directorate-General for Competition, noted that around six percent of mergers reviewed by the EC were conditioned on compliance with remedies, and this figure has remained constant over time, including for pharmaceuticals. Beaudouin stressed, however, that the EC only accepts remedies that are grounded in market reality, eliminate competition concerns entirely, are comprehensive and effective from all points of view, and are capable of being implemented effectively within a short period of time. He noted that the EC has a strong preference for structural remedies, and primarily for divestments generally meeting these conditions for all the markets giving rise to competition concerns.⁷ Remedies are also market tested, including by reaching out to customers and competitors. A suitable purchaser must generally include three standard criteria: (1) the purchaser is independent of the parties; (2) the purchaser has the financial resources, expertise, ability, and incentive to maintain and develop the divested business as a viable competitive force; and (3) the acquisition neither likely raises competition concerns itself nor gives rise to a risk of delay in the implementation of commitments. Other specific criteria may also be added, depending on the particular case.

In addition, Beaudouin noted that in very specific circumstances, the EC may accept non-divestment remedies. But past anticompetitive conduct has not been a decisive issue in cases to date. The EC also has a track record of assessing the non-horizontal effects of a merger, as, for example, with the assessment of conglomerate effects in complementary or neighboring markets in several medical device cases. There have been no judgements by European courts, however, that specifically address remedies adopted in pharmaceutical mergers.

⁷ E.g., EC, Case No. M.9461 – AbbVie / Allergan (2020) (EUR-Lex document no. 32020M9461), (examining innovation efforts in autoimmune diseases as a whole) and EC, Case No. M.8955 – Takeda / Shire (2018) (EUR-Lex document no. 32018M8955) (clearing transaction with conditions and obligations) and EC, Case No. M.8955 – Takeda / Shire (2020) (Decision on the implementation of the commitments – Waiver of the Commitments).

Synda Mark, Deputy Assistant Director of the FTC Office of Policy and Coordination, discussed the FTC's plans to rethink its merger guidelines and remedies practices.⁸ She noted that a comprehensive view of protecting competition through antitrust enforcement must include effective remedies that will fully preserve competition. Effective merger remedies, however, must learn from past agency practice. Mark cited the many changes in the economy as well as the changes across a variety of industries as a reason to consider whether to update the agency's thinking on remedies as a general matter, and on the effectiveness of remedies more specifically.⁹ According to Mark, the real goal is to determine whether remedies are actually that effective in resolving competition problems.

V. Assessment of Innovation Aspects in Pharmaceutical Mergers

This session combined academic knowledge and practical enforcement experience regarding the impact of pharmaceutical mergers on innovation. With the CMA's Assistant Director of Economics Ricardo Ferrari moderating, panelists for this session discussed the importance of innovation in the pharmaceutical sector and the impact that pharmaceutical mergers have on firms' incentives to innovate.

Carmine Ornaghi, Professor of Economics at the University of Southampton, gave a presentation on the role and importance of innovation in the pharmaceutical industry. According to Ornaghi, research and development in the pharmaceutical industry is among the most intense, as compared to semiconductors, software, and technological hardware for example, with an increasing number of new drugs approved since 2010. Empirical evidence indicates, however, that mergers and acquisitions in the pharmaceutical industry reduce the research efforts of merging companies and their competitors. There is also an increased risk that overlapping projects between acquirers and targets will be delayed or terminated. A 2009 study by Ornaghi found that merger and acquisition transactions lead to reduced research and development expenditures, patent output, and research productivity.¹⁰ A 2019 study by Haucap et al. reached similar conclusions.¹¹

According to Ornaghi, there is also suggestive evidence that mergers and acquisitions in the pharmaceutical industry fail to produce large dynamic efficiencies that can offset possible

⁸ See Press Release, FTC, Federal Trade Commission and Justice Dep't Seek to Strengthen Enforcement Against Illegal Mergers (Jan. 18, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/01/federal-trade-commission-justice-department-seek-strengthen-enforcement-against-illegal-mergers> (noting remedies as a topic of inquiry in the merger guidelines request for information). See Holly Vedova, Director, Bureau of Competition, FTC, Update from the FTC's Bureau of Competition, Remarks at 12th Annual GCR Live: Law Leaders Global Conference, Miami, Florida 10–12 (Feb. 3, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/vedova-gcr-law-leaders-global-conference.pdf.

⁹ The FTC Bureau of Competition has since taken a new approach to merger remedies. See Holly Vedova, Director, Bureau of Competition, FTC, Update from the FTC's Bureau of Competition, Remarks at 12th Annual GCR Live: Law Leaders Global Conference, Miami, Florida 10–12 (Feb. 3, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/vedova-gcr-law-leaders-global-conference.pdf.

¹⁰ Carmine Ornaghi, *Mergers and innovation in big pharma*, 27 INT'L. J. INDUS. ORG. 70 (2009).

¹¹ Justus Haucap et al., *How mergers affect innovation: Theory and evidence*, 63 INT'L. J. INDUS. ORG. 283 (2019).

anticompetitive effects.¹² Only a fraction of transactions in the pharmaceutical industry are examined by antitrust authorities, since many do not meet the threshold criteria that typically trigger antitrust scrutiny. Thus, there is increasing concern that mergers that might stifle innovation are not being scrutinized by antitrust authorities. Furthermore, Ornaghi questioned whether the intentions that drive a transaction actually matter and stressed the importance of the actual outcome. Ornaghi cautioned, however, that investigating efficiencies from mergers and acquisitions is difficult, and the lack of evidence in this area does not necessarily mean that merger-specific synergies do not exist.

Representatives from the EC, CMA, and FTC then shared their perspectives regarding the assessment of innovation in pharmaceutical mergers in a discussion moderated by Ferrari. Enforcers discussed the analytical frameworks that their agencies use to assess innovation competition in pharmaceutical mergers, as well as particular enforcement experiences.

Paul Csiszár, EC Director of Basic Industries, Manufacturing and Agriculture, stated that the EC leadership understands its mandate in the pharmaceutical area is to secure the provision of innovative and affordable medicines to citizens. Csiszár noted that the EC merger control regime has been understood for decades to preserve dynamic competition by fostering and preserving innovation competition, and potential and future competition, in addition to competition on price. Thus, a focus on innovation is not particularly new.

Csiszár cited the EC's clearance of the Novartis/GSK transaction in 2015 as the first instance of an intervention involving early pipeline pharmaceuticals, and as an example of a successful divestment.¹³ The EC has subsequently developed a four-layer analytical framework to assess competition and innovation concerns for all sectors of the economy, including pharmaceuticals. First, the framework examines the effects on actual products and price competition for existing products. Second, it looks at potential products (e.g., advanced-stage pipeline products) and overlaps with either existing marketed products or other potential products. Here, the theory of harm is the loss of potential competition with existing products or between forthcoming products. Third, the framework examines the parties' ongoing pipelines (e.g., early-stage pipeline products), and whether the merger could change the incentives of the combined firm to invest in parallel product pipelines. The theory of harm is the risk of discontinuation, delay, or redirection of overlapping pipelines. Fourth, the framework considers innovation competition at a broader level, including the firms' capabilities to innovate in certain therapeutic spaces. In particular, it considers whether the transaction might lead to the elimination of an important innovator, or whether a structural reduction of the overall level of innovation in certain therapeutical spaces might lead to a significant loss of innovation competition. Several published EC decisions have used this framework and provide useful precedents on how to assess overlaps involving pipeline products at all stages of the clinical development.¹⁴ Csiszár noted, however, that the EC has not had to examine a pharmaceutical

¹² See Colleen Cunningham et al., *Killer Acquisitions*, 129 J. POLITICAL ECON. 649 (2021) and William S. Comanor & F.M. Scherer, *Mergers and innovation in the pharmaceutical industry*, 32 J. HEALTH ECON. 106 (2013).

¹³ EC, Case No. COMP/M.7275 – Novartis / GlaxoSmithKline Oncology Business (2015) (EUR-Lex document no. 32015M7275).

¹⁴ E.g., EC, Case No. COMP/M.7932 – Dow / DuPont (2017).

transaction under the fourth layer, and research and development in pharmaceuticals is more dispersed among a multitude of players than agrichemicals, for example.

Elie Yoo, Director of Mergers at the CMA, emphasized that the importance of innovation as a parameter of competition is well-established in the CMA's decisional practice, particularly in life science and digital markets. Yoo also noted that the CMA's updated Merger Assessment Guidelines further address the importance of innovation competition more explicitly.¹⁵ For example, Yoo observed that pharmaceutical transactions often involve the acquisition of a potential entrant innovator that has not yet entered the market. In the face of such uncertainty, there are two modes of analysis. One is to examine the loss of future competition by assessing the likelihood and impact of that future competitive entry. A second is to focus on whether there could be a more immediate loss of competition from existing firms and potential competitors interacting with each other in an ongoing dynamic competitive process driven by efforts to enter or expand in a market, even before entry actually occurs. Yoo further stated that a loss of dynamic competition is more relevant when investment relating to entry or expansion is an important part of the competitive process, and observed that in the pharmaceutical industry it can take years to develop products that may never come to fruition.

Caroline Holland, Attorney Advisor to U.S. Federal Trade Commissioner Rebecca Kelly Slaughter, observed that the well-recognized goal of U.S. merger law is to arrest monopolies in their incipiency and prevent a tendency to create a monopoly. Holland noted that the U.S. antitrust agencies continue to use their 2010 merger guidelines while they work to revise them, and the guidelines clearly recognize innovation competition and the potential harm to innovation from a merger.¹⁶ Holland emphasized the importance of examining competition at all stages of innovation, separate and apart from any eventual product and service competition, in addition to examining product overlaps. According to Holland, protecting innovation also requires looking at the incentives of the merging firms, as well as the non-merging firms. For example, the incentives of non-merging firms may be relevant if a merger reduces the number of large firms that are the target sales-audience for an innovation that a start-up company is developing. If a merged firm gains the ability to foreclose other innovators, that may deter investment.

Csiszár and Holland expressed concern that certain transactions falling outside applicable jurisdictional thresholds could nonetheless harm competition. Csiszár noted that transactions falling outside the EC's thresholds may still be examined by individual Member States, and Member States can refer potentially harmful transactions to the EC pursuant to Article 22 of the Merger Regulation and related guidance.¹⁷ Csiszár cited the Illumina/Grail merger as the first

¹⁵ UNITED KINGDOM COMPETITION & MARKETS AUTHORITY, MERGER ASSESSMENT GUIDELINES (2021) (CMA129), <https://www.gov.uk/government/publications/merger-assessment-guidelines>.

¹⁶ See DOJ & FTC, HORIZONTAL MERGER GUIDELINES § 6.4 (2010), <https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf>.

¹⁷ EC, Communication from the Commission, Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases (2021/C 113/01) (EUR-Lex document no. 52021XC0331(01)), [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52021XC0331\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52021XC0331(01)). See also EUROPEAN UNION, COUNTRY PROFILES, https://european-union.europa.eu/principles-countries-history/country-profiles_en/ (listing 27 European Union member countries).

transaction referred to the EC under Article 22 and the related guidance.¹⁸ Holland noted that in the United States, the FTC has recently re-implemented consent decree provisions that require parties to seek prior approval or provide prior notice of certain transactions, including ones that fall under the reporting thresholds of the Hart-Scott-Rodino Act.¹⁹

Enforcers then discussed enforcement experiences in assessing pharmaceutical transactions with more particularity. Yoo discussed CMA enforcement experience with assessing pipeline-to-pipeline overlaps and innovation competition in pharmaceutical mergers. Yoo noted that when considering whether a pipeline product will come to market, the CMA recognizes that the uncertainty of the outcome can be the driving force of dynamic competition. Incumbent firms have an incentive to compete not only against products that are already on the market, but also against known pipeline products in development to win as many patients as possible before the pipeline product is commercialized, thereby reducing the eventual impact of the new product on the incumbent's sales. This type of innovation competition can result in improved competitive offerings from potential entrants and other market participants (i.e., to prevent the future loss of profits). Yoo stressed, however, that any assessment must be grounded in evidence. Such evidence may include internal documents and business plans.²⁰ It may also include evidence of steps taken towards entry or expansion.²¹

Camille Vardon, Case Handler at the EC Directorate-General for Competition, described the factors the EC uses to assess pipeline-to-pipeline overlaps. These factors include: the closeness of competition among the drugs in each merging firms' pipelines; the closeness of competition with competing drugs; the prospects of the merging firms' pipelines; and the overall number of competing marketed and pipeline drugs. Vardon stressed there is no magic number for the number of products, however, when making an assessment. Vardon also described the sources of information on which the EC relies. These sources include historic market data; scientific data, such as clinical guidelines; feedback from medical experts and competitors; and internal documents from the merging firms. Vardon further noted that the EC considers the "time to market" and "chances of success" of pipeline drugs in its assessment, but these factors do not determine the scope of an investigation. The EC has looked at pre-clinical assets in the past, as in the BMS/Celgene case.²² It has also been willing to make adjustments when needed, as in the

¹⁸ See Press Release, EC, Mergers: Commission opens in-depth investigation into proposed acquisition of GRAIL by Illumina (July 22, 2021), https://ec.europa.eu/commission/presscorner/detail/en/IP_21_3844.

¹⁹ See Press Release, FTC, FTC to Restrict Future Acquisitions for Firms that Pursue Anticompetitive Mergers (Oct. 25, 2021), <https://www.ftc.gov/news-events/news/press-releases/2021/10/ftc-restrict-future-acquisitions-firms-pursue-anticompetitive-mergers>.

²⁰ See, e.g., CMA, AstraZeneca / Alexion Pharmaceuticals merger inquiry (last updated Aug. 18, 2021), <https://www.gov.uk/cma-cases/astrazeneca-slash-alexion-pharmaceuticals-merger-inquiry#full-publication-update-history> (transaction cleared).

²¹ See, e.g., CMA, Roche Holdings, Inc / Spark Therapeutics, Inc merger inquiry (last updated Feb. 10, 2020), <https://www.gov.uk/cma-cases/roche-holdings-inc-spark-therapeutics-inc-merger-inquiry> (transaction cleared).

²² EC, Case No. M.9294 – BMS / Celgene (2019) (EUR-Lex document no. 32019M9294).

Takeda/Shire case where the EC waived prior commitments based on subsequent developments.²³

Holland and Vardon stated that enforcement agencies will continue to closely scrutinize the concentration in research and development capabilities in pharmaceuticals. Holland stated that she sees a risk of reduction in research and development capabilities by merging companies and their competitors, citing to Ornaghi's presentation. Vardon agreed with Holland and stated that the EC will continue to request from merging firms information on topics including the firms' own research and development and integration plans; research and development expenditures; the number of full-time employees involved in research programs; the number of new products launched based on new molecules; and the ability of firms to enter into research and development partnerships.

In addition, Csiszár stated that policy makers and enforcers should always carefully reflect on the possible "chilling effect" on investment that might result from a rulemaking action or individual case decision. Csiszár stated that while experience and several academic studies have found that the acquisition of nascent competitors or mergers involving overlapping pipelines may negatively impact innovation in the sector, claims by some critics that the merger review process itself causes an alleged chilling effect on investment do not appear to have sufficient evidentiary basis.

Holland agreed that enforcers should not ignore claims about the possible chilling effect on investment because of merger enforcement. Holland further emphasized, however, that when innovative drugs are at issue, under-enforcement (i.e., type-two error) poses a greater risk to competition than over-enforcement (i.e., type-one error).

VI. Prior Bad Acts as Factors in Pharmaceutical Merger Reviews

The final session addressed how past anticompetitive conduct might relate to a current merger. David Lawrence, Policy Director for the Department of Justice Antitrust Division, moderated the discussion.

Gwendolyn Cooley, Assistant Attorney General for Antitrust for the state of Wisconsin, observed that both unilateral and multilateral anticompetitive conduct in pharmaceuticals can take a variety of forms. She discussed pay-for-delay cases where the branded manufacturer pays a generic to stay off the market for a period of time, ostensibly to settle patent infringement litigation. She cited misusing the FDA's Risk Evaluation and Mitigation Strategy ("REMS") drug safety process, committing fraud on the patent office, using patent thicket strategies, and restricting access to a drug's active ingredient as being mostly unilateral conduct, but cited price fixing and territorial allocation as examples of multilateral conduct where companies have agreed not to compete to produce generic pharmaceuticals. All these behaviors are attempts to corner the market on particular drugs and maximize profits, according to Cooley.

Cooley also raised concerns about mergers between brand drug companies and companies that may have a competitive drug in their pipeline. In that circumstance, it is

²³ EC, Case No. M.8955 – Takeda / Shire (2018) (EUR-Lex document no. 32018M8955) (clearing transaction with conditions and obligations) and EC, Case No. M.8955 – Takeda / Shire (2020) (Decision on the implementation of the commitments – Waiver of the Commitments).

important to look at past conduct to observe whether the brand company has engaged in anticompetitive conduct. The brand pharmaceutical company may have an incentive to prevent competition that may arise from a nascent pipeline product. Cooley stated that prior coordination in a market tests for the same sorts of things that a Herfindahl-Hirschman Index (“HHI”) does.²⁴ Those analyses ask whether the market already has an oligopolistic structure that should give rise to concern. This should be effective and persuasive for a judge evaluating a merger.

Scott Hemphill, Professor at New York University School of Law, offered views on how to think about the sequencing between a merger and anticompetitive conduct, and the synergies that might emerge from how enforcers think about that sequencing. Often, the sequence of events is that a merger investigation uncovers a price-fixing scheme, which then leads to an investigation of that prior conduct. But insights might also be gained by initially considering how prior bad acts might inform merger policy. First, Hemphill suggested that a firm’s prior conduct can be informative of its intent, and that intent can then be informative of a merger’s effect. Hemphill argued that intent provides information about the expectations of parties. In particular, previous demonstrated bad conduct, and the parties’ willingness to plan and engage in that conduct, might inform how to think about a subsequent merger and its effects. Second, Hemphill suggested that prior bad conduct, particularly if it has continuing effects, might amplify the concerns about a merger. For example, the suppression of competition through a unilateral policy or some contractual restraint could be amplified by an acquisition. Thus, Hemphill suggested that examining how prior bad conduct and intent relate to effects should be part of evaluating the role of past conduct in merger reviews.

Michael Carrier, Professor at Rutgers Law School, followed the discussion on sequencing and synergies by noting that prior bad acts can also reveal a firm’s incentive and ability to engage in future anticompetitive conduct. He reviewed several cases involving conduct ranging from pay-for-delay settlements to attempts to invoke tribal immunity by transferring patents to Native American tribes. He argued that a firm that has engaged in prior bad conduct has a greater incentive and heightened ability to engage in bad acts in the future. Carrier also noted that the Supreme Court in *FTC v. Actavis* recognized that instances of a branded pharmaceutical paying a generic to stay off the market may indicate market power.²⁵ Carrier and Cooley agreed that prior unilateral conduct to preserve market power can also indicate the existence of market power that could be the focus of a subsequent merger review. Carrier also cited the FTC’s review of the AbbVie/Allergan acquisition as an example of a merger that raised a variety of anticompetitive conduct issues.²⁶ Carrier suggested adopting a presumption against mergers between two large drug companies and employing heightened scrutiny of mergers involving mid-size firms.²⁷

²⁴ The HHI is a measure of market concentration. A given market’s HHI is the sum of the squares of the individual market shares of all market participants. For example, a four-firm market with market shares of 30 percent, 30 percent, 20 percent, and 20 percent has an HHI of 2600 [(30*30) + (30*30) + (20*20) + (20*20) = 2600]. HHIs range from 10,000 in a one-firm (pure monopoly) market to a number close to zero in a highly unconcentrated market.

²⁵ See *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013).

²⁶ FTC, *In re AbbVie Inc.* (2020) (FTC File No. 191 0169), <https://www.ftc.gov/legal-library/browse/cases-proceedings/191-0169-abbvie-inc-allergan-plc-matter>.

²⁷ Patricia M. Danzon & Michael A. Carrier, *The Neglected Concern of Firm Size in Pharmaceutical Mergers*, 84 ANTITRUST L. J. 487 (2022).

Raksha Koppam, Senior Research Assistant at the Washington Center for Equitable Growth, emphasized that enforcers should consider implications for economic inequality and vulnerable communities in their enforcement activities. She described recent price increases for certain prescription drugs, stated that such price increases are affecting more than half the U.S. population, and asserted that drug manufacturers are enjoying boosted profits at the expense of the most vulnerable. Koppam recommended that enforcement agencies consider the most vulnerable people when deciding which mergers to pursue. Koppam also emphasized the importance of understanding the makeup of consumer populations, including whether a merger would amplify harms more for communities that have experienced historic discrimination than for other communities.

VII. Conclusion

The Future of Pharmaceuticals workshop provided a timely examination of pharmaceutical merger review practices and related issues on concentration, remedies, innovation, and prior anticompetitive conduct. A key theme of the workshop was that looking back at a firm's past practices and those of the antitrust enforcers can help to improve merger analysis going forward.

Appendix

Below is a list of the ideas mentioned in this summary, organized by order of appearance in the summary.

Concentration Levels in the Pharmaceutical Sector

- Apply a presumption of harm to merger and acquisition activity involving two large originator firms (i.e., in the top decile of U.S. sales), which would shift the burden to firms to show merger-specific efficiency gains that outweigh potential competitive harms.
- Apply heightened scrutiny to combinations involving large- and mid-size firms or two mid-size firms (i.e., in the second decile of U.S. sales), especially if either firm has a must-have or blockbuster product that increases the risk of anticompetitive bundling or cross-market leverage.
- Abandon the use of divestiture settlements in merger challenges.
- Promote greater transparency into the U.S. supply chain.

Broken Fixes? Remedies in Pharmaceutical Mergers

- Adopt a robust “second look” policy of post-merger review to ensure that past decisions had the intended result, and to improve future evaluations.
- Seek divestiture of existing drug products, rather than pipeline drug products.
- Develop a two-part purchasing analysis to account for the role of intermediaries, like the approach the FTC pioneered to evaluate hospital mergers and the intermediary role of insurance.
- Develop structural models that could predict which firms might be incentivized to engage in anticompetitive conduct post-merger.
- Continue monitoring research and development levels and patent output post-merger.
- Require a commitment to maintain certain levels of research and development and patent output post-merger.

- Update thinking on remedies generally, and the effectiveness of those remedies more specifically.

Assessment of Innovation Aspects in Pharmaceutical Mergers

- Scrutinize competition at all stages in innovation, including the potential loss of innovation competition that is separate and apart from any eventual product or service competition.
- Examine incentives of the non-merging firms, in addition to those of the merging firms.
- Examine changes to incentives of non-merging firms, for example whether they will continue to invest in certain R&D or efforts to bring a drug to market.
- Weigh the risk to competition of under-enforcement against the risk of over-enforcement.

Prior Bad Acts as Factors in Pharmaceutical Merger Reviews

- Examine the relationship between prior bad conduct and intent and effects in merger reviews.
- Consider the most vulnerable people when deciding which mergers to pursue.