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

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 cine ndsrns Scesn t1 (i)-ta (l)-2(ci)-6z(c)4 (o)-10 (m)

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 crimh8azing dier l0 (-8 Tc (n)2 (s)1 (,))6 (s)1 (p)2 (e) w 8.55 0 Td[(fo)

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

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 th

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 determ(e r)-1 (e)-9.L(t)-16 5ce9 al (e)]TJnnete5 (M)-5 (ar)

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 iio2- ih-h ne.d (n

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]

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

Holland and Vardon stated that enforstat enhvhrtoototl (o)-y5 (t) etated t05 7 (i)-2 (t-5 (t).004 Tc).004 Te

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 invot ases

frog 0 involving002 Tw 10(ar)(r)3 (shduc)4 (t)-2 n futurd conductt

Raksha Kopparam, 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. Kopparam recommended that enforcement agencies consider the most vulnerable people when deciding which mergers to pursue. Kopparam 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.