Dechert LLP's Comments to the Federal Trade Commission

Multilateral Pharmaceutical Merger Task Force
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Introduction

Dechert commends the U.S. Federal Trade Commission (FTC) and counterpart agencies for seeking input to inform their decision-making on standards for pharmaceutical merger enforcement. While many of these issues transcend borders, Dechert's comments focus on FTC merger enforcement. These comments are not submitted on behalf of any company or organization and arise from the experience of Dechert attorneys both at the FTC and in the private sector.

As a threshold matter, there is insufficient empirical support for jettisoning current merger enforcement guidelines and adopting new ones for application to the pharmaceutical or life sciences sector. Contrary to assertions by FTC critics, the agency's pharmaceutical merger enforcement efforts over the past decade have been robust with challenges to mergers valued at $327 billion. Our systematic analysis of FTC merger enforcement in this sector over a ten-year period shows that the FTC deserves credit for active enforcement and achievements.

New approaches—whether to theories of harm, economic models, or evidentiary sources –should be considered and adopted when supported by evidence and experience. Changing industry dynamics must be accounted for in all settings and the existing Horizontal Merger Guidelines (Guidelines) provide sufficient flexibility. But altering the fundamental enforcement criteria for market definition, identification of market participants, entry analysis, or other well-tested doctrines should not be undertaken lightly and should be pursued only if supported by a deep well of empirical evidence. We see insufficient support for any drastic policy changes that would single out this industry.

Moreover, the FTC should consider providing greater clarity on standards for applying the potential competition doctrine in the pharmaceutical and other sectors. Our analysis of recent enforcement actions suggests the FTC has departed from the Guidelines and has done so without identifying consistently-applied, new criteria that can be easily understood and relied upon by decision-makers.

Finally, the potential competition doctrine should be reconciled with other merger enforcement doctrines that address whether and when a firm is likely to compete effectively. Such a question is addressed in entry analysis where the guidelines provide enforcement standards and the agencies evaluate the evidence against those standards to assess whether a third-party firm is likely to enter the marketplace and succeed in replacing one of the merging parties. Similarly, when assessing potential divestiture buyers, the FTC applies clearly-articulated criteria to determine whether a company has the capabilities—whether production, intellectual property, or management expertise—to compete effectively and whether its business plans and other documents confirm that it is likely to succeed. In contrast, it is not apparent that those same standards are applied when assessing whether one of the merging parties is a potential future competitor of the other merging party.

The absence of clear standards for the potential competition doctrine may lead to either over- or under-enforcement and to inconsistency and uncertainty. Standards should apply equally across sectors, accounting for the factual dynamics particular to each. The potential competition standard will benefit from consideration of how the FTC evaluates evidence when deciding

whether a firm is likely to enter successfully and whether a divestiture buyer is likely to compete successfully.

Our analysis focuses on the criteria and evidentiary standards used by the agencies when applying the Horizontal Merger Guidelines. The Guidelines, consistent with Clayton Act Section 7, should drive investigations and enforcement decisions involving proposed mergers in the pharmaceutical and other sectors. If the FTC (or DOJ) is applying Sherman Act Section 2 or monopolization law to evaluate the loss of potential competition through a merger, the agency should indicate that and explain how those standards differ from the well-established Guidelines' standards. For example, if the FTC views nascent competition as a Section 2 doctrine, it should explain how that doctrine differs from the Guidelines' treatment of potential competitors or third-party entrants. Similarly, to the extent that the FTC draws a material distinction between potential and nascent competitors, the agency should clarify how it treats each of those categories of competitors in its merger reviews.

I. FTC Merger Enforcement Levels in the Pharmaceutical Sector Have Been Robust

Before pursuing untested and empirically unsupported theories of harm, the FTC and its critics should consider the significant extent of relief the agency has obtained, the theories of harm it has investigated, and the remedial successes it has achieved under its current approach to pharmaceutical merger reviews.

A. Enforcement Results

The FTC has built an impressive enforcement record in the area of pharmaceutical mergers. Appendix A to this comment provides detailed information regarding each of the FTC's enforcement actions involving pharmaceutical mergers during the period between 2011 and 2021.

During this ten-year period, the FTC has filed and settled 31 enforcement actions against merging pharmaceutical companies. The combined deal value of the challenged transactions is approximately $327 billion. The FTC has required some form of divestiture spanning a total of 207 pharmaceutical products to settle these challenges.

The significance of the FTC's pharmaceutical merger enforcement is demonstrated by its ability to obtain relief in cases arguably at the outer boundaries of the Clayton Act. For example, the FTC routinely obtains relief in pharmaceutical markets where the merger results in the number of competitors going from five to four and from four to three. The FTC challenged and obtained relief in one or more 5-to-4 markets in 12 matters (over a third of the 2011-21 cases) and in one or more 4-to-3 markets in 15 matters (nearly half of the 2011-21 cases).[1] Although competitor counts may be an oversimplified portrayal of competition in a particular market, the vast majority of the FTC's pharmaceutical merger actions have involved generic drug markets, where the product is a commodity and the number of competitors plays an outsized role in the analysis.

[1] *See* Appendix A.

Similarly, the extent of the relief obtained by the FTC via its consent orders is demonstrated by the number of cases involving potential competition claims, which the courts often reject.[2] Each of the four brand drug mergers challenged and settled by the FTC during the 2011-21 period featured an overlap that included a product in either Phase 2 or Phase 3 of clinical trials.[3] In 12 of the 31 generic drug mergers during the 2011-21 period, the FTC obtained divestitures where the generic drug market had not even formed yet.[4] Eight of the generic drug mergers involved challenged overlaps where both parties were still developing their products.[5]

B. Theories of Harm

Some critics have suggested that the FTC does not adequately evaluate theories of competitive harm outside traditional current product-level overlaps. Yet, the agency already analyzes competitive effects that go beyond such overlaps, including, among others, effects on innovation and R&D, portfolio competition, incentives to engage in anticompetitive bundling, and incentives to challenge patents.

The following table identifies a non-exhaustive list of pharmaceutical merger matters in which the FTC stated publicly that it investigated theories of harm going beyond traditional current product overlaps:

Merger	Theories of Harm	Scope of Investigation
Genzyme/ Novazyme (2004)	Innovation competition	"[T]he competition between Genzyme and Novazyme would not have had a substantial effect on the amount or timing of Genzyme's or Novazyme's R&D spending on Pompe, or on when the first Pompe therapy would reach the market. . . . There is no evidence that the merger reduced R&D spending on either the Genzyme or the Novazyme program or slowed progress along either of the R&D paths."[6]

[2] *See, e.g., United States v. Sabre Corp.*, 452 F. Supp. 3d 97 (D. Del. 2020) (dismissing DOJ challenge to Sabre's proposed acquisition of Farelogix); *FTC v. Steris Corp.*, 133 F. Supp. 3d 962 (N.D. Ohio 2015) (dismissing FTC challenge to Steris' proposed acquisition of Synergy Health).

[3] These include: AbbVie/Allergan, FTC File No. 191-0169 (2020) (current/Phase 2 overlap); Bristol-Myers Squibb/Celgene, FTC File No. 191-0061 (2019) (current/Phase 3 overlap); Mallinckrodt/Novartis, FTC File No. 131-0172 (2017) (current/Phase 2 overlap); and Novartis/GSK, FTC File No. 141-0141 (2015) (current/Phase 3 overlap). *See* Appendix A for additional details regarding these matters.

[4] *See* Appendix A.

[5] *See id.*

[6] Statement of Chairman Timothy J. Muris in the Matter of Genzyme Corporation / Novazyme Pharmaceuticals, Inc., FTC File No. 021-0026, at 12, 17 (Jan. 13, 2004), https://www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./murisgenzymestmt.pdf.

Merger	Theories of Harm	Scope of Investigation
Pfizer/ Wyeth (2009)	Innovation competition, anticompetitive bundling, and use of patent thickets	"Beyond the[] specific overlaps, the staff thoroughly investigated whether the transaction could have an impact on competition in human pharmaceutical markets more broadly, whether on innovation, the intellectual property landscape, clinical development, or marketing." "[Further], staff evaluated whether the acquisition would change the negotiating power between Pfizer and its customers such that consumers would be harmed because of unlawful tying, bundling, or exclusive dealing by Pfizer."[7]
Teva/ Allergan (2016)	Anticompetitive bundling and reduced incentives to challenge brand drug patents and develop new generic products	"First, we considered whether the merger would likely lead to anticompetitive effects from the bundling of generic products. . . . Second, we examined whether the merger would likely decrease incentives to challenge the patents held by brand-name pharmaceutical companies and bring new generic drugs to market. . . . Finally, we analyzed whether the proposed transaction might dampen incentives to develop new generic products."[8]
BMS/ Celgene (2019)	Innovation competition	"The investigation identified a likely harm to innovation involving oral products to treat moderate-to-severe psoriasis; the identified overlap includes a product that is still in development by BMS. In addition, staff investigated whether the proposed transaction would decrease innovation competition; instead, the investigation found that reduced innovation competition was unlikely."[9]

[7] Statement of the Federal Trade Commission Concerning Pfizer/Wyeth, FTC File No. 091-0053, at 2, 3 (Oct. 14, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/10/091014pwyethstmt.pdf.

[8] Statement of the Federal Trade Commission in the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc, FTC File No. 151-0196, at 2-3 (July 27, 2016), https://www.ftc.gov/public-statements/2016/07/statement-federal-trade-commission-matter-teva-pharmaceuticals-industries.

[9] Statement of Commissioner Christine Wilson in the Matter of Bristol-Myers Squibb Company / Celgene Corporation, FTC File No. 191-0061, at 1 n.2 (Nov. 15, 2019), https://www.ftc.gov/public-statements/2019/11/statement-commissioner-christine-s-wilson-matter-bristol-myers-squibb.

Merger	Theories of Harm	Scope of Investigation
AbbVie/ Allergan (2020)	Innovation competition and impact on rebating practices	"Consistent with the Horizontal Merger Guidelines, staff investigated whether the 'merger will diminish innovation competition by combining two of a very small number of firms with the strongest capabilities to successfully innovate in a specific direction.' . . . The staff also investigated whether the merger eliminated competitive restraints on either AbbVie or Allergan that would allow for rebating practices that otherwise had failed due to the independence of the two companies, and did not find evidence to support such a theory."[10]

Because the FTC often does not issue public statements discussing theories of harm it investigated that did not result in any enforcement action, this summary understates the extent to which the FTC investigates additional theories beyond overlaps of currently commercialized products.

C. Remedies

In January 2017, the FTC published an extensive retrospective study of merger remedies showing substantial success in remedying pharmaceutical merger concerns.[11] The study included 24 pharmaceutical industry mergers covering 92 pharmaceutical product divestitures between 2006 and 2012. The FTC found that remedies succeeded for 84% of these pharmaceutical products. This success rate was comparable to non-pharmaceutical industries, including an 83% success rate for industries evaluated through case studies and a 91% success rate for industries evaluated through questionnaires.[12]

Although the FTC did not achieve a 100% success rate in pharmaceutical merger remedies, the study helped the FTC identify the reasons that certain divestitures failed and why others succeeded. For example, the FTC found problems with several remedies involving complex generics that required the transfer of manufacturing capabilities for on-market products. The FTC also found that remedy risks increased when the buyer was required to establish a new production source. Conversely, the FTC found that all of the divested assets related to products that were in development at the time of divestiture were successfully transferred to approved buyers. These

[10] Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Allergan plc by AbbVie Inc., FTC File No. 191-0169, at 9-10 (May 5, 2020), https://www.ftc.gov/public-statements/2020/05/statement-chairman-joseph-j-simons-commissioner-noah-j-phillips.

[11] Federal Trade Comm'n, The FTC's Merger Remedies 2006-2012 (Jan. 2017), https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.

[12] The FTC's success rate was 83% in non-pharmaceutical merger orders for which a "case study" methodology was used. *Id*. at 17. And 91% of remedies succeeded in divestitures evaluated through questionnaires involving supermarkets, retail pharmacies, nuclear pharmacies, funeral homes and cemeteries, and a variety of healthcare facilities. *Id*. at 29.

learnings were converted into "best practices" to be used in the future to help increase the agency's remedial success rate.

The FTC's remedy study demonstrates the value of a thorough, fact-based study to create targeted solutions. The FTC should use at least the same level of rigor as in the remedy study to better understand whether there has been insufficient merger enforcement, and then develop careful, well-tailored solutions to the extent a fact-based study shows any under-enforcement.

II. The FTC Should Articulate the Standard for Assessing Potential Competition and Apply It Consistently

As detailed in the prior section, the FTC often imposes conditions on pharmaceutical mergers that implicate potential or future competition. The agency should develop and consistently and transparently apply a clear standard to assess whether an early-stage company or research program counts as a competitor.

The Horizontal Merger Guidelines explain that a merger between an incumbent and a potential entrant can raise competition concerns and identifies several factors to consider in evaluating the likely effects of such a merger:

> A merger between an incumbent and a potential entrant can raise significant competitive concerns. The lessening of competition resulting from such a merger is more likely to be substantial, the larger is the market share of the incumbent, the greater is the competitive significance of the potential entrant, and the greater is the competitive threat posed by this potential entrant relative to others.[13]

The Guidelines also note that firms committed to entering the relevant market should be considered market participants: "Firms not currently earning revenues in the relevant market, but that have committed to entering the market in the near future, are also considered market participants."[14] The Guidelines thus call for a factual analysis focusing on whether the incumbent's market share is relatively large, whether the company is "committed to entering," and whether the time frame for entering is "in the near future."

In practice, the FTC has used several formulations to describe firms that have not yet entered the relevant market but whose acquisition would likely eliminate potential or future competition. Those formulations do not necessarily align with the factors identified in the Guidelines for evaluating potential competition. For example, the FTC's 2017 complaint challenging Mallinckrodt's consummated acquisition of U.S. rights to Synacthen, a drug in Phase 2 at the time it was acquired, stated: "Synacthen constituted a nascent competitive threat to Questor's ACTH drug monopoly, notwithstanding the significant uncertainty that Synacthen, a

[13] Federal Trade Comm'n & Dep't of Justice Horizontal Merger Guidelines § 5.3 (2010).

[14] *Id.* § 5.1.

preclinical drug, would be approved by the FDA."[15] Despite this "significant uncertainty" regarding FDA approval for Synacthen, the FTC treated this research program as a competitor.

Further, the FTC's complaints in pharmaceutical merger cases often include allegations that the merging parties are two of a limited number of "likely potential" suppliers of a given product, without identifying factual support for such allegations. As noted in the prior section, the FTC even applies this standard in generic drug mergers where the generic drug market has not yet formed—that is, before a single generic product has been introduced. Following is a typical allegation along these lines: "Currently, there are no AB-rated generic versions of Epiduo available in the United States, but Watson and Actavis are two of a limited number of likely potential suppliers of generic Epiduo."[16]

Also within the life sciences sector, the FTC's 2019 complaint challenging Illumina's acquisition of PacBio described the target as "poised" to enter the relevant market:

> The Acquisition, if consummated, would eliminate the nascent competitive threat that an independently owned PacBio poses to Illumina's monopoly power. . . . Respondents, customers, and other market participants recognize that . . . PacBio is poised to take increasing sequencing volume from Illumina in the future.[17]

More recently, the FTC's lawsuit seeking to block Illumina's acquisition of Grail—effectively a potential vertical case—again featured an allegation that a firm is "poised" to compete with an incumbent:

> [Multi-cancer early detection] tests are poised to revolutionize how cancer is detected and treated, having the potential to save millions of lives in the United States and around the world. . . . Although no MCED test is currently commercialized, Illumina, test developers, and others in the industry expect the U.S. MCED market to be large and have sales of tens of billions of dollars annually. . . . . Several Illumina customers are poised to become close competitors with Grail in the sale of MCED tests . . . .[18]

Both the FTC and merging parties would benefit from greater clarity regarding the standard the FTC applies to determine whether a merger is likely to eliminate potential or future

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[15] *FTC v. Mallinckrodt ARD, Inc.*, Complaint ¶ 34, Civil Action No. 1:17-cv-001120 (D.D.C. Jan. 25, 2017); *see also* David Gonen, "Protecting challenges to monopolies," FTC Competition Matters Blog, Feb. 28, 2017, https://www.ftc.gov/news-events/blogs/competition-matters/2017/02/protecting-challenges-monopolies.

[16] In the Matter of Watson Pharmaceuticals, Inc., Analysis to Agreement Containing Consent Orders to Aid Public Comment at 5, FTC File No. 121-0132 (Oct. 15, 2012), https://www.ftc.gov/sites/default/files/documents/cases/2012/10/121015watsonactavisanal.pdf.

[17] *FTC v. Illumina, Inc.*, Complaint ¶¶ 68, 81, FTC Docket No. C-9387 (Dec. 17, 2019), https://www.ftc.gov/system/files/documents/cases/d9387_illumina_pacbio_administrative_part_3_complaint_public.pdf.

[18] *FTC v. Illumina, Inc.*, Complaint ¶¶ 2, 39, 72, FTC Docket No. C-9401 (Mar. 30, 2021), https://www.ftc.gov/system/files/documents/cases/redacted_administrative_part_3_complaint_redacted.pdf.

competition. The Guidelines identify certain factors that are relevant to a potential competition analysis, including the incumbent's market share, and the firm's commitment to enter and ability to do so in the near future. The FTC should indicate whether these Guidelines factors remain valid and, if so, explain how it applies those factors in its potential competition analyses. Whatever standard the agency develops, it ought to apply it consistently and transparently in pharmaceutical and other merger reviews.

III. The Criteria for Evaluating Ease of Entry Provide Guidance for Analyzing the Likely Success of Potential Competitors

The Horizontal Merger Guidelines set clear criteria for when the agencies should credit potential new entry from third parties.[19] At a high level, the agencies look for evidence that entry by third parties would be timely, likely, and sufficient to deter or counteract the anticipated competitive effects of a transaction.[20] In making this assessment, the agencies consider the capability of a potential entrant to overcome challenges such as obtaining necessary permits and licenses, building manufacturing facilities or outsourcing manufacturing, obtaining access to inputs, reaching minimum viable scale to be profitable, developing distribution networks, and engaging in promotion, marketing, and other efforts to obtain customer acceptance of the new entrant's products.[21] The agencies also give "substantial weight" to "the actual history of entry into the relevant market" when assessing the likelihood of future entry.[22]

When applying the Guidelines to pharmaceutical sector mergers, the FTC has highlighted the high costs, long lead times, and uncertainty of obtaining FDA regulatory approvals. As the FTC explained in AbbVie/Allergan:

> New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.[23]

In practice, the FTC commonly alleges that entry by third parties would not be timely, likely, or sufficient.[24]

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[19] *See generally* Federal Trade Comm'n & Dep't of Justice, Horizontal Merger Guidelines § 9 (2010).

[20] *Id.*

[21] *Id*.

[22] *Id.*

[23] In the Matter of AbbVie Inc. and Allergan plc, Analysis of Agreement Containing Consent Orders to Aid Public Comment at 3, FTC File No. 191-0169 (May 5, 2020).

[24] *E.g.*, In the Matter of Stryker and Wright Medical, Complaint ¶ 10, FTC Docket No. C-4728 (Nov. 3, 2020); In the Matter of Pfizer Inc., Upjohn, Inc., Viatris, Inc, Mylan Inc., and Utah Acquisition Sub Inc., Complaint ¶ 20, FTC Docket No. C-4727 (Oct. 13, 2020); In the Matter of Össur Hf, Össur American Holdings, Inc., and College Park Industries, Inc., Complaint ¶ 11, FTC Docket No. C-4712 (Apr. 6, 2020); In the Matter of Danaher Corp. and

The FTC's filings in pharmaceutical consent orders, however, do not appear to apply this same exacting standard when analyzing whether one of the merging parties would be a potential future competitor of the other merging party. In particular, for transactions where one merging party has an approved pharmaceutical product and the other party has a product in development, FTC consent filings often do not explain why the merging party's developmental product is likely to overcome the regulatory challenges that make third-party entry untimely, unlikely, and insufficient.

For example, when evaluating the proposed Amneal acquisition of Impax, the FTC focused on products in ten relevant markets, including "seven markets in which Amneal or Impax is a current competitor and the other is likely to enter the market[.]"[25] When discussing the prospect of entry by third parties in any of the ten relevant markets, the complaint alleged:

> Entry into the ten markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.[26]

At the same time, the complaint in Amneal/Impax was silent as to the reasons why it deemed one of the merging parties to be a potential entrant in the seven potential competition markets. The strongest case presumably could have been made for one of the products (Azelastine nasal spray) that had already received tentative FDA approval.[27] For each of the remaining products, however, the complaint said nothing about why the merging parties' developmental products were likely to overcome the regulatory hurdles that made third-party entry unlikely. The complaint instead alleged only that the other merging party is one of "a limited number" or "a few" suppliers "capable of entering" the market.[28] The complaint did not explain what facts or evidence supported a conclusion that the merging parties were "capable of entering" each of these markets while other companies were treated as unlikely to enter.

The same dynamic is evident in other recent complaints in which the FTC alleged that one of the merging parties' products was a potential entrant or nascent competitor. In Baxter/Claris,

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General Electric Co., Complaint ¶¶ 16-17, FTC Docket No. C-4710 (Mar. 10, 2020); In the Matter of Bristol-Myers Squibb Co. and Celgene Corp., Complaint ¶ 8, FTC Docket No. 4690 (Nov. 15, 2019); In the Matter of Grifols S.A. and Grifols Shared Services North America Inc., Complaint ¶ 14, FTC Docket No C-4654 (Jul. 31, 2018); In the Matter of Abbott Laboratories and Alere, Inc., Complaint ¶ 10, FTC Docket No. C-4625 (Sept. 28, 2017); In the Matter of Integra Lifesciences Holdings Corp. and Johnson & Johnson, Complaint ¶ 13, FTC Docket No. C-4624 (Sept. 26, 2017).

[25] In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC, Analysis of Agreement Containing Consent Orders to Aid Public Comment at 2, FTC File No. 181-0017 (Apr. 27, 2018).

[26] *Id.* at 3.

[27] *Id.* at 2-3.

[28] *Id.*

for example, the complaint described Claris as "one of a limited number of suppliers capable of entering" one of two alleged relevant markets,[29] even as the FTC alleged that entry by third parties would not be timely, likely, or sufficient due to "the combination of drug development times and lengthy FDA approval requirements."[30] The FTC took the same approach in Bristol-Myers Squibb/Celgene, in which it alleged that third-party entry was unlikely because "developmental efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market" but concluded without explanation that Bristol-Myers Squibb's developmental product was a likely entrant.[31]

Similarly, in *FTC v. Mallinckrodt*, the complaint alleged that there are "high barriers to entry," including the requirement of "successfully conducting clinical trials necessary for FDA approval."[32] This allegation was used to support an inference of the acquirer's monopoly power, even as the complaint described the acquired developmental product, which remained preclinical in the United States, as a "nascent competitive threat . . . notwithstanding the uncertainty that Synacthen, a preclinical drug, would be approved by the FDA."[33]

At a minimum, the standards for evaluating potential or future competition between merging parties should be aligned with the established standards for analyzing the likelihood of new entry from third parties. This applies with even more force if the FTC intends to bring enforcement actions where there are no current or even developmental product overlaps between the parties. In its complaints, consent orders, and other statements, the FTC should make more apparent the evidentiary basis or standards for concluding that one of the merging parties is likely to overcome the challenges that the FTC believes make third-party entry unlikely.

IV. The Criteria for Evaluating Divestiture Buyers Provide Guidance for Analyzing the Likely Success of Potential Competitors

Based on past practice, the FTC has developed a robust set of criteria for evaluating the capabilities of candidate buyers of divested products to ensure that those buyers are both competitively and financially viable.[34] To assess competitive viability, the FTC requires a divestiture buyer to submit a detailed business plan demonstrating that it has "sufficient experience to compete in the market, that it has done adequate due diligence, that it knows what is needed to compete in the market, and that it is committed to the market."[35] To assess financial viability, the FTC conducts a thorough review of the divestiture buyer's financial information and data to

[29] In the Matter of Baxter International Inc., Claris Lifesciences Limited, and Arjun Handa, Complaint ¶ 9, FTC Docket No. C-4620 (July 20, 2017).

[30] *Id.* ¶ 10.

[31] Bristol-Myers Squibb/Celgene, Analysis to Aid Public Comment at 2-3, FTC File No. 191-0061 (Nov. 15, 2019).

[32] *FTC v. Mallinckrodt ARD, Inc.*, Complaint ¶ 32, Case No. 1:17-cv-001120 (D.D.C. Jan. 25, 2017).

[33] *Id.* ¶ 34.

[34] *See* Statement of the Bureau of Competition of the Federal Trade Commission on Negotiating Merger Remedies, at 10 (Jan. 2012).

[35] *Id.* at 11.

"determine whether the buyer has the necessary financial resources."[36] The goal of this thorough vetting of candidate buyers is to ensure that the divested business remains a viable competitor.

The FTC's rigorous vetting process for evaluating candidate buyers is outlined in its recent *Guide for Potential Buyers* and requires proposed buyers to provide detailed financial and business plans with supporting documentation, explain the structure and sources of funding and financing for the investment, and explain the underlying assumptions of the financial and business plans and any contingency plans if sales and other financials do not meet projections.[37] Moreover, in situations where the buyer is acquiring less than an ongoing business "there will be additional scrutiny of the asset package" and the buyer's business plans to assess how the buyer plans to maintain or restore competition with the selected asset package and the assets and services that the buyer believes are necessary to "operate as a viable and competitive business in the relevant market."[38] The FTC staff often interviews the buyer, market participants, and the buyer's financing entities before recommending that the Commission approve the buyer and the divested assets.[39]

These divestiture criteria are not a rubber stamp. Instead, the FTC and DOJ have routinely taken strong positions against divestiture packages or divestiture buyers viewed as inadequate to remedy competitive concerns.[40] In *United States v. Aetna*, for example, the DOJ emphatically objected to a divestiture buyer where the divestiture was "contingent on federal and state regulatory action and thus may not happen" and where the divestiture was "not the sale of an existing business entity meaning that [the buyer] . . . would need to develop critical competitive assets like provider networks, skilled employees, sales infrastructure, data analysis and IT systems, and an individual [Medicare Advantage] brand."[41] Another source of evidence was internal documents from the divestiture buyer raising doubts about its ability to succeed.[42] Using this evidence, DOJ argued that the divestiture "would not preserve competition in the Complaint counties or be a good deal for seniors."[43] Both the district and appellate courts agreed.[44]

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[36] *Id.* at 10.

[37] Federal Trade Comm'n, *A Guide for Potential Buyers: What to Expect During the Divestiture Process*, at 1 (June 2019).

[38] *Id.* at 2.

[39] *Id.*

[40] *See, e.g.*, *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304-08 (D.D.C. 2020) (evaluating FTC objections to proposed divestiture buyer); *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 63-74 (D.D.C.) (evaluating DOJ objections to proposed divestiture buyer), *aff'd*, 855 F.3d 345 (D.C. Cir. 2017); *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 100-24 (D.D.C. 2015) (same).

[41] U.S. Dep't of Justice, *United States v. Aetna, Inc.*, Plaintiffs' Proposed Findings of Fact and Conclusions of Law ¶ 255, Civil Action No. 1:16-cv-01494 (D.D.C. Jan. 5, 2017).

[42] *Id.* ¶ 266.

[43] *Id.*

[44] *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 73-74 (D.D.C.), *aff'd*, 855 F.3d 345 (D.C. Cir. 2017).

The divestiture process is difficult enough when the divested assets include a pre-existing and already viable product. The situation is even more complex when the product being divested is only a developmental product with no history of past sales. This is the situation commonly faced with pharmaceutical sector mergers, where concerns are at times raised when one merging party has pharmaceutical products in the developmental pipeline that might eventually compete with products offered by the other merging party.

Acknowledging the inherent risk of failure for pipeline pharmaceutical products in particular, the FTC recently began requiring merging parties to divest pharmaceutical products already on the market instead of products in the pipeline. At the time, the Director of the Bureau Competition explained the policy shift as follows: "Based on a history of problems with divestitures in this area, our view is that divesting ongoing manufacturing rather than products that haven't yet come to market places the greater risk of failure on the merging firms, rather than the American public."[45]

This divestiture policy reflects substantial doubt about whether products in the pipeline are likely to achieve commercial success. Accordingly, where the FTC justifiably believes the risk of failure for a product in the pipeline is high, questions should be raised about whether a divestiture is even necessary.

The well-established criteria for evaluating divestiture buyers provides a useful framework for evaluating each of the merging parties' likelihood of success as a potential competitor with any pipeline pharmaceutical products before determining whether there is a competitive problem that needs to be remedied. Applying the divestiture criteria to the pharmaceutical industry to assess whether a potential competitor may succeed, the FTC staff should conduct a thorough investigation to determine whether the firm has both the required financial resources to be successful, as well as robust business plans detailing how the potential product may be approved and brought to market. Without this same level of scrutiny, the FTC may be unnecessarily requiring a divestiture for a pipeline pharmaceutical product that already has a low probability of success and remains at high risk of failure. It may even be preventing a combination that would provide the resources or infrastructure needed to accelerate or achieve commercialization.

[45] D. Bruce Hoffman, Acting Director, Bureau of Competition, U.S. Federal Trade Commission, "It Only Takes Two to Tango: Reflections on Six Months at the FTC," Remarks at GCR Live 7th Annual Antitrust Law Leaders Forum, at 6 (Feb. 2, 2018).

Appendix A – FTC Pharmaceutical Sector Merger Enforcement Actions (2011-2021)[1]

Merger	Date of FTC Action[2]	Deal Value	Brand/ Generic[3]	Overlap(s): Current or Potential Competition[4]	Change(s) in Market Concentration	Number of Divested Products[5]
Hikma/Baxter	4/27/11	$112 M	Generic	• Current/Current	3-to-2	2
Perrigo/Paddock	6/26/11	$540 M	Generic	• Current/Current • Current (brand)/Developing (generic) (pre-generic market) • Developing/Developing	3-to-2	6
Teva/Cephalon	10/7/11	$6.8 B	Generic	• Current/Current • Current (brand)/Pending ANDA (pre-generic market) • Current (brand)/Developing (generic) (pre-generic market)	3-to-2	3
Valeant/Johnson & Johnson	12/12/11	$345 M	Generic	• Current/Current	2-to-1	2
Valeant/Sanofi	12/12/11	$425 M	Generic	• Current/Current	5-to-4; 2-to-1	2
Novartis/Fougera	7/16/12	$1.5 B	Generic	• Current/Current • Current (brand)/Developing (generic) (pre-generic market)	4-to-3; 3-to-2; 2-to-1	4
Watson/Actavis	10/15/12	$5.9 B	Generic	• Current/Current • Current/Developing • Developing/Developing (pre-generic market)	5-to-4; 4-to-3; 3-to-2; 2-to-1	21
Mylan/Agila	9/26/13	$1.75 B	Generic	• Current/Current • Current/Developing • Developing/Developing • Developing/Developing (pre-generic market)	5-to-4; 4-to-3	11
Actavis/Warner Chilcott	9/27/13	$8.5 B	Generic	• Current/Current • Current (brand)/Pending ANDA (pre-generic market) • Current (brand)/Developing (generic) (pre-generic market)	3-to-2	4

Merger	Date of FTC Action[2]	Deal Value	Brand/ Generic[3]	Overlap(s): Current or Potential Competition[4]	Change(s) in Market Concentration	Number of Divested Products[5]
Endo/Boca Life Science	1/31/14	$225 M	Generic	• Current/Current • Exited ANDA/Developing • Developing/Developing (pre-generic market)	4-to-3; 3-to-2; 2-to-1	7
Akorn/Hi-Tech Pharmacal	4/14/14	$640 M	Generic	• Current/Current • Current/Developing	4-to-3; 3-to-2	5
Actavis/Forest Laboratories	6/30/14	$25 B	Generic	• Current/Current • Current (brand)/ANDA (pre-generic market)	4-to-3; 3-to-2	4
Valeant Pharmaceuticals/ Precision Dermatology	7/3/14	$500 M	Generic	• Current/Current	5-to-4; 3-to-2; 2-to-1	2
Akorn/VersaPharm	8/4/14	$324 M	Generic	• ANDA/Pending ANDA	Not applicable	1
Sun/Ranbaxy	1/30/15	$4 B	Generic	• Current/Pending ANDA	Not applicable	1
Novartis/GSK	2/23/15	$16 B	Brand	• Current/Phase 3	Not applicable	2
Impax Laboratories/CorePharma	3/6/15	$700 M	Generic	• Current/Pending ANDA • ANDA/ANDA	5-to-4	2
Pfizer/Hospira	8/24/15	$17 B	Generic	• Current/Current • Current/Developing • Developing/Developing	4-to-3; 3-to-2	4
Endo/Par	9/25/15	$8.05 B	Generic	• Current/Current	4-to-3; 3-to-2	2
Mylan/Perrigo	11/3/15	$27 B	Generic	• Current/Current • Current/ANDA • Current/Pending ANDA • ANDA/Pending ANDA (pre-generic market)	3-to-2; 2-to-1	7
Lupin/Gavis	2/19/16	$850 M	Generic	• Current/Current • Developing/Developing (pre-generic market)	5-to-4; 4-to-3	2
Hikma/Ben Venue Labs	2/19/16	$5 M	Generic	• Current/ANDA • Current/Exited ANDA • Exited ANDA/ANDA • ANDA/Pending ANDA	5-to-4; 4-to-3	5

Merger	Date of FTC Action[2]	Deal Value	Brand/ Generic[3]	Overlap(s): Current or Potential Competition[4]	Change(s) in Market Concentration	Number of Divested Products[5]
Hikma/Roxane	2/26/16	$2 B	Generic	• Current/Current • Current/Pending ANDA	5-to-4; 4-to-3	3
Mylan/Meda	7/27/16	$7.2 B	Generic	• Current/Current • Current/ANDA	4-to-3; 3-to-2	2
Teva/Allergan	7/27/16	$40.5 B	Generic	• Current/Current • Current (brand)/Current (generic) • Current/Exited ANDA • Current/Pending ANDA • ANDA/ANDA • ANDA/Pending ANDA (pre-generic market) • Pending ANDA/Pending ANDA (pre-generic market) • Developing/Developing (pre-generic market)	5-to-4; 4-to-3; 3-to-2; 2-to-1	79
Mallinckrodt/Novartis[6]	1/18/17	$135 M	Brand	• Current/Phase 2	Not applicable	1
Baxter/Claris	7/20/17	$625 M	Generic	• Current/Current • Current/Pending ANDA	5-to-4	2
Amneal Pharmaceutical/ Impax Laboratories	4/27/18	$1.45 B	Generic	• Current/Current • Current/ANDA • Current/Developing • ANDA/Developing	5-to-4; 4-to-3	10
Bristol-Myers Squibb/Celgene	11/15/19	$74 B	Brand	• Current/Phase 3	Not applicable	1
AbbVie/Allergan	5/5/20	$63 B	Brand	• Current/Current • Phase 3/Phase 2	4-to-3	3
Pfizer/Mylan	10/30/20	$12 B	Generic	• Current/Current • Current/Exited ANDA • Current (brand)/Pending ANDA	5-to-4; 4-to-3; 3-to-2	7

[1] Excludes mergers in which relief obtained involved plasma-derived products, medical devices, over-the-counter products, long-term-care pharmacy services, and animal health products. Sources include the Dechert Antitrust Merger Investigation Timing Tracker (DAMITT); FTC complaints and analyses to aid public comment; company press releases.

[2] Refers to the date of the first FTC action, which, for the vast majority of the identified matters, means the date on which the FTC accepted a consent order for public comment.

[3] Indicates whether the predominant focus of the FTC's competitive analysis is on branded or generic drug competition.

[4] "Current" refers to a firm with commercial sales. "ANDA" refers to a firm with an FDA-approved generic product but that has not yet made any commercial sales. "Exited ANDA" refers to a firm that formerly made commercial sales and still holds the ANDA. "Pending ANDA" refers to a firm that has filed an ANDA with the FDA but has not obtained approval for the ANDA. "Developing" refers to a firm with a branded or generic product in development. Because public-facing FTC materials typically do not identify the exact stage of development of pre-approval drugs, this could be anywhere from pre-clinical to Phase III (in the case of branded drugs) or near ANDA approval (in the case of generic drugs). "Pre-generic market" indicates that there are no generic drug companies—including both the merging parties and competitors—that have made any commercial sales.

[5] Includes divestitures of product rights and/or assets, long-term supply agreements, product licenses, and terminations or returns of rights to market a product. For purposes of this analysis, we count separate dosages of a particular drug product as a single product.

[6] The FTC pursued this consummated acquisition under Sherman Act Section 2. The deal value was reported to be $135 million, with potential upside, depending on the relevant product achieving certain milestones.