# Entrenching and Leveraging Market Dominance in the 2023 Merger Guidelines: Insights from Amgen/Horizon

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In December 2023, the Federal Trade Commission and Department of Justice (jointly, the Agencies) released revised merger guidelines (2023 Merger Guidelines).[1] The 2023 Merger Guidelines present 11 guidelines regarding how the Agencies will evaluate the risk that a merger may limit competition.[2] Guideline 6 introduces a concern that mergers may entrench or extend a firm's existing dominant position and thus cause anticompetitive harm, but the guideline does not provide a clear analytical framework for assessing the effects of such market dominance on post-merger competition.[3] Prior merger guidelines do not resolve this ambiguity, as they do not discuss dominance-based theories of anticompetitive harm.

Given Guideline 6's novel theories of harm and paucity of analytical framework, the FTC's May 2023 challenge to Amgen Inc.'s acquisition of Horizon Therapeutics provides helpful insight. In the Amgen/Horizon merger challenge, the FTC pursued a dominance-based theory akin to the concern described in Guideline 6: namely, the risk that merging parties could leverage existing dominance in one market to extend dominance to another market via bundling.[4] As a result, the factors, analysis, and considerations relevant to the assessment of anticompetitive harm in the Amgen/Horizon merger challenge provide a model for the factors, considerations, and analysis that could arise in future Agency challenges based on a Guideline 6 theory of harm involving leveraging via bundling. The analysis in the Amgen/Horizon merger challenge ultimately reveals that, when a Guideline 6 theory involves foreclosure of competition, as is the case with a theory of leveraging via bundling, many of the "ability and incentive to foreclose" analyses set out in another guideline, Guideline 5, will apply.

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1 Press Release, Fed. Trade Comm'n, Federal Trade Commission and Justice Department Release 2023 Merger Guidelines (Dec. 18, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/federal-trade-commission-justice-department-release-2023-merger-guidelines.

2 U.S. Dep't of Justice & Federal Trade Comm'n, Merger Guidelines (2023), https://www.ftc.gov/system/files/ftc_gov/pdf/P234000-NEW-MERGER-GUIDELINES.pdf, at 2-3.

3 2023 Merger Guidelines, *supra note 2*, at 3.

4 2023 Merger Guidelines, *supra note 2*, at 21; Press Release, Fed. Trade Comm'n, FTC Sues to Block Biopharmaceutical Giant Amgen from Acquisition That Would Entrench Monopoly Drugs Used to Treat Two Serious Illnesses (May 16, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-sues-block-biopharmaceutical-giant-amgen-acquisition-would-entrench-monopoly-drugs-used-treat (FTC Amgen-Horizon Press Raelease); Complaint for Temporary Restraining Order and Preliminary Injunction Pursuant to Section 13(b) of the Federal Trade Commission Act, *Fed. Trade Comm'n v. Amgen Inc. and Horizon Therapeutics Plc*, No. 23-CV-3053 (N.D. Ill. May 16, 2023) (Complaint); Complaint, *In the Matter of Amgen Inc., and Horizon Therapeutics Plc.*, Dkt. No. 9414 (Fed. Trade Comm'n June 22, 2023) (FTC Administrative Complaint).

## The 2023 Merger Guidelines introduce an expanded set of potential antitrust concerns, including entrenchment and leveraging of market dominance (Guideline 6), but provide little guidance on the analysis necessary to evaluate these concerns

The Agencies' stated intentions in releasing a new set of merger guidelines were to update the merger guidelines (i) to more comprehensively reflect the ways in which anticompetitive harm can arise from a merger in the modern economy and (ii) to expand the Agencies' toolkit to better reflect this wider range of potential concerns.[5] In implementing these goals with the 2023 Merger Guidelines, the Agencies departed from previous merger guidelines by presenting 11 guidelines regarding how the Agencies will approach the question: "How do firms in this industry compete, and does the merger threaten to substantially lessen competition or to tend to create a monopoly?"[6] The 2023 Merger Guidelines indicate that Guidelines 1–6 identify "frameworks the Agencies use to identify that a merger raises prima facie concerns."[7] Some of the frameworks in these six Guidelines align fairly closely with frameworks of anticompetitive harm articulated in prior merger guidelines, such as the 2010 Horizontal Merger Guidelines (HMG) or the 2020 Vertical Merger Guidelines (VMG).[8] Others, such as Guideline 6, introduce more novel frameworks of anticompetitive harm.

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In particular, Guideline 6 discusses a variety of dominance-based theories that can lead to the anticompetitive effects of "Entrenching a Dominant Position" and "Extending a Dominant Position into Another Market."[9] The theories include, for example, the acquisition of nascent competitive threats,[10] the acquisition and subsequent degradation of services that allow for use of products from multiple providers (i.e., "multi-homing"),[11] and the exclusion of rivals through "tying, bundling, conditioning, or otherwise linking sales of two products."[12]

While Guideline 6 introduces these new theories of anticompetitive harm, it provides little direction on the economic analysis needed to assess their competitive effects in a merger. When the Agencies invited comments on their initial draft merger guidelines (Draft Merger Guidelines), which were released in July 2023 and included proposed Guideline 6 (as Guideline 7 in the Draft Merger Guidelines), several commentators, ranging from academics to practitioners, noted the dearth of direction regarding relevant economic analysis for the Guideline 6 theories of harm.[13] Guideline 6's lack of direction on economic analysis stands in contrast to the Agencies' approach for other

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5 Press Release, Fed. Trade Comm'n, FTC and DOJ Seek Comment on Draft Merger Guidelines (July 19, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-doj-seek-comment-draft-merger-guidelines.

6 2023 Merger Guidelines, *supra note 2*, at 2.

7 *Id.* at 2.

8 For example, the "ability and incentive" framework set out in Guideline 5 closely aligns with the "Foreclosure and Raising Rivals' Costs" framework that the Agencies set out in the 2020 VMG for the assessment of theories of competitive foreclosure. See U.S. Dep't of Justice & Federal Trade Comm'n, Vertical Merger Guidelines (2020), https://www.ftc.gov/system/files/documents/public_statements/1580003/vertical_merger_guidelines_6-30-20.pdf, at 4–5.

9 2023 Merger Guidelines, *supra note 2*, at 19–21.

10 *Id.* at 20.

11 *Id.* at 19.

12 *Id.* at 21.

13 Herbert Hovenkamp, *The 2023 Draft Merger Guidelines: A Review* 4–5, 10 (Sept. 8, 2023); Fiona Scott Morton, *Comments on the 2023 draft merger guidelines* 5 (Sept. 18, 2023); Carl Shapiro, *Recommended Revisions to the Draft Merger Guidelines* 9 (Sept. 14, 2023); Jeremy Nighohossian, Susan Manning, Andrea Chung, and Sabiha Quddus, FTI, *Draft Merger Guidelines (FTC-2023-0043)*, at 6 (Sept. 18, 2023); Ana McDowall, Lorenzo Michelozzi, and Andrew Sfekas, Cornerstone Research, *Comments on the 2023 Draft Merger Guidelines* 12 (Sept. 14, 2023).

guidelines, such as Guideline 2 about unilateral effects and Guideline 5 about foreclosure effects. Appendix 2 sets out the tools that can be used to evaluate the loss of competition between merging firms (the analytical framework linked to Guideline 2 in the 2023 Merger Guidelines). Similarly, Guideline 5 sets out the "ability and incentive framework" for evaluating the risk of competitive foreclosure.

Given Guideline 6's paucity of recommended economic analyses, evaluating an actual merger challenge brought under a Guideline 6 theory is a helpful way to understand the factors, considerations, and analysis that are likely to be relevant in a Guideline 6 challenge. The FTC's May 2023 challenge of the Amgen/Horizon merger under the Guideline 6 theory of leveraging via bundling is such an example. As such, the Amgen/Horizon merger challenge provides insight on how to assess a theory of excluding rivals through "tying, bundling, conditioning, or otherwise linking sales of two products."[14] The subsequent sections of this article discuss the analysis in the Amgen/Horizon merger challenge and the insights it provides for evaluating this novel theory of anticompetitive harm.

## The FTC's May 2023 Amgen/Horizon merger challenge has several characteristics consistent with the dominance-based theory of leveraging via bundling in Guideline 6

On May 16, 2023, the FTC challenged biotechnology firm Amgen's acquisition of another biotechnology firm, Horizon Therapeutics.[15] At the time, Amgen had approximately $26 billion in total revenue and a portfolio of 27 pharmaceutical products approved by the U.S. Food and Drug Administration.[16] Amgen's portfolio did not include pharmaceutical products designed to treat rare diseases.[17] Horizon, on the other hand, had total revenue of $3.6 billion[18] and "market[ed] and distribute[d] 11 drug products in the United States," with a "focus[] on medicines treating rare, autoimmune, and severe inflammatory diseases."[19] Horizon's two top-selling products were Tepezza, a treatment for thyroid eye disease (TED), which had 2022 sales of $2.0 billion, and Krystexxa, a treatment for chronic refractory gout (CRG), which had 2022 sales of $716 million.[20] Both Tepezza and Krystexxa were the only FDA-approved drugs in their therapeutic areas and both had some form of U.S. patent protection until at least 2027, according to publicly available sources.[21]

The FTC's challenge to the proposed acquisition centered on the FTC's claim that "the [a]cquisition would enable Amgen to leverage its portfolio of blockbuster drugs [drugs with over

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[14] 2023 Merger Guidelines, *supra note 2*, at 21.

[15] In its May 16, 2023, complaint filed in federal court, the FTC sought to enjoin the acquisition. Complaint, *supra* note 4, at 1. On June 22, 2023, the FTC filed a second complaint via its administrative process seeking the same outcome based on arguments substantively the same as those articulated in its May 2023 complaint. FTC Administrative Complaint, *supra* note 4, at 17.

[16] Amgen Inc., 2022 Letter to Shareholders and SEC Form 10-K (Mar. 18, 2023), https://investors.amgen.com/static-files/cb90e5d6-72b9-4291-ba59-85281072b4be, at 2; FTC Amgen-Horizon Press Release, *supra* note 4.

[17] The Orphan Drug Act considers a disease "rare" if it affects fewer than 200,000 people in the United States. *See* U.S. Food and Drug Administration, Rare Diseases at FDA (Dec. 13, 2022), https://www.fda.gov/patients/rare-diseases-fda.

[18] Horizon Therapeutics plc, 2022 SEC Form 10-K (Mar. 1, 2023), 108.

[19] FTC Amgen-Horizon Press Release, *supra* note 4.

[20] Horizon Therapeutics plc, 2022 SEC Form 10-K, 5.

[21] *See* Jillian Dabney, *Introducing Krystexxa, the Latest Addition to Horizon's Orphan Portfolio*, Yahoo! Finance (Mar. 31, 2016), https://finance.yahoo.com/news/introducing-krystexxa-latest-addition-horizon-160847869.html; U.S. Patent and Trademark Office, Certificate Extending Patent Term, Product: Tepezza, Patent No. 7,572,897 (Oct. 18, 2023), https://ppubs.uspto.gov/dirsearch-public/print/downloadPdf/7572897.

*Because the Amgen/Horizon merger challenge is consistent with Guideline 6's theory of leveraging dominance via bundling, the factors, considerations, and analysis that arose in it could be relevant to assessing the competitive effects in a future Guideline 6 challenge based on a theory of leveraging dominance via bundling.*

$1 billion in 2022 sales] to foreclose actual or potential rivals to Horizon's top-selling medications [Tepezza and Krystexxa], thereby substantially lessening competition in the markets for the sale of FDA-approved drugs to treat TED and CRG."[22] In particular, the FTC claimed that Amgen would provide its customers—pharmacy benefits managers (PBMs) and third-party payers (e.g., insurers)—bundled discounts on its blockbuster drugs in exchange for favorable treatment of Tepezza and Krystexxa over other products in the same therapeutic areas on the customers' formularies, once other products were available.[23] These bundled discounts, the FTC claimed, could "foreclose or disadvantage future rivals in these markets, raise their barriers to entry, and dissuade them from competing aggressively,"[24] thereby "sustain[ing] and entrench[ing] Horizon's dominance in the markets for FDA-approved drugs to treat TED and CRG."[25]

Thus, the FTC alleged that Amgen would extend its purported dominance in the markets of its blockbuster drugs to entrench the dominance of Tepezza and Krystexxa in the markets for TED and CRG. This is consistent with Guideline 6's theory of extending a dominant position in one market to another market by "tying, bundling, conditioning, or otherwise linking sales of two products" to exclude rival firms and substantially lessen competition in the second market.[26]

## The Amgen/Horizon merger challenge sheds light on the factors, considerations, and analysis that could be relevant in a Guideline 6 challenge based on a theory of leveraging via bundling

Because the Amgen/Horizon merger challenge is consistent with Guideline 6's theory of leveraging dominance via bundling, the factors, considerations, and analysis that arose in it could be relevant to assessing the competitive effects in a future Guideline 6 challenge based on a theory of leveraging dominance via bundling. These factors, considerations, and analysis are: (i) the logistical feasibility of the potential bundling, (ii) the market power of the "anchor" product, (iii) product differentiation and the likelihood that the bundle will steer buyers to the merged firm's "protected" product, (iv) institutional features of the "anchor" and "protected" product markets that can affect the incentives for bundling, and (v) the potential impact of the bundled incentives and the merger more generally on anticompetitive harm. An assessment of these factors can help determine whether a theory of leveraging dominance via bundling could lead to anticompetitive harm in a particular merger.

In the Amgen/Horizon merger challenge, as the below discussion demonstrates, with each of these factors, some evidence was inconsistent with the alleged anticompetitive effects of the proposed merger. Ultimately, the FTC and the merging parties entered into a consent decree allowing the merger to proceed, subject to certain conditions.[27] As part of the consent decree, Amgen and Horizon agreed to several terms. First, they agreed not to engage in the types of bundled incentives that concerned the FTC—namely, Amgen offering discounts on its blockbuster drugs in exchange

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[22] Complaint, *supra* note 4, ¶ 1.

[23] Complaint, *supra* note 4, ¶¶ 10, 66.

[24] Complaint, *supra* note 4, ¶ 59.

[25] Complaint, *supra* note 4, ¶ 10.

[26] 2023 Merger Guidelines, *supra note 2*, at 21.

[27] Press Release, Amgen, Amgen and Horizon Therapeutics plc Resolve FTC Lawsuit, Clearing Path to Close Acquisition (Sept. 1, 2023), https://www.amgen.com/newsroom/press-releases/2023/09/amgen-and-horizon-therapeutics-plc-resolve-ftc-lawsuit-clearing-path-to-close-acquisition.

for preferential treatment of Tepezza and Krystexxa.[28] Amgen had publicly stated as early as May 2023, when the FTC filed its complaint, that such bundling was "entirely speculative, . . . [did] not reflect the real world competitive dynamics behind providing rare-disease medicines to patients," and Amgen "would not bundle the Horizon products raised as issues."[29] Second, Amgen and Horizon agreed to notify the FTC if Tepezza and Krystexxa become available for self-administration or as pharmacy-benefit drugs, the latter of which affects Amgen's incentive and ability to create a bundled discount involving the blockbuster drugs and Tepezza or Krystexxa, as discussed below.[30] Third, they agreed to obtain prior approval from the FTC for the purchase of any drug that treats TED or CRG.[31]

***The logistical feasibility of potential bundling.*** An initial consideration in a theory of leveraging via bundling is whether the potential bundle is logistically feasible. For example, do the products in the potential bundle have many of the same customers? If not, then the potential bundle would be difficult to implement because a customer has no reason to accept favorable terms on one product in exchange for receiving favorable terms on another product for which the customer has little use.

In the Amgen/Horizon merger challenge, the FTC alleged that the merged entity would implement a bundle involving a discount on Amgen's blockbuster drugs, which were pharmacy benefit drugs (i.e., drugs dispensed in a pharmacy), in exchange for preferential formulary treatment of Horizon's two top-selling, rare-disease drugs, which were medical benefit drugs (i.e., drugs dispensed in a medical facility, such as a hospital).[32] For insured individuals, pharmacy benefit drugs and medical benefit drugs are often covered, or at least managed, by different entities, even if the insured individual pays a single premium to a single entity.[33] Hence, a bundled offer from a merged Amgen/Horizon would not be attractive to a PBM or payer that covered or managed only one type of drug, or that used separate entities to manage the two different types of drugs. For example, a payer that managed only medical benefit drugs would not gain anything by restricting access to one of its medical benefit drugs in exchange for discounts that it would not receive because it did not manage pharmacy benefit drugs.

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[28] Public Decision and Order, *In the Matter of Amgen Inc., and Horizon Therapeutics Plc.*, Dkt. No. 9414 (Fed. Trade Comm'n Dec. 13, 2023) (Decision and Order), Section II. As part of this agreement not to engage in bundled rebating, Amgen and Horizon also agreed to compliance monitoring, including (i) submitting to a compliance monitor all of their contracts with payers related to Tepezza and Krystexxa, (ii) having their personnel who contract for Tepezza and Krystexxa review the consent decree, (iii) providing information on the prohibition of bundled discounts to any third parties who contract for Tepezza and Krystexxa, and on the merged entity's website, and (iv) providing written compliance reports at several points during the first year following the merger and annually for the next 14 years. *See* Decision and Order, Sections III.A.1, III.B, III.C, and VI.A.

[29] Press Release, Amgen, Amgen Responds to FTC Action Re: Proposed Acquisition of Horizon Therapeutics (May 16, 2023), https://www.amgen.com/newsroom/press-releases/2023/05/amgen-responds-to-ftc-action-re-proposed-acquisition-of-horizon-therapeutics.

[30] Decision and Order, *supra* note 30, Section III.A.2.

[31] Decision and Order, *supra* note 30, Section V.

[32] Complaint, *supra* note 4, ¶ 1.

[33] Pharmacy benefit drugs are often managed by PBMs, while medical benefit drugs are usually managed by insurers. Even if an insurer is vertically integrated with a PBM, in most cases, "[c]overage under the medical benefit occurs independent of the plan's PBMs," and vice versa. Biomatrix, Understanding Specialty Drug Coverage: Medical and Pharmacy Benefit (Nov. 21, 2023), https://www.biomatrixsprx.com/news/understanding-specialty-drug-coverage-medical-and-pharmacy-benefit. For example, even after Cigna's acquisition of Express Scripts Inc. in 2018, Cigna's pharmacy benefit covered over 98 million lives, while Cigna's medical benefit covered only about 20 million lives. Press Release, Cigna, The Cigna Group Reports Strong Third Quarter 2023 Results, Raises 2023 Adjusted EPS, Revenue, and Cash Flow Outlook, (Nov. 2, 2023), https://www.prnewswire.com/news-releases/the-cigna-group-reports-strong-third-quarter-2023-results-raises-2023-adjusted-eps-revenue-and-cash-flow-outlook-301975561.html.

***The market power of the "anchor" product.*** If the bundled incentives are logistically feasible, then a second question arises as to the market power of the "anchor" product in the potential bundle. The anchor product is the product that the merged entity will allegedly use—often, by giving a discount on it—to lessen competition in the market of a "protected" product. The anchor product needs to have sufficient market power in its own market to persuade customers to adopt the bundle rather than to continue to use competitor products in the protected product market.

In the Amgen/Horizon merger challenge, a question arose as to the market power of the potential anchor products the FTC identified. The FTC identified as potential anchor products Amgen's "blockbuster" drugs, which were drugs with $1 billion or more in 2022 revenue.[34] The FTC claimed that, "[d]ue to the enormous sales and consistent volume of Amgen's blockbuster drugs—such as Enbrel, which last year generated over $4 billion in global sales—even small enhancements to rebates can ensure payers accept such [bundled] contracts."[35] But it was not clear that these blockbuster drugs had market power in their therapeutic areas, let alone that they would have it in the future, when potential competitors were expected to enter the markets for TED and CRG. In its 2022 annual report, Amgen described the substantial competition its blockbuster drugs faced. Enbrel, Amgen's highest-revenue blockbuster drug in 2022 ($4.1 billion), had multiple branded competitor drugs in its therapeutic area (rheumatoid arthritis and psoriatic arthritis), as well as existing and expected future competition from biosimilar products, which are non-branded products similar to a branded biologic product.[36] Enbrel was also one of the ten drugs that the Inflation Reduction Act identified in August 2023 as a drug for which Medicare could negotiate prices.[37] This put further potential price pressure on Enbrel, thereby further diminishing the appeal of conditional discounts on it and its attractiveness as an anchor product in a future bundled discount.

Similarly, Amgen's other blockbuster drugs faced competitive pressures, making them less viable as anchor products as well. Amgen's denosumab drugs (bone loss treatment drugs)—Prolia ($3.6 billion in 2022 revenue; its second-highest revenue product) and Xgeva ($2.0 billion; its fourth-highest revenue product)[38]—compete with generic drugs and will likely face biosimilar competition in the future, as the FDA accepted an application for a denosumab biosimilar from Sandoz in February 2023, and other denosumab biosimilars are in the final phases of drug

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[34] Complaint, *supra* note 4, ¶ 60.

[35] *Id.* at ¶ 4.

[36] Amgen Inc., 2022 SEC Form 10-K, FY 2022, (Feb. 9, 2023), at 8-9, 59, https://investors.amgen.com/static-files/0a0104cc-6a5d-4afa-b4c2-558adc8a4e9b; Lucy Hicks, *Humira Biosimilars: Five Things to Know*, MEDSCAPE (July 18, 2023), https://www.medscape.com/viewarticle/994498?form=fpf; Press Release, U.S. Food and Drug Administration, FDA approves Erelzi, a biosimilar to Enbrel (Aug. 30, 2016), https://www.fda.gov/news-events/press-announcements/fda-approves-erelzi-biosimilar-enbrel; *FDA approves etanercept biosimilar Eticovo*, Generics and Biosimilars Initiative (Mar. 5, 2019), https://www.gabionline.net/biosimilars/news/FDA-approves-etanercept-biosimilar-Eticovo; *Etanercept biosimilars delayed until 2029 in US*, Generics and Biosimilars Initiative (Jan. 14, 2022), https://www.gabionline.net/biosimilars/news/etanercept-biosimilars-delayed-until-2029-in-us.

[37] Press Release, U.S. Dep't of Health and Human Services, HHS Selects the First Drugs for Medicare Drug Price Negotiation (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

[38] Amgen Inc., 2022 SEC Form 10-K (Feb. 9, 2023), at 59.

development, Phase 3 clinical trials.[39] Likewise, Amgen's public filings assert that Otezla ($2.3 billion; its third-highest revenue product) and Repatha ($1.3 billion; its seventh-highest revenue product) [40] operate in "highly competitive" environments with branded competition and, in the case of Otezla, face generic and biosimilar competition.[41] The remaining four Amgen blockbuster drugs also faced competition from branded products and, in two cases, biosimilars.[42]

Thus, in the Amgen/Horizon merger challenge, the dominance of the proposed anchor products in their own markets, particularly in the future, when the alleged bundled discounts would purportedly have taken place, was not clear. This uncertainty made it less likely that the merged entity could have used a bundled discount to bring about anticompetitive harm in the protected product's market.

***Product differentiation and the likelihood that the bundle will steer buyers to the merged firm's "protected" product.*** A third factor in the Amgen/Horizon merger challenge that was relevant to assessing the competitive effects of the leveraging via bundling theory of harm was the type of competition in the "protected" product's market. The extent of product differentiation among competitors in the protected product's market was important because that competition affects the incentive of a merged entity to implement a bundled incentive. This is especially true if certain customer characteristics impact the willingness or ability of customers to switch away from the bundled products, as that willingness affects the profitability and attractiveness of a potential bundle to the merged entity.

The more differentiated the competitor products are from the protected product, the less profitable is a bundling strategy for a merged entity. This is because, all else equal, customers will be more reluctant to switch away from rival products to the protected product if the customers do not see the protected product as a close substitute. Less substitutability therefore makes it more costly for the merged firm to "poach" customers from rivals, and correspondingly reduces the upside of a bundled incentive. A lack of substitutability can arise particularly often in the healthcare setting, where individual patients respond differently to different treatments and a lack of access to the best treatment option for an individual can have negative health consequences.

In the Amgen/Horizon merger challenge, this issue arose because, according to the FTC, the competitors that the protected products—Tepezza and Krystexxa—were expected to face were differentiated products. In the TED market, the FTC identified four differentiated competitor

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[39] Press Release, Sandoz, Sandoz Biologics License Application for proposed biosimilar denosumab accepted by US FDA (Feb. 6, 2023), https://www.novartis.com/news/media-releases/sandoz-biologics-license-application-proposed-biosimilar-denosumab-accepted-us-fda; *see also, e.g.*, A Phase 3 Study to Compare Between CT-P41 and US-licensed Prolia in Postmenopausal Women With Osteoporosis, ClinicalTrials.gov (Aug. 2023), https://classic.clinicaltrials.gov/ct2/show/NCT04757376?term=CT-P41&draw=2&rank=2; A Study to Test if TVB-009P is Effective in Relieving Postmenopausal Osteoporosis, ClinicalTrials.gov (June 2023), https://classic.clinicaltrials.gov/ct2/show/NCT04729621; Skylar Jeremias, *FDA Accepts Sandoz Denosumab BLA for Review*, AJMC - THE CENTER FOR BIOSIMILARS (Feb. 6, 2023), https://www.centerforbiosimilars.com/view/fda-accepts-sandoz-denosumab-bla-for-review.

[40] Amgen Inc., 2022 SEC Form 10-K (Feb. 9, 2023), at 59.

[41] *Id.* at 8–10. For additional evidence of the competition between Repatha and Praluent, *see, e.g.*, Caroline Humer, *CVS chooses Amgen's new cholesterol drug over competitor*, REUTERS (Nov. 23, 2015), https://www.reuters.com/article/us-cvs-health-amgen/cvs-chooses-amgens-new-cholesterol-drug-overcompetitor-idINKBN0TC28I20151123; Gerardo Sison, *Praluent vs. Repatha: Differences, similarities, and which is better for you*, SingleCare (May 16, 2023), https://www.singlecare.com/blog/praluent-vs-repatha/; Amber R. Watson, *Repatha vs. Praluent*, MedicalNewsToday (Jan. 26, 2023), https://www.medicalnewstoday.com/articles/drugs-repatha-vs-praluent; Arlene Weintraub, *Amgen escalates PCSK9 pricing war with permanent 60% price cut on Repatha*, FIERCE PHARMA (Oct. 25, 2019), https://www.fiercepharma.com/pharma/cholesterol-war-escalates-as-amgen-makes-60-price-cut-repatha-permanent.

[42] Amgen Inc., 2022 SEC Form 10-K (Feb. 9, 2023), at 9.

products to Tepezza that were in the later stages of the FDA-approval process in mid-2023.[43] The first drug, VRDN-001, manufactured by Viridian Therapeutics, Inc. and in clinical trials, had data that "suggest[ed] that it could have a higher … overall response than Tepezza after [six] weeks of treatment."[44] Three other Viridian drugs in development were subcutaneous products that would "more conveniently administer[] therapy to patients with TED."[45] Another product, Immunovant Inc.'s Batoclimab, would provide an even more convenient administration of TED therapy via a self-administered, subcutaneous injection.[46] In addition, Horizon noted in its 2022 annual report a Sling Therapeutics oral product for TED that was in a Phase 2b study.[47] Similarly, for the treatment of CRG, the latest-stage competitor product in development, Selecta Biosciences Inc.'s SEL-212, was differentiated from Krystexxa. According to the FTC, SEL-212 had a "favorable differentiated profile in safety and durability" compared to Krystexxa.[48] These sources of differentiation made it less likely that Tepezza's and Krystexxa's customers—PBMs and payers—would be willing to exclude the competitor products from formularies. Such customer reluctance would make the alleged bundle more difficult for the merged entity to implement.

In addition, it is relevant that the protected products, TED and CRG, are both treatments for rare diseases.[49] Rare diseases tend to be treated by specialists with detailed expertise in the relative benefits of each drug option and, therefore, firmer views on which drugs are suitable for particular kinds of patients.[50] When physicians have stronger preferences for particular drugs, payers may face greater risk of physician backlash when excluding treatments from formulary lists. The greater prevalence of treatment by specialist physicians in the markets for Tepezza and Krystexxa made it less likely that future rivals to these products would be excluded, as the FTC alleged they would as part of the potential bundle.

***Institutional features of the "anchor" and "protected" product markets that can affect the incentives for bundling.*** Beyond competition, institutional features of the markets for the protected and anchor products can also affect the ability and incentive to bundle. For example, certain government regulations can reduce or enhance the profitability of a potential bundle.

Consideration of institutional features like these in the markets for the anchor and protected products arose in the Amgen/Horizon merger challenge because federal rules for reimbursing physician-administered drugs reduced the long-term profitability of the potential bundle. Medicare reimburses providers for provider-administered drugs like Tepezza and Krystexxa according to the drugs' "average sales price" (ASP) in the commercial market. ASP, a term defined by the Centers

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[43] Complaint, *supra* note 4, ¶¶ 53–56.

[44] *Id.* at ¶ 54.

[45] *Id.* at ¶ 55.

[46] *Id.* at ¶ 56.

[47] Horizon Therapeutics plc, 2022 SEC Form 10-K, at 7.

[48] Complaint, *supra* note 4, ¶ 58.

[49] TEPEZZA received an orphan drug designation from the FDA for the treatment of TED in 2013. Search Orphan Drug Designations and Approvals, FDA, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=387812. KRYSTEXXA received an orphan drug designation from the FDA for the treatment of CRG in 2001. Search Drug Orphan Designations and Approvals, FDA, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=135600.

[50] For instance, the TEPEZZA website notes that not all eye doctors are "used to" treating TED, and most endocrinologists do not treat TED either. Eye specialists such as oculoplastic surgeons or neuro-ophthalmologists are more likely to have experience treating TED. Thyroid Eye Disease Specialists, Tepezza, https://www.tepezza.com/thyroid-eye-disease/thyroid-eye-disease-specialists. The KRYSTEXXA website notes that CRG is treated by rheumatologists. Find a Gout Specialist, Krystexxa, https://www.krystexxahcp.com/rheumatology/support-and-resources/find-a-gout-specialist.

for Medicare and Medicaid Services (CMS), measures prices inclusive of almost all rebates and discounts to private third-party payers and providers.[51] Drug manufacturers calculate the ASP for each of their provider-administered drugs quarterly and report the ASPs to CMS, which publishes the ASPs.[52] Medicare and many private third-party payers then use the published ASPs in formulas that determine reimbursement amounts for providers.[53] For example, beginning in 2013, Medicare reimbursed providers for most provider-administered drugs based on the drug's ASP plus 4.3 percent (i.e., reimbursing at 104.3 percent of ASP).[54]

Notable for the Amgen/Horizon merger challenge, when calculating ASP in the presence of a bundle, CMS also requires that all of the drugs in the bundle receive a single discount percentage based on "the total dollar value of the units of all drugs or products sold under the bundled arrangement."[55] This means that, if the merged entity were to offer the bundled discounts that the FTC alleged, with discounts to payers on the Amgen "blockbuster" drugs and no discounts on Tepezza and Krystexxa, then the ASPs of Tepezza and Krystexxa would still fall, even without discounts on those two drugs, because of the bundle.

Discounts to payers on provider-administered drugs like Tepezza and Krystexxa can lead to an "ASP death spiral." Such discounts mechanically lower a drug's ASP and, in turn, ASP-based reimbursement to providers, but leave provider acquisition and administration costs unchanged. This, in turn, makes a drug less profitable to providers because it costs the same but commands lower reimbursement. To prevent or remediate financial losses to providers, the drug manufacturer must therefore increase provider discounts. But this fresh round of provider discounts further lowers ASP and drives down provider reimbursement anew, leading to even more provider discounts necessary to keep provider reimbursement above provider costs. The continual decrease in ASP that results is known as an ASP death spiral.

Accordingly, the extent to which providers of Tepezza and Krystexxa received ASP-based reimbursement was a factor in the Amgen/Horizon merger challenge—because the greater the prevalence of ASP-based reimbursement, the greater the risk that bundled incentives from the merged entity would trigger an ASP death spiral for Tepezza and Krystexxa. Hence, the prevalence of ASP-based reimbursement affected the merged entity's incentive to engage in the alleged bundled incentives. More generally, institutional features of the anchor and protected product markets are likely to be important when evaluating a merger challenge based on a leveraging via bundling theory.

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[51] For a description of the methodology of computing ASP, see, e.g., *Use of Average Sales Price Payment Methodology*, Social Security Administration, https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm; 42 C.F.R. § 414.904.

[52] 42 C.F.R. § 414.904 at (5)(A); s*ee also* Susan Weidner, et al., *Observations Regarding the Average Sales Price Reimbursement Methodology*, 27 EVIDENCE-BASED ONCOLOGY SP156, SP156(2021) [hereinafter "Weidner, et al. (2021)"].

[53] For a discussion of Medicare's use of ASPs in determining provider reimbursement, see Weidner, et al. (2021), *supra* note 54, at SP156. The ASP reimbursement rate for Medicare was previously set at six percent but was lowered in 2013 following the implementation of budget sequestration measures. *See* Weidner, Susan, et al. (2021), *supra* note 54, at SP156. For a discussion of third-party payers using ASPs in determining provider reimbursement, see NEWDIGS at Tufts Medical Center FoCUS Project, *Analyzing 340B and ASP interactions: Do Federal program rules disincentivize the use of VBCs, despite Medicaid Best Price reform?*, NEWDIGS FoCUS (Oct. 9, 2023), https://newdigs.tuftsmedicalcenter.org/wp-content/uploads/2023/10/NEWDIGS-Analyzing-340B-and-ASP-Interactions-2023F210v057.pdf, at 2; and Bryan Johnson, *Site of Care Optimization*, National Infusion Center Association (May 2, 2019), https://infusioncenter.org/infusion-center-news/site-of-care-optimization/.

[54] *See* Weidner, Susan, et al. (2021), *supra* note 54, at SP156.

[55] Dep't of Health & Human Services, Center for Medicare & Medicaid Services, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5169 (Feb. 1, 2016), at 5348.

***The potential impact of the bundled incentives and the merger more generally on anticompetitive harm.*** In assessing the anticompetitive harm that bundled incentives—and the merger more generally—can generate, a useful point of comparison remains the world without the bundled incentives or the merger. Were the bundled incentives and the merger necessary conditions for an increase in market power and anticompetitive harm? Or could one of the entities in the merger increase its alleged market power or cause similar, alleged anticompetitive harm with single-product incentives (e.g., single-product discounts)? Ultimately, a dollar paid by the merged entity to a customer via a bundled incentive is worth no more or less to the customer—or competition generally—than a dollar paid via a traditional discount on just the protected product. If the protected product's pre-merger profits exceed what the merged entity would allegedly pay as an anticompetitive bundled incentive, then the protected product firm could foreclose competition without the merger because the firm has the financial resources to offer discounts large enough to drive its rivals out of the marketplace. In that case, the protected product firm would not need bundled discounts or the merger to inflict the purported anticompetitive harm. It could simply foreclose competitors by offering a single-product discount. On the other hand, if excluding rivals would require the merged entity to pay a bundled incentive that outstrips the pre-merger profits of the "protected" product, then the pre-merger, single product firm lacks the ability to exclude rivals. And if the merged entity possesses the ability to provide a sufficiently large discount through a bundled incentive, then the merged entity could uniquely exclude rivals. However, in this scenario, the bundled discounts could serve as predatory pricing of the "protected" product because the manufacturer may effectively be pricing the "protected" product below its marginal cost. Predatory pricing is illegal conduct that could be addressed after the merger if the merged entity appeared to be engaging in such conduct to eliminate competitors.[56]

*In the Amgen/Horizon merger challenge, this fundamental question was relevant: could Horizon alone profitably offer discounts on Tepezza and Krystexxa that were large enough to foreclose potential future competitors, or were the merger and the alleged bundled discounts required for the anticompetitive harm?*

In the Amgen/Horizon merger challenge, this fundamental question was relevant: could Horizon alone profitably offer discounts on Tepezza and Krystexxa that were large enough to foreclose potential future competitors, or were the merger and the alleged bundled discounts required for the anticompetitive harm? If Horizon could profitably offer single-product discounts on its own that would foreclose competition, then there were not any incremental anticompetitive effects of the potential bundle or the merger.

## Can Guideline 5 provide a roadmap for evaluating future leveraging via bundling challenges brought under Guideline 6?

The theory of leveraging dominance via bundling is ultimately a theory of competitive foreclosure, a broader concern addressed in Guideline 5 of the 2023 Merger Guidelines. Some commenters to the Draft Merger Guidelines remarked that there was overlap between Guidelines 5 and 7, the latter of which became Guideline 6 in the 2023 Merger Guidelines.[57] In this section, we evaluate

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[56] Predatory or Below-Cost Pricing, FTC, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/single-firm-conduct/predatory-or-below-cost-pricing.

[57] *See, e.g.,* Carl Shapiro, *Recommended Revisions to the Draft Merger Guidelines* 9 (Sept. 14, 2023) ("For non-horizontal mergers that entrench a dominant position . . . Guideline 5 can and should address this latter category of harmful mergers."); Fiona Scott Morton, *Comments on the 2023 draft merger guidelines* 5 (Sept. 18, 2023) ("Guideline 7 [Guideline 6 in the 2023 Merger Guidelines] also seems to duplicate Guidelines 5 and 6 because the acquisition of an asset that could be used to foreclose or raise rivals' costs could also entrench a dominant position or extend it into an adjacent market."); Ana McDowall, Lorenzo Michelozzi, and Andrew Sfekas, Cornerstone Research, Comments on the 2023 Draft Merger Guidelines 13 (Sept. 14, 2023) ("The second part of Guideline 7 [Guideline 6 in the 2023 Merger Guidelines] discusses . . . examples of foreclosure effects for complementary products (also known as "conglomerate effects") and therefore lend themselves well to the ability and incentive framework set out in Guideline 5.").

whether Guideline 5 may provide an analytical framework for evaluating competitive harm under the Guideline 6 theory of leveraging dominance via bundling.

Guideline 5 provides a high-level "ability and incentive" analytical framework for analyzing competitive concerns around foreclosure. It sets out four factors that should be examined to determine whether a merged firm would have the ability and incentive to foreclose rivals. Below is a short summary of those factors and how they were relevant in the Amgen/Horizon merger challenge. This analysis shows that, even though much of the detail described in Guideline 5 focuses on a vertical foreclosure setting, Guideline 5's general "ability and incentive to foreclose" framework and analyses lend themselves well to evaluating a theory of harm based on leveraging via bundling. Indeed, the 2023 Merger Guidelines recognize the applicability of the "ability and incentive to foreclose" analysis to a broader set of relationships between product markets than the vertical case.[58]

- First, Guideline 5 recommends examining whether the merged entity has the ability to limit access to the anchor product due to a lack of substitutes.[59] A lack of substitutes to the anchor product gives the merged entity market power in the anchor product's market. The Amgen/Horizon merger challenge showed that the degree of the merged entity's market power in the anchor product's market is critical when analyzing the potential for leveraging via bundling.
- Second, Guideline 5 instructs that one should investigate whether limiting access to the anchor product has competitive significance for rivals in the protected market.[60] That is, one should investigate the extent to which rivals in the protected market would be weakened or excluded from that market if their access to the anchor product was limited.[61] In a leveraging via bundling case, like the Amgen/Horizon merger challenge, the competitive significance of limiting access to the anchor product for protected product rivals increases with either of two conditions. First, the more overlap there is between the buyers of the anchor product and the buyers of the protected product, as discussed in the previous section, the greater is the competitive significance of limiting access. This is because the more buyers that are purchasing both products, the more that purchases in the protected market will be influenced by the bundled incentive that involves the anchor product market. Second, the more valuable the anchor product is compared to the protected product, the greater is the competitive significance of limiting access to the anchor product. This is because the costlier the

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[58] Guideline 5 focuses on a merger that creates an entity "that may limit access to products or services that its rivals use to compete" 2023 Merger Guidelines, *supra note 2*, at 3, 13. But Guideline 5 also acknowledges that "[m]any types of related products can implicate these concerns [of a merged entity limiting access to its products or services], including . . . products that . . . influence customers' purchase decisions" and that, "[e]ven if the related product is not currently being used by rivals, it might be competitively significant." 2023 Merger Guidelines, *supra note 2*, at 13. In a leveraging via bundling case, rivals of the merged entity may not use the merged entity's products directly as an input. However, rivals' ability to compete can be affected if buyers in the rivals' product markets also purchase products in the other market in the bundle, and the bundle limits access to the merged entity's product in that other market. In this way, restricting access to one product can influence the purchase decisions over the other product. In the Amgen/Horizon merger challenge, the FTC claimed that the alleged bundling of blockbuster drugs and rare disease drugs would influence at least some buyers' decisions in the rare disease drugs' markets by limiting access to Amgen's blockbuster drugs. As explained above, the number of buyers who purchased in both markets was an area of investigation, but the FTC's claim nevertheless illustrates how a leveraging via bundling case can fall under the broader class of settings described in Guideline 5. As a result, Guideline 5's "ability and incentive to foreclose" framework and analyses can be applicable in a leveraging via bundling setting. It is with this context in mind that the subsequent paragraphs apply Guideline 5 to the leveraging via bundling setting.

[59] 2023 Merger Guidelines, *supra note 2*, at 14.

[60] *Id.*

[61] *Id.*

anchor product is, the more customers will be enticed to use the bundled incentive to lower the anchor product's price. When customers use the bundled incentive, it makes it harder for rivals in the protected market to compete.

- Third, Guideline 5 recommends that one should "assess the importance of the dependent firms [i.e., the firms in the protected market] for competition in the relevant [protected] market."[62] In particular, Guideline 5 highlights that "[c]ompetition can be particularly affected when the dependent firms would be excluded from the market altogether."[63] In the Amgen/Horizon merger challenge, the FTC alleged that the bundled incentives would deter other firms from entering the protected markets and thereby foreclose all entry in those markets, preserving the merged entity's monopolies.[64]
- Fourth, Guideline 5 instructs that one should assess competition between the merged entity and the firms that it would foreclose in the protected market.[65] The closer is the competition between the merged entity and the firms that it would foreclose in the protected market, the stronger is the merged entity's incentive to try to exclude the other firms.[66] This effect arises because the closer is the competition, the greater is the sales increase that the merged entity can expect when the other firms are foreclosed. In the Amgen/Horizon merger challenge, the degree of competition and product differentiation in the protected market arose as an issue because, as discussed in the preceding section, the differentiation between the protected products and their competitors affected the incentive of the merged entity to implement the alleged bundled incentives.

Thus, Guideline 5's "ability and incentive to foreclose" framework addresses many of the factors, considerations, and analyses that arose in assessing anticompetitive harm under a theory of leveraging via bundling in the Amgen/Horizon merger challenge. Because a theory of leveraging via "tying, bundling, conditioning, or otherwise linking sales of two products" is a foreclosure theory, Guideline 5 can provide a helpful analytical framework for assessing such concerns within Guideline 6, and can aid the merging parties, as well as the Agencies, in identifying the critical risk factors for a challenge under such a theory. ●

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62 *Id.*

63 *Id.*

64 Complaint, *supra* note 4, at ¶¶ 10, 74.

65 2023 Merger Guidelines, *supra note 2*, at 14.

66 *Id.*