UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

Statement of Chair Lina M. Khan Joined By
Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro Bedoya
In the Matter of Amgen, Inc. and Horizon Therapeutics plc
Commission File No. 231-0037

September 1, 2023

All too often, Americans can't afford the medicines they need. Drug prices in America are higher than they are anywhere else in the world. At the Federal Trade Commission, we hear regularly from people about how high drug prices harm, and even wreck, lives. At one of our Open Commission Meetings, a parent recounted how high costs forced her son to ration insulin, with fatal results.[1] We've heard from people about how high drug prices have forced them to stay in jobs they would otherwise leave or stunted the growth of their small businesses.[2] These stories reflect a broader crisis, with around 18 million Americans now reporting that high drug prices lead them to routinely ration their medicines or skip them altogether.[3]

Contributing to the high and rising costs of medicines are business practices that may constitute unfair methods of competition, in violation of Section 5 of the FTC Act. These practices include schemes by pharmaceutical manufacturers to extend or exploit the exclusionary power of their patents beyond their lawful patent rights, such as pay-for-delay agreements, product hopping, and patent thicketing. Other practices can impede competition from generics and biosimilars, including restrictive agreements that deny critical inputs to generics[4] and kickbacks from brand-name pharmaceutical manufacturers to middlemen like pharmacy benefit managers ("PBMs").[5] These potentially unlawful practices can be enabled by mergers that give

[1] Fed. Trade Comm'n, Tr. of Open Comm'n Meeting, at 18-19 (Oct. 21, 2021), https://www.ftc.gov/system/files/documents/public_events/1597522/20211021opencommissionmeetingtranscript.pdf.
[2] *Id.* at 14-19, 18-19; Colo. Dep't of Law, *Prescription Insulin Drug Pricing Report* (Nov. 2020), https://coag.gov/app/uploads/2020/11/Insulin-Report-102020.pdf.
[3] Dan Witters, *In U.S., an Estimated 18 Million Can't Pay for Needed Drugs*, GALLUP (Sept. 21, 2021), https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx.
[4] Statement of Chair Lina M. Khan on the Ruling by Judge Denise L. Cote, *Federal Trade Commission et al v. Vyera Pharmaceuticals, LLC et al* (Jan. 14, 2022), https://www.ftc.gov/system/files/documents/public_statements/1599663/chair_khan_statement_on_the_ruling_by_judge_cote_regarding_ftc_v_vyera_pharmaceuticals_llc.pdf.
[5] Remarks of Chair Lina M. Khan Regarding Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Chair-Lina-Khan-Regarding-Policy-Statement-Rebates-Fees.pdf; Statement of Chair Lina M. Khan Regarding the Policy Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/StatementofChairLinaMKhanrePBMLetterWithdrawal.pdf; Statement of Commissioner Rohit Chopra Regarding the Commission's Report on Pharmacy Benefit Manager Rebate Walls (May 28, 2021), https://www.ftc.gov/system/files/documents/public_statements/1590528/statement_of_commissioner_rohit_chopra_regarding_the_commissions_report_on_pharmacy_benefit_manager.pdf.

pharmaceutical companies the power to raise entry barriers and exclude rivals in ways that hike prices, inhibit access, and suppress innovation.[6]

Today the Commission announces a settlement of charges that Amgen, Inc.'s acquisition of Horizon Therapeutics plc would violate the antitrust laws. In its complaint, the FTC charged that this $27.8 billion deal—one of the largest pharmaceutical deals in recent memory— would likely lessen competition in the market for FDA-approved drugs to treat two rare diseases and would tend to create a monopoly in those markets.[7] In particular, the complaint stated that the deal would enable Amgen to leverage its portfolio of blockbuster drugs to protect the monopoly positions of two Horizon drugs. Not only was this complaint the Commission's first challenge to an unconsummated pharmaceutical merger in over fourteen years,[8] but it also represented a significant advancement in the Commission's pharmaceutical merger enforcement program.

In recent years, the FTC has been examining and updating our approach to pharmaceutical mergers. As a growing number of analysts, researchers, and advocates have increasingly recognized, pharmaceutical mergers can stifle competition and harm patients even where the merging parties do not sell or develop any overlapping drugs.[9] For example, consolidation among pharmaceutical companies can facilitate collusion, distort incentives to research and develop new drugs, increase the bargaining leverage of large incumbents, and reduce potential entrants' access to capital. Acquisitions by the largest pharmaceutical companies can unlock additional means of profitably exploiting market power, especially where the company has a history of illegal behavior. The Pharmaceutical Merger Task Force—launched by the FTC, DOJ, and state and international competition enforcers during Commissioner Slaughter's tenure as Acting Chair—worked to better understand the market behavior, incentives, and business decisions of pharmaceutical companies and the full set of mechanisms by which mergers and acquisitions in the pharmaceutical industry can harm patients and competition.[10]

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[6] Statement of Commissioners Rohit Chopra and Rebecca Kelly Slaughter, Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes (June 24, 2019), https://www.ftc.gov/system/files/documents/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices/p180101_section_5_report_dissenting_statement_by_chopra_and_slaughter_6-27-19.pdf.

[7] Complaint ¶¶ 77 & 79, *In re Amgen Inc. & Horizon Therapeutics plc*, Docket No. 9414 (FTC June 22, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Amgen-Horizon-Part-III-Complaint-PUBLIC.pdf.

[8] Press Release, Fed. Trade Comm'n, FTC Authorizes Suit to Stop CSLs Proposed $3.1 Billion Acquisition of Talecris Biotherapeutics (May 27, 2009), https://www.ftc.gov/news-events/news/press-releases/2009/05/ftc-authorizes-suit-stop-csls-proposed-31-billion-acquisition-talecris-biotherapeutics.

[9] *See, e.g.*, Michael A. Carrier & Gwendolyn J. Lindsay Cooley*, Prior Bad Acts and Merger Review*, 111 GEO. L.J. ONLINE 106 (2023); Robin Feldman & Mark Lemley, *Atomistic Antitrust*, 63 WM. & MARY L. REV. 1869 (2022); Patricia Danzon & Michael Carrier, *The Neglected Concern of Firm Size in Pharmaceutical Mergers*, 84 ANTITRUST L.J. No. 2 (2022); Justus Haucap, Alexander Rasch, & Joel Stiebale*, How Mergers Affect Innovation: Theory and Evidence*, 63 INT'L J. INDUS. ORG. 283 (2019).

[10] Press Release, Fed. Trade Comm'n, FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers (Mar. 16, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach-pharmaceutical-mergers; Press Release, Fed. Trade Comm'n, FTC and Justice Department to Hold Two-Day Virtual Public Workshop Examining Antitrust Enforcement in the Pharmaceutical Industry (May 31, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/05/ftc-justice-department-hold-two-day-virtual-public-workshop-examining-antitrust-enforcement;

Drawing on this experience and learning, the Commission's lawsuit against Amgen and Horizon reflects an advance in our pharmaceutical merger program. While the companies do not have drugs that directly compete with one another, Commission staff focused on the deal rationale and assessed how the acquisition would change the combined firm's power and incentive to thwart competition.

Several of Amgen's major revenue streams could dry up in coming years. Patents covering Enbrel, the blockbuster rheumatoid arthritis drug that Amgen acquired in 2002 and that generates billions of dollars in annual revenue, will expire by 2030. The Inflation Reduction Act of 2022, which empowers Medicare and Medicaid to negotiate drug prices, could further reduce future revenues from Enbrel. Other Amgen drugs face similar pressures. Against this backdrop, Amgen sought an acquisition that could reliably replace its key moneymakers.

What Amgen found in Horizon was a pair of "orphan drugs" that are the only FDA-approved therapies for treating two rare diseases: thyroid eye disease and chronic refractory gout. Horizon's monopoly positions in these drugs have allowed it to charge monopoly prices: around $400,000 for a six-month course of treatment for Tepezza and around $650,000 for a course of treatment of Krystexxa. At 72% of Horizon's sales, these two drugs comprise the vast majority of Horizon's value. The profitability and security of Horizon's monopolies account for the premium that Amgen was willing to pay, resulting in the $27.8 billion deal value.

Reaping the full value of this investment, however, would require protecting Horizon's monopolies from rivals that could enter these markets once Horizon's orphan drug exclusivity ends after 2027. Competitors are already actively developing their own drugs to treat thyroid eye disease and chronic refractory gout. One exclusionary tactic that Amgen has previously deployed is cross-product bundling, where it uses its blockbuster drugs to secure from PBMs preferential placements or exclusionary access for its non-blockbuster drugs, thereby excluding rivals. This sort of cross-product bundling scheme can lock out new competitors—even if their products are more affordable or effective. Based on these facts, the Commission's complaint charged that Amgen's acquisition of Horizon would give Amgen the ability and incentive to engage in similar cross-product bundling that would exclude Horizon's rivals and maintain its monopolies, harming patients in the long run.

The order announced today prohibits Amgen from engaging in any cross-product bundling or exclusionary rebating schemes involving Horizon's monopoly drugs. Several features of this conduct suggest that an order alone can effectively halt it. For example, because this deal would not give a firm control over products or services that its rivals use to compete, it does not raise traditional concerns about degrading competitors' access to key inputs or improper information exchange, which can be achieved through subtle and varied means that are difficult to detect. By contrast, Amgen can only engage in exclusionary rebating schemes and cross-product bundling in partnership with PBMs, who would need to agree to accept rebates in exchange for privileging Amgen's drugs or excluding those of its rivals. Given the significant financial sums involved, these agreements would be documented, and the FTC's proposed order will require Amgen to regularly submit all such agreements and other key documents to aid the

Fed. Trade Comm'n and U.S. Dep't of Justice, *The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers, FTC-DOJ Workshop Summary* (June 1, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Future%20of%20Pharma%20Workshop%20--%20Summary.pdf.

Commission in identifying even implicit efforts to bundle. Amgen is also required to notify its trading partners about the FTC's order, ensuring that market participants are on alert about the prohibited conduct and are positioned to report any suspected violations.[11]

The proposed order also prohibits Amgen from acquiring any drugs that could compete with Horizon's two monopoly drugs without first seeking the Commission's approval. Because Amgen could try to neutralize Horizon's rivals not just through excluding them but also through acquiring them, this prior approval provision will position the FTC to block acquisitions that would unlawfully maintain Horizon's monopolies.[12]

Critically, the six state attorneys general who joined the FTC's complaint will be able to independently monitor Amgen's compliance with the proposed order. California, Illinois, Minnesota, New York, Washington, and Wisconsin will also have access to Amgen's documents and reports and will serve as another key check on any violations. I am grateful to our state partners for their close collaboration on this enforcement matter, and empowering them to independently monitor compliance with our consent orders—and take corrective action as appropriate—positions our remedies for greater success.

The FTC assesses each merger based on the specific facts at hand, and there is no guarantee that the relief achieved in this matter would adequately resolve concerns about cross-product bundling in any future merger actions. A distinct feature of the conduct at issue here is that it involves bundling across different insurance benefit arrangements, which makes it easier to detect. The conduct also involves orphan drugs for rare diseases, the selection and administration of which involves providers with incentives to resist and report exclusionary behavior. As the Commission evaluates proposals to settle charges in future pharmaceutical mergers, we will continue to learn from past experience and seek to fully protect the public from deals that violate the antitrust laws. The merger guidelines we recently proposed with the U.S. Department of Justice further describe how we will assess transactions to determine if they may lessen competition or tend to create a monopoly.[13]

Tackling unlawful pharmaceutical mergers is just one aspect of the FTC's work addressing high drug prices. The bundling and exclusionary rebating practices at issue in this matter highlight deeper concerns about how pharmaceutical companies and pharmacy benefit managers may work together to deprive Americans of access to affordable drugs. The FTC continues to scrutinize these practices through its inquiry into PBMs.[14] And our teams will

[11] Any suspicions of order violations by Amgen may be submitted to the Bureau of Competition by email at antitrust@ftc.gov.

[12] Statement of the Commission on Use of Prior Approval Provisions in Merger Orders, Fed. Trade Comm'n (Oct. 25, 2021), https://www.ftc.gov/system/files/documents/public_statements/1597894/p859900priorapprovalstatement.pdf.

[13] U.S. Dep't of Justice and Fed. Trade Comm'n, *Merger Guidelines: Draft for Public Comment Purposes* (July 19, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf; Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya Regarding FTC-DOJ Proposed Merger Guidelines (July 19, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p234000_chair_statement_re_draft_merger_guidelines.pdf.

[14] Statement of Chair Lina M. Khan Regarding 6(b) Study of Pharmacy Benefit Managers, Commission File No. P221200 (June 8, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-Khan-6b-Study-Pharmacy-Benefit-

continue to challenge unlawful practices that raise drug prices, inhibit access, stifle innovation, or otherwise hurt patients.

I commend the talented FTC team for their rigor, agility, and fortitude in investigating and litigating this matter. This effort marked a major advancement in our pharmaceutical merger program and would not be possible without their terrific work. We will be collecting public comments on our proposed order for 30 days and look forward to reviewing the feedback and input.

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Managers.pdf; Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices (June 8, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.