Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–19770 Filed 9–12–23; 8:45 am]

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FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 28, 2023.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *Santander Holdings USA, Inc., Boston, Massachusetts;* to engage in community development activities pursuant to section 225.28(b)(12) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–19773 Filed 9–12–23; 8:45 am]

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FEDERAL TRADE COMMISSION

[File No. 231 0037]

Amgen Inc. and Horizon Therapeutics plc; Analysis of Agreement Containing Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before October 13, 2023.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: ''Amgen Inc. and Horizon Therapeutics plc; File No. 231 0037'' on your comment and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex T), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Stephen Mohr (202–326–2850), Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule § 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of 30 days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 13, 2023. Write ''Amgen Inc. and Horizon Therapeutics plc; File No. 231 0037'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the agency's heightened security screening, postal mail addressed to the Commission will be delayed. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. If you prefer to file your comment on paper, write ''Amgen Inc. and Horizon Therapeutics plc; File No. 231 0037'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex T), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form,

must be clearly labeled ''Confidential,'' and must comply with FTC Rule § 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule § 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on *https://www.regulations.gov*—as legally required by FTC Rule § 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *https://www.ftc.gov* to read this document and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before October 13, 2023. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Order (''Consent Agreement'') from Amgen Inc. (''Amgen'') and Horizon Therapeutics plc (''Horizon'') to remedy the anticompetitive effects resulting from Amgen's proposed acquisition of Horizon (the ''Acquisition''). Amgen is one of the world's largest biopharmaceutical companies and Horizon currently enjoys a monopoly on the medicines that treat thyroid eye disease (''TED'') and chronic refractory gout (''CRG''). The Commission alleged in its Complaint that the Acquisition, if consummated, would violate section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by enabling Amgen to leverage its portfolio of blockbuster drugs to foreclose actual or potential rivals to Horizon's top-selling medications, thereby substantially lessening competition in the markets for the sale of FDA-approved drugs to treat TED and CRG and tending to create a monopoly in those same markets.

The Consent Agreement, which contains the proposed Decision and Order (''Order'' or ''D&O'') will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Acquisition. Specifically, under the terms of the proposed Order, Amgen is prohibited from leveraging its drug portfolio to foreclose or disadvantage competitors to Tepezza or Krystexxa for 15 years from the date of the issuance of the proposed Order. To protect robust future competition in the TED and CRG markets, including due to acquisitions by Amgen that may or may not be reportable under the Hart-Scott-Rodino (''HSR'') Premerger Notification Act, the proposed Order requires Amgen to obtain the Commission's prior approval for the acquisition of any product or business interest involved in: (1) the manufacture or sale of any drug indicated to treat TED or CRG, or (2) the pre-commercial development of any drug in development for TED or CRG that has completed an FDA Phase II or Phase III clinical trial until December 31, 2032.

The Consent Agreement with the proposed Order has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the D&O as well as any comments received, and decide whether it should withdraw, modify, or make final the D&O.

I. The Parties and Transaction

Amgen is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at One Amgen Center Drive, Thousand Oaks, California. Amgen is a biotechnology company that develops, manufactures, and delivers human therapeutics. In 2022, Amgen had global product sales of about $24.8 billion (and total revenues of about $26.3 billion). The United States is Amgen's largest market, representing approximately 72% of its sales. Amgen's current product portfolio includes 27 approved drugs, nine of which generated 2022 sales in excess of $1 billion.

Horizon is a public limited company organized, existing, and doing business under and by virtue of the laws of Ireland with its principal executive offices located at 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland. Horizon is a global biotechnology company focused on the discovery, development, and commercialization of medicines that treat rare, autoimmune, and severe inflammatory diseases. Horizon markets and distributes eleven drug products in the United States through its wholly owned subsidiary, Horizon Therapeutics USA, Inc. Horizon's U.S. headquarters is in Deerfield, Illinois. The company's two leading marketed drugs are Tepezza for the treatment of TED and Krystexxa for the treatment of CRG. The two drugs accounted for approximately 74% of Horizon's approximately $3.6 billion in net sales in 2022, with Tepezza generating $1.96 billion and Krystexxa netting $716 million.

Pursuant to an agreement, dated December 11, 2022, Amgen agreed to acquire all the issued and ordinary share capital of Horizon through a newly formed, wholly owned subsidiary of Amgen for $116.50 per share in cash. The total value of the Acquisition is approximately $28 billion.

II. The Relevant Products and Market Structure

The Sale of FDA-Approved Drugs To Treat Thyroid Eye Disease

A relevant line of commerce in which to analyze the effects of the Acquisition is the sale of FDA-approved drugs to treat TED. TED is a serious, progressive, and vision-threatening rare autoimmune condition, with a potential patient population of over 60,000 in the United States. While TED often occurs in people living with hyperthyroidism or Graves' disease, it is a distinct disease that is caused by autoantibodies activating an IGF–1R-mediated signaling complex on cells within the retro-orbital space. This disease leads to a cascade of negative effects that may cause long-term, irreversible eye damage including proptosis (eye bulging), strabismus (misalignment of the eyes) and diplopia (double vision)—and in some cases can lead to blindness.

Horizon's Tepezza (teprotumumab-trbw), a fully human monoclonal antibody and a targeted inhibitor of the insulin-like growth factor-1 receptor, is the first and only drug approved by the FDA to treat TED. The FDA granted Tepezza an orphan drug designation in January 2020. Tepezza is administered to patients intravenously by a healthcare provider, typically in an outpatient infusion center or a doctor's office. The wholesale acquisition cost for a single vial of Tepezza is almost $15,000, and a full course of treatment of Tepezza can cost over $350,000.

As the only FDA-approved TED treatment, Tepezza currently faces no

direct competition in the United States. However, Tepezza's monopoly in the TED market is threatened by potential entry in the coming years from rivals developing competing drugs. For example, Viridian Therapeutics, Inc. (''Viridian'') is advancing multiple candidates through clinical programs for the treatment of patients with TED that could threaten Tepezza's monopoly. Viridian has initiated a Phase 3 clinical trial for its leading candidate, VRDN–001, in patients with active TED. In addition to its program for intravenously administered VRDN–001, Viridian is developing subcutaneous products with the goal of providing a more conveniently administered therapy to patients with TED.

The Sale of FDA-Approved Drugs To Treat Chronic Refractory Gout

A relevant line of commerce in which to analyze the effects of the Acquisition is the sale of FDA-approved drugs to treat CRG in adult patients. Gout is one of the most common forms of inflammatory arthritis and is associated with multiple comorbidities. CRG is severe chronic gout in adult patients that is refractory to conventional therapy. Of the 9.5 million gout sufferers in the United States, more than 100,000 patients may have CRG, which frequently causes crippling disabilities and significant joint damage.

Horizon's Krystexxa (pegloticase injection) is the first and only FDA-approved drug to treat CRG. The FDA granted Krystexxa an orphan drug designation in September 2010, and subsequently approved a supplemental Biologics License Application in July 2022, expanding the drug's labeling to include Krystexxa co-administered with methotrexate, an immunomodulatory therapy. Krystexxa is a PEGylated uric acid specific enzyme that is administered intravenously in an outpatient infusion center or doctor's office by healthcare providers. The annual wholesale acquisition cost of a course of treatment of Krystexxa is approximately $650,000.

As the only FDA-approved CRG treatment, Krystexxa currently faces no direct competition in the United States. However, Krystexxa's monopoly in the CRG market is threatened by potential entry in the coming years. For example, Selecta Biosciences (''Selecta'') initiated a Phase 3 clinical program of a candidate, SEL–212, for the treatment of CRG. SEL–212 is a combination of Selecta's ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase).

III. The Relevant Geographic Market

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. FDA-approved drugs to treat TED and CRG are prescription pharmaceutical products and regulated by FDA. As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

IV. Competitive Effects of the Acquisition

Emerging competition to Tepezza and Krystexxa promises to generate a host of benefits for patients who suffer from TED and CRG, for doctors who prescribe treatments for the conditions, and for patients, employers, and health plans that ultimately pay for the medications. The Acquisition, however, would likely result in substantial competitive harm by foreclosing or disadvantaging such emerging competition and entrenching Tepezza's and Krystexxa's monopoly positions.

Post-Acquisition, Amgen Would Possess the Ability and Incentive To Foreclose or Disadvantage Rivals to Tepezza or Krystexxa

Post-Acquisition, Amgen would have the ability and incentive to sustain and entrench its dominant positions in the markets for FDA-approved TED and CRG drugs by leveraging its portfolio of blockbuster drugs to foreclose or disadvantage future rivals in these markets.

Negotiations with PBMs and payers (*i.e.,* health plans or plan sponsors) are crucial to Amgen, as these entities' formulary and utilization management decisions effectively determine which medications patients can access. Amgen often gives these entities substantial rebates in exchange for favorable formulary positions for its drugs. Drugs reimbursed through the pharmacy benefit are typically self-administered and dispensed through a retail or specialty pharmacy. Most of Amgen's blockbuster drugs, such as Enbrel, are covered under payers' pharmacy benefits. In contrast, drugs that are administered by a healthcare provider, such as Tepezza and Krystexxa, are typically reimbursed under payers' medical benefits. Payers typically rely on PBMs to negotiate their pharmacy benefit coverage and rebates, while medical benefit managers (often owned by the same PBMs) or health plans themselves generally negotiate their medical benefit policies and rebates.

With its broad and powerful drug portfolio, Amgen does not limit itself to single-product rebate agreements with PBMs and payers. For example, one tactic Amgen employs is providing cross-market bundles or bundled rebates. Through this strategy, Amgen provides greater rebates on one or more of its blockbuster products to secure favorable formulary placement for other medications in different product markets. Due to the enormous sales and consistent volume of Amgen's blockbuster drugs, which last year generated over $4 billion in global sales, even small enhancements to rebates can ensure payers accept such contracts. Therefore, Amgen post-Acquisition may have the ability to insulate Tepezza and Krystexxa from competitive threats through strategies that include conditioning rebates on one or more of its must-have blockbuster drugs in return for payer agreements to deny coverage to, or otherwise disfavor, potential or actual rivals to the two medications. That strategy would have the effect of raising rivals' barriers to entry and foreclosing them from effectively competing in the markets for the sale of FDA-approved drugs to treat TED and CRG.

A bundle of one of Amgen's blockbuster drugs such as Enbrel with Tepezza or Krystexxa would be both a cross-market bundle (*i.e.,* a bundle involving drugs in different product markets) and a cross-benefit bundle (*i.e.,* a bundle that includes drugs managed by a health plan's medical benefit with drugs managed by its pharmacy benefit). Although payers have historically siloed pharmacy and medical benefits from one another, the same payer determines coverage for drugs that are reimbursed through its beneficiaries' pharmacy and medical benefits and bears the cost of the drug regardless of whether it is reimbursed through the pharmacy or medical benefit. Additionally, each of the three largest PBMs, in part due to recent consolidation, is now vertically integrated with payers that manage patients' medical benefits: OptumRx/United Healthcare, CVS Caremark/Aetna, and Express Scripts/Cigna. Even non-vertically integrated PBMs are increasingly able to combine pharmacy and medical benefit capabilities that allow them to market cross-benefit management tools to their clients. These industry trends, which are altering a market structure that previously siloed pharmacy and medical benefits from one another, would facilitate Amgen's ability to implement cross-benefit bundles that link its blockbuster pharmacy benefit drugs, like Enbrel, and medical benefit drugs acquired through

the Acquisition, like Tepezza and Krystexxa.

Post-Acquisition, Amgen also will have the incentive to leverage its portfolio to bias decisions about drug coverage to protect the value of its newly acquired monopoly products. Multiple rivals are developing competitors to Tepezza and Krystexxa, threatening the massive profit pools generated by these drugs. Competitive entry would likely lead to competition on the merits, with payers leveraging drugs off one another to secure lower prices. Thus, the merged firm will have an incentive to leverage Amgen's blockbuster drugs to defend the monopoly share of the Tepezza and Krystexxa markets.

The Acquisition Would Entrench Tepezza's and Krystexxa's Monopolies

The Acquisition would entrench and extend Tepezza's and Krystexxa's monopolies in the TED and CRG markets by substituting Amgen, with its broad and powerful portfolio of blockbuster drugs, for Horizon with its smaller portfolio, thus raising entry barriers and dissuading smaller firms from aggressively competing. Currently, Horizon has only three prominent on-market drugs focused on small patient populations with rare diseases. The merged firm, however, would have Amgen's large portfolio of blockbuster drugs and ability to contract for cross-benefit bundles to secure preferential formulary placement, which Tepezza's and Krystexxa's impending competitors lack. Any potential competitor to Tepezza or Krystexxa would need a similar portfolio of highly utilized and rebated blockbuster drugs to compete effectively for payer coverage in the TED and CRG markets. As a result, the Acquisition could deter future entry and deprive patients, doctors, and payers of the benefits of competition and access to new treatments for two rare diseases.

V. The Proposed Order

The proposed Order eliminates the competitive concerns raised by the proposed Acquisition by prohibiting the combined company from leveraging Amgen's drug portfolio to foreclose or disadvantage competitors to Tepezza or Krystexxa for 15 years from the date of the issuance of the D&O.

Pursuant to the proposed Order, post-Acquisition Amgen will be prohibited from directly, indirectly, explicitly, or implicitly conditioning any product rebate on, or any contract terms related to, any Amgen product in exchange for the purchase, coverage, placement, or positioning, individually or in any combination, of Krystexxa or Tepezza. The proposed Order defines rebates broadly to cover any concession or dollar amount provided by Amgen including, rebates, administrative fees, volume discounts, patient conversion payments, market share-related payments, formulary placement fees, disease management program payments, promotional allowances, portal fees, data fees, and specialty pharmacy discounts.

Pursuant to the proposed Order, post-Acquisition Amgen also will be prohibited from directly, indirectly, explicitly, or implicitly conditioning any product rebate on, or any contract terms related to, any Amgen product in exchange for the exclusion, detriment, or disadvantage, individually or in any combination, of any competitor to Tepezza or Krystexxa. This prohibition applies to both drugs and biologics, as well as biosimilars and other drugs that are therapeutic equivalents, which share an FDA indication with Tepezza or Krystexxa, as well as products which are used as off-label treatments for TED or CRG.

If Amgen believes that a federal, state, or local statute, rule, or regulation requires Amgen to enter into a contract which would be prohibited by the proposed Order, Amgen is required to provide 30-days prior notice to the Commission before entering into such a contract. Additionally, because of the concentrated nature of the relevant markets, as well as the possibility of future acquisitions by Amgen in these markets, the proposed Order includes a prior approval for the acquisition of any product or business interest involved in: (1) the manufacture or sale of any drug indicated to treat TED or CRG, or (2) the pre-commercial development of any drug in development for TED or CRG that has completed an FDA Phase II or Phase III clinical trial. This provision is effective until December 31, 2032.

To ensure compliance with the proposed Order, the Commission will appoint a monitor to observe and report on Amgen's compliance. Among other obligations, the proposed Order requires Amgen to submit to the monitor all contracts with payers related to the purchase, coverage, placement, or positioning of Tepezza or Krystexxa in the United States and to maintain any documents related to any offers, negotiations, disputes, or enforcement for such contracts. Additionally, Amgen is required to submit regular reports to the Commission to enable the Commission to determine independently whether Amgen is complying with the proposed Order.

The purpose of the proposed Order is, among other things, to address the theories of harm to competition alleged by the Commission in its Complaint, in this matter, and in the Commission's Joint Federal Court Complaint for Temporary Restraining Order and Preliminary Injunction filed with the states of California, Illinois, Minnesota, New York, Washington and Wisconsin (''Interested States'') in the United States District Court, Northern District of Illinois, June 22, 2023, Case # 1:23–cv–03053, by formalizing Amgen's commitment not to engage in the leveraging or conditioning of Amgen's drug products with Tepezza or Krystexxa, as described above. The Interested States will be receiving certain information from Amgen and the monitor as those states have had a strong interest in the resolution of the federal court complaint, have contributed significantly to the investigation of Amgen's potential anticompetitive transaction with Horizon, and will be kept apprised of Amgen's ongoing compliance with the proposed Order.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro Bedoya

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

[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.*

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 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]

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

[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.*

[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;* 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.*

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

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[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-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.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1198]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) During Investigations of Foodborne Disease Clusters and Outbreaks'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 7, 2023, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who