UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION, *Plaintiff*, v. AMGEN INC. and HORIZON THERAPEUTICS PLC, *Defendants*.	No. 23-CV-3053 **REDACTED – PUBLIC VERSION**

COMPLAINT FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION PURSUANT TO SECTION 13(b) OF THE FEDERAL TRADE COMMISSION ACT

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys, petitions this Court for a temporary restraining order and preliminary injunction enjoining Amgen Inc. ("Amgen") and its subsidiaries from consummating its proposed acquisition (the "Proposed Acquisition") of Horizon Therapeutics plc ("Horizon"). The Commission seeks this relief pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), and Section 16 of the Clayton Act, 15 U.S.C. § 26. Absent such relief, Amgen and Horizon (collectively, "Defendants") have represented that they would be free to consummate the Proposed Acquisition after 11:59 PM Eastern Time on May 21, 2023.

Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission, whenever it has reason to believe that a proposed merger is unlawful, to seek preliminary injunctive relief to prevent consummation of a merger until the Commission has had an opportunity to issue an

administrative complaint, and if such complaint is issued, adjudicate the merger's legality in an administrative proceeding. The Commission therefore seeks this preliminary relief "pending the issuance of a[n administrative] complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final." 15 U.S.C. § 53(b)(2). Pursuant to 15 U.S.C. § 53(b)(2), such an administrative complaint must be filed no later than 20 days after this Court grants a temporary restraining order.

A temporary restraining order enjoining the Proposed Acquisition is necessary to preserve this Court's ability to provide full and effective relief after considering the Commission's motion for a preliminary injunction. Preliminary injunctive relief is imperative to preserve the status quo and to protect competition "pending the issuance of a[n administrative] complaint by the Commission," and if such complaint is issued, while the Commission adjudicates whether the Proposed Acquisition is unlawful. Allowing the Proposed Acquisition to proceed would harm competition and consumers and undermine the Commission's ability to remedy the anticompetitive effects of the Proposed Acquisition if the Commission issues an administrative complaint and the Proposed Acquisition is found unlawful after a full administrative trial on the merits and any subsequent appeals.

NATURE OF THE CASE

1. Amgen, one of the world's largest biopharmaceutical companies, proposes to acquire Horizon, which currently enjoys a monopoly on the medicines that treat thyroid eye disease ("TED") and chronic refractory gout ("CRG"). If consummated, the Acquisition would enable 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. Additionally, or in the alternative, the Acquisition would tend to create a monopoly in those same markets.

2. Through a number of acquisitions, Amgen has grown into one of the largest biopharmaceutical companies in the world. Amgen purchased the rights to its top-selling drug, Enbrel, through a roughly $16 billion acquisition of Immunex Corporation in 2002. It bought the rights to its third-best selling drug, Otezla, through a $13.4 billion acquisition in 2019. Its proposed acquisition of Horizon, valued at $27.8 billion, would be by far Amgen's largest ever purchase. Each acquisition has successively expanded Amgen's product portfolio, thereby increasing its leverage in negotiations over its products' availability and reimbursement rates.

3. Negotiations with pharmacy benefit managers ("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. In other words, Amgen pays these entities to give its drugs favorable access at the expense of drugs offered by its rivals.

4. Amgen does not limit itself to single-product rebate agreements. Instead, a second prong of the company's negotiating strategy involves leveraging its broad drug portfolio, including the drugs it acquires. 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—such as Enbrel, which last year generated over $4 billion in global sales—even small enhancements to rebates can ensure payers accept such contracts. Since 2020,

Amgen has contracted for multiple cross-market drug bundles with some of the largest PBMs, [redacted].

5. Cross-market rebating and bundling can also block smaller rivals from being able to compete on the merits. For example, Amgen has offered additional rebates on [redacted] to payers who agree to grant exclusive or preferred formulary status to its [redacted]. A complaint pending in federal court, which recently survived a motion to dismiss, alleges that these cross-market bundles foreclosed competition and entrenched Repatha's monopoly position in violation of Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act.

6. If permitted to acquire Horizon, Amgen would have the ability and incentive to sustain and entrench the monopolies of Horizon's drugs using similar multi-product contracting strategies. Those strategies would be especially appealing for two drugs: (a) Tepezza, the only FDA-approved treatment for TED, which in 2022 generated $1.96 billion, or 54% of Horizon's net sales; and (b) Krystexxa, the only FDA-approved treatment for CRG, which in 2022 generated $716 million, or 19.7% of Horizon's net sales. Amgen expects both drugs to grow significantly in the coming years, with Tepezza projected to achieve peak sales of approximately $[redacted] annually.

7. Tepezza is a monopoly product. As Horizon recognizes in its 2022 SEC Form 10-K, "[a]s the only FDA-approved medication for the treatment of TED, TEPEZZA has no direct approved competition." Krystexxa occupies a similar monopolistic position. "As the only FDA-approved medication for the treatment of [CRG], KRYSTEXXA faces limited direct competition," the Horizon filing boasts.

8. These monopoly positions have enabled Horizon to charge exorbitant prices. A six-month course of treatment of Tepezza is typically priced at around $350,000. Krystexxa has an annual wholesale acquisition cost of around $650,000.

9. But Horizon's TED and CRG market dominance is not slated to last forever. Instead, the company expects to face increasing competition from clinical-stage rivals in the coming years. As an internal Horizon presentation observes, the "[redacted]." Amgen, too, recognizes these entrants as serious threats and anticipates that they could capture substantial market share from Horizon's drugs if they successfully enter. This emerging competition promises to generate a host of benefits for patients who suffer from TED and CRG, for the doctors who prescribe treatments for the conditions, and for patients, employers, and health plans that ultimately pay for the medications.

10. Amgen's acquisition of Horizon, however, threatens to suppress that emerging competition and sustain and entrench Horizon's dominance in the markets for FDA-approved drugs to treat TED and CRG. The most likely strategy through which Amgen could accomplish that goal is by leveraging its existing portfolio of blockbuster drugs in multi-product contracts with PBMs and payers. Specifically, the Proposed Acquisition would give Amgen the ability and incentive to insulate Tepezza and Krystexxa from competitive threats. Amgen's history suggests this would likely include conditioning rebates to PBMs or payers on one or more of its must-carry blockbuster drugs in exchange for the PBMs or payers denying coverage to, or otherwise disfavoring, actual or potential rivals to Tepezza and Krystexxa.

11. Two market trends will likely increase Amgen's post-Acquisition ability to entrench Tepezza's and Krystexxa's monopolies through these multi-product contracting

strategies. First, in large part due to recent consolidation, the nation's largest PBMs and payers are now vertically integrated. In turn, these entities are increasingly employing cross-benefit management strategies that involve integrated management of drugs under the pharmacy benefit, under which many of Amgen's products, such as Enbrel, are covered, and the medical benefit, under which Horizon's Tepezza and Krystexxa are covered.

12. This market reality may strengthen Amgen's future ability to implement multi-product contracts linking its pharmacy benefit drugs with Tepezza or Krystexxa. As an internal Horizon presentation observes, these vertically integrated payer/PBM entities are increasingly seeking "[redacted]" And an Amgen document, in discussing one of these large integrated entities, recognizes that "[redacted]."

13. A second emerging market dynamic will further increase Amgen's post-Acquisition leverage to entrench Tepezza's monopoly: Horizon is currently developing a subcutaneously administered version of Tepezza, which it estimates will receive FDA approval [redacted]. The planned introduction of this subcutaneous Tepezza formulation promises to further lower Amgen's logistical and economic barriers to establishing multi-product contracts between its pharmacy benefit products, like Enbrel, and Tepezza.

14. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Proposed Acquisition. Neither entry nor expansion by other market

participants would be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the Proposed Acquisition's anticompetitive harm.

15. Defendants cannot show cognizable, merger-specific efficiencies that would offset the reasonably probable and substantial competitive harm resulting from the Proposed Acquisition.

16. On May 16, 2023, the Commission authorized its staff to file this Complaint seeking preliminary relief pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). In doing so, the Commission determined that it has reason to believe that the Proposed Acquisition would violate the Clayton Act and the FTC Act. The Commission is entitled to preliminary relief in this Court because of its likelihood of success on the merits and the weight of the equities. To succeed on the merits, the FTC must prove that the Proposed Acquisition violates Section 7 of the Clayton Act, which prohibits mergers the effect of which "may be substantially to lessen competition, or to tend to create a monopoly." For the reasons described below, the FTC is likely to succeed in proving an antitrust violation, and the equities weigh strongly in favor of enforcing the antitrust laws.

17. Preliminary injunctive relief restraining Defendants from proceeding with the Proposed Acquisition is necessary to prevent interim harm to competition "pending the issuance of a[n administrative] complaint by the Commission," and if such complaint is issued, during any subsequent administrative proceeding. Absent preliminary relief, Defendants can close the Proposed Acquisition and combine Amgen's and Horizon's operations. Allowing Defendants to consummate the Proposed Acquisition before the Commission issues an administrative complaint, and before any administrative proceeding has concluded, is likely to cause immediate harm to competition and consumers and would undermine the Commission's ability to remedy

the anticompetitive effects of the Proposed Acquisition if it is found unlawful after a full trial on the merits and any subsequent appeals.

18. A temporary restraining order enjoining the Proposed Acquisition is necessary to preserve the status quo and protect competition while the Court considers Plaintiff's application for a preliminary injunction. Unless temporarily restrained by the Court, Defendants would be free to consummate the Proposed Acquisition on or after 11:59 PM Eastern Time on May 21, 2023.

JURISDICTION AND VENUE

19. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and under 28 U.S.C. §§ 1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies and is brought by an agency of the United States authorized by an Act of Congress to bring this action.

20. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part: Whenever the Commission has reason to believe

> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public – the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond[.]. . .

21. Defendants are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

22. The FTC Act, 15 U.S.C. § 53(b), authorizes nationwide service of process, and personal jurisdiction exists where service is effected pursuant to federal statute. Fed. R. Civ. P. 4(k)(1)(C). Venue is proper in the Northern District of Illinois under 28 U.S.C. § 1391(c)(3), as well as under 28 U.S.C. § 1391(c)(2). Defendants are found, reside, and/or transact business in this state and district, and are subject to personal jurisdiction therein.

23. Assignment to the Eastern Division is proper. This action arises in Lake County because a substantial part of the events giving rise to these claims occurred in Lake County, where Defendant Horizon's U.S. headquarters is located.

THE PARTIES AND THE PROPOSED ACQUISITION

24. Plaintiff, the Federal Trade Commission, is an agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 *et seq.*, with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The Commission is vested with authority and responsibility for enforcing, *inter alia*, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

25. Defendant 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, manufacturers, 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. Three drugs—Enbrel, Prolia, and Otezla—accounted for 41% of Amgen's total sales in 2021.

Amgen's research and development efforts are focused primarily on three therapeutic areas: (1) inflammation, (2) oncology and hematology, and (3) cardiovascular and metabolic diseases.

26. Defendant 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 located in Deerfield, Illinois. The company's two leading marketed drugs are Tepezza and Krystexxa. 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.

27. Pursuant to the Agreement, dated December 11, 2022, Amgen agreed to acquire all of 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 Proposed Acquisition is approximately $28 billion.

28. Unless this Court grants Plaintiff's temporary restraining order, Defendants are free to close the proposed Acquisition after 11:59 PM Eastern Time on May 21, 2023.

THE RELEVANT PRODUCT MARKETS

A. Drugs Approved to Treat Thyroid Eye Disease

29. A relevant line of commerce in which to analyze the effects of the Acquisition is the sale of FDA-approved drugs to treat TED.

30. As Horizon describes in its annual report, "TED is a serious, progressive and vision-threatening rare autoimmune condition. 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 leads to a cascade of negative effects, which may cause long-term, irreversible eye damage. As TED progresses, it causes serious damage—including proptosis (eye bulging), strabismus (misalignment of the eyes) and diplopia (double vision)—and in some cases can lead to blindness. Historically, patients have had to live with TED until the inflammation subsides, after which they are often left with permanent and vision-impairing consequences and may require multiple surgeries that do not completely return the patient to their pre-disease state."

31. The annual incidence of TED in the United States is approximately 19 in 100,000 people, which corresponds to a potential patient population of over 60,000 patients. Roughly 20,000 patients suffer from moderate-to-severe acute TED each year.

32. In January 2020, the FDA approved Horizon's Tepezza for the treatment of TED. Tepezza (teprotumumab-trbw) is a fully human monoclonal antibody and a targeted inhibitor of the insulin-like growth factor-1 receptor, or IGF1R. Tepezza is administered to patients intravenously by a healthcare provider, typically in an outpatient infusion center or a doctor's office.

33. As the first and only drug approved by the FDA to treat TED, Tepezza has no direct competition. The FDA granted Tepezza an Orphan Drug designation in January 2020. Under the Orphan Drug Act, Pub. L. No. 97-414, and applicable FDA regulations, 21 C.F.R. § 316, a manufacturer developing a treatment for a rare unmet disease or condition can seek Orphan Drug designation and obtain marketing exclusivity, such that no approval will be given

to a subsequent sponsor of the same drug for the same use or indication for seven years. In its press release announcing its approval of Tepezza, the FDA declared Tepezza "the first drug approved for the treatment of thyroid eye disease" and noted the lack of viable alternative treatment options to TED, explaining: "Today's approval marks an important milestone for the treatment of thyroid eye disease. Currently, there are very limited treatment options for this potentially debilitating disease. This treatment has the potential to alter the course of the disease, potentially sparing patients from needing multiple invasive surgeries by providing an alternative, non-surgical treatment option."

34. Because of its unique characteristics, Tepezza is not reasonably interchangeable with other treatments. Before Tepezza was approved, physicians used other therapies, such as corticosteroid medications or surgical procedures, to alleviate some of the symptoms of TED. However, while these other therapies could reduce or delay symptoms for some patients, they have not proved effective in treating the underlying disease—and they carry with them the potential for significant side effects. For example, while intravenous steroids may be used off-label to treat the symptoms of TED, their effectiveness is temporary for the vast majority of patients, who then move on to other treatments, usually Tepezza, when their symptoms reappear. In addition, long-term steroid use is associated with side effects that can present significant safety concerns. FDA-approved drugs to treat TED are also preferred over surgical procedures, which are considered less efficacious and can be extremely invasive.

35. The lack of reasonable substitutes for FDA-approved drugs to treat TED is also demonstrated by the lack of cross-elasticity of demand between Tepezza and other TED therapies. Since its market launch, Tepezza has achieved significant sales growth, even though it is priced significantly higher than alternative TED treatments. 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. By comparison, a full course of treatment using steroids costs approximately $4,000, or less than a third of the cost of a single vial of Tepezza. Surgical procedures similarly cost several thousand dollars. The distinct difference in price between Tepezza and other medications—and the fact that Horizon's annual price increases for Tepezza has not spurred switching to alternative products—show that there is little cross-elasticity of demand between Tepezza and alternative TED therapies.

36. Industry participants, including, but not limited to, the Defendants, recognize the existence of a separate and distinct market for FDA-approved drugs to treat TED in their regular course of business, referring to it as the "TED market" or "Tepezza market." Notably, when the parties and other firms identify participants in this market, they focus on Tepezza and other potential future prescription drugs in the development pipeline, rather than alternative options such as off-label steroid treatments.

37. The sale of FDA-approved drugs to treat TED is therefore a line of commerce and a relevant product market within the meaning of the Clayton Act.

B. Drugs Approved to Treat Chronic Refractory Gout

38. 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. CRG occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors ("XOIs") at the maximum medically appropriate dose or for whom these drugs are contraindicated.

39. Gout is one of the most common forms of inflammatory arthritis and is associated with multiple comorbidities. Gout can be assessed by a simple blood test for the amounts of uric

acid in the blood (sUA levels). Typically, when uric acid levels are greater than 6.8 milligrams per deciliter, urate will crystallize and deposit. These hard deposits, known as tophi, may occur anywhere in the body, including joints as well as organs, such as the kidney and heart. When undertreated, tophi often lead to bone erosions and loss of functional ability. Gout flares, a common characteristic of CRG, are intensely painful. Of the 9.5 million gout sufferers in the United States, more than 100,000 patients may have CRG. A systemic disease, CRG frequently causes crippling disabilities and significant joint damage.

40. Marketed by Horizon, Krystexxa (pegloticase injection) is the first and only FDA-approved drug for CRG. Krystexxa is a PEGylated uric acid specific enzyme that is administered intravenously in an outpatient infusion center or physician's office by healthcare providers.

41. Krystexxa was first granted an Orphan Drug designation by the FDA in September 2010. There are still no other FDA-approved drugs to treat CRG on the market today. Although Horizon's Orphan Drug marketing exclusivity for Krystexxa expired in 2017, Krystexxa's composition of matter patent expires in [redacted], and its patent estate for Krystexxa expires in [redacted]. In July 2022, the FDA approved the supplemental Biologics License Application, expanding the drug's labeling to include Krystexxa co-administered with methotrexate, an immunomodulatory therapy. The co-administration of Krystexxa with methotrexate helps to reduce the development of anti-drug antibodies that can limit the efficacy of the drug over time. By reducing the development of drug resistance, Krystexxa with methotrexate helps CRG patients achieve greater recovery than Krystexxa alone. In clinical studies, patients receiving the combination drug also experienced fewer infusion reactions.

42. Compared to previously available gout medications, Krystexxa has a unique mechanism of action that can rapidly reverse disease progression. Unlike XOIs or uricosurics,

which address the over-production or under-excretion of uric acid, Krystexxa converts uric acid into allantoin, a water-soluble molecule that the body can more easily eliminate through urine. Renal excretion of allantoin is significantly more efficient than uric acid excretion. Additionally, many chronic kidney disease ("CKD") patients suffer from gout, and the disease tends to be more prevalent as CKD advances. Whereas XOI gout therapies can place additional burden on the kidneys and have dosing limitations, Krystexxa has been proven effective and safe for CKD patients with CRG without the need to adjust dosing.

43. As the only FDA-approved medication for the treatment of CRG, Krystexxa does not compete directly with other drugs. By definition, patients with CRG have a condition that is uncontrolled by other medications, including XOIs and uricosurics, or for whom these other drugs are contraindicated. Therefore, there are no other treatments that are reasonable substitutes.

44. Industry participants, including, but not limited to, the Defendants, recognize the existence of a separate and distinct market for CRG. Internal documents from Horizon and its potential competitor Selecta Biosciences ("Selecta") indicate that FDA-approved drug treatment for CRG is the relevant market for Krystexxa. A Horizon presentation from May 2021 on the gout competitive pipeline explicitly states that [redacted]."

45. There is little cross-elasticity of demand between Krystexxa and other gout medications. Krystexxa is priced significantly higher than other gout medications, with an annual wholesale acquisition cost of approximately $650,000. Drug treatments for conventional gout have generics available. Colchicine, for example, has a retail cost of approximately $183 per month, with an even lower cost to the patient.

46. The sale of FDA-approved drugs to treat CRG is therefore a line of commerce and a relevant product market within the meaning of the Clayton Act.

THE RELEVANT GEOGRAPHIC MARKET

47. The United States is the relevant geographic area in which to assess the competitive effects of the Proposed Acquisition in the relevant lines of commerce. The FDA regulates the production, research, development, testing, manufacture, marketing, and promotion of drug products in the United States. A company must obtain FDA approval before marketing a drug product in the United States. Accordingly, drug products sold outside the United States, but not approved for sale in the United States, do not provide viable alternatives for customers.

48. Performing the necessary clinical trials and navigating the FDA approval process may take as long as a decade for branded drugs such as those to treat TED and CRG. Thus, medicines sold outside the United States that lack FDA approval are not competitive alternatives for U.S. consumers, who cannot turn to these products even if the prices for drugs to treat TED or CRG currently available in the United States increase significantly.

49. Indeed, the Defendants consider the United States to be a distinct market for drugs to treat TED and CRG in their regular course of business due to, among other reasons, its separate regulatory and approval process.

MARKET STRUCTURE

A. Thyroid Eye Disease Drugs

50. As the only FDA-approved medication for the treatment of TED, Horizon's Tepezza does not face direct competition from any other approved medication in the United

States.

51. While Tepezza currently is administered by a healthcare provider as an intravenous infusion, typically in an outpatient infusion center or a doctor's office, Horizon is researching and developing potential subcutaneous formulations of the product that a patient could self-administer. The leading project, which involves subcutaneous [redacted], is currently in Phase 1 clinical trials and could become available in the United States in [redacted], pending further clinical study. Horizon is also working with Xeris Pharmaceuticals, Inc., to develop a subcutaneous injection that could be self-administered [redacted]. Should that product's clinical trials be successful, it could launch in the United States by [redacted].

52. Horizon documents recognize that the "[redacted]," as new products (that are primarily designed to be injected subcutaneously) are introduced to the market:



53. For example, although it currently does not offer a commercially administered product, Viridian Therapeutics, Inc. ("Viridian") is advancing multiple candidates through clinical programs for the treatment of patients with TED that could threaten Tepezza's monopoly. It has initiated a Phase 3 clinical trial for its leading candidate, VRDN-001, in patients with active TED. VRDN-001, like Tepezza, is a monoclonal antibody that inhibits the activity of a cell surface receptor called insulin-like growth factor-1 receptor ("IGF-1R") and would be administered by a healthcare provider intravenously. Viridian is also evaluating VRDN-001 in a Phase 2 proof-of-concept trial in patients with chronic TED. Horizon forecasts that VRDN-001 could be approved to treat patients with active TED in [redacted].

54. Horizon internal documents project that VRDN-001 will [redacted]. VRDN-001 early data suggests that it could have a higher proptosis response rate and overall response rate than Tepezza after 6 weeks of treatment:



55. In addition to its program for intravenously administered VRDN-001, Viridian is developing three subcutaneous products with the goal of providing a more conveniently administered therapy to patients with TED. Viridian is currently developing VRDN-002 and VRDN-003 as IGF-1R monoclonal antibodies targeting IGF-1R for self-administered subcutaneous injection for the treatment of TED. Depending on the outcome of the clinical trials, Viridian projects that either VRDN-002 or VRND-003 will be approved in [redacted]

56. Another example of a potential rival that may threaten Tepezza's monopoly is Immunovant, Inc. ("Immunovant"). Immunovant is a clinical-stage, publicly traded biopharmaceutical company focused on treating autoimmune diseases using Batoclimab, a fully

human, monoclonal antibody targeting the neonatal fragment crystallizable receptor. Immunovant is currently developing Batoclimab as a self-administered subcutaneous injection for treatment of TED and expects Phase 3 top-line results to be available in the first half of 2025 and [redacted]

B. Chronic Refractory Gout Drugs

57. As the only FDA-approved medication for the treatment of CRG, Horizon's Krystexxa does not face direct competition from any other approved medication in the United States.

58. 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). Phase 3 clinical data from March 2023 for SEL-212 shows that it has a favorable safety and durability profile compared to Krystexxa. Because of SEL-212's favorable differentiated profile in safety and durability, SEL-212 could threaten Krystexxa's monopoly when it comes to market as early as [redacted]

ANTICOMPETITIVE EFFECTS

59. Post-Acquisition, Amgen will possess 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, such as Enbrel, to foreclose or disadvantage future rivals in these markets, raise their barriers to entry, and dissuade them from competing aggressively.

60. Through the Proposed Acquisition, Amgen would gain the ability to leverage its portfolio of blockbuster drugs to secure preferred (or even exclusive) access for Tepezza and/or

Krystexxa, thus foreclosing or disadvantaging Amgen's rivals. Amgen's product portfolio includes nine different drugs that generated more than $1 billion in annual net sales in 2022, and is in high demand by PBMs, payers, and physicians. This portfolio includes: Enbrel ($4.1 billion), Prolia ($3.6 billion), Otezla ($2.3 billion), Xgeva ($2.0 billion), Aranesp ($1.4 billion), Nplate ($1.3 billion), Repatha ($1.3 billion), Kyprolis ($1.2 billion), and Neulasta ($1.1 billion). Amgen also has several potential blockbuster drugs in its research and development pipeline.

61. For example, Amgen's Enbrel is a highly utilized drug indicated to treat rheumatoid arthritis, psoriatic arthritis, moderate to severe plaque psoriasis, ankylosing spondylitis, and moderate to severe juvenile idiopathic arthritis, with greater than 85% first-line payer formulary coverage for commercial and Medicare Part D lives. Amgen offers significant rebates (a percentage discount off of list price) to secure favorable positioning for Enbrel on payers' formularies. As of 2022, Enbrel was a "[redacted]." For example, the PBM CVS Caremark and its GPO Zinc received approximately $[redacted] in rebates from Amgen for Enbrel in 2021. Another PBM, Express Scripts, received approximately $[redacted] in Enbrel rebates in 2021.

62. Because of its extensive and valuable portfolio of products, Amgen has a much greater ability to offer cross-market bundled rebates than Horizon, which focuses primarily on rare disease markets. Indeed, internal business documents show Amgen employees recognize the importance of the company's broad inflammation product portfolio during payer contracting. Describing this portfolio as the "[redacted]," they note that "[redacted]." Elsewhere, Amgen touts its [redacted] A 2021 internal Amgen "V&A Strategy" presentation suggested a "[redacted]

[redacted]." In the same document, Amgen boasts that "[redacted]."

63. The prospect that Amgen could leverage its portfolio of blockbuster drugs to gain advantages over potential rivals is not hypothetical. Amgen has deployed this very strategy to extract favorable terms from payers to protect sales of Amgen's struggling drugs. Specifically, Amgen has engaged in cross-market bundling, which involves the conditioning of rebates (or offering incremental rebates) on a product such as [redacted] in exchange for preferred formulary placements for Amgen drugs in other, unrelated product markets. Since 2020, Amgen has contracted for [redacted] separate cross-market drug bundles, including with the [redacted].

64. One cross-market bundle that Amgen negotiated with [redacted]. In May 2022, Regeneron sued Amgen in the District of Delaware alleging that Amgen's rebating strategy was an anticompetitive means to foreclose Regeneron's Praluent from competing with Amgen's Repatha and served to entrench Repatha's monopoly position. Earlier this year, the district court denied Amgen's motion to dismiss the complaint. *Regeneron Pharms., Inc. v. Amgen Inc.*, No. 22-697, 2023 WL 2587809 (D. Del. Mar. 21, 2023).

65. Such multi-product deals can also undermine competition by distorting how PBMs and payers make decisions about which drugs to make available to patients. For example, the sheer magnitude and/or predictability of the rebates that Amgen can offer on its high-volume

drugs as part of its cross-market bundles may ensure PBMs and payers grant Amgen's products preferred status. It also may be effectively impossible for smaller rivals, such as potential entrants to the TED and CRG markets, to match the value of bundled rebates that Amgen would be able to offer. Multiple payers agreed that cross-market bundling was a plausible outcome post-Acquisition.

66. Post-Acquisition, Amgen would have the incentive to sustain the Horizon drugs' monopolies using those same multi-product contracting strategies. An Amgen "Summary Observations" deal document explained that "[redacted]" Tepezza generated $1.96 billion, or 54% of Horizon's 2022 net sales, and Krystexxa generated $716 million, or 19.7% of Horizon's 2022 net sales. Amgen expects both drugs to grow significantly in the coming years, with Tepezza projected to achieve peak sales of approximately $[redacted] annually and Krystexxa projected to achieve peak sales of up to $[redacted] annually. Thus, protecting and growing these products' revenues is core to Amgen's deal rationale. With potentially billions of dollars at stake, Amgen has ample incentive to preserve the monopoly positions of these two drugs.

67. While Tepezza and Krystexxa are each currently monopolies, their dominance in the TED and CRG markets is threatened by potential entry in the coming years from rivals developing competing drugs, especially Viridian's TED drug. Amgen recognizes these entrants as serious threats, and models that they will take substantial revenue from Horizon's drugs if they successfully enter. For example, in November 2022, an Amgen business development plan modeled both a "[redacted]" and a [redacted]" for the Acquisition. According to the "[redacted]" model, there are several "key sensitivities" impacting valuation, including [redacted]

[redacted]. The first key sensitivity impacting valuation is a "[redacted]. The second key sensitivity impacting valuation is a "[redacted].

68. The most straightforward strategy through which Amgen could limit rivals' market access is by using the same tactic it has utilized in the past to secure favorable formulary placement for its drugs over competition—leveraging its existing portfolio of blockbuster drugs, including [redacted], in multi-product contracts with payers. Indeed, three days after the Proposed Transaction was announced, Amgen's SVP of Finance emailed Amgen's EVP and CFO: "[redacted]" which currently receives preferred formulary placement [redacted].

69. Specifically, 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-carry blockbuster drugs on 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.

70. 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. Drugs reimbursed through the pharmacy benefit are typically self-administered and dispensed through a retail or

specialty pharmacy, whereas drugs reimbursed through the medical benefit are typically administered by a healthcare provider. Ultimately, 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.

71. Market trends promise to further heighten Amgen's ability to implement multi-product contracts that foreclose or disadvantage Tepezza's and Krystexxa's future rivals. In particular, 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.

72. In light of this trend toward consolidation between pharmacy and medical benefit managers, Defendants' internal business documents forecast that cross-benefit management practices will continue to grow. One Horizon document predicts that "[redacted]." Another Horizon document states that "[redacted]." This growing trend towards cross-benefit management is removing a market structure that previously siloed pharmacy and medical benefits from one another, allowing payers to now evaluate drugs regardless of whether they are reimbursed through a pharmacy or medical benefit. In turn, this

may further facilitate Amgen's ability to implement cross-benefit bundles that link pharmacy benefit drugs, like Enbrel, and medical benefit drugs, like Tepezza and Krystexxa.

73. Cross-benefit management aside, Tepezza's interaction with PBMs is also poised to grow because Horizon is developing a subcutaneous formulation of the drug that promises greater ease of use relative to its current, intravenous mode of administration. The company expects that this product will expand [redacted]." Horizon projects that this subcutaneous formulation of Tepezza, for which it expects to receive FDA approval as soon as [redacted]. That development may further facilitate Amgen's ability to establish multi-product contracts between Tepezza and its pharmacy benefit products, like Enbrel, in turn raising Tepezza rivals' barriers to entry and dissuading competition.

74. In short, due to these existing and emerging market trends, permitting Amgen—with its portfolio of blockbuster drugs, contracting leverage, and existing multi-product contracting strategies—to purchase Horizon would likely sustain and entrench Tepezza's and Krystexxa's monopolies, as the combined firm would possess the ability and incentive to foreclose or disadvantage any future rivals. As a result, the Proposed 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.

LACK OF COUNTERVAILING FACTORS

A. Entry Barriers

75. Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. De novo entry would not be timely because the combination of drug

development times and FDA approval requirements is lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Proposed Acquisition.

76. For entry to occur, a potentially suitable molecule must be identified and developed, usually through preclinical trials that focus on non-human subjects. The development then progresses to clinical trials in humans. The preclinical and clinical trials can cost hundreds of millions of dollars to complete, all without a guarantee of success. The Department of Health and Human Services estimates that it can take $300-500 million and 14 years on average to develop and bring a drug to market.

77. Assuming the clinical studies show a drug profile that is safe and efficacious, a new entrant would also incur substantial marketing costs to bring the drug to market and raise awareness of its availability.

78. Biosimilar entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition.

79. The complexity of manufacturing Tepezza and Krystexxa could pose a barrier to potential biosimilar competition.

80. Horizon has biologic reference product exclusivity in the United States covering Tepezza that would prevent biosimilar competition until [redacted].

81. According to Horizon's documents, Krystexxa's composition of matter patent expires in [redacted], and its patent estate for Krystexxa expires in [redacted]. Horizon's documents estimate that biosimilar entry could occur in [redacted]

[redacted].

82. There are currently no manufacturers developing a Krystexxa biosimilar.

B. Efficiencies

83. Defendants cannot demonstrate merger-specific, verifiable, and cognizable efficiencies sufficient to rebut the evidence of the Proposed Acquisition's likely anticompetitive effects. As Amgen acknowledges in one of its own deal documents, this is [redacted]."

VIOLATION

COUNT I – ILLEGAL ACQUISITION

84. The allegations of Paragraphs 1 through 83 above are incorporated by reference.

85. The Proposed Acquisition, if consummated, would be likely to lessen competition substantially in interstate trade and commerce in each of the markets for (1) the sale of FDA-approved drugs to treat TED and (2) the sale of FDA-approved drugs to treat CRG throughout the country in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

LIKELIHOOD OF SUCCESS ON THE MERITS, BALANCE OF EQUITIES, AND NEED FOR RELIEF

86. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission, whenever it has reason to believe that a proposed acquisition is unlawful, to seek preliminary injunctive relief to prevent consummation of the acquisition until the Commission has had an opportunity to adjudicate the acquisition's legality in an administrative trial. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities. The principal public equity weighing in favor of issuance

of preliminary injunctive relief is the public interest in effective enforcement of the antitrust laws. Private equities affecting only Defendants' interest cannot defeat a preliminary injunction.

87. The Commission is likely to succeed in proving that the effect of the Proposed Acquisition may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, or Section 5 of the FTC Act, 15 U.S.C § 45. In particular, the Commission is likely to succeed in demonstrating, among other things, that:

a. The Proposed Acquisition would have anticompetitive effects in the United States, in a relevant product market of the sale of FDA-approved drugs to treat TED;

b. The Proposed Acquisition would have anticompetitive effects in the United States, in a relevant product market of the sale of FDA-approved drugs to treat CRG;

c. Substantial and effective entry or expansion is difficult and would not be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition; and

d. The efficiencies and procompetitive benefits asserted by Defendants do not justify the Proposed Acquisition.

88. Preliminary relief is warranted and necessary. Should the Acquisition ultimately be adjudicated unlawful, reestablishing the status quo ante if the Proposed Acquisition has already occurred in the absence of preliminary relief would be extremely difficult. Allowing the Acquisition to close before the Commission issues an administrative complaint and the completion of any administrative proceeding would cause irreparable harm by, among other things, enabling the combined firm to begin altering Horizon's operations and business plans,

accessing Horizon's sensitive business information, potentially eliminating Horizon personnel, and influencing Horizon's product development efforts. In the absence of relief from this Court, substantial harm to competition would likely occur in the interim.

89. Accordingly, the equitable relief requested here is in the public interest. The Commission respectfully requests that the Court:

a. Enter the temporary restraining order and preliminarily enjoin Defendants from taking any further steps to consummate the Proposed Acquisition and any related transactions, stock assets, or acquisition of any other interests of one another either directly or indirectly; carrying out any other agreement, understanding, or plan by which Amgen would acquire control over Horizon or any of its assets;

b. Retain jurisdiction and maintain the status quo until the Commission issues an administrative complaint and any administrative proceeding initiated by the Commission is concluded; and

c. Award such other and further relief as the Court may determine is appropriate, just, and proper.

Dated: May 16, 2023

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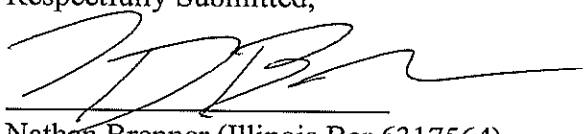
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