UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION, *Plaintiff*, v. AMGEN INC. and HORIZON THERAPEUTICS PLC, *Defendants*.	Case No. 1:23-cv-03053 Judge John F. Kness

ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS AMGEN INC. AND HORIZON THERAPEUTICS PLC TO PLAINTIFF'S COMPLAINT

Defendants Amgen Inc. ("Amgen") and Horizon Therapeutics plc ("Horizon") (together "Defendants") hereby answer the Complaint for Temporary Restraining Order and Preliminary Injunctive Relief Pursuant to Section 13(b) of the Federal Trade Commission Act (Dkt. No. 20) (the "Complaint") filed by the Federal Trade Commission (the "FTC"), denying any allegation not specifically admitted herein and stating that the proposed transaction is lawful, procompetitive and good for consumers.

PRELIMINARY STATEMENT

Amgen is a U.S.-based biotechnology company whose mission is to discover, develop and deliver first-in-class and best-in-class medicines to patients around the globe suffering from serious illnesses. In December 2022, Amgen announced its agreement to acquire Horizon, an Ireland-based biotechnology company focused on developing medicines to treat patients suffering from rare, autoimmune and severe inflammatory diseases, for approximately

$27.8 billion (the "Transaction"). The Transaction will extend Amgen's ability to treat the world's most devastating illnesses, benefitting patients in the United States and around the globe with the application of cutting-edge scientific innovation.

Horizon's medicines treat serious rare diseases. The FTC's claim focuses on two of those medicines: TEPEZZA®, the first and only FDA-approved treatment for thyroid eye disease ("TED"), and KRYSTEXXA®, the first and only FDA-approved treatment for chronic refractory gout ("CRG"). TED and CRG are debilitating illnesses, as are other illnesses that Horizon's medicines are indicated to treat. Notably, the FTC does not allege that Amgen competes with *any* of Horizon's medicines, including TEPEZZA® or KRYSTEXXA®.

As an independent business, Horizon does not have the resources Amgen has to bring its medicines to all of the patients around the world who badly need them. The Transaction gives Horizon the capabilities, expertise, and global scale it needs to do that. Amgen and Horizon expect that, together, they can utilize Amgen's industry-leading research and development and manufacturing capabilities, strong provider relationships, extensive global presence, and decades of experience to make Horizon's medicines accessible to many more patients, more quickly than Horizon could on its own, not only in the United States but around the world.

Against that background, the FTC's attempt to prevent this procompetitive merger is as misguided as it is unprecedented. The FTC has never challenged a merger between pharmaceutical companies based on allegations that did not include a horizontal product overlap or claims of potential head-to-head competition between the merging parties. The Complaint does not allege any such concerns – and there are none. Given the lack of any material competition between Amgen and Horizon, the Transaction should have been cleared months ago

under well-established precedent; and Amgen, Horizon and their patients should already be realizing the Transaction's significant benefits. Instead, the FTC has delayed the Transaction for months, and now asks this Court to effectively scuttle it. It does so based on a novel and highly speculative "cross-benefit" and "cross-market" bundling theory that has no legal or factual support. And it does so despite Amgen committing to the FTC, before the agency filed its Complaint, that it would not engage in the very conduct about which the FTC alleges concern. Putting to one side that Amgen would have neither motive nor ability to engage in that conduct, Amgen also made clear that it would be willing to formalize that commitment in a binding consent order.

To obtain the extraordinary relief it seeks, the FTC has the burden of proving that the Transaction is reasonably likely to imminently and substantially lessen competition and that the balance of equities tips in its favor. 15 U.S.C. § 18; *United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974). The FTC cannot meet its burden based on presumptions, which apply only in merger cases involving actual horizontal overlaps. *See United States v. AT&T*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). And it cannot rest on "antitrust theory and speculation" or "guesswork"; rather, it must put forward facts demonstrating a "reasonable probability" that the Transaction is likely to cause imminent competitive harm. *FTC v. Rag-Stiftung*, 436 F. Supp. 3d 278, 290 (D.D.C. 2020). Further, where the defendant has made a commitment, prior to the filing of the complaint, that fully addresses the alleged concerns – as Amgen did here – the Court must take that commitment into account in determining the merits of the FTC's claim that the transaction is likely to substantially lessen competition. *See, e.g.*, *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018). The FTC's Complaint fails to make the required showing.

In particular, the FTC's allegations are far too speculative to support a showing of probable and imminent harm to competition. TEPEZZA® and KRYSTEXXA® currently are the only FDA-approved treatments for their respective diseases. The FTC's case is based on its assertion that, in the event a TED or CRG rival emerged, Amgen would respond to such a future rival by giving pharmacy benefit managers ("PBMs") rebates on Amgen products (such as Enbrel®) to "ensure" favorable formulary placement for TEPEZZA® or KRYSTEXXA® and thereby exclude that rival. Even setting aside Amgen's commitment that it will not do that, in the real world there are many reasons why Amgen would not have an incentive or the ability to engage in that type of conduct. First, TEPEZZA® and KRYSTEXXA® both are primarily reimbursed through medical benefit plans, rather than pharmacy benefit plans. In the medical benefit context, bundled discounting is rare. And cross-benefit bundling, *i.e.*, bundling between medical benefit products like Horizon's TEPEZZA® and KRYSTEXXA® and pharmacy benefit products like Amgen's Enbrel®, is even rarer – if it is ever done at all – due to a number of logistical, economic, legal and regulatory barriers. Indeed, Amgen does not have *any* contracts that bundle a pharmacy benefit product with a medical product today, and has no plans to try to pursue such a bundle in the future, including with any Horizon product.

Even setting aside the genuine distinctions between pharmacy and medical benefit products, the real-world dynamics of treating rare diseases present another significant barrier. In the context of medicines like TEPEZZA® and KRYSTEXXA®, indicated to relieve suffering from serious rare diseases for which treatment options are limited and differentiated, and where treatment decisions can have life-altering consequences, patients and physicians often have strong treatment preferences and would be highly likely to resist any attempt to restrict access to a preferred treatment. For such treatments, clinical utility and patient and provider preferences

drive utilization, not discounting for formulary positioning. Particularly as applied to rare diseases, the FTC's hypothesized bundling theory – that Amgen could foreclose rare disease competitors through bundled rebates – is a square peg in a round hole.

In its Complaint, the FTC does not meaningfully address the real-world factors that refute its incentive and ability theory. The Complaint is utterly silent as to the actual dynamics of rare disease treatment. When addressing the barriers that exist to bundling across medical benefit and pharmacy benefit products, the FTC relies on inaccurate generalizations and speculation. It asserts that vertical integration among insurance plans and PBMs has eroded the distinctions between the two types of benefits. But in the real world, there are many plans and PBMs that are not vertically integrated, and a majority of covered patients get a medical benefit from one firm and a pharmacy benefit from another. And the FTC ignores the many other real world regulatory and structural impediments to such bundles, including that rebates involving medical benefit products generally erode profitability because of how medical benefit products are reimbursed.

The FTC claims that the barriers may not apply because a subcutaneous version of TEPEZZA®, today in early stages of development by Horizon, *may* be successful. And if it is, it *may* be approved by the FDA for patient self-administration (which is in addition to approval for subcutaneous use and can be limited to physician-administration by the FDA). And if it is, it *may* be covered as a pharmacy benefit product for *some* patients at *some point* in the future (and even then, the FTC's theory would further require that the future TEPEZZA® competitor *also* obtain approval for a comparable self-administered offering, which is even more speculative). There are a number of factual inaccuracies in those assertions – and the assertions say nothing about KRYSTEXXA®. But even setting those aside, such speculation about possibilities that

may or may not come to pass years in the future are not enough to block a merger under the Clayton Act. And *if* those events came to pass, and *if* the FTC in the future had concerns about such events, the FTC has an entire division focused on investigating and challenging anticompetitive conduct when it believes a company has engaged in it.

On top of its conjecture regarding a subcutaneous version of TEPEZZA®, the FTC's case goes on to pile more speculation on speculation. The FTC repeatedly alleges that there are no rivals to TEPEZZA® or KRYSTEXXA® today, and thus acknowledges there is no existing incentive to engage in the hypothesized bundling. The FTC speculates that, while not present today, rivals to Horizon's TEPEZZA® and KRYSTEXXA® products may emerge in the future and threaten Horizon's position as a supplier of treatments for TED and CRG. Never mind that the handful of pipeline products identified in the Complaint are in early stages of development and must overcome several clinical development and regulatory hurdles to get to market; or that, if any do, the timing and impact of their entry is highly uncertain. The Complaint also ignores that these pipeline products are all differentiated from TEPEZZA® and KRYSTEXXA® and provides no basis for predicting that any would ever threaten Amgen's sales in a way that would support the FTC's theory. As the FTC tells it, entry may happen at some point, or it may not, and that is enough. That is wrong, and insufficient reason to block this Transaction.

On top of that, the FTC speculates that, if and when any such entry occurs, though years away at best, the competitive conditions for the Amgen medicines the FTC claims would be used in the bundle, such as Enbrel®, will not have changed—that is, the alleged coercive power that the FTC claims Amgen now has and could theoretically exert to gain favorable formulary placement for KRYSTEXXA® and TEPEZZA® will not have eroded. Put to one side

that this unsupported claim is at odds with widely reported commercial realities faced by Amgen's products;[1] or that, even today, Enbrel®, with shares below 20% in any conceivable market, faces significant competition and declining sales; or that the other Amgen products cited in the Complaint face similar, or even more, competitive markets, which are also growing more competitive by the day. The notion that PBMs are vulnerable to economic coercion by Amgen when negotiating for coverage of medicines like Enbrel® is also implausible given the reality that PBMs hold the leverage in such negotiations, a reality the FTC acknowledges in other contexts.[2] But commercial realities are of no moment to the FTC's speculation-fueled case here. Brushing facts aside, the FTC bases its entire theory on the contention that Amgen's products, though they plainly have no coercive power even today, may somehow have coercive power years from now. Again, that is not a proper basis for a merger challenge.

The Complaint makes several additional baseless assumptions. It assumes without support that Amgen would earn greater profits by excluding putative future rivals of TEPEZZA® or KRYSTEXXA® than it would lose from giving discounts on medicines like Enbrel®. This wholly unfounded proposition ignores that Amgen has many, and far more plausible, ways to compete against any future TED and CRG competitors that do not involve bundling, such as lowering the weighted average cost for TEPEZZA® and KRYSTEXXA®, offering non-bundled discounts on TEPEZZA® or KRYSTEXXA® alone, or competing with non-price tools such as differentiating medical evidence about safety and efficacy. The Complaint

[1] *See, e.g.*, David Wainer, *Elizabeth Warren and the FTC are the Least of Amgen's Problems*, WALL ST. J., Mar. 24, 2023, https://www.wsj.com/articles/elizabeth-warren-and-the-ftc-are-the-least-of-amgens-problems-889163a6.

[2] *See, e.g.*, Fed. Trade Comm'n, Press Release, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry* (June 7, 2022), *available at* https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

also baselessly assumes that the theoretically targeted rivals of TEPEZZA® and KRYSTEXXA® would not be able to offer competitive inducements in favor of their own treatments. And it assumes that enough payors would respond to the hypothesized bundling by excluding the theoretically targeted rival from enough formularies to deprive it of competitive scale and harm competition. All of those assumptions are wholly unfounded.

For all its speculation, the Complaint revealingly does not identify a *single* document produced by Amgen (or Horizon) suggesting any plan to engage in the conduct alleged by the FTC. Rather, the documents tell a consistent story that Amgen's plan is to increase sales of TEPEZZA® by expanding its availability in international geographies and for patients suffering from chronic TED symptoms (as opposed to acute). Instead, the Complaint implausibly alleges that Amgen spent $28 billion to buy Horizon and somehow did not create even a single document describing its supposed "real" plan to bundle its products with Horizon's medicines. Particularly considering that bundling is often procompetitive and not inherently anticompetitive, it is implausible that an acquiror in Amgen's position would not reduce to writing such a strategy if it was at all contemplated. There is a reason for the total lack of documentary support for the FTC's claim – the FTC's bundling allegations are simply made up.

The FTC attempts, but fails, to compensate for the total lack of documentary support by pointing to unproven (and easily disproved) allegations made by a rival pharmaceutical company in a separate case that has nothing to do with Horizon's products; and even tries to rely upon a motion to dismiss ruling which the court in that case itself observed followed from its inability to consider extrinsic evidence (such as the actual Amgen contracts at issue and other facts not pleaded in the complaint). That case, and that decision, plainly have no relevance to this case, and the FTC does not even allege that that bundle is actually

anticompetitive. That the FTC must resort to citing unproven allegations of an Amgen rival only further underscores the weakness of its claims.

Even if the FTC were able to show that, at some point in the future post-merger, Amgen was likely to offer bundled discounts for favorable formulary placement of Horizon medicines (and it cannot), that would not automatically mean that the Transaction is likely to substantially lessen competition. The law recognizes that "[b]undled discounts are pervasive, and examples abound" across the economy, and that they "generally benefit buyers because the discounts allow the buyer to get more for less." *Cascade Health Sol. v. PeaceHealth*, 515 F.3d 884, 894-95 (9th Cir. 2008). Indeed, "cutting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). For that reason, it is well understood that bundled discounting is often procompetitive and can harm competition in only limited circumstances. *E.g.*, *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264 (6th Cir. 2015) (bundled discount anticompetitive only where it is significant enough to take the competitive product below cost such that an equally efficient competitor will be unable to compensate buyers for the foregone discount). There is no basis to assume that the bundled discounts about which the FTC speculates – which will not come about in any event for all the reasons explained – would be the rare form of competition-reducing price cutting.

Finally, as noted, if (hypothetically) Amgen ever engaged in activity unlawful under the antitrust laws, the FTC could of course file suit at that time. Both the Sherman Act and Section 5 of the FTC Act supply a cause of action to the FTC to enjoin anticompetitive conduct such as bundling that harms the competitive process in a relevant market. There is simply no good reason, and no legal basis under Section 7 of the Clayton Act, to prevent the consummation

of a highly complementary Transaction, and to forestall the benefits it will deliver to patients in need, when the alleged conduct not only is entirely unfounded, but also addressable under the antitrust laws if, hypothetically, it ever occurred in the future.

For all of these reasons, the FTC's challenge lacks any factual or legal support. Accordingly, the FTC's motion for a preliminary injunction should be denied.

Defendants provide their specific responses to the FTC's allegations below.

RESPONSES TO THE SPECIFIC ALLEGATIONS OF THE COMPLAINT

Except to the extent specifically stated herein, Defendants deny each and every allegation contained in the Complaint, including all allegations contained in headings or otherwise not contained in one of the Complaint's numbered paragraphs.

The first paragraph of the preamble to the Complaint characterizes this action and asserts legal conclusions and arguments to which no response is required; to the extent that a response is deemed necessary, Defendants state that the FTC has petitioned this Court for a temporary restraining order and a preliminary injunction enjoining the Transaction and in all other respects deny the allegations in the first paragraph of the preamble to the Complaint.

The second and third paragraphs of the preamble to the Complaint characterize this action and assert legal conclusions and arguments to which no response is required. To the extent that a response is required, Defendants deny the allegations in these paragraphs. In particular, Defendants deny that a temporary restraining order enjoining the Transaction is necessary to preserve the Court's ability to provide full and effective relief, deny that competition will be harmed if the Court denies the FTC's request for a preliminary injunction enjoining the Transaction, and deny that preliminary injunctive relief is imperative to protect competition and consumers pending the issuance of an administrative complaint.

Defendants respond to the numbered paragraphs of the Complaint as follows:

NATURE OF THE CASE

1. Defendants deny the allegations of paragraph 1, except admit that Amgen proposes to acquire Horizon pursuant to an agreement dated December 11, 2022, and that Horizon has certain medicines indicated for the treatment of thyroid eye disease ("TED") and chronic gout in adult patients refractory to conventional therapy ("CRG").

2. Defendants deny the allegations of paragraph 2, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about Amgen's alleged prior acquisitions, except (a) Amgen admits that in 2002 Amgen acquired each share of Immunex common stock for a fixed ratio of 0.44 shares of Amgen common stock and cash of $4.50; (b) Amgen admits that in 2019 it acquired Otezla for $13.4 billion in cash, or approximately $11.2 billion net of anticipated future cash tax benefits as part of a divestiture that the FTC sanctioned; (c) Defendants admit that Amgen proposes to acquire Horizon in a Transaction that values the entire issued and to be issued ordinary share capital of Horizon at approximately $27.8 billion on a fully diluted basis; and (d) Amgen admits it has a portfolio of marketed medicines and a pipeline of development programs relating to different therapeutic areas.

3. Defendants deny the allegations in paragraph 3, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's negotiations with PBMs and payers.

4. Defendants deny the allegations in paragraph 4, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations

relating to Amgen's alleged agreements, negotiations with PBMs and payers or product sales, except Amgen admits in 2022 Enbrel® generated $4.044 billion in global sales.

5. Defendants deny the allegations in paragraph 5, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged negotiations with payers, except admit that the United States District Court for the District of Delaware is presiding over a case captioned *Regeneron Pharms., Inc. v. Amgen Inc.*, 1:22-cv-00697-RHA-JHL (D. Del.) and refer to the filings in that case for their full and accurate contents.

6. Defendants deny the allegations in paragraph 6, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about Amgen's alleged expectations for TEPEZZA®'s growth, except admit that (a) TEPEZZA® is currently the only FDA-approved medicine that is indicated for the treatment of TED and KRYSTEXXA® is currently the only FDA-approved medicine that is indicated for the treatment of CRG; (b) TEPEZZA®'s net sales for 2022 were approximately $1.97 billion, or approximately 54% of Horizon's net sales, and KRYSTEXXA®'s net sales for 2022 were approximately $716 million, or approximately 19.7% of Horizon's net sales; and (c) TEPEZZA® has significant growth potential in key ex-U.S. markets, which complements Amgen's international growth strategy.

7. Defendants deny the allegations in paragraph 7, except admit that Horizon filed a 2022 SEC Form 10-K on March 1, 2023, and refer to that document for its full and accurate contents. To the extent any of the allegations in paragraph 7 purport to state a legal conclusion, no response is required as to such allegations.

8. Defendants deny the allegations in paragraph 8.

9. Defendants deny the allegations in paragraph 9, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents; (b) Horizon states that it is without knowledge or information sufficient to form a belief about Amgen's beliefs; and (c) Horizon admits that certain Horizon employees produced an internal document and refers to that document for its full and accurate contents.

10. Defendants deny the allegations of paragraph 10. To the extent any of the allegations in paragraph 10 purport to state a legal conclusion, no response is required as to such allegations.

11. Defendants deny the allegations in paragraph 11. Defendants further state that they are without knowledge or information sufficient to form a belief about the alleged "management strategies" of the unnamed "entities" referenced therein. To the extent any of the allegations in paragraph 11 purport to state a legal conclusion, no response is required as to such allegations.

12. Defendants deny the allegations in paragraph 12, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents; (b) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents; (c) Horizon admits that certain Horizon employees produced an internal document and refers to that document for its full and accurate contents; and (d) Amgen admits that certain Amgen employees created an internal document and refers to that document for its full and accurate contents.

13. Defendants deny the allegations of paragraph 13, except admit that Horizon is currently in Phase 1 clinical trials for a subcutaneously administered version of TEPEZZA® that could potentially obtain FDA approval in the future, subject to significant remaining risk and uncertainty including the results of a Phase 3 clinical trial and FDA review. To the extent any of the allegations in paragraph 13 purport to state a legal conclusion, no response is required as to such allegations.

14. Defendants deny the allegations of paragraph 14. To the extent any of the allegations in paragraph 14 purport to state a legal conclusion, no response is required as to such allegations.

15. Defendants deny the allegations of paragraph 15. To the extent any of the allegations in paragraph 15 purport to state a legal conclusion, no response is required as to such allegations.

16. Defendants deny the allegations in paragraph 16, and further deny that Plaintiff is entitled to the relief sought. Defendants refer to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) and Section 7 of the Clayton Act for their contents. Defendants further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether 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). To the extent any of the allegations in paragraph 16 purport to state a legal conclusion, no response is required as to such allegations.

17. Defendants deny the allegations in paragraph 17. To the extent any of the allegations in paragraph 17 purport to state a legal conclusion, no response is required as to such allegations.

18. Defendants deny the allegations in paragraph 18, and further state that pursuant to a stipulated order filed in this action on June 2, 2023, Defendants have agreed that they will not consummate the Transaction until the earlier of (i) October 31, 2023, or (ii) two business days after a ruling by this Court on the FTC's motion for a preliminary injunction under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) and Section 7 of the Clayton Act, 15 U.S.C. § 18.

JURISDICTION AND VENUE

19. Defendants admit that the FTC purports to bring this action under Section 13(b) of the FTC Act, 15 U.S.C. §53(b) and under 28 U.S.C. §§ 1331, 1337, and 1345 and refers to those statutes for their contents. To the extent any of the allegations in paragraph 19 purport to state a legal conclusion, no response is required as to such allegations.

20. Defendants refer to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) for its contents. To the extent any of the allegations in paragraph 20 purport to state a legal conclusion, no response is required as to such allegations.

21. Defendants state that because the allegations in paragraph 21 purport to state a legal conclusion, no response is required as to such allegations.

22. Defendants deny the allegations of paragraph 22, except admit that the Defendants transact business in the Northern District of Illinois. To the extent any of the allegations in paragraph 22 purport to state a legal conclusion, no response is required as to such allegations.

23. Defendants deny the allegations of paragraph 23, except admit that Horizon's U.S. headquarters are located in Lake County, Illinois. To the extent any of the

allegations in paragraph 23 purport to state a legal conclusion, no response is required as to such allegations.

THE PARTIES AND THE PROPOSED ACQUISITION

24. Defendants admit, based on public sources, that (a) 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 and (b) the FTC Act, 15 U.S.C. § 45 outlines the powers and responsibilities of the Commission. To the extent any of the allegations in paragraph 24 purport to state a legal conclusion, no response is required as to such allegations.

25. Defendants admit the allegations in paragraph 25, insofar as the phrase "largest market" means the country in which Amgen makes the majority of its revenues, except Horizon states it is without knowledge or information sufficient to form a belief about the allegations in the last four sentences of paragraph 25 regarding Amgen's product sales and the focus of its research or development.

26. Defendants admit the allegations in paragraph 26, insofar as the word "leading" in the fourth sentence means medicines with the largest amount of net sales in 2022. To the extent the allegations in paragraph 26 repeat allegations contained in paragraph 6, Defendants incorporate their answer to paragraph 6.

27. Defendants admit the allegations in paragraph 27.

28. Defendants deny the allegations in paragraph 28, and further state that pursuant to a stipulated order filed in this action on June 2, 2023, Defendants have agreed that they will not consummate the Transaction until the earlier of (i) October 31, 2023, or (ii) two business days after a ruling by this Court on the FTC's motion for a preliminary injunction under

Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), and Section 7 of the Clayton Act, 15 U.S.C. § 18.

THE ALLEGED RELEVANT PRODUCT MARKETS

29. Defendants deny the allegations of paragraph 29. To the extent any of the allegations in paragraph 29 purport to state a legal conclusion, no response is required as to such allegations.

30. Defendants admit that the quoted language is excerpted from Horizon's annual report for the fiscal year ended December 31, 2021, and refer to that report for its full and accurate contents.

31. Defendants are without knowledge or information regarding the truth of the allegations concerning the annual incidence of TED in the United States, the potential patient population, or the population suffering from moderate-to-severe acute TED each year. To the extent the allegations in paragraph 31 are based on public sources, Defendants refer to those sources for their full and accurate content.

32. Defendants admit the allegations in paragraph 32.

33. Defendants deny the allegations in paragraph 33, except admit that (a) TEPEZZA® is the first and only medicine approved by the FDA to treat TED; (b) the Orphan Drug Act, Pub . L. No. 97-414 and the FDA regulations, 21 C.F.R. § 316, govern Orphan Drug designation and refer to the Orphan Drug Act, Pub . L. No. 97-414 and the FDA regulations, 21 C.F.R. § 316, for their contents; and (c) the FDA issued a press release dated January 21, 2020, and refer to the press release for its full and accurate contents.

34. Defendants deny the allegations of paragraph 34, and state that, to the extent the allegations of paragraph 34 purport to summarize any sources describing the efficacy,

differentiating factors and benefits of TEPEZZA® vis-à-vis other options for the treatment of TED, Defendants refer to those sources for their full and accurate contents. To the extent any of the allegations in paragraph 34 purport to state a legal conclusion, no response is required as to such allegations.

35. Defendants deny the allegations in paragraph 35, except admit that TEPEZZA® has achieved sales growth since the introduction of TEPEZZA®, and state that, to the extent the allegations of the first sentence of paragraph 35 purport to summarize any public sources describing the efficacy, differentiating factors and benefits of TEPEZZA® vis-à-vis other options for the treatment of TED, Defendants refer to those sources for their full and accurate contents. To the extent any of the allegations in paragraph 35 purport to state a legal conclusion, no response is required as to such allegations.

36. Defendants deny the allegations in paragraph 36. Defendants further state that they are without knowledge or information sufficient to form a belief regarding the allegations as to what unnamed "other firms" purportedly identify or recognize. To the extent any of the allegations in paragraph 36 purport to state a legal conclusion, no response is required as to such allegations.

37. Defendants deny the allegations in paragraph 37. To the extent any of the allegations in paragraph 37 purport to state a legal conclusion, no response is required as to such allegations.

38. Defendants deny the allegations in paragraph 38, except admit that KRYSTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for

whom these drugs are contraindicated. To the extent any of the allegations in paragraph 38 purport to state a legal conclusion, no response is required as to such allegations.

39. Defendants are without knowledge or information regarding the truth of the allegations in Paragraph 39. To the extent the allegations in paragraph 39 are based on public sources, Defendants refer to those sources for their full and accurate content.

40. Defendants deny the allegations in paragraph 40 on the basis that they provide an incomplete description of KRYSTEXXA® and how it is administered, except admit that KRYSTEXXA® is marketed by Horizon and is the only FDA-approved medicine that is indicated for the treatment of CRG.

41. Defendants deny the allegations of paragraph 41, except admit that (a) there are no other FDA-approved medicines to treat CRG available today; (b) Horizon's Orphan Drug marketing exclusivity for KRYSTEXXA® expired in 2017; (c) KRYSTEXXA®'s composition of matter patent expires in the year stated in the allegation in paragraph 41; (d) in July 2022, the FDA approved the supplemental Biologics License Application, expanding the KRYSTEXXA®'s labeling to include KRYSTEXXA® co-administered with methotrexate, an immunomodulatory therapy; (e) the co-administration of KRYSTEXXA® with methotrexate is expected to help to reduce the development of anti-drug antibodies that can limit the efficacy of the medicine; (f) by reducing the development of drug resistance, KRYSTEXXA® with methotrexate is expected to help CRG patients achieve greater recovery than KRYSTEXXA® alone; and (g) in clinical studies, patients receiving the combination medicine experienced fewer infusion reactions.

42. Defendants state they are without information or knowledge sufficient to admit or deny the allegations of paragraph 42, except admit that KRYSTEXXA® has a different

mechanism of action (MOA) from XOIs and uricosurics and differs in safety and efficiency in treating certain patients, and state that to the extent paragraph 42 purports to state information from medical literature or the results of clinical studies, Defendants refer to such literature or studies for their full and accurate contents.

43. Defendants deny the allegations in paragraph 43, except admit that KRYSTEXXA® is currently the only FDA-approved medicine that is indicated for the treatment of CRG. To the extent any of the allegations in paragraph 43 purport to state a legal conclusion, no response is required as to such allegations.

44. Defendants deny the allegations in paragraph 44, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents and (b) Horizon admits that certain Horizon employees created an internal document and refers to that document for its full and accurate contents. Defendants further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what other industry participants supposedly consider as the relevant market for KRYSTEXXA®.

45. Defendants deny the allegations in paragraph 45. To the extent any of the allegations in paragraph 45 purport to state a legal conclusion, no response is required as to such allegations.

46. Defendants deny the allegations in paragraph 46. To the extent any of the allegations in paragraph 46 purport to state a legal conclusion, no response is required as to such allegations.

THE ALLEGED RELEVANT GEOGRAPHIC MARKET

47. Defendants deny the allegations in paragraph 47, except admit that the FDA regulates drug products in the United States and that companies must obtain FDA approval before marketing a drug product in the United States. To the extent any of the allegations in paragraph 47 purport to state a legal conclusion, no response is required as to such allegations.

48. Defendants deny the allegations in paragraph 48, except admit that the FDA approval process for branded drugs such as those to treat TED and CRG can be lengthy. To the extent any of the allegations in paragraph 48 purport to state a legal conclusion, no response is required as to such allegations.

49. Defendants deny the allegations in paragraph 49. To the extent any of the allegations in paragraph 49 purport to state a legal conclusion, no response is required as to such allegations.

THE ALLEGED MARKET STRUCTURE

50. Defendants deny the allegations in paragraph 50, except admit that TEPEZZA® is the only FDA-approved medication for the treatment of TED.

51. Defendants deny the allegations in paragraph 51, except admit that (a) TEPEZZA® is administered by a healthcare provider as an intravenous infusion, typically in an outpatient infusion center or a doctor's office; (b) Horizon is researching and developing a potential subcutaneous injector version of TEPEZZA®, which is currently in Phase 1 clinical trials and for which the prospects and timing for launch are uncertain; and (c) Horizon is working with Xeris Pharmaceuticals, Inc., to potentially develop a subcutaneous version of TEPEZZA®, which is currently in early stages of development and for which the prospects and timing for approval and launch are uncertain.

52. Defendants deny the allegations in paragraph 52, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents and (b) Horizon admits that certain Horizon employees created the document referenced in paragraph 52 and refers to the document for its full and accurate contents.

53. Defendants deny the allegations in paragraph 53, except, to the extent they purport to summarize information in public sources, Defendants refer to those materials for their true and accurate contents; further, to the extent any of the allegations in paragraph 53 purport to state a legal conclusion, no response is required as to such allegations. Amgen further states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents. Horizon furthers admits that certain Horizon employees produced the document referenced in paragraphs 52 and 53 and refers to that document for its full and accurate contents.

54. Defendants deny the allegations in paragraph 54, which depicts an Amgen document, not a Horizon document, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that certain Amgen employees produced the document referenced in paragraph 54 and refers to that document for its full and accurate contents.

55. Defendants deny the allegations in paragraph 55, except to the extent they purport to summarize information in public sources, Defendants refer to those materials for their true and accurate contents. Defendants further state that they are without knowledge or

information sufficient to form a belief as to the truth of the allegations regarding Viridian's ongoing development or projections for FDA approval of VRDN-002 and VRDN-003.

56. Defendants deny the allegations in paragraph 56, except admit based on public sources that (a) Immunovant is a publicly traded, clinical-state biopharmaceutical company focused on treating autoimmune diseases and (b) Batoclimab is Immunovant's investigational compound and is a novel, fully human, monoclonal antibody targeting the neonatal Fc receptor (FcRn). Defendants further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Immunovant's expectations or projections. To the extent any of the allegations in paragraph 56 purport to state a legal conclusion, no response is required as to such allegations.

57. Defendants deny the allegations in paragraph 57, except admit that Horizon's KRYSTEXXA® is the only FDA-approved medication that is indicated for the treatment of CRG. To the extent any of the allegations in paragraph 57 purport to state a legal conclusion, no response is required as to those allegations.

58. Defendants deny the allegations in paragraph 58, except to the extent they purport to summarize information in public or other sources, Defendants refer to those materials for their true and accurate contents. To the extent any of the allegations in paragraph 58 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED ANTICOMPETITIVE EFFECTS

59. Defendants deny the allegations in paragraph 59. To the extent the allegations in paragraph 59 purport to state a legal conclusion, no response is required as to those allegations.

60. Defendants deny the allegations in paragraph 60, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's product sales and research and development pipeline, except Amgen admits that its product portfolio includes nine medicines that have generated more than $1 billion in annual net sales in 2022: 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). To the extent the allegations in paragraph 60 purport to state a legal conclusion, no response is required as to those allegations.

61. Defendants deny the allegations in paragraph 61, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's product utilization, pricing practices or product sales, except admit that Enbrel® is a medicine indicated to treat rheumatoid arthritis, psoriatic arthritis, moderate to severe plaque psoriasis, ankylosing spondylitis, and moderate to severe juvenile idiopathic arthritis. To the extent the allegations in paragraph 61 purport to summarize Amgen documents or public sources, Defendants refer to those materials for their full and accurate contents.

62. Defendants deny the allegations of paragraph 62, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to internal, non-public Amgen documents, except that to the extent the allegations in paragraph 62 purport to summarize Amgen documents or public sources, Defendants refer to those documents and materials for their full and accurate contents. To the extent the allegations in paragraph 62 purport to state a legal conclusion, no response is required as to those allegations.

63. Defendants deny the allegations of paragraph 63, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged PBM contracts. To the extent the allegations in paragraph 63 purport to state a legal conclusion, no response is required as to those allegations.

64. Defendants deny the allegations in paragraph 64, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged PBM contracts, except admit that the United States District Court for the District of Delaware is presiding over a case captioned *Regeneron Pharms., Inc. v. Amgen Inc.*, 1:22-cv-00697-RHA-JHL (D. Del.) and refer to the filings in that case for their full and accurate contents.

65. Defendants deny the allegations in paragraph 65. To the extent the allegations in paragraph 65 purport to state a legal conclusion, no response is required as to those allegations. Defendants further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what "multiple payers" purportedly "agreed" to.

66. Defendants deny the allegations of paragraph 66, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that certain Amgen employees created a document titled "Summary Observations" and refers to that document for its full and accurate contents. To the extent the allegations in paragraph 66 purport to state a legal conclusion, no response is required as to those allegations. To the extent the allegations in paragraph 66 repeat allegations contained in paragraph 6, Defendants incorporate their answer to paragraph 6.

67. Defendants deny the allegations in paragraph 67, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that certain Amgen employees produced a document as part of Amgen's evaluation of the Transaction, refers to that document for its full and accurate contents, and notes that none of Amgen's valuation analyses/models suggest any plan or intent to bundle Amgen products with Horizon products regardless of whether entry may or may not occur in the future. To the extent the allegations in paragraph 67 purport to state a legal conclusion, no response is required as to those allegations.

68. Defendants deny the allegations in paragraph 68, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that Amgen's SVP of Finance emailed Amgen's EVP and CFO and refers to that email for its full and accurate contents. To the extent the allegations in paragraph 68 purport to state a legal conclusion, no response is required as to those allegations.

69. Defendants deny the allegations in paragraph 69. To the extent the allegations in paragraph 69 purport to state a legal conclusion, no response is required as to those allegations.

70. Defendants deny the allegations in paragraph 70, including because Defendants are without knowledge or information sufficient to form a belief about the activities of unnamed third parties, except admit in general that (a) PBMs negotiate pharmacy benefit coverage and rebates for payers; (b) medical benefit managers or health plans generally negotiate their medical benefit policies and rebates; (c) drugs reimbursed through pharmacy benefits are

typically self-administered and dispensed through a retail or specialty pharmacy; and (d) drugs reimbursed through medical benefits are typically administered by a healthcare provider.

71. Defendants deny the allegations in paragraph 71, except state, upon information and belief, OptumRx and United Healthcare are owned (directly or indirectly) by the same ultimate parent entity; CVS Caremark and Aetna are owned (directly or indirectly) by the same ultimate parent entity; and Express Scripts and Cigna are owned (directly or indirectly) by the same ultimate parent entity. To the extent the allegations in paragraph 71 purport to state a legal conclusion, no response is required as to those allegations.

72. Defendants deny the allegations of paragraph 72, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents and (b) Horizon admits that the quoted language is partially excerpted from documents created by Horizon employee(s) and refers to those documents for their full and accurate contents. To the extent the allegations in paragraph 72 purport to state a legal conclusion, no response is required as to those allegations.

73. Defendants deny the allegations of paragraph 73, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents, and (b) Horizon admits that the quoted language is a partial excerpt from a document created by Horizon employee(s) and refers to that document for its full and accurate contents. To the extent the allegations in paragraph 73 purport to state a legal conclusion, no response is required as to those allegations.

74. Defendants deny the allegations of paragraph 74. To the extent the allegations in paragraph 74 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED LACK OF COUNTERVAILING FACTORS

75. Defendants deny the allegations of paragraph 75, except admit that for TED and CRG therapies, drug development times and FDA approval requirements are lengthy such that future entry is inherently speculative. To the extent the allegations in paragraph 75 purport to state a legal conclusion, no response is required as to those allegations.

76. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the allegations in paragraph 76, including because it uses terms such as "entry" and "suitable" that are not defined and because its source(s) is not identified. To the extent the allegations in paragraph 76 purport to summarize information from public sources, Defendants refer to those materials for their full and accurate contents.

77. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the allegations in paragraph 77, including because it uses terms such as "entrant" that are not defined and because there are no identified source(s) for the allegations. To the extent the allegations in paragraph 77 purport to summarize information from public sources, Defendants refer to those materials for their full and accurate contents.

78. Defendants deny the allegations of paragraph 78. To the extent the allegations in paragraph 78 purport to state a legal conclusion, no response is required as to those allegations.

79. Defendants deny the allegations of paragraph 79. To the extent the allegations in paragraph 79 purport to state a legal conclusion, no response is required as to those allegations.

80. Defendants deny the allegations in paragraph 80, except admit that Horizon has biologic reference product exclusivity in the United States covering TEPEZZA®

until the year stated in the allegation. To the extent the allegations in paragraph 80 purport to state a legal conclusion, no response is required as to those allegations.

81. Defendants deny the allegations in paragraph 81. To the extent paragraph 81 purports to summarize any document created by Horizon employee(s), (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents, and (b) Horizon refers to such document for its full and accurate contents.

82. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the allegation that no manufacturers are currently developing a KRYSTEXXA® biosimilar.

83. Defendants deny the allegations of paragraph 83. To the extent the allegations in paragraph 83 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED VIOLATION

COUNT I – ALLEGED ILLEGAL ACQUISITION

84. The answers to the allegations in paragraphs 1 through 83 above are incorporated by reference.

85. Defendants deny the allegations of paragraph 85. To the extent the allegations in paragraph 85 purport to state a legal conclusion, no response is required as to those allegations.

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

86. The allegations in paragraph 86 purport to state a legal conclusion to which no response is required. To the extent a further response is required, Defendants deny the allegations of paragraph 86.

87. The allegations in paragraph 87 purport to state a legal conclusion to which no response is required. To the extent a further response is required, Defendants deny the allegations of paragraph 87.

88. Defendants deny the allegations of paragraph 88 and further state that Amgen has committed not to bundle TEPEZZA® or KRYSTEXXA® with any Amgen products. To the extent the allegations in paragraph 88 purport to state a legal conclusion, no response is required as to those allegations.

89. Defendants deny the allegations of paragraph 89, except admit that the Commission requests the Court to (a) enter a temporary restraining order and preliminary injunction to prevent Amgen from acquiring Horizon; (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 deem appropriate, just, and proper. Defendants further state that pursuant to a stipulated order filed in this action on June 2, 2023, Defendants have agreed that they will not consummate the Transaction until the earlier of (i) October 31, 2023, or (ii) two business days after a ruling by this Court on the FTC's motion for a preliminary injunction under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), and Section 7 of the Clayton Act, 15 U.S.C. § 18. To the extent the allegations in paragraph 89 purport to state a legal conclusion, no response is required as to those allegations.

DEFENSES

Defendants assert the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with Plaintiff.

1. The Complaint fails to state a claim on which relief can be granted.

2. The combination of Defendants' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies and other procompetitive effects that will directly benefit consumers. These benefits greatly outweigh any and all alleged anticompetitive effects.

3. The FTC's claims are too speculative to support any claim on which relief can be granted.

4. Amgen's commitment not to bundle Amgen products with TEPEZZA® or KRYSTEXXA® fully addresses and prevents the alleged anticompetitive effects.

5. The FTC has failed to define appropriate relevant markets.

6. The FTC has failed to sufficiently allege market power with respect to any relevant product or service.

7. The FTC's claim reflects improper selective enforcement of the antitrust laws.

8. The FTC's claim is barred in whole or in part by failure to show any plausible harm to consumers or consumer welfare or any plausible anticompetitive effect.

9. The FTC fails to allege a time frame for the alleged anticompetitive effects.

10. The Complaint does not allege a proper basis for relief pursuant to the Federal Trade Commission Act or the Clayton Act.

11. The injunctive relief that the FTC seeks is inconsistent with the public interest, the equities favor consummation of the Transaction and alternative remedies are available to the Court.

12. The FTC seeks relief in support of an administrative process that runs afoul of the U.S. Constitution. The process:

a. violates Article I of the Constitution, which provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States," U.S. Const. art. I, § 1, in that (i) Congress delegated to the FTC the power to decide whether to bring antitrust enforcement actions in administrative proceedings rather than in an Article III court and (ii) Congress did not provide the FTC with an intelligible principle by which to exercise that power, giving it total, unguided discretion to decide whether to bring an antitrust enforcement action in an administrative proceeding rather than in an Article III court;

b. violates Article II of the Constitution and its separation of powers principles because (i) the FTC's Commissioners and Administrative Law Judges can only be removed for cause, (ii) the FTC bears no resemblance to the "quasi-legislative or quasi-judicial" body whose for-cause removal provisions were upheld in now-inapposite Supreme Court precedent, (iii) rather, the FTC today operates primarily as an enforcement agency (*e.g.*, by regularly bringing suit in administrative proceedings and federal court for injunctive and monetary relief, including relief to stop the consummation of transactions that could improve the lives of numerous patients in the United States and globally), *see, e.g.*, Daniel A. Crane, *Debunking Humphrey's Executor*, 83 Geo. Wash. L. Rev. 1835, 1859-68 (2015), and therefore (iv) the for-cause removal restriction impermissibly the President's removal powers;

c. violates Article III of the Constitution by adjudicating private rights before a non-Article III body without meaningful review of the FTC's factual findings by an Article III court;

d. violates Defendants' right to Due Process under the Fifth Amendment by depriving Defendants of their right to adjudication before a neutral arbiter - specifically, the combining investigative, prosecutorial and adjudicative functions violates due process where "the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable," *Withrow v. Larkin*, 421 U.S. 35, 47, 58 (1975), as is the case here considering the FTC Commissioners vote out the complaint, direct its prosecution and pass judgment on its merits, relying on evidence that would not be admissible in an Article III court, and in a proceeding where the FTC reportedly has not lost in 25 years, "reveal[ing] just how tilted this game is", *Axon Enter., Inc. v. FTC*, 143 S. Ct. 890, 917 (2023) (Gorsuch, J., concurring); and

e. violates Defendants' right to Equal Protection under the Fifth Amendment, in that the FTC and the Department of Justice ("DOJ") arbitrarily decide between them which agency will review a transaction through a black box "clearance" process, and as a result of that arbitrary decision, the Transaction was reviewed by the FTC, which has the ability to judge its merits through an in-house proceeding that lacks the protections of an Article III court (such as the ability to rely on evidence not admissible under the Federal Rules of Evidence, and where the same decision-makers initiate, prosecute and decide the merits of the case), whereas if the DOJ reviewed the Transaction and decided to challenge it, such challenge could *only* be brought in an Article III court for final adjudication of the merits of the challenge.

Defendants reserve the right to assert any other available defenses.

Dated: June 9, 2023

New York, New York

Respectfully submitted,

/s/ David R. Marriott

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