UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION,
STATE OF CALIFORNIA,
STATE OF ILLINOIS,
STATE OF MINNESOTA,
STATE OF NEW YORK,
STATE OF WASHINGTON
and
STATE OF WISCONSIN,

Plaintiffs,

v.

AMGEN INC.
and
HORIZON THERAPEUTICS PLC,

Defendants.

Case No. 1:23-cv-03053

Judge John F. Kness

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANTS AMGEN INC. AND HORIZON THERAPEUTICS PLC TO PLAINTIFFS' AMENDED COMPLAINT

ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS AMGEN INC. AND HORIZON THERAPEUTICS PLC TO PLAINTIFFS' AMENDED COMPLAINT

Defendants Amgen Inc. ("Amgen") and Horizon Therapeutics plc ("Horizon") (together "Defendants") hereby answer the Amended Complaint for Preliminary Injunctive Relief Pursuant to Section 13(b) of the Federal Trade Commission Act (Dkt. No. 66) (the "Amended Complaint") filed by the Federal Trade Commission (the "FTC"), Washington, California, Wisconsin, New York, Minnesota and Illinois (collectively, "Plaintiffs") 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. Plaintiffs' 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, Plaintiffs do 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, Plaintiffs' 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 Amended 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 the initial Complaint in this Court, that it would not bundle its products with TEPEZZA® or KRYSTEXXA®—the very conduct about which Plaintiffs allege 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. Amgen continues to stand ready to enter into such a binding commitment, which would fully resolve the FTC's hypothesized concerns of Amgen bundling its products with TEPEZZA® or KRYSTEXXA®, avoid further delay in delivering the patient benefits from the Transaction, and avoid further waste of judicial resources.

To obtain the extraordinary relief they seek, Plaintiffs have the burden of proving that the Transaction is reasonably likely to imminently and substantially lessen competition and that the balance of equities tips in their favor. 15 U.S.C. § 18; *United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974). Plaintiffs cannot meet their 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 Plaintiffs cannot rest on "antitrust theory and speculation" or "guesswork"; rather, they 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 Plaintiffs' 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). Plaintiffs' Amended Complaint fails to make the required showing.

In particular, the Plaintiffs' 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. Plaintiffs' case is based on their 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, Plaintiffs' hypothesized bundling theory – that Amgen could foreclose rare disease competitors through bundled rebates – is a square peg in a round hole.

In the Amended Complaint, Plaintiffs do not meaningfully address the real-world factors that refute their incentive and ability theory. The Amended 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, Plaintiffs rely on inaccurate generalizations and speculation. Plaintiffs assert 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 Plaintiffs ignore 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.

Plaintiffs claim 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 Plaintiffs' 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* Plaintiffs 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 Plaintiffs' conjecture regarding a subcutaneous version of TEPEZZA®, Plaintiffs' case goes on to pile more speculation on speculation. Plaintiffs repeatedly allege that there are no rivals to TEPEZZA® or KRYSTEXXA® today, and thus acknowledge there is no existing incentive to engage in the hypothesized bundling. Plaintiffs speculate 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 Amended 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 Amended 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 Plaintiffs' theory. As Plaintiffs tell 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, Plaintiffs speculate that, if and when any such entry occurs, though years away at best, the competitive conditions for the Amgen medicines Plaintiffs claim would be used in the bundle, such as Enbrel®, will not have changed—that is, the alleged coercive power that Plaintiffs claim 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

[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.

market, faces significant competition and declining sales; or that the other Amgen products cited in the Amended 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 implausible given the reality that PBMs hold the leverage in such negotiations, a reality Plaintiffs acknowledge in other contexts.[2] But commercial realities are of no moment to Plaintiffs' speculation-fueled case here. Brushing facts aside, Plaintiffs base their 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 Amended 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 price 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 Amended Complaint 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

[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.

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 Amended Complaint revealingly does not identify a *single* document produced by Amgen (or Horizon) suggesting any plan to engage in the conduct alleged by Plaintiffs. 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). The Amended 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 Plaintiffs' claim – Plaintiffs' bundling allegations are simply made up.

Plaintiffs attempt, but fail, 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 Plaintiffs do not even allege that that bundle is actually anticompetitive. That Plaintiffs must resort to citing unproven allegations of an Amgen rival only further underscores the weakness of their claims.

Even if Plaintiffs 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 Plaintiffs speculate – which will not come about in any event for all the reasons explained – would be the rare form of competition-reducing price cutting.

As noted, if (hypothetically) Amgen ever engaged in activity unlawful under the antitrust laws, Plaintiffs 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 substantially harms competition 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 (and contrary to Amgen's commitment not to engage in such conduct), it ever occurred in the future.

Finally, while the Amended Complaint is joined by six states, their addition adds no force to the FTC's allegations. The FTC called upon most (if not all) states to join this action, and only six did. Not a single U.S. state sent Amgen or Horizon a subpoena or even placed a call to inquire about the proposed transaction until after the FTC filed its initial complaint. No state reached out to Amgen or Horizon about the proposed transaction when it was announced on December 12, 2022. And no state reached out to Amgen or Horizon when the parties publicly disclosed on January 31, 2023 that the FTC had issued a Second Request. Only after the FTC filed its initial complaint on May 16, 2023, over six months after the proposed transaction was announced, did any of the joining states even bother to have a substantive conversation about the deal (though for less than 30 minutes). Remarkably, most of the states (at least four of the six) signed the Amended Complaint without even seeing it in its entirety, i.e., without seeing or knowing what is contained in the confidential/redacted portions of the Amended Complaint (Illinois, Minnesota, New York and Washington)—notwithstanding the requirements of Federal Rule of Civil Procedure 11.[3]

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

[3] The FTC has represented to Defendants that it inadvertently sent to California and Wisconsin confidential Amgen and Horizon information before the Amended Complaint was filed, though federal law prohibited the FTC from doing so. Prior to its filing of the Amended Complaint, the FTC sent Wisconsin an unredacted copy of the FTC's initial complaint as well as certain materials that referenced Amgen and Horizon confidential information, and sent California certain materials that referenced Amgen and Horizon confidential information. Counsel for each of California and Wisconsin have represented to Defendants that they did not rely on those confidential materials in joining the Amended Complaint. There have also been other unauthorized disclosures by the FTC of confidential information concerning this transaction, including with the filing of an administrative complaint in the FTC's administrative court, which was initially publicly filed in an improperly-redacted form, exposing sensitive information to the public.

Defendants provide their specific responses to Plaintiffs' allegations below.

RESPONSES TO THE SPECIFIC ALLEGATIONS OF THE AMENDED COMPLAINT

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

The first paragraph of the preamble to the Amended 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 Plaintiffs have 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 Amended Complaint.

The second and third paragraphs of the preamble to the Amended 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 Plaintiffs' 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 Amended 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 Amended 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, except Defendants admit that Defendants have agreed not to consummate the Proposed Acquisition 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 preliminary injunction.

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 in paragraph 22, except Defendants refer to Section 16 of the Clayton Act, 15 U.S.C. § 26, for its contents.

23. Defendants state that because the allegations in paragraph 23 purport to state a legal conclusion, no response is required as to such allegations. To the extent a response is required, Defendants deny the allegations in paragraph 23.

24. Defendants deny the allegations of paragraph 24, except admit that the Defendants transact business in the Northern District of Illinois. 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 deny the allegations of paragraph 25, except admit that Horizon's U.S. headquarters are located in Lake County, Illinois. To the extent any of the allegations in paragraph 25 purport to state a legal conclusion, no response is required as to such allegations.

THE PARTIES AND THE PROPOSED ACQUISITION

26. To the extent the allegations of paragraph 26 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 26 except 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.

27. To the extent the allegations of paragraph 27 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 27 except admit, based on public sources, that (a) the State of California is a sovereign state of the United States; (b) Attorney General Rob Bonta is the chief law enforcement officer of the State, with the authority to bring this action on behalf of the state and as parens patriae on behalf of the citizens, general welfare, and economy of California; and (c) the Office of the Attorney General of the State of California has its principal offices at 300 S. Spring Street, Suite 1702, Los Angeles, CA 90013.

28. To the extent the allegations of paragraph 28 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 28 except admit, based on public sources, that (a) the State of Illinois is a sovereign state of the United States; (b) Attorney General Kwame Raoul, is the chief law enforcement officer of the State, with the authority to bring this action on behalf of the state of Illinois; and (c) the Office of the Attorney General of the State of Illinois has its principal offices at 100 West Randolph Street, Chicago, Illinois 60601.

29. To the extent the allegations of paragraph 29 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 29 except admit, based on public sources, that (a) the State of Minnesota is a sovereign state of the United States; (b) Attorney General Keith Ellison is the chief legal officer for the state, and brings this action on behalf of the state Minnesota; and (c) the Office of the Attorney General of the State of Minnesota has its principal offices at 445 Minnesota Street, Saint Paul, Minnesota 55101.

30. To the extent the allegations of paragraph 30 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 30 except admit, based on public sources, that (a) the State of New York is a sovereign state; (b) Attorney General Letitia James is the chief legal officer for the state, and brings this action on behalf of the state of New York; and (c) the Office of the Attorney General of the State of New York has its principal offices at The Capitol, Albany, NY 12224-0341.

31. To the extent the allegations of paragraph 31 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 31 except admit, based on public sources, that (a) the State of Washington is a sovereign state; (b) Attorney General Robert W. Ferguson is the chief legal officer for the state, and brings this action on behalf of the state of Washington; and (c) the Office of the Attorney General of the State of Washington has its principal offices at 1125 Washington St. SE, Olympia, WA 98504.

32. To the extent the allegations of paragraph 32 purport to state a legal conclusion, no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 32 except admit, based on public sources, that (a) the State of Wisconsin

is a sovereign state; (b) Attorney General Joshua L. Kaul is the chief legal officer for the state, with the authority to bring this action on behalf of the state of Wisconsin; and (c) the Wisconsin Attorney General has his principal offices at 17 West Main Street, Madison, Wisconsin 53707.

33. Defendants admit the allegations in paragraph 33, 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 33 regarding Amgen's product sales and the focus of its research or development.

34. Defendants admit the allegations in paragraph 34, 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 34 repeat allegations contained in paragraph 6, Defendants incorporate their answer to paragraph 6.

35. Defendants admit the allegations in paragraph 35.

36. Defendants deny the allegations in paragraph 36, except Defendants admit that Defendants have agreed not to consummate the Proposed Acquisition 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 preliminary injunction.

THE ALLEGED RELEVANT PRODUCT MARKETS

37. Defendants deny the allegations of paragraph 37, except 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. 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 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 38 are based on public sources, Defendants refer to those sources for their full and accurate content.

39. Defendants admit the allegations in paragraph 39.

40. Defendants deny the allegations in paragraph 40, 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.

41. Defendants deny the allegations of paragraph 41, and state that, to the extent the allegations of paragraph 41 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 41 purport to state a legal conclusion, no response is required as to such allegations.

42. Defendants deny the allegations in paragraph 42, 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 42 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 42 purport to state a legal conclusion, no response is required as to such allegations.

43. Defendants deny the allegations in paragraph 43. 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 43 purport to state a legal conclusion, no response is required as to such allegations.

44. Defendants deny the allegations in paragraph 44. To the extent any of the allegations in paragraph 44 purport to state a legal conclusion, no response is required as to such allegations.

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

46. Defendants are without knowledge or information regarding the truth of the allegations in Paragraph 46. To the extent the allegations in paragraph 46 are based on public sources, Defendants refer to those sources for their full and accurate content.

47. Defendants deny the allegations in paragraph 47 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.

48. Defendants deny the allegations of paragraph 48, 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; (g) in clinical studies, patients receiving the combination medicine experienced fewer infusion reactions; and (h) KRYSTEXXA® has a different mechanism of action (MOA) from XOIs and uricosurics and differs in safety and efficiency in treating certain patients. Defendants state that to the extent paragraph 48 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.

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

50. Defendants deny the allegations in paragraph 50, 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®.

51. Defendants deny the allegations in paragraph 51. To the extent any of the allegations in paragraph 51 purport to state a legal conclusion, no response is required as to such allegations.

52. Defendants deny the allegations in paragraph 52. To the extent any of the allegations in paragraph 52 purport to state a legal conclusion, no response is required as to such allegations.

THE ALLEGED RELEVANT GEOGRAPHIC MARKET

53. Defendants deny the allegations in paragraph 53, 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 53 purport to state a legal conclusion, no response is required as to such allegations.

54. Defendants deny the allegations in paragraph 54, 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 54 purport to state a legal conclusion, no response is required as to such allegations.

55. Defendants deny the allegations in paragraph 55. To the extent any of the allegations in paragraph 55 purport to state a legal conclusion, no response is required as to such allegations.

THE ALLEGED MARKET STRUCTURE

56. Defendants deny the allegations in paragraph 56, except admit that TEPEZZA® is the only FDA-approved medication for the treatment of TED.

57. Defendants deny the allegations in paragraph 57, 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.

58. Defendants deny the allegations in paragraph 58, 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 58 and refers to the document for its full and accurate contents.

59. Defendants deny the allegations in paragraph 59, 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 59 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 58 and 59 and refers to that document for its full and accurate contents.

60. Defendants deny the allegations in paragraph 60, 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 60 and refers to that document for its full and accurate contents.

61. Defendants deny the allegations in paragraph 61, 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.

62. Defendants deny the allegations in paragraph 62, 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 62 purport to state a legal conclusion, no response is required as to such allegations.

63. Defendants deny the allegations in paragraph 63, 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 63 purport to state a legal conclusion, no response is required as to those allegations.

64. Defendants deny the allegations in paragraph 64, 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 64 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED ANTICOMPETITIVE EFFECTS

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.

66. Defendants deny the allegations in paragraph 66, 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 66 purport to state a legal conclusion, no response is required as to those allegations.

67. Defendants deny the allegations in paragraph 67, 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 67 purport to summarize Amgen documents or public sources, Defendants refer to those materials for their full and accurate contents.

68. Defendants deny the allegations of paragraph 68, 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 68 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 68 purport to state a legal conclusion, no response is required as to those allegations.

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

70. Defendants deny the allegations in paragraph 70, 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.

71. Defendants deny the allegations in paragraph 71. To the extent the allegations in paragraph 71 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.

72. Defendants deny the allegations of paragraph 72, 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 72 purport to state a legal conclusion, no response is required as to those allegations. To the extent the allegations in paragraph 72 repeat allegations contained in paragraph 6, Defendants incorporate their answer to paragraph 6.

73. Defendants deny the allegations in paragraph 73, 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 73 purport to state a legal conclusion, no response is required as to those allegations.

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

75. Defendants deny the allegations in paragraph 75. To the extent the allegations in paragraph 75 purport to state a legal conclusion, no response is required as to those allegations.

76. Defendants deny the allegations in paragraph 76, 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.

77. Defendants deny the allegations in paragraph 77, except state that, 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 77 purport to state a legal conclusion, no response is required as to those allegations.

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

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

80. Defendants deny the allegations of paragraph 80. To the extent the allegations in paragraph 80 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED LACK OF COUNTERVAILING FACTORS

81. Defendants deny the allegations of paragraph 81, 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 81 purport to state a legal conclusion, no response is required as to those allegations.

82. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the allegations in paragraph 82, 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 82 purport to summarize information from public sources, Defendants refer to those materials for their full and accurate contents.

83. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the allegations in paragraph 83, 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 83 purport to summarize information from public sources, Defendants refer to those materials for their full and accurate contents.

84. Defendants deny the allegations of paragraph 84. To the extent the allegations in paragraph 84 purport to state a legal conclusion, no response is required as to those allegations.

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.

86. Defendants deny the allegations in paragraph 86, 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 86 purport to state a legal conclusion, no response is required as to those allegations.

87. Defendants deny the allegations in paragraph 87. To the extent paragraph 87 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.

88. 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.

89. Defendants deny the allegations of paragraph 89. To the extent the allegations in paragraph 89 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED VIOLATION

COUNT I – ALLEGED ILLEGAL ACQUISITION

90. The answers to the allegations in paragraphs 1 through 89 above are incorporated by reference.

91. Defendants deny the allegations of paragraph 91. To the extent the allegations in paragraph 91 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

92. The allegations in paragraph 92 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 92.

93. The allegations in paragraph 93 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 93.

94. The allegations in paragraph 94 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 94.

95. Defendants deny the allegations of paragraph 95 and further state that Amgen has committed not to bundle TEPEZZA® or KRYSTEXXA® with any Amgen products.

To the extent the allegations in paragraph 95 purport to state a legal conclusion, no response is required as to those allegations.

96. Defendants deny the allegations of paragraph 96, 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 96 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 Plaintiffs.

1. The Amended 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. Plaintiffs' 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. Plaintiffs have failed to define appropriate relevant markets.

6. Plaintiffs have failed to sufficiently allege market power with respect to any relevant product or service.

7. Plaintiffs' claim reflects improper, selective enforcement of the antitrust laws.

8. Plaintiffs' 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. Plaintiffs fail to allege a time frame for the alleged anticompetitive effects.

10. The Amended 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 Plaintiffs seek is inconsistent with the public interest, the equities favor consummation of the Transaction and alternative remedies are available to the Court.

12. Plaintiffs' requested remedy is impermissibly overbroad. Even if there were merit to Plaintiffs' case (and there is not), the appropriate remedy would not be to enjoin the Transaction, but instead simply—and at most—to enter an order limiting the bundling of certain Amgen products with either TEPEZZA® or KRYSTEXXA® in certain circumstances.

13. Plaintiffs seek 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 restricts 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);

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; and

f. violates Defendants' right to a jury trial under the Seventh Amendment, in that the FTC review process includes no right for a regulated defendant to receive a trial by jury, while the Seventh Amendment applies whenever a defendant's private rights are at issue, which are historically understood to include property rights, and where the FTC seeks to directly regulate Defendants' rights to use their property, including Defendants' ability to engage in a private commercial transaction and the possibility of future civil penalties, *see* 15 U.S.C. § 45(l).

Defendants reserve the right to assert any other available defenses.

COUNTERCLAIMS

Amgen Inc. ("Amgen") and Horizon Therapeutics plc ("Horizon") (collectively, "Counterclaim Plaintiffs") hereby petition this Court for declaratory and injunctive relief precluding the Federal Trade Commission ("FTC") from pursuing an unconstitutional administrative proceeding to prevent Amgen from acquiring Horizon (the "Transaction").

NATURE OF THE ACTION

1. This case concerns a misguided effort by the FTC and six states to kill a merger of two pharmaceutical companies, Amgen and Horizon, that seek to combine to better serve patients suffering from serious rare diseases. The FTC's case is wholly novel and impossibly speculative. The Transaction is entirely complementary—the FTC does not allege that Amgen competes with *any* of Horizon's medicines. The FTC has never before 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. Rather than allow an Article III court to adjudicate the merits of its novel challenge, the FTC seeks to have the ultimate merits of its case adjudicated in an administrative proceeding that is riddled with constitutional defects. That proceeding will not only make it harder for patients with devastating illnesses to get access to needed treatments, but also it runs roughshod over multiple provisions of the U.S. Constitution. These counterclaims seek to redress those violations.

2. 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 cutting-edge scientific innovation. Horizon's medicines treat serious and rare diseases, but as an independent business, Horizon does not have the resources that Amgen has to bring its medicines to all of the patients who badly need them. The Transaction gives Horizon the capabilities,

expertise, and global scale it needs to do that. Together, Amgen and Horizon will be able to 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 across the globe, including in the U.S., more quickly and efficiently than Horizon could on its own.

3. The FTC filed a Complaint in this Court for preliminary injunctive relief, and this Court set an evidentiary hearing for September 11, 2023. On June 22, 2023, an Amended Complaint was filed adding the states of California, Illinois, Minnesota, New York, Washington and Wisconsin, and the FTC initiated an administrative proceeding seeking a permanent injunction based on the same flawed allegations before this Court. By proceeding in this way, the FTC seeks to limit this Court's consideration of the ultimate merits of its case. As it stands, the FTC will adjudicate the ultimate merits of the Transaction in a tribunal in which the FTC will be the judge of its own allegations and where it enjoys a nearly 100% success rate, instead of permitting this Court to decide the ultimate merits of the FTC's claim.

4. The FTC's administrative process runs afoul of multiple provisions of the U.S. Constitution:

a) it violates Article I because the FTC is proceeding pursuant to an unfettered delegation of legislative power;

b) it violates Article II because the FTC Commissioners who voted to bring the administrative complaint and the ALJ who will hear the case are insulated from at-will removal by the President;

c) it violates the Due Process clause of the Fifth Amendment because the FTC will play the role of investigator, prosecutor and judge;

d) it violates the Equal Protection clause of the Fifth Amendment because the process by which the case was assigned to the FTC instead of the Department of Justice ("DOJ") is arbitrary and lacks a rational basis; and

e) it violates the Seventh Amendment because the FTC's administrative proceedings adjudicate Counterclaim Plaintiffs' private rights without the ability to assert their right to a jury trial.

THE PARTIES

5. Counterclaim Defendant FTC is an administrative agency of the United States Government, established, organized and existing pursuant to the FTC Act, 15 U.S.C. § 45, and is authorized under certain circumstances by Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin ongoing or imminent violations of any law the FTC enforces.

6. Counterclaim Plaintiff 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.

7. Counterclaim Plaintiff 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.

JURISDICTION AND VENUE

8. This action arises under the Constitution and laws of the United States, and this Court has federal question jurisdiction over this action pursuant to Article III of the Constitution and 28 U.S.C. § 1331.

9. Counterclaim Plaintiffs' right to immediate judicial review in this Court with respect to Counterclaim Defendant's alleged conduct is based on Articles I and II of the U.S. Constitution, the Due Process and Equal Protection Clauses of the Fifth Amendment, the Seventh Amendment and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201.

10. Venue is proper under 5 U.S.C. § 703 and 28 U.S.C. §§ 1391(b), (c), and (e).

FACTUAL BACKGROUND

A. The Transaction

11. On December 11, 2022, Amgen announced its agreement to acquire Horizon for approximately $27.8 billion.

12. The Transaction will deliver large patient benefits, operational efficiencies and cost savings. Globally, including in the U.S., the combined company will benefit from Amgen's experience in commercial operations, such as access, medical, patient support, and overall scale and expertise in marketing and sales. For example, Amgen has relationships with providers who treat patients in need of Horizon's treatments; Amgen has vastly more experience with developing combination products that bring together a drug and a device that will increase the odds new product innovations are successfully brought forward for patients in need; and Amgen has global manufacturing and distribution networks that will reduce the significant execution risks and capital expenditures Horizon would otherwise need to incur in attempting to bring its treatments to additional patients.

13. Amgen forecasts significant cost savings resulting from the combined company leveraging Amgen's footprint and salesforce, lowering Horizon's distribution costs, bringing Horizon's operations into Amgen's existing systems and processes, and utilizing Amgen's R&D capabilities to increase the chances that innovative development efforts, which inherently face long odds of FDA approval, succeed, lower the cost of clinical trials and optimize development of Horizon's pipeline.

B. Northern District of Illinois Preliminary Injunction Action

14. 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 Amended 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 seeks to enjoin its consummation based on a novel and impossibly speculative "cross-benefit" and "cross-market" bundling theory that has no legal or factual support.

15. While Counterclaim Plaintiffs maintain that the FTC's purported concerns are baseless, Amgen committed to the FTC, before the agency filed its initial Complaint in this Court, that it would not bundle its products with TEPEZZA® or KRYSTEXXA®—the very conduct about which the FTC alleges concern, and also made clear that it would be willing to formalize that commitment in a binding consent order. Amgen continues to stand ready to enter into such a binding commitment, which would fully resolve the FTC's hypothesized concerns of

Amgen bundling its products with TEPEZZA® or KRYSTEXXA®, avoid further delay in delivering the patient benefits from the Transaction and avoid further waste of judicial resources.

16. Despite this, on May 16, 2023, the FTC filed a Complaint for Temporary Restraining Order and Preliminary Injunction against Counterclaim Plaintiffs in the Northern District of Illinois. *See* Complaint, *FTC v. Amgen Inc. and Horizon Therapeutics plc*, No. 23-cv-3053 (N.D. Ill.) (May 16, 2023), ECF No. 1.

17. On June 9, 2023, Counterclaim Plaintiffs answered the initial Complaint, and discovery is underway.

18. On June 22, 2023, an Amended Complaint was filed, adding the states of California, Illinois, Minnesota, New York, Washington and Wisconsin.

19. The evidentiary hearing on the FTC's motion for preliminary injunction is set to begin on September 11, 2023.

C. Part III Proceedings

20. On June 22, 2023, the FTC instituted an administrative proceeding against Amgen and Horizon before its own administrative law judge ("ALJ"). By that proceeding, the FTC seeks to prevent Amgen and Horizon from engaging in the Transaction without this Court's input.

21. The FTC seeks to proceed in its own tribunal where the playing field is tilted significantly in its favor and, as a result, the FTC almost never loses, *Axon Enter., Inc. v. FTC*, 986 F.3d 1173, 1187 (9th Cir. 2021), *rev'd and remanded*, 143 S. Ct. 890 (2023).

22. Once the trial on the merits is complete and an ALJ decision is rendered, any review of that decision will be by the Commissioners themselves—the same Commissioners who voted to institute proceedings. 16 C.F.R. §§ 3.42(a), 3.54. Any Circuit Court review of the

Commissioners' opinion will be further insulated by the deferential substantial-evidence standard. *See Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1385 (7th Cir. 1986).

D. Article I – Nondelegation Doctrine

23. Article I of the U.S. Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1.

24. Congress cannot delegate that power to an executive agency unless it "provides an 'intelligible principle' by which the [agency] can exercise it." *Jarkesy v. SEC*, 34 F.4th 446, 460-61 (5th Cir. 2022) (quoting *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989)).

25. 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. *See* 15 U.S.C. §§ 45(b), 53(b).

26. The "power to assign disputes to agency adjudication" is a "legislative power." *Jarkesy*, 34 F.4th at 461.

27. Congress did not provide the FTC with an intelligible principle by which to exercise that power. *See id.* at 462.

28. Congress gave the FTC unfettered and unguided discretion to decide whether to bring antitrust enforcement actions in administrative proceedings instead of in Article III courts. *See* 15 U.S.C. § 45(b).

E. Article II – Removal Restrictions

29. Article II of the U.S. Constitution provides that "[t]he executive Power shall be vested in a President of the United States of America." U.S. Const. art. II, § 1.

30. Under Article II, "the 'executive Power'—all of it—is 'vested in a President.'" *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2191 (2020).

31. Principal executive officers "must remain accountable to the President, whose authority they wield." *Id.* at 2197.

32. The President's executive power "generally includes the ability to remove" such officers on an "unrestricted" basis, as "has long been confirmed by history and precedent." *Id.* at 2197-98; *see Myers v. United States*, 272 U.S. 52, 163-64 (1926).

33. That removal power is important to the democratic legitimacy of the Executive Branch because it makes officers less likely to deviate from the President's will.

34. An officer who knows that disobedience will be met with removal is less likely to take an action at odds with the President's agenda.

35. The removal power gives the People political recourse if they are displeased with the actions taken by those who enforce federal law. Although the People cannot vote for (or against) an Executive officer directly, they can vote for (or against) the President, who bears ultimate responsibility for federal law enforcement.

36. FTC Commissioners are not subject to removal by the President absent a finding of "inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41.

37. In 1935, the Supreme Court upheld the constitutionality of this provision insulating FTC Commissioners from removal by the President. *Humphrey's Executor v. United States*, 295 U.S. 602, 623-32 (1935).

38. But *Humphrey's Executor* established only a narrow "exception" for multimember expert agencies that "perform legislative and judicial functions" and do not exercise "any executive power." *Seila Law*, 140 S. Ct. at 2199.

39. As the Supreme Court has subsequently admonished, the holding in *Humphrey's Executor* rested on the premise that the FTC—"as it existed in 1935"—exercised "'no part of the executive power.'" *Id.* at 2198 (quoting *Humphrey's Executor*, 295 U.S. at 628).

40. That characterization of the FTC "has not withstood the test of time": "under our constitutional structure," the "activities of administrative agencies … *must be* exercises of[] the 'executive Power.'" *Id.* at 2198 n.2 (quoting *City of Arlington v. FCC*, 569 U.S. 290, 305 n.4 (2013)).

41. The modern FTC is a different animal from the "quasi-legislative or quasi-judicial" body the Supreme Court considered in *Humphrey's Executor*.

42. The FTC today operates primarily as an enforcement agency—bringing suit in both administrative proceedings and federal court for injunctive and monetary relief—that bears no resemblance to the "quasi-legislative or quasi-judicial" body described in *Humphrey's Executor*.

43. Additionally, there is no question that FTC ALJs enjoy two layers of protection from the President. *See In re Otto Bock HealthCare N. Am., Inc.*, No. 9378, 2019 WL 5957363, at *49 (F.T.C. Nov. 1, 2019) (acknowledging that FTC ALJs enjoy dual-layer protection from presidential review).

44. Like the Public Company Accounting Oversight Board ("PCAOB"), FTC ALJs may be removed only "for good cause established and determined by" someone other than the President, namely the Merit Systems Protection Board ("MSPB"). 5 U.S.C. § 7521(a); *see Free Enterprise Fund v. Public Co. Accounting Oversight Board*, 561 U.S. 477, 483-84 (2010).

45. By limiting the President's authority over FTC ALJs and Commissioners, and thus the Commission itself, the FTC operates without accountability to the President.

F. Fifth Amendment – Due Process Violation

46. "A fair trial in a fair tribunal is a basic requirement of due process." *In re Murchison*, 349 U.S. 133, 136 (1955).

47. This requirement applies to any adjudicative body, including administrative tribunals. *Gibson v. Berryhill*, 411 U.S. 564, 579 n.17 (1973).

48. 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 (1975).

49. "[A]n unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case." *Williams v. Pennsylvania*, 579 U.S. 1, 8 (2016).

50. The Commission voted out the administrative complaint after investigation, is directing its prosecution and will pass judgment on the decision of the ALJ—playing the roles of "investigator, prosecutor, and judge." *Axon Enter., Inc. v. FTC*, 143 S. Ct. 890, 917 (2023) (Gorsuch, J., concurring); *see* FTC Press Release (May 16, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-sues-block-biopharmaceutical-giant-amgen-acquisition-would-entrench-monopoly-drugs-used-treat.

51. As one court noted, the "FTC has not lost a single case [in administrative proceedings] in the past quarter-century. Even the 1972 Miami Dolphins would envy that type of record." *Axon Enter.*, 986 F.3d at 1187.

52. The potential for unconstitutional bias here is intolerable given the FTC's control of every part of these proceedings.

G. Fifth Amendment – Equal Protection Violation

53. Under the Equal Protection Clause, "[t]he guaranty of equal protection of the laws is a pledge of the protection of equal laws." *Romer v. Evans*, 517 U.S. 620, 633-34 (1996) (citations omitted).

54. The Equal Protection Clause protects against "arbitrary and irrational discrimination" by the Government, *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 83 (1988), and demands that "all persons similarly situated should be treated alike," *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (citation omitted).

55. Differential treatment "run[s] afoul of the Equal Protection Clause" when there is no "rational relationship between the disparity of treatment and some legitimate governmental purpose." *Heller v. Doe*, 509 U.S. 312, 320 (1993).

56. The choice of whether a merger review (and any subsequent challenge) is conducted by DOJ or FTC is decided by the agencies through an informal, non-public unwritten process.

57. The review of this merger was arbitrarily assigned to FTC, which will result in the following discrepancies in treatment from how the merger would be reviewed by DOJ:

a) Difference in the forum for adjudicating the merits. The parties to a merger challenged by DOJ are entitled to have the challenge adjudicated in a U.S. district court. 15 U.S.C. § 25. In contrast, the parties to a merger challenged by the FTC are not entitled to have the matter adjudicated in federal district court; they can be compelled to litigate in an internal administrative proceeding, U.S. district court, or both—at the FTC's election. 15 U.S.C. § 45(b).

b) Difference in the preliminary injunction standard. The parties to a merger challenged by DOJ cannot be preliminarily enjoined except upon the traditional four-part showing under the common law: (i) the probability of success on the merits; (ii) the significance of the threat of irreparable harm to plaintiff if the injunction is granted; (iii) the balance between this harm and the injury the injunction would inflict on the defendant; and (iv) the public interest. *United States v. Gillette Co.*, 828 F. Supp. 78, 80 (D.D.C. 1993). The parties to a merger challenged by the FTC, however, can be enjoined upon a lesser showing under Section 13(b) of the FTC Act, which courts have interpreted as "a unique 'public interest' test . . . rather than the more stringent, traditional 'equity standard for injunctive relief." *FTC v. Exxon Corp.*, 636 F.2d 1336, 1343 (D.C. Cir. 1980).

c) Difference in the number of fora in which the challenge must be defended. The parties to a merger challenged by DOJ are subject to a single proceeding in which DOJ has no legal recourse in the event it loses, except to appeal to the circuit court. 28 U.S.C. § 1291; Fed. R. App. P. 3(a)(1). In contrast, the parties to a merger challenged by the FTC run the risk of the FTC proceeding in two fora simultaneously (federal court and an administrative proceeding) or challenging the merger in U.S. district court and if the court rules against the challenge, retrying the entire merits proceeding in an administrative proceeding within the FTC itself. 15 U.S.C. § 45(b). In addition, if the FTC loses before an FTC ALJ, the Commission may itself reverse that decision as to both factual and legal findings. 16 C.F.R. § 3.54(b); *see In re Illumina, Inc. & Grail, Inc.*, No. 9401, Opinion of the Commission (Mar. 31, 2023).

d) Difference in the independence of the factfinder. The parties to a merger challenged by DOJ are entitled to an independent factfinder—an Article III judge appointed by the President and confirmed by the Senate, with no allegiance to DOJ. 15 U.S.C. § 25. In contrast, parties to a merger challenged by the FTC in an internal administrative proceeding face an ALJ whom the FTC can replace at any time and can reverse on a *de novo* review, and appeal to the very Commissioners who voted out the complaint and directed its prosecution. 16 C.F.R. §§ 3.42(a), 3.54. Indeed, the FTC just recently amended its internal rules such that ALJs may only render a "recommended" decision rather than an "initial" decision, meaning that ALJ decisions are automatically reviewed by the Commissioners.

e) Difference in applicable procedural and evidentiary rules. The parties to a merger challenged by DOJ are entitled to the protections of the Federal Rules of Civil Procedure and the Federal Rules of Evidence. *See* 15 U.S.C. § 25. Failure by DOJ to abide by the applicable procedural rules results in exclusion of evidence and potential sanctions against DOJ. Antitrust Div., U.S. Dep't of Just., Template Pursuant to Section 3(a) of the ICN Framework on Competition Agency Procedures 3. In contrast, the parties to a merger challenged by the FTC are subject to rules created by the FTC itself, do not necessarily enjoy the protections of the Federal Rules of Civil Procedure or the Federal Rules of Evidence, and must petition their accuser for relief from subpoenas and Civil Investigative Demands. 16 C.F.R. § 3.1.

f) Difference in ability to change a merits decision before circuit court appeal. The parties to a merger challenged by DOJ face no risk that DOJ will change the district court's merits decision before appeal to the circuit court, as DOJ has no power to do so.

By contrast, the parties to a merger challenge in the FTC's administrative proceedings run the significant risk that the Commission will change a merits decision, including a decision that is adverse to the FTC, prior to appeal to the circuit court. 15 U.S.C. § 45(c); 16 C.F.R. § 3.54(b). The Commission is empowered to ignore an ALJ's determinations in their entirety and substitute the Commission's own legal and factual findings prior to appeal. 16 C.F.R. § 3.54.

g) Difference in circuit court appellate standards. The parties to a merger challenged by DOJ are entitled to factual review under the clearly erroneous standard. *Baker Hughes, Inc.*, 908 F.2d at 983 (citing Fed. R. Civ. P. 52(a)). In contrast, parties to a merger challenged by the FTC are subject to factual review under the lesser, substantial-evidence standard. *See Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1385 (7th Cir. 1986).

58. There is no rational basis for these differences, which can be outcome determinative. Treating parties differently based on whether their merger is reviewed by the FTC instead of DOJ is unrelated to any legitimate governmental purpose.

H. Seventh Amendment – Right to a Jury Trial

59. As part of its administrative proceedings, the FTC determines the rights of parties to engage in private transactions.

60. The FTC review process includes no right for a regulated defendant to receive a trial by a jury.

61. The Seventh Amendment explicitly provides this right "in Suits at common law, where the value in controversy shall exceed twenty dollars." This includes actions "analogous to Suits at common law." *Tull v. United States*, 481 U.S. 412, 417 (1987) (internal quotation marks omitted).

62. The Supreme Court has interpreted the Seventh Amendment to apply whenever an action's claims arise "at common law," *see Tull*, 481 U.S. at 417, and do not center on "public rights," *see Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 54 (1989).

63. Private rights were historically understood to include "rights to life, liberty, and property, . . . the three absolute rights . . . so called because they appertain and belong to particular men . . . merely as individuals, not to them as members of society or standing in various relations to each other—that is, not dependent upon the will of the government." *Wellness Int'l Network, Ltd. v. Sharif*, 575 U.S. 665, 713-714 (2015) (Thomas, J., dissenting).

64. The FTC directly regulates the right of parties to use their property and therefore their private rights as historically understood. FTC administrative proceedings allow for the possibility of disgorgement of a party's assets. Moreover, an FTC order in these administrative proceedings brings with it the possibility of future civil penalties. 15 U.S.C. § 45(l). Civil penalties require a party to surrender its property and so also implicate "private rights." *See Tull*, 481 U.S. at 422 ("A civil penalty was a type of remedy at common law that could only be enforced in courts of law.").

65. The FTC's actions in its administrative proceedings that implicate the rights of parties to engage in private commercial transactions and create the possibility of civil penalties are analogous to actions at common law and so implicate parties' Seventh Amendment rights.

66. The failure to provide parties to these proceedings with a right to a jury trial violates the Seventh Amendment.

COUNT I

(Violation of Article I of the U.S. Constitution – Improper Delegation of Legislative Power)

67. Counterclaim Plaintiffs restate and incorporate by reference each and every allegation of the preceding paragraphs.

68. The Administrative Proceeding, in which the FTC will act as prosecutor, judge and jury, violates Counterclaim Plaintiffs' constitutional rights under Article I.

69. Congress gave the FTC unfettered and unguided discretion to decide whether to bring antitrust enforcement actions in administrative proceedings instead of in Article III courts.

70. In electing to initiate the Administrative Proceeding against Amgen and Horizon, the FTC acted under an unconstitutional delegation of legislative power.

71. The Commission's conduct has caused and will continue to cause Amgen and Horizon to suffer immediate and irreparable harm to their constitutional rights.

72. No money damages can remedy this harm, and Amgen and Horizon have no legal avenue by which to recover any money damages against the FTC.

73. The Administrative Proceeding is not speculative. It is happening and ongoing.

74. This violation of constitutional rights entitles Counterclaim Plaintiffs to declaratory relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, as well as injunctive relief against the continuation of the Administrative Proceeding.

COUNT II

(Violation of Article II of the U.S. Constitution – Improper Removal Protections)

75. Counterclaim Plaintiffs restate and incorporate by reference each and every allegation of the preceding paragraphs.

76. The FTC Commissioners' insulation from accountability and removal by the President today is unconstitutional.

77. The FTC ALJ's insulation from accountability and removal by the President is unconstitutional.

78. Because the FTC's structure violates Article II, any actions taken against Counterclaim Plaintiffs under its present structure are invalid.

79. The Commission's conduct has caused and will continue to cause Amgen and Horizon to suffer immediate and irreparable harm to their constitutional rights.

80. No money damages can remedy this harm, and Amgen and Horizon have no legal avenue by which to recover any money damages against the FTC.

81. The Administrative Proceeding is not speculative. It is happening and ongoing.

82. This violation of constitutional rights entitles Counterclaim Plaintiffs to declaratory relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, as well as injunctive relief against the continuation of the Administrative Proceeding.

COUNT III

(Violation of Fifth Amendment of the U.S. Constitution – Right to Due Process)

83. Counterclaim Plaintiffs restate and incorporate by reference each and every allegation of the preceding paragraphs.

84. The Administrative Proceeding, in which the FTC will act as prosecutor, judge and jury, violates Counterclaim Plaintiffs' constitutional right to Due Process under the Fifth Amendment.

85. Given the combination of investigative, prosecutorial and adjudicative functions, the potential for unconstitutional bias here is intolerable, preventing Counterclaim Plaintiffs from receiving a fair trial in a fair tribunal.

86. The Commission's conduct has caused and will continue to cause Amgen and Horizon to suffer immediate and irreparable harm to their constitutional rights.

87. No money damages can remedy this harm, and Amgen and Horizon have no legal avenue by which to recover any money damages against the FTC.

88. The Administrative Proceeding is not speculative. It is happening and ongoing.

89. This violation of constitutional rights entitles Counterclaim Plaintiffs to declaratory relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, as well as injunctive relief against the continuation of the Administrative Proceeding.

COUNT IV

(Violation of Fifth Amendment of the U.S. Constitution – Right to Equal Protection)

90. Counterclaim Plaintiffs restate and incorporate by reference each and every allegation of the preceding paragraphs.

91. The assignment of the review of this merger to the FTC, rather than DOJ, lacks any rational basis and therefore violates Counterclaim Plaintiffs' equal protection rights.

92. The Commission's conduct has caused and will continue to cause Amgen and Horizon to suffer immediate and irreparable harm to their constitutional rights.

93. No money damages can remedy this harm, and Amgen and Horizon have no legal avenue by which to recover any money damages against the FTC.

94. The Administrative Proceeding is not speculative. It is happening and ongoing.

95. This violation of constitutional rights entitles Counterclaim Plaintiffs to declaratory relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, as well as injunctive relief against the continuation of the Administrative Proceeding.

COUNT V

(Violation of Seventh Amendment of the U.S. Constitution – Right to Jury Trial)

96. Counterclaim Plaintiffs restate and incorporate by reference each and every allegation of the preceding paragraphs.

97. The Administrative Proceeding at issue here involves the adjudication of private rights, particularly, Counterclaim Plaintiffs' ability to engage in a private commercial transaction and the risk that Counterclaim Plaintiffs will have to disgorge their property, pay a fine or otherwise be prevented from operating their business in the manner they see fit.

98. Because Counterclaim Plaintiffs' private rights are at stake, Counterclaim Plaintiffs are entitled to assert the right to a jury trial under the Seventh Amendment.

99. The Commission's conduct has caused and will continue to cause Amgen and Horizon to suffer immediate and irreparable harm to their constitutional rights.

100. No money damages can remedy this harm, and Amgen and Horizon have no legal avenue by which to recover any money damages against the FTC.

101. The Administrative Proceeding is not speculative. It is happening and ongoing.

102. This violation of constitutional rights entitles Counterclaim Plaintiffs to declaratory relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, as well as injunctive relief against the continuation of the Administrative Proceeding.

NOTICE OF CONTEMPLATED RELIEF

WHEREFORE, Counterclaim Plaintiffs respectfully request that the Court enter judgment:

A. Declaring the Administrative Proceeding unconstitutional;

B. Enjoining the FTC from pursuing an administrative enforcement action against Counterclaim Plaintiffs;

C. Awarding Counterclaim Plaintiffs the costs and fees incurred in bringing this action and expenses; and

D. Awarding such other and further relief to Counterclaim Plaintiffs as the Court may deem just and proper.

Dated: June 29, 2023

New York, New York

Respectfully submitted,

/s/ David R. Marriott

David R. Marriott
dmarriott@cravath.com
Timothy G. Cameron (*admitted pro hac vice*)
tcameron@cravath.com
Daniel K. Zach (*admitted pro hac vice*)
dzach@cravath.com
Jesse M. Weiss (*admitted pro hac vice*)
jweiss@cravath.com
CRAVATH, SWAINE & MOORE LLP
825 Eighth Avenue
New York, New York 10019
Telephone: (212) 474-1000
Facsimile: (212) 474-3700

Renata B. Hesse (*admitted pro hac vice*)
hesser@sullcrom.com
Samantha F. Hynes (*admitted pro hac vice*)
hyness@sullcrom.com
SULLIVAN & CROMWELL LLP
1700 New York Avenue, NW
Washington, DC 20006
Telephone: (202) 956-7575

James R. Figliulo
jfigliulo@sgrlaw.com
Dylan Smith
dylansmith@sgrlaw.com
SMITH, GAMBRELL & RUSSELL, LLP
10 S. LaSalle, Suite 3600
Chicago, IL 60603
Telephone: (312) 360-6000
Facsimile: (312) 360-6520

Attorneys for Defendant Amgen Inc.

/s/ Ethan Glass

Ethan Glass
eglass@cooley.com
Jacqueline Grise (*admitted pro hac vice*)
jgrise@cooley.com
David Burns (*admitted pro hac vice*)
dburns@cooley.com
COOLEY LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004
Telephone: (202) 842-7800
Facsimile: (202) 842-7899

Matthew Kutcher
mkutcher@cooley.com
COOLEY LLP
110 N. Wacker Drive, Suite 4200
Chicago, IL 60606
Telephone: (312) 881-6500
Facsimile: (312) 881-6598

Attorneys for Defendant Horizon Therapeutics plc