

COMMISSIONERS: Lina M. Khan, Chair
Rebecca Kelly Slaughter
Alvaro Martin Bedoya

**PUBLIC
DECISION AND ORDER
DOCKET NO. 9414**

The Commission considered the matter and accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Amgen Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its executive offices and principal place of business located at One Amgen Center Drive, Thousand Oaks, California, 91320.
2. Respondent Horizon Therapeutics plc 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.
3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

I. Definitions

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. "Amgen" means Amgen Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Amgen Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. "Horizon" means Horizon Therapeutics plc, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, including Horizon Therapeutics USA, Inc., partnerships, divisions, groups, and affiliates controlled by Horizon Therapeutics plc, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. "Commission" means the Federal Trade Commission.
- D. "Acquisition Date" means the date on which Amgen acquires Horizon.
- E. "Amgen Product" means any Product sold by Respondent Amgen, including after the Acquisition Date excluding the Horizon Products identified in Appendix B.
- F. "ANDA" means an Abbreviated New Drug Application.
- G. "Biosimilar" means any biologic drug product approved under section 351(k) of the Public Health Services Act.
- H. "BLA" means a Biologics License Application.
- I. "Competitive Product to KRYSTEXXA" means a Product, or a Biosimilar or Therapeutic Equivalent of that Product that (1) also shares an FDA-labeled indication with

KRYSTEXXA or (2) is used as an Off-Label Treatment for CRG or to treat an FDA-labeled indication shared with KRYSTEXXA.

- J. “Competitive Product to TEPEZZA” means a Product, or a Biosimilar or Therapeutic Equivalent of that Product that (1) also shares an FDA-labeled indication with TEPEZZA, or (2) is used as an Off-Label Treatment for TED or to treat an FDA-labeled indication shared with TEPEZZA.
- K. “Contract” means an agreement, contract, mutual understanding, arrangement, license agreement, lease, consensual obligation, commitment, promise, or undertaking, whether written or oral, express or implied, or legally binding or not and amendments thereto. In no event does Contract mean drafts or documents that have not been fully executed.
- L. “CRG” means severe chronic gout in adult patients refractory to conventional therapy, the indication that has been recognized as an Orphan Disease by the FDA. CRG does not include either (1) mild or moderate gout or (2) severe gout that is treated by or with conventional therapy.
- M. “FDA” means the United States Food and Drug Administration.
- N. “FTC Form 712” means the FTC’s certification form titled “Request for Non-public Materials and Certification of Intent to Maintain Confidentiality and to Restrict Use to Law Enforcement Purposes” that was submitted by each of the Interested States and approved by the FTC pursuant to authority granted under 15 U.S.C. §§ 46(f) and 57b-2(b)(6) and 16 C.F.R. §4.11(c), as part of the sharing of information and documents in this matter, and continues to be in effect for the term of this Order.
- O. “Interested States” mean the states of California, Illinois, Minnesota, New York, Washington and Wisconsin (subject to approval by the Wisconsin state legislature).
- P. “KRYSTEXXA” means the Product currently manufactured and sold under Biologics License Application #125293 that is indicated to treat CRG with the active ingredient of pegloticase, regardless of formulation, strength, or mode and method of administration, including NDC Number 75987-080, and any supplements, amendments, or revisions to this NDC.
- Q. “Monitor” means any Person appointed by the Commission to serve as a monitor pursuant to this Order.
- R. “NDA” means a New Drug Application.
- S. “Off-Label Treatment for CRG” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, that has been assigned a BLA number or NDA number that is not indicated for, but is included in the same line of therapy as KRYSTEXXA in all three of the following medical guidelines for CRG treatments published by the: (1) American College of Rheumatology, (2) American

College of Physicians, and (3) Gout, Hyperuricemia and Crystal-Associated Disease Network.

- T. “Off-Label Treatment for TED” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, that has been assigned a BLA number or NDA number that is not indicated for, but is included in the same line of therapy as TEPEZZA in all three of the following medical guidelines for TED treatments published by the: (1) American Thyroid Association, (2) Endocrine Society, and (3) American Academy of Ophthalmology.
- U. “Payer” means any pharmacy benefit manager, group purchasing organization (or an equivalent or similar entity), Medicare Advantage plan, and commercial plan sponsor or commercial health plan (including any affiliated specialty pharmacies of such foregoing entities) to the extent that such foregoing entities reimburse, or arrange for reimbursement for all or any part of a Product or is involved in designing the formulary benefit design for such reimbursement.
- V. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture, governmental body, or other entity.
- W. “Pharmacy Benefit Product” means any Product that has been approved for patient self-administration by the FDA and therefore may be eligible for coverage or reimbursement under a pharmacy benefit policy.
- X. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, that has been assigned a BLA number, NDA number, or ANDA number.
- Y. “Product Rebate” means any concession or dollar amount provided by pharmaceutical companies for items including, rebates, administrative fees, volume discounts, patient conversion payments, market share-related payments, formulary placement fees, disease management program payments, promotional allowances, portal fees, data fees, and specialty pharmacy discounts.
- Z. “TED” means active thyroid eye disease, the indication that has been recognized as an Orphan Disease by the FDA.
- AA. “TEPEZZA” means the product currently manufactured and sold under Biologics License Application #761143 that is indicated to treat TED with the active ingredient of teprotumumab, regardless of formulation, strength, or mode and method of administration, including NDC Number: 75987-130, and any supplements, amendments, or revisions to this NDC.

- BB. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA’s criteria for such classification.

II. Prohibited Conduct

IT IS FURTHER ORDERED that Respondent Amgen shall not directly, indirectly, explicitly, or implicitly condition any Product Rebate on, or any contract terms related to, an Amgen Product, in exchange for either (1) the purchase, coverage, placement, or positioning, individually or in any combination, of KRYSTEXXA or TEPEZZA, or (2) the exclusion, detriment, or disadvantage, individually or in any combination, of a Competitive Product to KRYSTEXXA or a Competitive Product to TEPEZZA.

Provided, however, that if Respondent Amgen believes that a Contract that is prohibited in this Section II is required by a federal, state, or local statute, rule, or regulation, Respondent Amgen shall provide 30 days’ notice to the Commission prior to entering into such Contract. Additionally, Respondent Amgen agrees to provide the same 30 days’ notice to the Interested States, consistent with the Interested States’ ability to receive such information pursuant to FTC Form 712, prior to entering into such Contract at the addresses in Appendix A.

III. Required Obligations

IT IS FURTHER ORDERED that:

- A. Respondent Amgen shall:
1. Submit to the Monitor all Contracts with Payers related to the purchase, coverage, placement, or positioning of KRYSTEXXA or TEPEZZA in the United States, including all contact numbers and names for persons involved from Amgen and from the other entities, within 30 days of entering into such Contract. For all such Contracts, Respondent Amgen shall keep any documents related to any offers, negotiations, disputes, or enforcement for a period of at least one year from the date of the Contract; and
 2. Notify the Monitor if either KRYSTEXXA or TEPEZZA meets all three of the following conditions: (a) KRYSTEXXA or TEPEZZA has been approved by the FDA for patient self-administration; (b) the self-administered version of KRYSTEXXA or TEPEZZA is available on the market; and (c) the self-administered version of KRYSTEXXA or TEPEZZA is otherwise eligible to be covered as a Pharmacy Benefit Product.
- B. Respondent Amgen shall require, annually, all Amgen employees with direct involvement in contracting or negotiations with Payers related to the purchase, coverage, placement, or positioning of KRYSTEXXA and/or TEPEZZA in the United States to review this Order and acknowledge in writing (including by email) that they understand and are complying with the obligations of the Order.

- C. Respondent Amgen shall provide notification that includes: (1) the Order, (2) the Analysis to Aid Public Comment, (3) the Complaint, and (4) contact information for the Monitor and Commission staff:
1. Annually, to the relevant third-party personnel who contract for the purchase, coverage, placement, or positioning of KRYSTEXXA or TEPEZZA at Payers in the United States; and
 2. On Amgen's website.

IV. Monitor

IT IS FURTHER ORDERED that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a Monitor to observe and report on Respondents' compliance with all their obligations as required by this Order.
- B. The Commission shall select the Monitor, subject to the consent of Respondent Amgen, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within 10 days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
- C. If a Monitor is appointed, the Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement:
1. Shall be subject to the approval of the Commission;
 2. Shall not limit, and the signatories shall not construe it to limit, the terms of this Section IV of this Order, and to the extent any provision in the agreement varies from or conflicts with any provision in this Order, Respondents and the Monitor shall comply with this Order; and
 3. Shall include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Order in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Order, Respondents and the Monitor shall comply with the Order.
- D. The Monitor shall:
1. Have the authority to monitor Respondents' compliance with the obligations set forth in this Order;
 2. Act in consultation with the Commission or its staff;

3. Serve as an independent third party and not as an employee or agent of Respondents or of the Commission;
4. Serve without bond or other security;
5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall also enter into a non-disclosure or other confidentiality agreement with the Commission;
7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;
8. Report in writing to the Commission, with a copy to the Interested States, consistent with the Interested States' ability to receive such information pursuant to FTC Form 712, at the addresses in Appendix A or other electronic address supplied by the Interested States, concerning Respondents' compliance with the Order on a schedule set by Commission staff and at any other time requested by Commission staff. The Monitor understands that Interested States will consult with the Commission staff before seeking access to the Monitor, any individuals or entities, or information or documents disclosed or referenced in any such reports sent to the Interested States. After such consultation, the Commission staff will facilitate access by the Interested States to the Monitor, or any relevant individuals, entities, information or documents; and
9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents have satisfied all obligations pursuant to this Order.

E. Respondents shall:

1. Cooperate with and assist the Monitor in performing his or her duties for the purpose of reviewing Respondents' compliance with his or her obligations under this Order, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, data, information, and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;

2. Not interfere with the ability of the Monitor to perform his or her duties pursuant to this Order;
 3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing his or her duties under this Order, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out his or her duties and responsibilities;
 4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to this Order; and
 5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under this Order, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.
- F. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement, so long as the agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission or the Interested States, as described in this Order, or otherwise observe and report on the Respondents' compliance with this Order.
- G. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor section of this Order. The Commission shall select the substitute Monitor, subject to the consent of the Respondents.
- Respondents:
1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;
 2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and

3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph IV.C; or (b) receives Commission approval.
- H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

V. Prior Approval

IT IS FURTHER ORDERED that until and including December 31, 2032, Respondent Amgen shall not, without the prior approval of the Commission, enter into any agreement or understanding to acquire any Product or interest in any business that, at the time such agreement or understanding is entered into, is engaged in the (x) manufacture or sale of Products, or their Therapeutic Equivalents or Biosimilars, that are indicated for TED or CRG, or (y) development of a pre-commercial Product that is in or has completed FDA Phase 2 or Phase 3 clinical trials for TED or CRG. Additionally, Respondent Amgen agrees to provide the non-redacted petition for prior Commission approval to the Interested States, consistent with the Interested States' ability to receive such information pursuant to FTC Form 712, at the addresses in Appendix A.

VI. Compliance Reporting Requirements

IT IS FURTHER ORDERED that:

- A. Respondents shall submit verified written reports ("compliance reports") in accordance with the following:
1. Interim compliance reports 30 days after this Order is issued, and every 60 days thereafter for the first year;
 2. Annual compliance reports one year after the date this Order is issued, and annually for the next 14 years on the anniversary of that date; and
 3. Additional compliance reports as the Commission or its staff may request, including the submission of any Contracts related to Sections II and III of this Order relating to KRYSTEXXA or TEPEZZA. Additionally, Respondent Amgen agrees that the Interested States may request that the Commission staff request an additional compliance report from Respondent Amgen.
- B. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are in compliance with this Order. Conclusory statements that Respondents have complied with their obligations under this Order are insufficient. Respondents shall include in their reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondents have implemented and plan to implement to

comply with each paragraph of this Order including a list of Contracts with Payers related to the terms of purchase, coverage, placement, or positioning of KRYSTEXXA or TEPEZZA in the United States, and a list of recipients of notice pursuant to Paragraphs III.B and III.C.

- C. Respondents shall verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondents shall file their compliance reports with the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov, as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondents shall provide a copy of each non-redacted compliance report to the Monitor if the Commission has appointed one in this matter, and to the Interested States, consistent with the Interested States' ability to receive such information pursuant to FTC Form 712, at the addresses in Appendix A.

VII. Change in Respondent

IT IS FURTHER ORDERED that Respondent Amgen shall notify the Commission at least 30 days prior to:

- A. The proposed dissolution of Amgen Inc.;
- B. The proposed acquisition, merger, or consolidation of Amgen Inc.; or
- C. Any other change in Respondent Amgen, including assignment and the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

VIII. Access

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon 5 days' notice to Respondents, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession, or under the control, of the Respondents related to compliance with this Order, which copying services shall be provided by the Respondents at their expense; and
- B. To interview officers, directors, or employees of the Respondents, who may have counsel present, regarding such matters.

IX. Purpose of Order

IT IS FURTHER ORDERED that the purpose of this Order is, among other things, to address the theories of harm to competition alleged by the Commission in its Complaint, in this matter, and in the Commission's Joint Federal Court Complaint for Temporary Restraining Order and Preliminary Injunction filed with the Interested States in the United States District Court, Northern District of Illinois, June 22, 2023, Case # 1:23-cv-03053, by formalizing Respondent Amgen's commitment not to engage in the Prohibited Conduct in Section II of this Order.

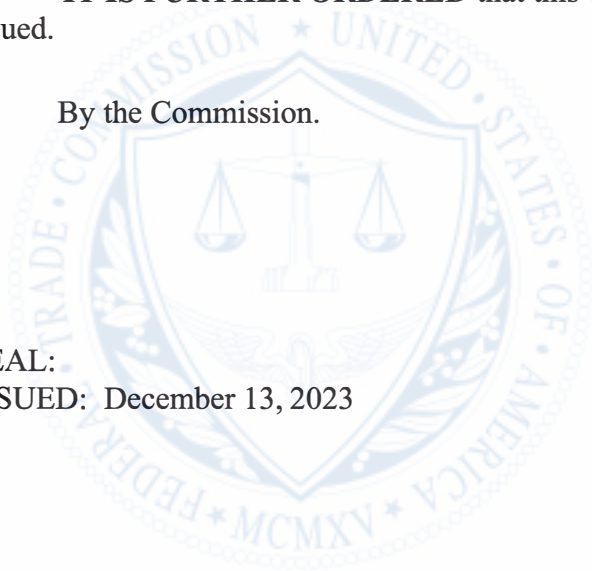
X. Expiration of Order

IT IS FURTHER ORDERED that this Order shall terminate 15 years from the date it is issued.

By the Commission.

April J. Tabor
Secretary

SEAL:
ISSUED: December 13, 2023



APPENDIX A

1. The State of California at email addresses: Emilio.Varanini@doj.ca.gov; Malinda.Lee@doj.ca.gov; Sophia.TonNu@doj.ca.gov
2. The State of Illinois at email addresses: Elizabeth.Maxeiner@ilag.gov; Richard.Schultz@ilag.gov
3. The State of Minnesota at email address: justin.moor@ag.state.mn.us
4. The State of New York at email addresses: saami.zain@ag.ny.gov; amy.mcfarlane@ag.ny.gov; elinor.hoffmann@ag.ny.gov
5. The State of Washington at email addresses: lumi.nodit@atg.wa.gov; atseaef@atg.wa.gov
6. The State of Wisconsin at email address: cooleygj@doj.state.wi.us

PUBLIC APPENDIX B
EXCLUDED HORIZON PRODUCTS FROM AMGEN PRODUCTS DEFINITION

Marketed Products (including ongoing development programs)

- ACTIMMUNE®
- BUPHENYL®
- DUEXIS®
- KRYSTEXXA®
- PENNSAID®2%
- PROCYSBI®
- QUINSAIR®
- RAVICTI®
- RAYOS®
- TEPEZZA®
- UPLIZNA®
- VIMOVO®

Pipeline Therapies

- Bempikibart
- [CONFIDENTIAL]
- Dazodalibep
- Daxdilimab
- [CONFIDENTIAL]
- [CONFIDENTIAL]
- [CONFIDENTIAL]
- [CONFIDENTIAL]
- [CONFIDENTIAL]
- [CONFIDENTIAL]
- [CONFIDENTIAL]
- HZN-457
- HZN-825
- HZN-1116
- [CONFIDENTIAL]

Collaboration Therapies

- All Products resulting from the collaboration and drug discovery agreement with HemoShear LLC that was originally entered into on April 1, 2019 (inclusive of any Products resulting from amendments and modifications to that agreement entered into since or any time in the future)
- All Products resulting from the collaboration and option agreement with Q32 Bio Inc. that was originally entered into on August 12, 2022 (inclusive of any Products resulting

from amendments and modifications to that agreement entered into since or any time in the future)

- All Products resulting from the collaboration and option agreement with Xeris Pharmaceuticals Inc. that was originally entered into on November 22, 2022 (inclusive of any Products resulting from amendments and modifications to that agreement entered into since or any time in the future)
- All Products resulting from the development agreement with West Pharmaceutical Services, Inc. that was originally entered into on August 5, 2020 (inclusive of any Products resulting from amendments, work orders, supply agreements and modifications to that agreement entered into since or any time in the future)
- All Products resulting from the global agreement with Arrowhead Pharmaceuticals Inc. that was originally entered into on June 18, 2021 (inclusive of any Products resulting from amendments and modifications to that agreement entered into since or any time in the future)
- All Products resulting from the global agreement with Halozyme Therapeutics Inc. that was originally entered into on November 21, 2020 (inclusive of any Products resulting from amendments and modifications to that agreement entered into since or any time in the future)
- All Products resulting from the licensing agreement with Alpine Immune Sciences Inc. that was originally entered into on December 15, 2021 (inclusive of any Products resulting from amendments and modifications to that agreement entered into since or any time in the future)