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**Pro hac vice* application forthcoming

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC. and HOFFMAN-LA ROCHE INC., Plaintiffs, v. SHANGHAI HENLIUS BIOTECH, INC., SHANGHAI HENLIUS BIOLOGICS CO., LTD., ORGANON LLC, and ORGANON & CO., Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and Hoffman-La Roche Inc. ("Hoffman-La Roche"), by and through their undersigned attorneys, for their Complaint against Defendants Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd. (together, "Henlius") and Organon LLC and Organon & Co. (together, "Organon," and together with Henlius, "H&O"), hereby allege as follows:

NATURE OF THE CASE

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was

enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("BPCIA"), and the Declaratory Judgment of Act of 1934, 28 U.S.C. §§ 2201-02.

2. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as the "subsection (k) pathway") allows a biosimilar applicant (here, Henlius, acting in concert with Organon) to rely on the prior licensure and approval status of the innovative biological product (here, Genentech's Perjeta®) that the biosimilar purports to copy.

3. Genentech is the sponsor of the reference product (the "reference product sponsor" or "RPS"), Perjeta® (pertuzumab) which is approved by the U.S. Food and Drug Administration ("FDA") in combination with trastuzumab and chemotherapy: (1) for treatment of adults with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; (2) for neoadjuvant therapy of adults with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer; and (3) for adjuvant therapy of adults with HER2-positive early breast cancer at high risk of recurrence. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that the proposed biosimilar product is safe, pure, and potent, as Genentech was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

4. To avoid burdening the courts and parties with unnecessary disputes, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42

U.S.C. § 262(*l*)(2)-(*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

5. The asserted patents in this action cover pertuzumab, pharmaceutical compositions comprising pertuzumab, methods of treatment using pertuzumab, and innovative methods of manufacturing therapeutic antibodies like pertuzumab. The asserted patents are as follows: U.S. Patent No. 7,862,817, U.S. Patent No. 8,652,474, U.S. Patent No. 9,181,346, U.S. Patent No. 11,414,498, U.S. Patent No. 11,597,776, U.S. Patent No. 12,110,341, U.S. Patent No. 7,449,184, U.S. Patent No. 8,404,234, U.S. Patent No. 10,689,457, U.S. Patent No. 11,655,305, U.S. Patent No. 11,077,189, U.S. Patent No. 11,638,756, U.S. Patent No. 11,992,529, U.S. Patent No. 12,128,103, U.S. Patent No. 10,808,037, U.S. Patent No. 11,078,294, U.S. Patent No. 12,145,997, U.S. Patent No. 12,173,080, U.S. Patent No. 9,815,904, U.S. Patent No. 9,969,811, U.S. Patent No. 12,415,998, U.S. Patent No. 10,662,237, U.S. Patent No. 10,676,710, and U.S. Patent No. 12,103,975 (collectively, the "Asserted Patents").

6. On information and belief, Henlius, acting in concert with Organon, is seeking FDA approval of a biosimilar version of Perjeta®. On information and belief, H&O submitted to FDA an abbreviated Biologics License Application (the "Henlius aBLA") for a proposed biosimilar (the "Proposed Henlius Pertuzumab Biosimilar") to Genentech's Perjeta® product, seeking approval to begin commercial activity before the expiration of the Asserted Patents. On information and belief, FDA accepted Henlius's aBLA for review. On January 29, 2025, H&O, through their counsel, sent correspondence to Genentech's general counsel asserting that the Henlius aBLA had been accepted for review by FDA.

7. In February 2025, Genentech and H&O began exchanging information as required by the BPCIA, as detailed *infra* in paragraphs 54-60. The Asserted Patents were

included in Genentech's April 3, 2025 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(A) and its July 11, 2025 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

8. Under 35 U.S.C. § 271(e)(2)(C), the submission of "an application seeking approval of a biological product" for the purpose of obtaining FDA approval to engage in commercial manufacture, use, or sale, including any amendments or supplementations thereto constitutes one or more acts of infringement: (i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), or (ii) with respect to a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 12 (2017).

9. The submission of the Henlius aBLA, including on information and belief, any amendments or supplementations thereto, constitutes one or more acts of infringement of one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(C).

10. If FDA approves the Henlius aBLA and H&O make, offer to sell, sell, use, or import the Proposed Henlius Pertuzumab Biosimilar within the United States, H&O will also infringe one or more claims of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

11. This action also arises from H&O's imminent and actual import, and imminent commercial manufacture, offer for sale, and sale of that proposed biosimilar product. In the event H&O imports, manufactures, or launches its biosimilar product prior to the expiration of the Asserted Patents, Genentech also seeks monetary damages, including lost profits, and any further relief as this Court may deem just and proper.

THE PARTIES

12. Genentech, Inc. is a corporation existing under the laws of the State of Delaware, with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080. Genentech, Inc. is a biotechnology company that develops, manufactures, and commercializes medicines to treat patients with serious and life-threatening medical conditions. Genentech, Inc. employs a large number of scientists who routinely publish in top peer-reviewed journals and are among the leaders in their respective fields. Genentech, Inc. currently markets numerous approved pharmaceutical and biologic drugs for various serious or life-threatening medical conditions that include cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases.

13. Hoffman-La Roche Inc. is a corporation organized and existing under the laws of State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424. Hoffman-La Roche Inc. is a pharmaceutical company that researches, develops, and manufactures drugs to address unmet medical needs.

14. On information and belief, Shanghai Henlius Biotech, Inc. is a corporation organized and existing under the laws of the People's Republic of China ("China") with its principal place of business at Room 901, 9th Floor, Building 1, No. 367 Shengrong Road, China (Shanghai) Pilot Free Trade Zone, 201210.

15. On information and belief, Shanghai Henlius Biologics Co., Ltd. is a corporation organized and existing under the laws of China with its principal place of business at No. 182 Wenjun Road, Songjiang District, Shanghai, China 201603.

16. On information and belief, Shanghai Henlius Biologics Co., Ltd. is a wholly owned subsidiary of Shanghai Henlius Biotech, Inc.

17. On information and belief, Organon & Co. is a corporation existing under the laws of the State of Delaware, with its principal place of business at 30 Hudson Street, Floor 33, Jersey City, New Jersey 07302.

18. On information and belief, Organon LLC is a corporation existing under the laws of the State of Delaware, with its principal place of business at 30 Hudson Street, Floor 33, Jersey City, New Jersey 07302.

19. On information and belief, Organon LLC is a subsidiary of Organon & Co.

20. On information and belief, Shanghai Henlius Biotech, Inc., acting in concert with Shanghai Henlius Biologics Co., Ltd., Organon LLC, and Organon & Co., is in the business of developing, manufacturing, seeking regulatory approval for, importing, marketing, distributing, and selling biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in this judicial District and throughout the United States.

21. On information and belief, Shanghai Henlius Biotech, Inc., acting in concert with Shanghai Henlius Biologics Co., Ltd., Organon LLC, and Organon & Co., intends to develop, manufacture, import, market, distribute, offer for sale and/or sell in this judicial District and throughout the United States a biosimilar version of Perjeta® upon FDA approval and, in doing so, will improperly exploit Genentech's intellectual property.

22. On information and belief, Organon entered into a global license agreement with Henlius, which secured Organon United States commercialization rights related to the Henlius aBLA for pertuzumab.

23. On information and belief, Organon LLC, acting in concert with Organon & Co., will serve as the distributor of the Henlius Proposed Pertuzumab Biosimilar in the United States.

JURISDICTION

24. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

25. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a), 2201(a), and 2202.

26. This Court has personal jurisdiction over each of Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd. under Fed. R. Civ. P. 4(k) because, on information and belief, each is organized under the laws of China and because, on information and belief, each maintains continuous and systematic contacts with New Jersey through Henlius's collaboration with Organon LLC and Organon & Co., each of which has its principal place of business in Jersey City, New Jersey, and regularly and continuously conducts business within this state.

27. Alternatively, should either Shanghai Henlius Biotech, Inc. or Shanghai Henlius Biologics Co., Ltd. contest jurisdiction in this forum, this Court has personal jurisdiction over that entity under Fed. R. Civ. P. 4(k)(2) because, on information and belief, it is not subject to jurisdiction in any State's courts of general jurisdiction and because exercising jurisdiction is consistent with the United States Constitution and laws, including because Henlius has sufficient contacts with the United States and with New Jersey that relate to the claims in this case.

28. On information and belief, each of Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd., directly and through their respective subsidiaries, affiliates, or agents, develops, manufactures, seeks regulatory approval for, markets, distributes, and sells pharmaceutical products, for use throughout the United States, including in New Jersey.

29. This Court has personal jurisdiction over each of Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd. because, among other reasons, each such entity itself

and through its collaboration with Organon, has purposefully availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipated being sued in this Court.

30. This Court has personal jurisdiction over each of Organon LLC and Organon & Co. because their principal places of business are in New Jersey, and also because each, directly and through their respective subsidiaries, affiliates, or agents, is in the business of manufacturing biosimilar drugs that it distributes or has distributed in the State of New Jersey and throughout the United States, and has purposely availed itself of the rights and benefits of the State of New Jersey, has engaged in systematic and continuous contacts with the State of New Jersey, and regularly and continuously conducts business within this State, including by placing its products in the stream of commerce for distribution and consumption in New Jersey. Each derives substantial revenue from selling pharmaceutical products throughout the United States, including New Jersey.

31. On information and belief, each of Organon LLC and Organon & Co. collaborated with Henlius to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in New Jersey.

32. On information and belief, each of Organon LLC and Organon & Co. acted in collaboration and in concert with Henlius to take substantial steps to prepare for and undertake the filing of the Henlius aBLA and to file the Henlius aBLA for their proposed pertuzumab biosimilar product, intending to seek to market the Henlius Proposed Pertuzumab Biosimilar nationwide, including within this Judicial District.

33. This Court also has personal jurisdiction over each Defendant because this suit arises from and relates to their activities that are, and will be, directed to New Jersey. On information and belief, following any FDA approval of the Henlius aBLA, H&O will market and sell the Henlius Proposed Pertuzumab Biosimilar that is the subject of the infringement claims in this action in the State of New Jersey and throughout the United States, including in this Judicial District, to list the Henlius Proposed Pertuzumab Biosimilar on the State of New Jersey's prescription drug formulary, and to seek Medicaid reimbursement for sales of the Henlius Proposed Pertuzumab Biosimilar in the State of New Jersey, either directly or through one or more of H&O's subsidiaries, agents, and/or alter egos.

34. On information and belief, Defendants, acting in collaboration and in concert, have committed, or aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that will lead to foreseeable harm and injury to Genentech, which developed, obtained FDA approval for, manufactured, and/or distributed Perjeta® for sale and use throughout the United States, including in this Judicial District.

VENUE

35. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) over each of Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd. because, inter alia, each is incorporated in China and may be sued in any judicial district in the United States in which each is subject to the Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

36. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b) over each of Organon LLC and Organon & Co. because each has its headquarters and principal place of business at 30 Hudson Street, Floor 33, Jersey City, NJ 07302 and has systematic and continuous

contacts with New Jersey and, in particular, on information and belief, each has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting the Henlius aBLA for a proposed pertuzumab biosimilar in and from New Jersey, and receiving correspondence with FDA regarding the Henlius aBLA at its office in New Jersey.

BACKGROUND

A. Genentech's Innovative Biological Product Perjeta® (pertuzumab)

37. Breast cancer is the most common cancer in women in the U.S., and HER2-positive breast cancer accounts for about 20–25% of all breast cancer diagnoses. HER2-positive breast cancer is particularly aggressive and fast-growing. This subtype of breast cancer is characterized by overexpression of human epidermal growth factor receptor 2 ("HER2") proteins due to HER2 gene amplification.

38. HER2-positive breast cancer was previously associated with poor outcomes and higher mortality rates than other breast cancer subtypes. With the development of HER2-targeted agents mainly by Genentech, HER2-postive breast cancer is now a treatable disease and outcomes have dramatically improved for these patients.

39. Initially, the lives of millions of women suffering from HER2-positive breast cancer changed dramatically when Genentech developed Herceptin® (trastuzumab). Herceptin® was the first drug of its kind—an antibody called trastuzumab that specifically targets the HER2 protein. Since FDA approval of Herceptin® in 1998, Genentech has worked diligently to develop new methods of using Herceptin®.

40. Even though Herceptin® dramatically changed the lives of millions of women, it became quickly apparent that new targeted therapies would also be beneficial, especially for higher-risk early-stage breast cancer.

41. Genentech developed Perjeta®, another anti-HER2-antibody-based targeted therapy. Perjeta® includes pertuzumab, an antibody that targets a different part of the HER2 protein than trastuzumab does. When administered together, trastuzumab and pertuzumab work together to treat HER2-positive breast cancer.

42. Perjeta® is approved by FDA in combination with trastuzumab and chemotherapy: (1) for treatment of adults with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; (2) for neoadjuvant therapy of adults with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer; and (3) adjuvant therapy of adults with HER2-positive early breast cancer at high risk of recurrence.

43. The combination of Herceptin® and Perjeta® has changed cancer treatment drastically and has become the standard of care. This is all due to Genentech's work since the early 1990s in identifying and developing anti-HER2 antibodies.

44. All told, Genentech has spent billions of dollars over two decades to develop life-saving drugs like Herceptin® and Perjeta®.

45. Genentech's groundbreaking work in developing Perjeta® was the result of years of research. The United States Patent and Trademark Office ("USPTO") recognized Genentech's innovative work by granting numerous patents claiming Perjeta®, its manufacture and its use.

46. Before Genentech introduced Perjeta®, an innovative biologic medicine that has benefited millions of breast cancer patients, Genentech conducted extensive clinical trials and submitted the results of those trials to FDA in order to prove that Perjeta® is safe, pure, and potent.

47. Prior to the approval of Perjeta®, any other company wishing to sell its own version of pertuzumab would have had to undertake the same extensive effort to conduct clinical trials to prove to FDA that its proposed version was also safe, pure, and potent.

48. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biologic product at more than $2 billion, including the costs of failure.

49. Genentech, Inc. is the sponsor of the Biologics License Application ("BLA") for Perjeta®. Hoffman-La Roche Inc. is a co-owner of some of the Asserted Patents.

B. Defendants Seek Approval to Market a Proposed Biosimilar Version of Perjeta® by Taking Advantage of the Abbreviated Subsection (k) Pathway of the BPCIA

50. On information and belief, Henlius, acting in concert with Organon, submitted the Henlius aBLA to FDA pursuant to Section 351(k) of the Public Health Service Act to obtain approval to commercially manufacture, use, offer to sell, sell, and import into the United States the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta® product.

51. On information and belief, Defendants sought FDA approval for the Proposed Henlius Pertuzumab Biosimilar by submitting the Henlius aBLA under the abbreviated licensing pathway of 42 U.S.C. § 262(k), which allows H&O to reference and rely on the approval and licensure of Genentech's Perjeta® product in support of their request for FDA approval.

52. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is designed to compete with Genentech's Perjeta®.

53. The Henlius aBLA is predicated on Genentech's trailblazing efforts.

C. The Information Exchange Under 42 U.S.C. § 262(*l*)

54. On January 29, 2025, H&O, through their counsel, sent correspondence to Genentech's general counsel asserting that the Henlius aBLA had been "accepted for review by FDA on January 28, 2025" and "Henlius will produce the information required by § 262(*l*)(2)(A)."

55. On February 11, 2025, pursuant to 42 U.S.C. § 262(*l*)(2)(A), H&O, through its counsel, provided its aBLA to Genentech.

56. On April 3, 2025, Genentech identified, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and 35 U.S.C. § 271(e)(2)(C), 47 patents for which Genentech believes a claim of patent infringement could reasonably be asserted with respect to the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of Henlius's aBLA No. 761450.

57. On May 13, 2025, H&O provided their detailed statement under 35 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for its contentions that each of the listed patents is invalid, unenforceable, and/or will not be infringed by the commercial marketing of the biological product described in Henlius's aBLA No. 761450.

58. On July 11, 2025, Genentech provided its detailed statement under 35 U.S.C. § 262(*l*)(3)(C)) describing on a claim by claim basis, the factual and legal basis of Genentech's opinion that certain claims of the Asserted Patents will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA, and Genentech's response to the statement concerning validity and enforceability as to the Asserted Patents in H&O's May 13, 2025 statement under 42 U.S.C. § 262(*l*)(3)(B).

59. On July 16, 2025, H&O, through their counsel, informed Genentech that H&O "consent to . . . Genentech's list of patents for which it believes a claim of patent infringement

could reasonably be asserted" and H&O "agree that each of these patents shall be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6)."

60. Genentech filed this Complaint within the time required under 42 U.S.C. § 262(*l*)(6), i.e., within 30 days after Genentech and H&O reached agreement that the Asserted Patents would be the subject of an action for patent infringement under § 262(*l*)(6).

THE ASSERTED PATENTS

61. Genentech has spent decades and significant resources developing Perjeta®, and the USPTO has awarded Genentech numerous patents on innovative inventions related to Perjeta® and various manufacturing methods for antibody production. These patents cover the antibody pertuzumab and its use and manufacture.

62. Genentech has identified the following patents for which Genentech reasonably believes that it could assert a claim of infringement with respect to the Henlius Proposed Pertuzumab Biosimilar, based on the information that H&O have provided so far: U.S. Patent No. 7,862,817, U.S. Patent No. 8,652,474, U.S. Patent No. 9,181,346, U.S. Patent No. 11,414,498, U.S. Patent No. 11,597,776, U.S. Patent No. 12,110,341, U.S. Patent No. 7,449,184, U.S. Patent No. 8,404,234, U.S. Patent No. 10,689,457, U.S. Patent No. 11,655,305, U.S. Patent No. 11,077,189, U.S. Patent No. 11,638,756, U.S. Patent No. 11,992,529, U.S. Patent No. 12,128,103, U.S. Patent No. 10,808,037, U.S. Patent No. 11,078,294, U.S. Patent No. 12,145,997, U.S. Patent No. 12,173,080, U.S. Patent No. 9,815,904, U.S. Patent No. 9,969,811, U.S. Patent No. 12,415,998, U.S. Patent No. 10,662,237, U.S. Patent No. 10,676,710, and U.S. Patent No. 12,103,975.

A. The Composition Patent

63. U.S. Patent No. 7,862,817 ("'817 Patent" or the "Composition Patent") describes and claims compositions comprising humanized anti-ErbB2 antibodies and methods of treating cancer with anti-ErbB2 antibodies, specifically pertuzumab.

64. The '817 Patent, titled "Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the USPTO on January 4, 2011. A true and correct copy of the '817 Patent is attached as Exhibit 1. The listed inventors are Camellia W. Adams, Leonard G. Presta, and Mark Sliwkowski. Genentech, Inc. is the owner by assignment of the '817 Patent.

B. The Acidic Variant Patents

65. U.S. Patent Nos. 8,652,474 ("'474 Patent"), 9,181,346 ("'346 Patent"), 11,414,498 ("'498 Patent"), 11,597,776 ("'776 Patent"), and 12,110,341 ("'341 Patent") (collectively, the "Acidic Variant Patents") describe and claim compositions comprising a main species anti-HER2 antibody that binds to domain II of HER2 and its acidic variants, a method of making such a composition, and a method of a method of treating HER2-positive cancer comprising administering such a composition.

66. The '474 Patent, titled "Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof," was duly and legally issued by the USPTO on February 18, 2014. A true and correct copy of the '474 Patent is attached as Exhibit 2. The listed inventors are Reed J. Harris and Paul A. Motchnick. Genentech, Inc. is the owner by assignment of the '474 Patent.

67. The '346 Patent, titled "Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof," was duly and legally issued by the USPTO on November 10, 2015. A true and correct copy of the '346 Patent is attached as Exhibit 3. The

listed inventors are Reed J. Harris and Paul A. Motchnick. Genentech, Inc. is the owner by assignment of the ’346 Patent.

68. The ’498 Patent, titled “Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof,” was duly and legally issued by the USPTO on August 16, 2022. A true and correct copy of the ’498 Patent is attached as Exhibit 4. The listed inventors are Reed J. Harris and Paul A. Motchnick. Genentech, Inc. is the owner by assignment of the ’498 Patent.

69. The ’776 Patent, titled “Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof,” was duly and legally issued by the USPTO on March 7, 2023. A true and correct copy of the ’776 Patent is attached as Exhibit 5. The listed inventors are Reed J. Harris and Paul A. Motchnick. Genentech, Inc. is the owner by assignment of the ’776 Patent.

70. The ’341 Patent, titled “Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof,” was duly and legally issued by the USPTO on October 8, 2024. A true and correct copy of the ’341 Patent is attached as Exhibit 6. The listed inventors are Reed J. Harris and Paul A. Motchnick. Genentech, Inc. is the owner by assignment of the ’341 Patent.

C. The Fixed Dose Patents

71. U.S. Patent Nos. 7,449,184 (“’184 Patent”) and 8,404,234 (“’234 Patent”) (collectively, the “Fixed Dose Patents”) describe and claim a method of treating cancer comprising administering one or more fixed doses of a HER2 antibody, including pertuzumab, to a patient in an amount effective to treat cancer and an article of manufacture comprising a vial containing a fixed dose of the HER2 antibody, specifically pertuzumab, wherein the fixed dose is

selected from the group consisting of approximately 420 mg and approximately 840 mg, among others.

72. The ’184 Patent, titled “Fixed Dosing of HER Antibodies,” was duly and legally issued by the USPTO on November 11, 2008. A true and correct copy of the ’184 Patent is attached as Exhibit 7. The listed inventors are David E. Allison, Rene Bruno, Jian-Feng Lu, and Chee M. Ng. Genentech, Inc. is the owner by assignment of the ’184 Patent.

73. The ’234 Patent, titled “Fixed Dosing of HER Antibodies,” was duly and legally issued by the USPTO on March 26, 2013. A true and correct copy of the ’234 Patent is attached as Exhibit 8. The listed inventors are David E. Allison, Rene Bruno, Jian-Feng Lu, and Chee M. Ng. Genentech, Inc. is the owner by assignment of the ’234 Patent.

D. Metastatic Breast Cancer Indication Patents

74. U.S. Patent Nos. 10,689,457 (“’457 Patent”) and 11,655,305 (“’305 Patent”) (collectively, the “Metastatic Breast Cancer Indication Patents”) describe and claim methods of treatment of previously untreated HER2-positive metastatic breast cancer with a combination of trastuzumab, pertuzumab, and docetaxel, wherein the patient did not receive prior chemotherapy or anti-HER2 therapy.

75. The ’457 Patent, titled “Treatment of Metastatic Breast Cancer,” was duly and legally issued by the USPTO on June 23, 2020. A true and correct copy of the ’457 Patent is attached as Exhibit 9. The listed inventors are Virginia Paton, Anne Blackwood Chirchir, Pam Klein, and Graham Alexander Ross. Genentech, Inc. and Hoffman-La Roche are the owners by assignment of the ’457 Patent.

76. The ’305 Patent, titled “Treatment of Metastatic Breast Cancer,” was duly and legally issued by the USPTO on May 23, 2023. A true and correct copy of the ’457 Patent is

attached as Exhibit 10. The listed inventors are Virginia Paton, Anne Blackwood Chirchir, Pam Klein, and Graham Alexander Ross. Genentech, Inc. and Hoffman-La Roche are the owners by assignment of the '305 Patent.

E. Early Breast Cancer Adjuvant Treatment Patents

77. U.S. Patent Nos. 11,077,189 ("'189 Patent), 11,638,756 ("'756 Patent"), 11,992,529 ("'529 Patent"), and 12,128,103 ("'103 Patent") (collectively, the "Early Breast Cancer Adjuvant Treatment Patents") describe and claim methods for the adjuvant treatment of operable HER2-positive primary breast cancer in patients by administration of pertuzumab in addition to chemotherapy and trastuzumab.

78. The '189 Patent, titled "Adjuvant Treatment of HER2-Positive Breast Cancer," was duly and legally issued by the USPTO on August 3, 2021. A true and correct copy of the '189 Patent is attached as Exhibit 11. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech, Inc. and Hoffman-La Roche are the owners by assignment of the '189 Patent.

79. The '756 Patent, titled "Adjuvant Treatment of HER2-Positive Breast Cancer," was duly and legally issued by the USPTO on May 2, 2023. A true and correct copy of the '756 Patent is attached as Exhibit 12. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech, Inc. and Hoffman-La Roche are the owners by assignment of the '756 Patent.

80. The '529 Patent, titled "Adjuvant Treatment of HER2-Positive Breast Cancer," was duly and legally issued by the USPTO on May 28, 2024. A true and correct copy of the '529 Patent is attached as Exhibit 13. The listed inventors are Mark C. Benyunes and Graham

Alexander Ross. Genentech, Inc. and Hoffman-La Roche are the owners by assignment of the '529 Patent.

81. The '103 Patent, titled "Adjuvant Treatment of HER2-Positive Breast Cancer," was duly and legally issued by the USPTO on April 16, 2024. A true and correct copy of the '103 Patent is attached as Exhibit 14. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech, Inc. and Hoffman-La Roche are the owners by assignment of the '103 Patent.

F. Disulfide Bond Reduction Patents

82. U.S. Patent Nos. 10,808,037 ("'037 Patent"), 11,078,294 ("'294 Patent"), 12,145,997 ("'997 Patent), and 12,173,080 ("'080 Patent") (collectively, the "Disulfide Bond Reduction Patents") describe and claim methods for preventing the reduction of disulfide bonds of antibodies from recombinant host cell cultures.

83. The '037 Patent, titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued by the USPTO on October 20, 2020. A true and correct copy of the '037 Patent is attached as Exhibit 15. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech, Inc. is the owner by assignment of the '037 Patent.

84. The '294 Patent, titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued by the USPTO on August 3, 2021. A true and correct copy of the '294 Patent is attached as Exhibit 16. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech, Inc. is the owner by assignment of the '294 Patent.

85. The ’997 Patent, titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” was duly and legally issued by the USPTO on November 19, 2024. A true and correct copy of the ’997 Patent is attached as Exhibit 17. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech, Inc. is the owner by assignment of the ’997 Patent.

86. The ’080 Patent, titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” was duly and legally issued by the USPTO on December 24, 2024. A true and correct copy of the ’080 Patent is attached as Exhibit 18. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech, Inc. is the owner by assignment of the ’080 Patent.

G. Pertuzumab Variants Patents

87. U.S. Patent Nos. 9,815,904 (“’904 Patent”), 9,969,811 (“’811 Patent”), and 12,415,998 (“’998 Patent) (collectively, the “Pertuzumab Variants Patents”) describe and claim compositions of variants of pertuzumab including an unpaired cysteine variant comprising Cyc23/Cyc88 in one or both variable light domains of pertuzumab, an afucosylated variant, a low-molecular-weight-species of pertuzumab, and a high-molecular-weight species of pertuzumab, methods of treatment with such compositions, and a method of making an article of manufacture comprising such compositions.

88. The ’904 Patent, titled “Pertuzumab Variants and Evaluations Thereof,” was duly and legally issued by the USPTO on November 14, 2017. A true and correct copy of the ’904 Patent is attached as Exhibit 19. The listed inventors are Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang. Genentech, Inc. is the owner by assignment of the ’904 Patent.

89. The ’811 Patent, titled “Pertuzumab Variants and Evaluations Thereof,” was duly and legally issued by the USPTO on May 15, 2018. A true and correct copy of the ’811 Patent is attached as Exhibit 20. The listed inventors are Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang. Genentech, Inc. is the owner by assignment of the ’811 Patent.

90. The ’998 Patent, titled “Pertuzumab Variants and Evaluations Thereof,” was duly and legally issued by the USPTO on November 19, 2024. A true and correct copy of the ’998 Patent is attached as Exhibit 21. The listed inventors are Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang. Genentech, Inc. is the owner by assignment of the ’998 Patent.

H. U.S. Patent No. 10,662,237

91. U.S. Patent No. 10,662,237 (“’237 Patent”) describes and claims methods for increasing the filtration capacity of virus filters, by combined use of endotoxin removal and cation-exchange media in the prefiltration process.

92. The ’237 Patent, titled “Method to Improve Virus Filtration Capacity,” was duly and legally issued by the USPTO on May 26, 2020. A true and correct copy of the ’237 Patent is attached as Exhibit 22. The listed inventor is Amit Mehta. Genentech, Inc. is the owner by assignment of the ’237 Patent.

I. U.S. Patent No. 10,676,710

93. U.S. Patent No. 10,676,710 (“’710 Patent) describes and claims cell culture media comprising antioxidants, methods of using the media for cell culture and polypeptide production.

94. The ’710 Patent, titled “Cell Culture Compositions with Antioxidants and Methods for Polypeptide Production,” was duly and legally issued by the USPTO on June 9, 2020. A true and correct copy of the ’710 Patent is attached as Exhibit 23. The listed inventors

are Natarajan Vijayasankaran, Steven J. Meier, Sharat Varma, and Yi Yang. Genentech, Inc. is the owner by assignment of the ’710 Patent.

J. U.S. Patent No. 12,103,975

95. U.S. Patent No. 12,103,975 (“’975 Patent) describes and claims a process of producing recombinant proteins like antibodies, in asparagine-supplemented glutamine-free mammalian cell culture.

96. The ’975 Patent, titled “Production of Proteins in Glutamine-Free Cell Culture Media,” was duly and legally issued by the USPTO on October 1, 2024. A true and correct copy of the ’975 Patent is attached as Exhibit 24. The listed inventors are Martin Gawlitzek, Shun Luo, and Christina Teresa Bevilacqua. Genentech, Inc. is the owner by assignment of the ’975 Patent.

CAUSES OF ACTION

FIRST COUNT
(PATENT INFRINGEMENT OF THE ’817 PATENT)

97. The allegations of paragraphs 1–96 are repeated and incorporated herein by reference.

98. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s Perjeta®.

99. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar that was stock-piled prior to the expiration of the ’817 Patent.

100. Defendants committed an act or acts of infringement with respect to the '817 Patent under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

101. H&O's participation in, contribution to, inducement of, aiding, or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the '817 Patent under 35 U.S.C. § 271(e)(2)(C).

102. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the '817 Patent.

103. Representative claim 14 of the '817 Patent recites:

> A humanized antibody comprising the variable heavy amino acid sequence in SEQ ID NO:4, and the variable light amino acid sequence in SEQ ID NO:3.

104. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar comprises a humanized antibody comprising the variable heavy amino acid sequence in SEQ ID NO:4, and the variable light amino acid sequence in SEQ ID NO:3.

105. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the '817 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to

include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

106. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '817 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

107. To the extent H&O commercialize their product prior to the expiration of the '817 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

108. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '817 Patent will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SECOND COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '817 PATENT)

109. The allegations of paragraphs 1–108 are incorporated herein by reference.

110. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

111. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

112. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar that has been stock-piled prior to the expiration of the ’817 Patent, Defendants will infringe one or more claims of the ’817 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

113. H&O have knowledge of and are aware of the ’817 Patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O’s infringement of the ’817 Patent is willful.

114. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the ’817 Patent.

115. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the ’817 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the ’817 Patent.

116. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the ’817 Patent. Genentech does not have an adequate remedy at law.

117. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the ‘817 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

THIRD COUNT
(PATENT INFRINGEMENT OF THE ACIDIC VARIANT PATENTS)

118. The allegations of paragraphs 1–117 are repeated and incorporated herein by reference.

119. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

120. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Acidic Variant Patents, which include the '474 Patent, the'346 Patent, the '498 Patent, the '776 Patent, and the'341 Patent.

121. Defendants committed an act or acts of infringement with respect to the Acidic Variant Patents under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

122. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the Acidic Variant Patents under 35 U.S.C. § 271(e)(2)(C).

123. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the Acidic Variant Patents.

124. Representative claim 1 of the '474 Patent recites:

> A composition comprising a main species HER2 antibody that binds to domain II of HER2 and comprises variable light and variable heavy amino acid sequences in SEQ ID Nos. 3 and 4, respectively, and acidic variants thereof comprising disulfide reduced variant and non-reducible variant of the main species antibody.

125. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar comprises a main species HER2 antibody that binds to domain II of HER2 and comprises variable light and variable heavy amino acid sequences in SEQ ID Nos. 3 and 4, respectively, and acidic variants thereof comprising disulfide reduced variant and non-reducible variant of the main species antibody.

126. Representative claim 1 of the ’346 Patent recites:

> A method of treating HER2 positive cancer in a patient comprising administering a pharmaceutical formulation to the patient in an amount effective to treat the cancer, wherein the pharmaceutical formulation comprises a composition comprising a main species HER2 antibody comprising variable light and variable heavy sequences comprising SEQ ID Nos. 3 and 4, respectively, and acidic variants of the main species antibody, wherein the acidic variants include a glycated variant, a deamidated variant, a disulfide reduced variant, a sialylated variant, and a non-reducible variant in a pharmaceutically acceptable carrier.

127. On information and belief, the pharmaceutical formulation of the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of treating HER2-positive cancer to a patient in an effective amount to treat the cancer, wherein the pharmaceutical formulation comprises a composition comprising a main species HER2 antibody comprising variable light and variable heavy sequences comprising SEQ ID Nos. 3 and 4, respectively, and acidic variants of the main species antibody, wherein the acidic variants include a glycated variant, a deamidated variant, a disulfide reduced variant, a sialylated variant, and a non-reducible variant in a pharmaceutically acceptable carrier.

128. Representative claim 1 of the ’498 Patent recites:

> A method of making a pharmaceutical composition comprising: (1) preparing a composition comprising a main species HER2 antibody that binds to domain II of HER2 and comprises variable light and variable heavy amino acid sequences set forth in SEQ ID Nos. 3 and 4, respectively, and acidic variants thereof comprising disulfide reduced variant, and (2) determining the acidic variants in the composition, and confirming that the amount thereof is less than about 25%.

129. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be made by a method comprising: (1) preparing a composition comprising a main species HER2 antibody that binds to domain II of HER2 and comprises variable light and variable heavy amino acid sequences set forth in SEQ ID Nos. 3 and 4, respectively, and acidic variants thereof comprising disulfide reduced variant, and (2) determining the acidic variants in the composition, and confirming that the amount thereof is less than about 25%.

130. Representative claim 1 of the ’776 Patent recites:

> A method of making a pharmaceutical formulation comprising combining:
>
> (i) a composition comprising:
>
> (a) a main species HER2 antibody comprising light chain and heavy chain amino acid sequences set forth in SEQ ID Nos. 15 and 16, respectively; and
>
> (b) acidic variants of the main species antibody, comprising a disulfide reduced variant, with:
>
> (ii) a pharmaceutically acceptable carrier.

131. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be made by a method comprising: combining a composition comprising light chain and heavy chain amino acid sequences set forth in SEQ ID Nos. 15 and 16, respectively, and acidic variants of the main species antibody, comprising disulfide reduced variant, and a pharmaceutically acceptable carrier.

132. Representative claim 1 of the ’341 Patent recites:

> A method of treating HER2 positive cancer in a patient comprising administering a pharmaceutical formulation to the patient in an amount effective to treat the cancer, wherein the pharmaceutical formulation comprises:
>
> (i) a composition comprising:
>
> > (a) a main species HER2 antibody comprising light chain and heavy chain amino acid sequences set forth in SEQ ID Nos. 15 and 16, respectively; and
> >
> > (b) acidic variants of the main species antibody, comprising a disulfide reduced variant, and:
>
> (ii) a pharmaceutically acceptable carrier.

133. On information and belief, the pharmaceutical formulation of the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of treating HER2-positive cancer to a patient in an effective amount to treat the cancer, wherein the pharmaceutical formulation comprises a composition comprising light chain and heavy chain amino acid sequences set forth in SEQ ID Nos. 15 and 16, respectively, and acidic variants of the main species antibody, comprising disulfide reduced variant, and a pharmaceutically acceptable carrier.

134. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the Acidic Variant Patents, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patents will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

135. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the Acidic Variant Patents. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

136. To the extent H&O commercialize their product prior to the expiration of the Acidic Variant Patents, Genentech will also be entitled to damages under 35 U.S.C. § 284.

137. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Acidic Variant Patents will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

FOURTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ACIDIC VARIANT PATENTS)

138. The allegations of paragraphs 1–137 are incorporated herein by reference.

139. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

140. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

141. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the

Acidic Variant Patents, Defendants will infringe one or more claims of the Acidic Variant Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g).

142. H&O have knowledge of and are aware of the Acidic Variant Patents, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the Acidic Variant Patents is willful.

143. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the Acidic Variant Patents.

144. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the Acidic Variant Patents by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Acidic Variant Patents.

145. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Acidic Variant Patents. Genentech does not have an adequate remedy at law.

146. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Acidic Variant Patents will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

FIFTH COUNT
(PATENT INFRINGEMENT OF THE FIXED DOSE PATENTS)

147. The allegations of paragraphs 1–146 are repeated and incorporated herein by reference.

148. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

149. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Fixed Dose Patents, which include the '184 Patent and the '234 Patent.

150. Defendants committed an act or acts of infringement with respect to the Fixed Dose Patents under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

151. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the Fixed Dose Patents under 35 U.S.C. § 271(e)(2)(C).

152. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the Fixed Dose Patents.

153. Representative claim 1 of the '184 Patent recites:

> A method for treating HER2 expressing cancer comprising administering one or more fixed dose(s) of HER2 antibody to a human patient in an amount effective to treat the cancer, wherein the fixed dose is selected from the group consisting of approximately 420 mg, approximately 525 mg, approximately 840 mg, and approximately 1050 mg of the HER2 antibody, wherein the HER2 antibody comprises the variable light and variable heavy amino acid sequences in SEQ ID Nos. 3 and 4, respectively.

154. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of treating HER2-positive cancer to a patient in an amount effective to treat the cancer, wherein the fixed dose selected from the group consisting of approximately 420 mg, approximately 525 mg, approximately 840 mg, and approximately 1050 mg of the HER2 antibody, wherein the HER2 antibody comprises the variable light and variable heavy amino acid sequences in SEQ ID Nos. 3 and 4, respectively.

155. Representative claim 1 of the '234 Patent recites:

> An article of manufacture comprising a single dose vial containing a single fixed dose of pertuzumab, wherein the fixed dose is selected from the group consisting of 420 mg and 840 mg of pertuzumab.

156. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is an article of manufacture comprising a single dose vial containing a single fixed dose of pertuzumab, wherein the fixed dose is selected from the group consisting of 420 mg and 840 mg of pertuzumab.

157. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the Fixed Dose Patents, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patents will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

158. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the Fixed Dose Patents. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

159. To the extent H&O commercialize their product prior to the expiration of the Fixed Dose Patents, Genentech will also be entitled to damages under 35 U.S.C. § 284.

160. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Fixed Dose Patents will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SIXTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE FIXED DOSE PATENTS)

161. The allegations of paragraphs 1–160 are incorporated herein by reference.

162. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

163. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

164. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the

Fixed Dose Patents, Defendants will infringe one or more claims of the Fixed Dose Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g).

165. H&O have knowledge of and are aware of the Fixed Dose Patents, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the Fixed Dose Patents is willful.

166. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the Fixed Dose Patents.

167. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the Fixed Dose Patents by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Fixed Dose Patents.

168. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Fixed Dose Patents. Genentech does not have an adequate remedy at law.

169. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Fixed Dose Patents will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

SEVENTH COUNT
(PATENT INFRINGEMENT OF THE METASTATIC BREAST CANCER INDICATION PATENTS)

170. The allegations of paragraphs 1–169 are repeated and incorporated herein by reference.

171. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

172. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Metastatic Breast Cancer Indication Patents, which include the '457 Patent and the '305 Patent.

173. Defendants committed an act or acts of infringement with respect to the Metastatic Breast Cancer Indication Patents under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

174. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the Metastatic Breast Cancer Indication Patents under 35 U.S.C. § 271(e)(2)(C).

175. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the Metastatic Breast Cancer Indication Patents.

176. Representative claim 1 of the '457 Patent recites:

> A method for the treatment of a human patient with HER2 positive metastatic breast cancer who did not receive either prior chemotherapy or prior anti-HER2 therapy for their metastatic breast cancer, comprising administering to the patient an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein treatment with the combination increases overall survival without increase in cardiac-specific adverse events relative to administration of trastuzumab and docetaxel in the absence of pertuzumab, wherein the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks, the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks, and the docetaxel is administered by intravenous administration every three weeks for at least six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

177. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of treating HER2-positive cancer to a patient with HER2 positive metastatic breast cancer who did not receive either prior chemotherapy or prior anti-HER2 therapy for their metastatic breast cancer, comprising an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein treatment with the combination increases overall survival without increase in cardiac-specific adverse events relative to administration of trastuzumab and docetaxel in the absence of pertuzumab, wherein the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks, the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks, and the docetaxel is administered by intravenous administration every three weeks for at least six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

178. Representative claim 1 of the ’457 Patent recites:

> A method for the treatment of a human patient with HER2-positive metastatic breast cancer who has not received prior anti-HER2 therapy or chemotherapy for metastatic disease, comprising

> administering to the patient an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein:
>
> the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks;
>
> the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks; and
>
> the docetaxel is administered by intravenous infusion every three weeks for at least six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

179. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of treating HER2-positive cancer to a patient with HER2-positive metastatic breast cancer who did not receive either prior chemotherapy or prior anti-HER2 therapy for their metastatic breast cancer, comprising an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks; the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks; and the docetaxel is administered by intravenous infusion every three weeks for at least six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

180. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the Metastatic Breast Cancer Indication Patents, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patents will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not

permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

181. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the Metastatic Breast Cancer Indication Patents. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

182. To the extent H&O commercialize their product prior to the expiration of the Metastatic Breast Cancer Indication Patents, Genentech will also be entitled to damages under 35 U.S.C. § 284.

183. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Metastatic Breast Cancer Indication Patents will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

EIGHTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE METASTATIC BREAST CANCER INDICATION PATENTS)

184. The allegations of paragraphs 1–183 are incorporated herein by reference.

185. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

186. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius

Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

187. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Metastatic Breast Cancer Indication Patents, Defendants will infringe one or more claims of the Metastatic Breast Cancer Indication Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g).

188. H&O have knowledge of and are aware of the Metastatic Breast Cancer Indication Patents, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the Metastatic Breast Cancer Indication Patents is willful.

189. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the Metastatic Breast Cancer Indication Patents.

190. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the Metastatic Breast Cancer Indication Patents by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Metastatic Breast Cancer Indication Patents.

191. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Metastatic Breast Cancer Indication Patents. Genentech does not have an adequate remedy at law.

192. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Metastatic Breast Cancer Indication Patents will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

NINTH COUNT
(PATENT INFRINGEMENT OF THE EARLY BREAST CANCER ADJUVANT THERAPY PATENTS)

193. The allegations of paragraphs 1–192 are repeated and incorporated herein by reference.

194. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

195. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Early Breast Cancer Adjuvant Therapy Patents, which include the '189 Patent, the '756 Patent, the '529 Patent, and the '103 Patent.

196. Defendants committed an act or acts of infringement with respect to the Early Breast Cancer Adjuvant Treatment Patents under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

197. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the Early Breast Cancer Adjuvant Treatment Patents under 35 U.S.C. § 271(e)(2)(C).

198. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the Early Breast Cancer Adjuvant Treatment Patents.

199. Representative claim 1 of the '189 Patent recites:

> A method of increasing invasive disease free survival (IDFS) at 3 years in HER2-positive early breast cancer patients without increase in cardiac toxicity, wherein the patients have a high risk of cancer recurrence, have a baseline left ventricular ejection fraction (LVEF)≥55%, and have not received prior anti-HER2 therapy, comprising administering to said patients, following surgery:
>
> (a) anthracycline-based chemotherapy selected from:
>
> (i) 3-4 cycles of 500-600 mg/m^2 5-FU+90-120 mg/m^2 epirubicin+500-600 mg/m^2 cyclophosphamide, or of 500-600 mg/m^2 5-FU+50 mg/m^2 doxorubicin+500-600 mg/m^2 cyclophosphamide; or
>
> (ii) 4 cycles of 60 mg/m^2 doxorubicin+500-600 mg/m^2 cyclophosphamide, or of 90-120 mg/m^2 epirubicin+500-600 mg/m^2 cyclophosphamide;
>
> (b) following said anthracycline-based chemotherapy, taxane comprising 4 cycles of 75 mg/m^2 or 100 mg/m^2 docetaxel every 3 weeks or 12 cycles of 80 mg/m^2 paclitaxel every week, wherein the taxane is administered in combination with pertuzumab, and trastuzumab, and pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of the first taxane-containing cycle and administered for a total of 52 weeks, and wherein an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab, and an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab,
>
> wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom anthracycline-based chemotherapy, taxane, and trastuzumab without pertuzumab are administered, wherein the cardiac toxicity is a LVEF decline ≥10 points from baseline and a drop to less than 50%, and wherein said high risk patients are node positive or hormone receptor negative.

200. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of increasing invasive disease free survival (IDFS) at 3 years in HER2-

positive early breast cancer patients without increase in cardiac toxicity, wherein the patients have a high risk of cancer recurrence, have a baseline left ventricular ejection fraction (LVEF)≥55%, and have not received prior anti-HER2 therapy, comprising administering to said patients, following surgery: (a) anthracycline-based chemotherapy selected from: either (i) 3-4 cycles of 500-600 mg/m^2 5-FU+90-120 mg/m^2 epirubicin+500-600 mg/m^2 cyclophosphamide, or of 500-600 mg/m^2 5-FU+50 mg/m^2 doxorubicin+500-600 mg/m^2 cyclophosphamide; or (ii) 4 cycles of 60 mg/m^2 doxorubicin+500-600 mg/m^2 cyclophosphamide, or of 90-120 mg/m^2 epirubicin+500-600 mg/m^2 cyclophosphamide; (b) following said anthracycline-based chemotherapy, taxane comprising 4 cycles of 75 mg/m^2 or 100 mg/m^2 docetaxel every 3 weeks or 12 cycles of 80 mg/m^2 paclitaxel every week, wherein the taxane is administered in combination with pertuzumab, and trastuzumab, and pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of the first taxane-containing cycle and administered for a total of 52 weeks, and wherein an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab, and an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab, wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom anthracycline-based chemotherapy, taxane, and trastuzumab without pertuzumab are administered, wherein the cardiac toxicity is a LVEF decline ≥10 points from baseline and a drop to less than 50%, and wherein said high risk patients are node positive or hormone receptor negative.

201. Representative claim 1 of the ’756 Patent recites:

> A method of increasing invasive disease free survival (IDFS) at 3 years in HER2-positive early breast cancer patients without increase in cardiac toxicity, wherein the patients have a high risk of cancer recurrence, have a baseline left ventricular ejection fraction (LVEF) ≥55%, and have not received prior anti-HER2 therapy, comprising administering to said patients, following surgery, pertuzumab, trastuzumab, and non-anthracycline containing chemotherapy, wherein the non-anthracycline containing

> chemotherapy comprises 6 cycles every 3 weeks of 75 mg/m^2 docetaxel and 6 times Area Under the Concentration Time Curve (AUC6) carboplatin, wherein pertuzumab and trastuzumab are each administered intravenously starting on day-1 of the first non-anthracycline containing chemotherapy cycle and administered for a total of 52 weeks, and wherein an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab, and an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab, wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom the non-anthracycline containing chemotherapy and trastuzumab without pertuzumab are administered, wherein the cardiac toxicity is a LVEF decline ≥10 points from baseline and a drop to less than 50%, and wherein said high risk patients are node positive or hormone receptor negative.

202. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of increasing invasive disease free survival (IDFS) at 3 years in HER2-positive early breast cancer patients without increase in cardiac toxicity, wherein the patients have a high risk of cancer recurrence, have a baseline left ventricular ejection fraction (LVEF) ≥55%, and have not received prior anti-HER2 therapy, comprising administering to said patients, following surgery, pertuzumab, trastuzumab, and non-anthracycline containing chemotherapy, wherein the non-anthracycline containing chemotherapy comprises 6 cycles every 3 weeks of 75 mg/m^2 docetaxel and 6 times Area Under the Concentration Time Curve (AUC6) carboplatin, wherein pertuzumab and trastuzumab are each administered intravenously starting on day-1 of the first non-anthracycline containing chemotherapy cycle and administered for a total of 52 weeks, and wherein an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab, and an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab, wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom the non-anthracycline containing chemotherapy and trastuzumab without pertuzumab are administered, wherein the cardiac toxicity is a LVEF decline ≥10 points from baseline and a drop to less than 50%, and wherein said high risk patients are node positive or hormone receptor negative.

203. Representative claim 1 of the ’529 Patent recites:

> A method of adjuvant therapy for increasing invasive disease free survival (IDFS) at 3 years in patients with HER2-positive, node positive or hormone receptor negative, early breast cancer, comprising administering to said patients, following surgery:
>
> (a) anthracycline-based chemotherapy comprising:
>
> (i) 3 or 4 cycles of 5-fluorouracil+epirubicin+cyclophosphamide (FEC) or 5-fluorouracil+doxorubicin+cyclophosphamide (FAC); or
>
> (ii) 4 cycles of doxorubicin+cyclophosphamide (AC) or epirubicin+cyclophosphamide (EC);
>
> (b) following said anthracycline-based chemotherapy, pertuzumab, trastuzumab, and taxane-based chemotherapy, wherein:
>
> (i) pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of a first taxane-containing cycle and administered for 52 weeks;
>
> (ii) an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab;
>
> (iii) an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab; and
>
> (iv) said taxane-based chemotherapy comprises 3 or 4 cycles of 75 mg/m^2 and/or 100 mg/m^2 docetaxel every 3 weeks or 12 cycles of 80 mg/m^2 paclitaxel every week; and
>
> wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom anthracycline-based chemotherapy, taxane-based chemotherapy, and trastuzumab without pertuzumab are administered.

204. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of adjuvant therapy for increasing invasive disease free survival (IDFS) at 3 years in patients with HER2-positive, node positive or hormone receptor negative, early breast cancer, comprising administering to said patients, following surgery: (a) anthracycline-based chemotherapy comprising: (i) 3 or 4 cycles of 5-fluorouracil+epirubicin+cyclophosphamide (FEC) or 5-fluorouracil+doxorubicin+cyclophosphamide (FAC); or (ii) 4 cycles of

doxorubicin+cyclophosphamide (AC) or epirubicin+cyclophosphamide (EC); (b) following said anthracycline-based chemotherapy, pertuzumab, trastuzumab, and taxane-based chemotherapy, wherein: (i) pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of a first taxane-containing cycle and administered for 52 weeks; (ii) an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab; (iii) an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab; and (iv) said taxane-based chemotherapy comprises 3 or 4 cycles of 75 mg/m^2 and/or 100 mg/m^2 docetaxel every 3 weeks or 12 cycles of 80 mg/m^2 paclitaxel every week; and wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom anthracycline-based chemotherapy, taxane-based chemotherapy, and trastuzumab without pertuzumab are administered.

205. Representative claim 1 of the ’103 Patent recites:

> A method of adjuvant treatment for increasing invasive disease free survival (IDFS) at 3 years in patients with HER2-positive, node positive or hormone receptor negative, early breast cancer, said method comprising administering to said patients:
>
> > (a) pertuzumab intravenously every three weeks for 52 weeks, comprising an 840 mg loading dose of pertuzumab followed by 420 mg doses of mg pertuzumab;
> >
> > (b) trastuzumab intravenously every three weeks for 52 weeks, comprising an 8 mg/kg loading dose of trastuzumab followed by 6 mg/kg doses of trastuzumab;
> >
> > (c) taxane-based chemotherapy, comprising 3 or 4 cycles of 75 mg/m2 and/or 100 mg/m2 docetaxel every 3 weeks or 12 cycles of 80 mg/m2 paclitaxel every week, wherein pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of a first taxane-containing cycle;
> >
> > (d) anthracycline-based chemotherapy administered before pertuzumab and trastuzumab administrations comprising 3 or 4 cycles of 5-fluorouracil+epirubicin+cyclophosphamide (FEC) or 5-fluorouracil+doxorubicin+cyclophosphamide (FAC) or 4 cycles of doxorubicin+cyclophosphamide (AC) or epirubicin+cyclophosphamide (EC); and

> wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom trastuzumab, taxane-based chemotherapy, and anthracycline-based chemotherapy without pertuzumab are administered.

206. On information and belief, the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of adjuvant treatment for increasing invasive disease free survival (IDFS) at 3 years in patients with HER2-positive, node positive or hormone receptor negative, early breast cancer, said method comprising administering to said patients: (a) pertuzumab intravenously every three weeks for 52 weeks, comprising an 840 mg loading dose of pertuzumab followed by 420 mg doses of mg pertuzumab; (b) trastuzumab intravenously every three weeks for 52 weeks, comprising an 8 mg/kg loading dose of trastuzumab followed by 6 mg/kg doses of trastuzumab; (c) taxane-based chemotherapy, comprising 3 or 4 cycles of 75 mg/m2 and/or 100 mg/m2 docetaxel every 3 weeks or 12 cycles of 80 mg/m2 paclitaxel every week, wherein pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of a first taxane-containing cycle; (d) anthracycline-based chemotherapy administered before pertuzumab and trastuzumab administrations comprising 3 or 4 cycles of 5-fluorouracil+epirubicin+cyclophosphamide (FEC) or 5-fluorouracil+doxorubicin+cyclophosphamide (FAC) or 4 cycles of doxorubicin+cyclophosphamide (AC) or epirubicin+cyclophosphamide (EC); and wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom trastuzumab, taxane-based chemotherapy, and anthracycline-based chemotherapy without pertuzumab are administered.

207. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the Early Breast Cancer Adjuvant Therapy Patents, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patents

will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

208. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the Early Breast Cancer Adjuvant Therapy Patents. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

209. To the extent H&O commercialize their product prior to the expiration of the Early Breast Cancer Adjuvant Therapy Patents, Genentech will also be entitled to damages under 35 U.S.C. § 284.

210. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Early Breast Cancer Adjuvant Therapy Patents will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

TENTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE EARLY BREAST CANCER ADJUVANT THERAPY PATENTS)

211. The allegations of paragraphs 1–210 are incorporated herein by reference.

212. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

213. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

214. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Early Breast Cancer Adjuvant Therapy Patents, Defendants will infringe one or more claims of the Early Breast Cancer Adjuvant Therapy Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g).

215. H&O have knowledge of and are aware of the Early Breast Cancer Adjuvant Therapy Patents, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the Early Breast Cancer Adjuvant Therapy Patents is willful.

216. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the Early Breast Cancer Adjuvant Therapy Patents.

217. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the Early Breast Cancer Adjuvant Therapy Patents by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Early Breast Cancer Adjuvant Therapy Patents.

218. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Early Breast Cancer Adjuvant Therapy Patents. Genentech does not have an adequate remedy at law.

219. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Early Breast Cancer Adjuvant Therapy Patents will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

ELEVENTH COUNT
(PATENT INFRINGEMENT OF THE DISULFIDE BOND REDUCTION PATENTS)

220. The allegations of paragraphs 1–219 are repeated and incorporated herein by reference.

221. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

222. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Disulfide Bond Reduction Patents, which include the '037 Patent, the '294 Patent, the'997 Patent, and the '080 Patent.

223. Defendants committed an act or acts of infringement with respect to the Disulfide Bond Reduction Patents under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

224. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the Disulfide Bond Reduction Patents under 35 U.S.C. § 271(e)(2)(C).

225. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the Disulfide Bond Reduction Patents.

226. Representative claim 1 of the '037 Patent recites:

> A method for producing an antibody, comprising expressing the antibody in a Chinese Hamster Ovary (CHO) recombinant host cell culture, and following a production phase of the cell culture, sparging the pre-harvest cell culture fluid of the recombinant host cell with air to inhibit reduction of a disulfide bond in the antibody during processing,
>
> wherein the antibody is a therapeutic monoclonal antibody that binds to human epidermal growth factor receptor 2 (HER2), and wherein the air sparging is continued until the amount of dissolved oxygen (dO_2) in the pre-harvest cell culture fluid is at least 10%.

227. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be produced by a method for producing an antibody, comprising expressing the antibody in a Chinese Hamster Ovary (CHO) recombinant host cell culture, and following a production phase of the cell culture, sparging the pre-harvest cell culture fluid of the recombinant host cell with air to inhibit reduction of a disulfide bond in the antibody during processing, wherein the antibody is a therapeutic monoclonal antibody that binds to HER2, and wherein the air sparging is continued until the amount of dissolved oxygen in the pre-harvest cell culture fluid is at least 10%.

228. Representative claim 1 of the '294 Patent recites:

> A method for producing an antibody, comprising expressing the antibody in a Chinese Hamster Ovary (CHO) recombinant host cell

> culture, and following a production phase of the cell culture, sparging the pre-harvest cell culture fluid of the recombinant host cell with air to inhibit reduction of a disulfide bond in the antibody during processing,
>
> wherein the antibody is a therapeutic monoclonal antibody that binds to human epidermal growth factor receptor 2 (HER2), and wherein the air sparging is continued until the amount of dissolved oxygen (dO_2) in the pre-harvest cell culture fluid is at least 10%.

229. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be produced by a method for producing an antibody, comprising expressing the antibody in a CHO recombinant host cell culture, and following a production phase of the cell culture, sparging the pre-harvest cell culture fluid of the recombinant host cell with air to inhibit reduction of a disulfide bond in the antibody during processing, wherein the antibody is a therapeutic monoclonal antibody that binds to HER2, and wherein the air sparging is continued until the amount of dissolved oxygen in the pre-harvest cell culture fluid is at least 10%.

230. Representative claim 1 of the ’997 Patent recites:

> A method for the prevention of the reduction of a disulfide bond in a human epidermal growth factor receptor 2 (HER2) antibody expressed in a recombinant Chinese Hamster Ovary (CHO) host cell, comprising, following a production phase of a cell culture, sparging the pre-harvest cell culture fluid (CCF) or harvested culture fluid (HCCF) of said recombinant CHO host cell with air, wherein the amount of dissolved oxygen (dO2) in the CCF or HCCF is at least 10%.

231. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be produced by a method for the prevention of the reduction of a disulfide bond in an HER2 antibody expressed in a recombinant CHO host cell, comprising, following a production phase of a cell culture, sparging the pre-harvest cell culture fluid (CCF) or harvested culture fluid (HCCF) of said recombinant CHO host cell with air, wherein the amount of dissolved oxygen in the CCF or HCCF is at least 10%.

232. Representative claim 1 of the ’080 Patent recites:

> A method for the prevention of the reduction of a disulfide bond in an IgG1 monoclonal antibody that binds to HER2 expressed by a recombinant Chinese Hamster Ovary (CHO) host cell, comprising supplementing pre-harvest cell culture fluid or harvested cell culture fluid of the recombinant CHO host cell with a thioredoxin inhibitor, wherein the thioredoxin inhibitor is added in an amount effective to prevent disulfide bond reduction of the antibody that binds to HER2 following completion of a cell culture process, and wherein the antibody that binds to HER2 comprises a light chain variable domain amino acid sequence set forth in SEQ ID NO: 16 and a heavy chain variable domain amino acid sequence set forth in SEQ ID NO: 17.

233. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be produced by a method for the prevention of the reduction of a disulfide bond in an IgG1 monoclonal antibody that binds to HER2 expressed by a recombinant CHO host cell, comprising supplementing pre-harvest cell culture fluid or harvested cell culture fluid of the recombinant CHO host cell with a thioredoxin inhibitor, wherein the thioredoxin inhibitor is added in an amount effective to prevent disulfide bond reduction of the antibody that binds to HER2 following completion of a cell culture process, and wherein the antibody that binds to HER2 comprises a light chain variable domain amino acid sequence set forth in SEQ ID NO: 16 and a heavy chain variable domain amino acid sequence set forth in SEQ ID NO: 17.

234. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the Disulfide Bond Reduction Patents, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patents will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

235. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the Disulfide Bond Reduction Patents. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

236. To the extent H&O commercialize their product prior to the expiration of the Disulfide Bond Reduction Patents, Genentech will also be entitled to damages under 35 U.S.C. § 284.

237. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Disulfide Bond Reduction Patents will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

TWELFTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE DISULFIDE BOND REDUCTION PATENTS)

238. The allegations of paragraphs 1–237 are incorporated herein by reference.

239. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

240. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

241. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Disulfide Bond Reduction Patents, Defendants will infringe one or more claims of the Disulfide Bond Reduction Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g).

242. H&O have knowledge of and are aware of the Disulfide Bond Reduction Patents, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the Disulfide Bond Reduction Patents is willful.

243. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the Disulfide Bond Reduction Patents.

244. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the Disulfide Bond Reduction Patents by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Disulfide Bond Reduction Patents.

245. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Disulfide Bond Reduction Patents. Genentech does not have an adequate remedy at law.

246. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Disulfide Bond Reduction Patents will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

THIRTEENTH COUNT
(PATENT INFRINGEMENT OF THE PERTUZUMAB VARIANTS PATENTS)

247. The allegations of paragraphs 1–246 are repeated and incorporated herein by reference.

248. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

249. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Pertuzumab Variants Patents, which include the '904 Patent, the '811 Patent, and the '998 Patent.

250. Defendants committed an act or acts of infringement with respect to the Pertuzumab Variants Patents under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

251. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the Pertuzumab Variants Patents under 35 U.S.C. § 271(e)(2)(C).

252. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the Pertuzumab Variants Patents.

253. Representative claim 1 of the '904 Patent recites:

> A composition comprising Pertuzumab and unpaired cysteine variant thereof, wherein the unpaired cysteine variant comprises Cys23 and Cys88 in both variable light domains of Pertuzumab and Cys23/Cys88 unpaired cysteines in one or both variable light domains thereof.

254. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar comprises Pertuzumab and unpaired cysteine variant thereof, wherein the unpaired cysteine variant comprises Cys23 and Cys88 in both variable light domains of Pertuzumab and Cys23/Cys88 unpaired cysteines in one or both variable light domains thereof.

255. Representative claim 1 of the ’811 Patent recites:

> A method of treating a patient with cancer comprising administering a pharmaceutical composition to a cancer patient, wherein the pharmaceutical composition comprises: (a) a composition comprising Pertuzumab and unpaired cysteine variant thereof, wherein the unpaired cysteine variant comprises Cys23/Cys88 unpaired cysteines in one or both variable light domains of Pertuzumab, and (b) and one or more pharmaceutically acceptable excipients.

256. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be administered as a method of treating a patient with cancer comprising administering a pharmaceutical composition to a cancer patient, wherein the pharmaceutical composition comprises: (a) a composition comprising Pertuzumab and unpaired cysteine variant thereof, wherein the unpaired cysteine variant comprises Cys23/Cys88 unpaired cysteines in one or both variable light domains of Pertuzumab, and (b) and one or more pharmaceutically acceptable excipients.

257. Representative claim 1 of the ’998 Patent recites:

> A method of making an article of manufacture comprising a Pertuzumab pharmaceutical composition suitable for treating a cancer patient, comprising:
>
> (1) recombinantly expressing Pertuzumab from recombinant Chinese Hamster Ovary (CHO) cells at manufacturing scale, and purifying a Pertuzumab composition;

> (2) analyzing fragmentation at Asp-Pro Pertuzumab heavy chain residues 272-273 comprising measuring and identifying the presence of Peak 2 fragment in an amount from 0.3% to 0.9% by reduced capillary electrophoresis sodium dodecyl sulfate (R-CE-SDS) assay in the purified Pertuzumab composition;
>
> (3) combining the purified Pertuzumab composition with one or more pharmaceutically acceptable excipients to make a pharmaceutical composition, wherein step (3) is before or after step (2); and
>
> (4) preparing an article of manufacture comprising a container with the pharmaceutical composition therein, and a package insert with prescribing information instructing the user thereof to use the pharmaceutical composition to treat a cancer patient.

258. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be made by a method of making an article of manufacture comprising a Pertuzumab pharmaceutical composition suitable for treating a cancer patient, comprising: (1) recombinantly expressing Pertuzumab from recombinant CHO cells at manufacturing scale, and purifying a Pertuzumab composition; (2) analyzing fragmentation at Asp-Pro Pertuzumab heavy chain residues 272-273 comprising measuring and identifying the presence of Peak 2 fragment in an amount from 0.3% to 0.9% by reduced capillary electrophoresis sodium dodecyl sulfate (R-CE-SDS) assay in the purified Pertuzumab composition; (3) combining the purified Pertuzumab composition with one or more pharmaceutically acceptable excipients to make a pharmaceutical composition, wherein step (3) is before or after step (2); and (4) preparing an article of manufacture comprising a container with the pharmaceutical composition therein, and a package insert with prescribing information instructing the user thereof to use the pharmaceutical composition to treat a cancer patient.

259. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the Pertuzumab Variants Patents, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA.

Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

260. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the Pertuzumab Variants Patents. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

261. To the extent H&O commercialize their product prior to the expiration of the Pertuzumab Variants Patents, Genentech will also be entitled to damages under 35 U.S.C. § 284.

262. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Pertuzumab Variants Patents will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

FOURTEENTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PERTUZUMAB VARIANTS PATENTS)

263. The allegations of paragraphs 1–262 are incorporated herein by reference.

264. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

265. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

266. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Pertuzumab Variants Patents, Defendants will infringe one or more claims of the Pertuzumab Variants Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g).

267. H&O have knowledge of and are aware of the Pertuzumab Variants Patents, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the Pertuzumab Variants Patents is willful.

268. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the Pertuzumab Variants Patents.

269. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the Pertuzumab Variants Patents by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Pertuzumab Variants Patents.

270. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the Pertuzumab Variants Patents. Genentech does not have an adequate remedy at law.

271. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the Pertuzumab Variants Patents will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

FIFTEENTH COUNT
(PATENT INFRINGEMENT OF THE ’237 PATENT)

272. The allegations of paragraphs 1–271 are repeated and incorporated herein by reference.

273. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s Perjeta®.

274. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the ’237 Patent.

275. Defendants committed an act or acts of infringement with respect to the ’237 Patent under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

276. H&O’s participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the ’237 Patent under 35 U.S.C. § 271(e)(2)(C).

277. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the '237 Patent.

278. Representative claim 1 of the '237 Patent recites:

> A method of virus filtration comprising subjecting a composition comprising a recombinant protein produced in a mammalian host cell and having or suspected of having a parvovirus contaminant to a virus filtration process comprising a cation exchange step and an endotoxin removal step, simultaneously or in either order, immediately preceding a virus filter capable of removing a parvovirus, and wherein said virus filter's filtration capacity in kg/m^2 is improved between 1.5 to 20 fold, as compared to no prefiltration step or using either cation exchange step or endotoxin removal step alone.

279. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be made by a method of virus filtration comprising subjecting a composition comprising a recombinant protein produced in a mammalian host cell and having or suspected of having a parvovirus contaminant to a virus filtration process comprising a cation exchange step and an endotoxin removal step, simultaneously or in either order, immediately preceding a virus filter capable of removing a parvovirus, and wherein said virus filter's filtration capacity in kg/m^2 is improved between 1.5 to 20 fold, as compared to no prefiltration step or using either cation exchange step or endotoxin removal step alone.

280. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the '237 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to

include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

281. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '237 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

282. To the extent H&O commercialize their product prior to the expiration of the '237 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

283. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '237 Patent will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SIXTEENTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '237 PATENT)

284. The allegations of paragraphs 1–283 are incorporated herein by reference.

285. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

286. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

287. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '237 Patent, Defendants will infringe one or more claims of the '237 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

288. H&O have knowledge of and are aware of the '237 Patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the '237 Patent is willful.

289. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the '237 Patent.

290. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the '237 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '237 Patent.

291. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '237 Patent. Genentech does not have an adequate remedy at law.

292. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '237 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

SEVENTEENTH COUNT
(PATENT INFRINGEMENT OF THE ’710 PATENT)

293. The allegations of paragraphs 1–292 are repeated and incorporated herein by reference.

294. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s Perjeta®.

295. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the ’710 Patent.

296. Defendants committed an act or acts of infringement with respect to the ’710 Patent under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

297. H&O’s participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the ’710 Patent under 35 U.S.C. § 271(e)(2)(C).

298. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the ’710 Patent.

299. Representative claim 1 of the ’710 Patent recites:

> A method of producing a recombinant polypeptide composition with reduced color intensity, comprising the steps of:

culturing a Chinese hamster ovary (CHO) cell comprising a nucleic acid encoding the recombinant polypeptide in a cell culture medium, wherein the cell culture medium comprises one or more of components (a)-(h):
(a) hypotaurine,
(b) s-carboxymethylcysteine,
(c) carnosine,
(d) anserine,
(e) butylated hydroxyanisole,
(f) lipoic acid,
(g) quercitrin hydrate, and
(h) taurine; and
producing the recombinant polypeptide;
wherein the cell culture medium comprising the one or more of components (a)-(h) reduces the color intensity of the composition comprising the recombinant polypeptide produced by the cell as compared to a composition comprising the recombinant polypeptide produced by the cell cultured in a cell culture medium that does not comprise the one or more of components (a)-(h).

300. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be made by a method of producing a recombinant polypeptide composition with reduced color intensity, comprising the steps of culturing a Chinese hamster ovary (CHO) cell comprising a nucleic acid encoding the recombinant polypeptide in a cell culture medium, wherein the cell culture medium comprises one or more of components (a)-(h):

(a) hypotaurine,
(b) s-carboxymethylcysteine,
(c) carnosine,
(d) anserine,
(e) butylated hydroxyanisole,
(f) lipoic acid,
(g) quercitrin hydrate, and
(h) taurine; and

producing the recombinant polypeptide; wherein the cell culture medium comprising the one or more of components (a)-(h) reduces the color intensity of the composition comprising the recombinant polypeptide produced by the cell as compared to a composition comprising the recombinant polypeptide produced by the cell cultured in a cell culture medium that does not comprise the one or more of components (a)-(h).

301. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the '710 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

302. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '710 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

303. To the extent H&O commercialize their product prior to the expiration of the '710 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

304. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '710 Patent will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

EIGHTEENTH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’710 PATENT)

305. The allegations of paragraphs 1–304 are incorporated herein by reference.

306. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s Perjeta®.

307. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

308. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the ’710 Patent, Defendants will infringe one or more claims of the ’710 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

309. H&O have knowledge of and are aware of the ’710 Patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O’s infringement of the ’710 Patent is willful.

310. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the ’710 Patent.

311. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the ’710 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the ’710 Patent.

312. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '710 Patent. Genentech does not have an adequate remedy at law.

313. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '710 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

NINETEENTH COUNT
(PATENT INFRINGEMENT OF THE '975 PATENT)

314. The allegations of paragraphs 1-313 are repeated and incorporated herein by reference.

315. On information and belief, by their aBLA submissions to FDA, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

316. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '975 Patent.

317. Defendants committed an act or acts of infringement with respect to the '975 Patent under 35 U.S.C. § 271(e)(2)(C) when Henlius submitted the Henlius aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Henlius Pertuzumab Biosimilar.

318. H&O's participation in, contribution to, inducement of, aiding or abetting the submission of the Henlius aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the '975 Patent under 35 U.S.C. § 271(e)(2)(C).

319. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Henlius Pertuzumab Biosimilar will infringe, literally or under the doctrine of equivalents, one or more claims of the '975 Patent.

320. Representative claim 1 of the '975 Patent recites:

> A process for producing a therapeutic IgG antibody in a Chinese hamster ovary (CHO) host cell expressing said antibody, wherein the process comprises culturing the CHO host cell in a production phase of the culture, wherein the culture is essentially free of glutamine, and wherein the culture comprises asparagine provided at a concentration of 10 mM.

321. On information and belief, the composition in the Proposed Henlius Pertuzumab Biosimilar is to be made by a process for producing a therapeutic IgG antibody in a CHO host cell expressing said antibody, wherein the process comprises culturing the CHO host cell in a production phase of the culture, wherein the culture is essentially free of glutamine, and wherein the culture comprises asparagine provided at a concentration of 10 mM.

322. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided H&O with a detailed statement describing with respect to the '975 Patent , on a claim by claim basis, the factual and legal bases of Genentech's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Henlius aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that H&O provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Genentech is not permitted to

include confidential information provided by H&O "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

323. Genentech will be irreparably harmed if H&O are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '975 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing H&O from any further infringement. Genentech does not have an adequate remedy at law.

324. To the extent H&O commercialize their product prior to the expiration of the '975 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

325. The submission of the Henlius aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '975 Patent will cause and/or has caused injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

TWENTIETH COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '975 PATENT)

326. The allegations of paragraphs 1–325 are incorporated herein by reference.

327. On information and belief, H&O seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Henlius Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's Perjeta®.

328. On information and belief, H&O intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar upon FDA licensure of the Henlius aBLA, which on information and belief FDA accepted for review on January 28, 2025.

329. If H&O manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '975 Patent, Defendants will infringe one or more claims of the '975 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

330. H&O have knowledge of and are aware of the '975 Patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. H&O's infringement of the '975 Patent is willful.

331. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Henlius Pertuzumab Biosimilar will infringe one or more claims of the '975 Patent.

332. Genentech is entitled to a declaratory judgment that H&O will infringe one or more claims of the '975 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '975 Patent.

333. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting H&O from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Henlius Pertuzumab Biosimilar prior to the expiration of the '975 Patent. Genentech does not have an adequate remedy at law.

334. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Henlius Pertuzumab Biosimilar before the expiration of the '975 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Defendants and grant the following relief:

A. a judgment that each of Henlius and Organon has infringed directly, contributed to, or induced the infringement of one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(C) by submitting to FDA the Henlius aBLA and any amendment(s) or supplementation(s) thereto;

B. a preliminary and/or permanent injunction that enjoins Henlius, Organon, and each of their officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing any of the Asserted Patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use, offer for sale, sale, distribution, importation, or manufacture of which infringes any of the Asserted Patents, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

C. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Henlius aBLA would constitute infringement of one or more claims of each of the Asserted Patents, or inducement of or contribution to such conduct, by each of Henlius and Organon pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g);

D. a judgment compelling each of Henlius and Organon to pay to Plaintiffs damages adequate to compensate for Henlius's and Organon's infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

E. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees and costs pursuant to 35 U.S.C. § 285;

F. such other and further relief as this Court may deem to be just and proper.

DEMAND FOR A JURY TRIAL

Plaintiffs hereby demand a jury trial on all issues so triable.

Dated: August 14, 2025

By: */s/ Keith J. Miller*

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**Pro hac vice* application forthcoming

Attorneys for Plaintiffs Genentech, Inc. and Hoffmann-La Roche Inc.

Local Civil Rule 11.2 and 40.1 Certifications

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Pursuant to Local Civil Rule 40.1, I hereby certify that, to the best of my knowledge, this matter does not relate to any case already or previously pending in the District of New Jersey.

Dated: August 14, 2025

/s/ Keith J. Miller
Keith J. Miller