Rebekah R. Conroy
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: (973) 400-4181
rconroy@stoneconroy.com

Attorneys for Defendants Shanghai Henlius Biotech, Inc., Shanghai Henlius Biologics Co., Ltd., Organon LLC, and Organon & Co.

Of Counsel:

Maureen Rurka (to be admitted *pro hac vice*)
Julia Johnson (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
300 N LaSalle Drive
Chicago, IL 60654
Telephone: (312) 558-5600
MRurka@winston.com
JMJohnson@winston.com

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. 2:25-cv-14648 (CCC) (LDW) **JURY TRIAL DEMANDED**

DEFENDANTS SHANGHAI HENLIUS BIOTECH, INC., SHANGHAI HENLIUS BIOLOGICS CO., LTD., ORGANON LLC, AND ORGANON & CO.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Shanghai Henlius Biotech, Inc. ("Henlius Biotech") and Shanghai Henlius Biologics Co., Ltd. ("Henlius Biologics") (collectively, "Henlius") and Organon LLC and Organon & Co. (collectively, "Organon" and together with Henlius, "Defendants"), by and through its undersigned counsel, provide the following answers, defenses, and counterclaims to the complaint of patent infringement ("Complaint") (D.I. 1) of Plaintiffs Genentech, Inc.

("Genentech") and Hoffman-LaRoche Inc. ("Hoffman-LaRoche") (collectively, "Plaintiffs"). This pleading is based upon Defendants' knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiffs' Complaint except those admitted specifically below.

NATURE OF THE ACTION

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.

ANSWER: Defendants admit that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271(e)(2)(C), and 28 U.S.C. §§ 2201-02, but deny that Plaintiffs are entitled to any relief. Defendants deny the remaining allegations in Paragraph 1.

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.

ANSWER: Defendants admit the allegations in the first sentence of Paragraph 2. The remaining allegations in Paragraph 2 are allegations of law or characterizations of the BPCIA that require no response from Defendants, and Defendants, therefore, deny these allegations.

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).

ANSWER: Defendants admit that according to the FDA's website, Genentech is the alleged sponsor of the Biologics License Application ("BLA") for Perjeta® (pertuzumab), which is FDA-approved in combination with trastuzumab and docetaxel for the treatment of adults with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease, as well as in combination with trastuzumab and chemotherapy as: (1) neoadjuvant treatment of adults with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; and (2) adjuvant treatment of adults with HER2-positive early breast cancer at high risk of recurrence. The remaining allegations in Paragraph 3 are allegations of law or characterizations of the BPCIA that require no response from Defendants, and Defendants, therefore, deny these allegations.

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).

ANSWER: The allegations in Paragraph 4 are allegations of law or characterizations of the BPCIA that require no response from Defendants, and Defendants, therefore, deny these allegations.

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").

ANSWER: Defendants admit that Plaintiffs' Complaint alleges infringement of 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"). The remaining allegations contained in Paragraph 5 are allegations of law that require no response from Defendants, and therefore Defendants deny these allegations.

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' 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.

ANSWER: Defendants admit that Henlius Biotech submitted abbreviated Biologics License Application No. 761450 (the "Henlius aBLA") to the FDA seeking approval to engage in the sale of Henlius Biotech's proposed pertuzumab product ("Henlius' proposed pertuzumab product") in the United States. Defendants further admit that on January 29, 2025, Defendants sent notice to Genentech's general counsel that Henlius' aBLA was accepted for review by the FDA. Defendants deny the remaining allegations in Paragraph 6.

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).

ANSWER: Defendants admit that in February 2025, Genentech and Defendants began exchanging the information required under the BPCIA. Organon further admits that Genentech's

April 3, 2025 disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) and July 11, 2025 disclosure pursuant to 42 U.S.C. § 262(l)(3)(C) included the Asserted Patents. Defendants deny the remaining allegations in Paragraph 7.

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).

ANSWER: The allegations in Paragraph 8 are allegations of law that require no response from Defendants, and Defendants, therefore, denies these allegations.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 9.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Defendants deny the allegations in Paragraph 10.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 11.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 12, and on that basis deny these allegations.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 13, and on that basis deny these allegations.

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.

ANSWER: Defendants admit that 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.

ANSWER: Defendants admit that 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.

ANSWER: Defendants admit that Shanghai Henlius Biologics Co., Ltd. is a 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.

ANSWER: Defendants admit that 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.

ANSWER: Defendants admit that Organon LLC is a limited liability company 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.

ANSWER: Defendants admit that 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.

ANSWER: Defendants deny the allegations contained in Paragraph 20.

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.

ANSWER: Defendants admit that Henlius Biotech submitted aBLA No. 761450 to the FDA seeking approval to engage in the sale of Henlius' proposed pertuzumab product in the United States. Defendants deny the remaining allegations in Paragraph 21.

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.

ANSWER: Defendants admit that Organon entered into a license and supply agreement with Henlius, granting Organon commercialization rights for Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 22.

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.

ANSWER: Defendants admit that Organon entered into a license and supply agreement with Henlius, granting Organon commercialization rights for Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 23.

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**.**

ANSWER: Defendants admit that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271(e)(2)(C), and 28 U.S.C. §§ 2201-02, but deny that Plaintiffs are entitled to any relief. Defendants deny the remaining allegations in Paragraph 24.

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

ANSWER: Defendants admit that this Court has subject matter jurisdiction over the patent infringement claims in Plaintiffs' Complaint under 28 U.S.C. §§ 1331 and 1338(a). Defendants deny the remaining allegations in Paragraph 25.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 26.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any

other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 27.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 28.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 29.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 30.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 31.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 32.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for the purposes of this action only, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 33.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 34.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest venue for the purposes of this action only, and expressly reserve the right to contest venue in any other case as to any other party, including Plaintiffs. Defendants deny the remaining allegations in Paragraph 35.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants do not contest venue for the purposes of this action only, and expressly reserve the right to contest venue in any other case as to any other party,

including Plaintiffs. Defendants deny the remaining allegations in Paragraph 36.

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.

ANSWER: Defendants admit the allegations contained in Paragraph 37.

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-positive breast cancer is now a treatable disease and outcomes have dramatically improved for these patients.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 38, and therefore deny them.

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®.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 39, and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 40, and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 41, and therefore deny them.

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.

ANSWER: Defendants admit that Perjeta® is approved by the FDA in combination with trastuzumab and docetaxel for the treatment of adults with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease, as well as in combination with trastuzumab and chemotherapy as: (1) neoadjuvant treatment of adults with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; and (2) adjuvant treatment 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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 43, and therefore deny them.

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

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 44, and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 45, and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46, and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about

the truth of the allegations in Paragraph 47, and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 48, and therefore deny them.

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.

ANSWER: Defendants admit that according to the FDA's website, Genentech is the alleged sponsor of the BLA for Perjeta®. Defendants also admit that according to the face of the Asserted Patents, Hoffman-La Roche Inc. is an alleged 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.

ANSWER: Defendants admit that Henlius Biotech, in partnership with Organon, submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 50.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k), and that Henlius' aBLA meets all of the requirements of 42 U.S.C. § 262(k). The remaining allegations in Paragraph 51 are allegations of law or characterizations of the BPCIA that require no response from Defendants, and Defendant, therefore, deny these allegations.

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

ANSWER: Defendants deny the allegations in Paragraph 52.

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

ANSWER: Defendants deny the allegations in Paragraph 53.

A. 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)."

ANSWER: Defendants admit that they sent letter correspondence to Genentech's general counsel on January 29, 2025, which contains the quoted statements. Defendants deny the remaining allegations in Paragraph 54.

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.

ANSWER: Defendants admit that on February 11, 2025, they provided a copy of the

Henlius aBLA to Genentech. Defendants deny the remaining allegations in Paragraph 55.

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.

ANSWER: Defendants admit that on April 3, 2025, Genentech sent notice pursuant to 42 U.S.C. § 262(l)(3)(A) and 35 U.S.C. § 271(e)(2)(C), identifying 47 patents for which Genentech allegedly believed a claim of patent infringement could reasonably be asserted against Defendants ("Genentech's patent list"). Defendants deny the remaining allegations in Paragraph 56.

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.

ANSWER: Defendants admit that on May 13, 2025, Defendants provided a detailed statement containing the requisite information under 35 U.S.C. § 262(l)(3)(B) for each of the patents provided on Genentech's patent list. Defendants deny the remaining allegations in Paragraph 57.

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).

ANSWER: Defendants admit that on July 11, 2025, Genentech provided a detailed statement under 35 U.S.C. § 262(l)(3)(C) for the Asserted Patents. Defendants deny the remaining allegations in Paragraph 58.

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)."

ANSWER: Defendants admit that on July 16, 2025, they sent letter correspondence to Genentech's general counsel stating that "[f]or the purposes of the patent-exchange provisions of the BPCIA, Henlius and Organon consent to—*i.e.* do not seek to restrict or expand—Genentech's list of patents for which it believes a claim of patent infringement could reasonably be asserted. In particular, should Genentech elect to commence proceedings on any of the patents discussed in its July 11, 2025 letter, Henlius and Organon agree that each of these patents shall be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6), subject to all rights and defenses available to Henlius and Organon to any such claim of infringement, including but not limited to noninfringement defenses, invalidity defenses, unenforceability defenses, standing, and rights under 35 U.S.C. § 285." Defendants deny the remaining allegations in Paragraph 59.

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).

ANSWER: Defendants admit that Genentech filed its complaint on August 14, 2025, which was within 30 days after receiving Defendants' July 16, 2025 correspondence. Defendants

deny the remaining allegations in Paragraph 60.

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**.**

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 61, and therefore deny them.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs' Complaint alleged infringement of 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. Defendants deny the remaining allegations in Paragraph 62.

B. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on its face, the '817 patent is titled "Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies." Defendants deny that the '817 patent currently claims any invention because it is expired. Defendants deny the remaining allegations in Paragraph 63.

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.

ANSWER: Defendants admit that on its face, the '817 patent was titled "Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies," and was issued on January 4, 2011. Defendants admit that Exhibit 1 to the Complaint purports to be a copy of the '817 patent. Organon further admits that on its face, the '817 patent listed Camellia W. Adams, Leonard G.

Presta, and Mark Sliwkow as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. was the assignee of the '817 patent. Defendants specifically deny that the '817 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 64. Defendants further state that the '817 patent is expired.

C. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on their face, the '474 patent, the '346 patent, the '498 patent, the '776 patent, and the '341 patent are titled "Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof." Defendants deny the remaining allegations in Paragraph 65.

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.

ANSWER: Defendants admit that on its face, the '474 patent is titled "Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof," and was

issued on February 18, 2014. Defendants admit that Exhibit 2 to the Complaint purports to be a copy of the '474 patent. Organon further admits that on its face, the '474 patent lists Reed J. Harris and Paul A. Motchnick as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the '474 patent. Defendants specifically deny that the '474 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 66.

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.

ANSWER: Defendants admit that on its face, the '346 patent is titled "Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof," and was issued on November 10, 2015. Defendants admit that Exhibit 3 to the Complaint purports to be a copy of the '346 patent. Organon further admits that on its face, the '346 patent lists Reed J. Harris and Paul A. Motchnick as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the '346 patent. Defendants specifically deny that the '346 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 67.

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.

ANSWER: Defendants admit that on its face, the ’498 patent is titled “Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof,” and was issued on August 16, 2022. Defendants admit that Exhibit 4 to the Complaint purports to be a copy of the ’498 patent. Organon further admits that on its face, the ’498 patent lists Reed J. Harris and Paul A. Motchnick as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’498 patent. Defendants specifically deny that the ’498 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 68.

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.

ANSWER: Defendants admit that on its face, the ’776 patent is titled “Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof,” and was issued on March 7, 2023. Defendants admit that Exhibit 5 to the Complaint purports to be a copy of the ’776 patent. Organon further admits that on its face, the ’776 patent lists Reed J. Harris and Paul A. Motchnick as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’776 patent. Defendants specifically deny that the ’776 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 69.

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.

ANSWER: Defendants admit that on its face, the '341 patent is titled "Composition Comprising Antibody That Binds to Domain II of HER2 and Acidic Variants Thereof," and was issued on October 8, 2024. Defendants admit that Exhibit 6 to the Complaint purports to be a copy of the '341 patent. Organon further admits that on its face, the '341 patent lists Reed J. Harris and Paul A. Motchnick as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the '341 patent. Defendants specifically deny that the '341 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 70.

D. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on their face, the '184 patent and the '234 patent are titled "Fixed Dosing of HER Antibodies." Defendants deny the remaining allegations in Paragraph 71.

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.

ANSWER: Defendants admit that on its face, the ’184 patent is titled “Fixed Dosing of HER Antibodies,” and was issued on November 11, 2008. Defendants admit that Exhibit 7 to the Complaint purports to be a copy of the ’184 patent. Organon further admits that on its face, the ’184 patent lists David E. Allison, Rene Bruno, Jian-Feng Lu, and Chee M. Ng as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’184 patent. Defendants specifically deny that the ’184 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 72.

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.

ANSWER: Defendants admit that on its face, the ’234 patent is titled “Fixed Dosing of HER Antibodies,” and was issued on March 26, 2013. Defendants admit that Exhibit 8 to the Complaint purports to be a copy of the ’234 patent. Organon further admits that on its face, the ’234 patent lists David E. Allison, Rene Bruno, Jian-Feng Lu, and Chee M. Ng as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’234 patent. Defendants specifically deny that the ’234 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 73.

E. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on their face, the '457 patent and the '305 patent are titled "Treatment of Metastatic Breast Cancer." Defendants deny the remaining allegations in Paragraph 74.

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.

ANSWER: Defendants admit that on its face, the '457 patent is titled "Treatment of Metastatic Breast Cancer," and was issued on June 23, 2020. Defendants admit that Exhibit 9 to the Complaint purports to be a copy of the '457 patent. Organon further admits that on its face, the '457 patent lists Virginia Paton, Anne Blackwood Chirchir, Pam Klein, and Graham Alexander Ross as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. and Hoffman-La Roche are the assignees of the '457 patent. Defendants specifically deny that the '457 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 75.

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.

ANSWER: Defendants admit that on its face, the '305 patent is titled "Treatment of Metastatic Breast Cancer," and was issued on May 23, 2023. Defendants admit that Exhibit 10 to the Complaint purports to be a copy of the '305 patent. Organon further admits that on its face, the '305 patent lists Virginia Paton, Anne Blackwood Chirchir, Pam Klein, and Graham Alexander Ross as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. and Hoffman-La Roche are the assignees of the '305 patent. Defendants specifically deny that the '305 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 76.

F. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on their face, the '189, '756, '529, and '103 patents are titled "Adjuvant Treatment of HER2-Positive Breast Cancer." Defendants deny the remaining allegations in Paragraph 77.

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.

ANSWER: Defendants admit that on its face, the ’189 patent is titled “Adjuvant Treatment of HER2-Positive Breast Cancer,” and was issued on August 3, 2021. Defendants admit that Exhibit 11 to the Complaint purports to be a copy of the ’189 patent. Organon further admits that on its face, the ’189 patent lists Mark C. Benyunes and Graham Alexander Ross as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. and Hoffman-La Roche are the assignees of the ’189 patent. Defendants specifically deny that the ’189 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 78.

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.

ANSWER: Defendants admit that on its face, the ’756 patent is titled “Adjuvant Treatment of HER2-Positive Breast Cancer,” and was issued on May 2, 2023. Defendants admit that Exhibit 12 to the Complaint purports to be a copy of the ’756 patent. Organon further admits that on its face, the ’756 patent lists Mark C. Benyunes and Graham Alexander Ross as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. and Hoffman-La

Roche are the assignees of the ’756 patent. Defendants specifically deny that the ’756 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 79.

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.

ANSWER: Defendants admit that on its face, the ’529 patent is titled “Adjuvant Treatment of HER2-Positive Breast Cancer,” was issued on May 28, 2024. Defendants admit that Exhibit 13 to the Complaint purports to be a copy of the ’529 patent. Organon further admits that on its face, the ’529 patent lists Mark C. Benyunes and Graham Alexander Ross as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. and Hoffman-La Roche are the assignees of the ’529 patent. Defendants specifically deny that the ’529 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 80.

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.

ANSWER: Defendants admit that on its face, the ’103 patent is titled “Adjuvant Treatment of HER2-Positive Breast Cancer,” and was issued on April 16, 2024. Defendants admit that Exhibit 14 to the Complaint purports to be a copy of the ’103 patent. Organon further admits that on its face, the ’103 patent lists Mark C. Benyunes and Graham Alexander Ross as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. and Hoffman-La

Roche are the assignees of the '103 patent. Defendants specifically deny that the '103 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 81.

G. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on their face, the '037, '294, '997, and '080 patents are titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides." Defendants deny the remaining allegations in Paragraph 82.

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.

ANSWER: Defendants admit that on its face, the '037 patent is titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," and was issued on October 20, 2020. Defendants admit that Exhibit 15 to the Complaint purports to be a copy of the '037 patent. Organon further admits that on its face, the '037 patent lists Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the

assignee of the ’037 patent. Defendants specifically deny that the ’037 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 83.

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.

ANSWER: Defendants admit that on its face, the ’294 patent is titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” and was issued on August 3, 2021. Defendants admit that Exhibit 16 to the Complaint purports to be a copy of the ’294 patent. Organon further admits that on its face, the ’294 patent lists Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’294 patent. Defendants specifically deny that the ’294 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 84.

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.

ANSWER: Defendants admit that on its face, the ’997 patent is titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” and was issued on November 19, 2024. Defendants admit that Exhibit 17 to the Complaint purports to be a copy of

the ’997 patent. Organon further admits that on its face, the ’997 patent lists Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’997 patent. Defendants specifically deny that the ’997 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 85.

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.

ANSWER: Defendants admit that on its face, the ’080 patent is titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” and was issued on December 24, 2024. Defendants admit that Exhibit 18 to the Complaint purports to be a copy of the ’080 patent. Organon further admits that on its face, the ’080 patent lists Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’080 patent. Defendants specifically deny that the ’080 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 86.

H. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on their face, the '904, '811, and '998 patents are titled "Pertuzumab Variants and Evaluations Thereof." Defendants deny the remaining allegations in Paragraph 87.

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.

ANSWER: Defendants admit that on its face, the '904 patent is titled "Pertuzumab Variants and Evaluations Thereof," and was issued on November 14, 2017. Defendants admit that Exhibit 19 to the Complaint purports to be a copy of the '904 patent. Organon further admits that on its face, the '904 patent lists Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the '904 patent. Defendants specifically deny that the '904 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 88.

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.

ANSWER: Defendants admit that on its face, the ’811 patent is titled “Pertuzumab Variants and Evaluations Thereof,” and was issued on May 15, 2018. Defendants admit that Exhibit 20 to the Complaint purports to be a copy of the ’811 patent. Organon further admits that on its face, the ’811 patent lists Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’811 patent. Defendants specifically deny that the ’811 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 89.

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.

ANSWER: Defendants admit that on its face, the ’998 patent is titled “Pertuzumab Variants and Evaluations Thereof,” and was issued on November 19, 2024. Defendants admit that Exhibit 21 to the Complaint purports to be a copy of the ’998 patent. Organon further admits that on its face, the ’998 patent lists Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’998 patent. Defendants specifically deny that the ’998 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 90.

I. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Defendants admit that on its face, the ’237 patent is titled “Method to Improve Virus Filtration Capacity.” Defendants deny the remaining allegations in Paragraph 91.

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.

ANSWER: Defendants admit that on its face, the ’237 patent is titled “Method to Improve Virus Filtration Capacity,” and was issued on May 26, 2020. Defendants admit that Exhibit 22 to the Complaint purports to be a copy of the ’237 patent. Organon further admits that on its face, the ’237 patent lists Amit Mehta as the inventor. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’237 patent. Defendants specifically deny that the ’237 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 92.

J. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on its face, the ’710 patent is titled “Cell Culture Compositions with Antioxidants and Methods for Polypeptide Production.” Defendants deny the remaining allegations in Paragraph 93.

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.

ANSWER: Defendants admit that on its face, the ’710 patent is titled “Cell Culture Compositions with Antioxidants and Methods for Polypeptide Production,” and was issued on June 9, 2020. Defendants admit that Exhibit 23 to the Complaint purports to be a copy of the ’710 patent. Organon further admits that on its face, the ’710 patent lists Natarajan Vijayasankaran, Steven J. Meier, Sharat Varma, and Yi Yang as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the ’710 patent. Defendants specifically deny that the ’710 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 94.

K. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on its face, the ’975 patent is titled “Production of Proteins in Glutamine-Free Cell Culture Media.” Defendants deny the remaining allegations in Paragraph 95.

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.

ANSWER: Defendants admit that on its face, the '975 patent is titled "Production of Proteins in Glutamine-Free Cell Culture Media," and was issued on October 1, 2024. Defendants admit that Exhibit 24 to the Complaint purports to be a copy of the '975 patent. Organon further admits that on its face, the '975 patent lists Martin Gawlitzek, Shun Luo, and Christina Teresa Bevilacqua as inventors. Organon further admits that, according to USPTO assignment records, Genentech Inc. is the assignee of the '975 patent. Defendants specifically deny that the '975 patent was duly and legally issued, and further deny the remaining allegations in Paragraph 96.

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.

ANSWER: Defendants incorporate their responses to paragraphs 1-96 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 98.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the remaining allegations in Paragraph 99.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 100.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent

infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 101.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 102.

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.

ANSWER: Defendants admit that Paragraph 103 recites what was claim 14 of the '817 patent, which is now expired. Defendants deny the remaining allegations in Paragraph 103.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient. Defendants deny the remaining allegations in Paragraph 104.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Genentech provided Defendants with a detailed statement that complies with 42 U.S.C. § 262(l)(3)(C), as it relates to the '817 patent. Defendants deny the remaining allegations in Paragraph 105.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 106.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent

infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 107.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 108.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-108 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 110.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 111.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 112.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '817 patent. Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the remaining allegations in Paragraph 113.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '817 patent is infringed and enforceable because the '817 patent is expired. Defendants deny the remaining allegations in Paragraph 114.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 115.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 116.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs have stated any claim for patent infringement of the '817 patent because the '817 patent is expired. Defendants deny the allegations in Paragraph 117.

THIRD COUNT
(PATENT INFRINGEMENT OF THE ACIDIC VARIANT PATENTS)

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

ANSWER: Defendants incorporate their responses to paragraphs 1-117 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 119.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 120.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 121.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 122.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 123.

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.

ANSWER: Defendants admit that Paragraph 124 recites claim 1 of the '474 patent. Defendants deny the remaining allegations in Paragraph 124.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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.

ANSWER: Defendants admit that Paragraph 126 recites claim 1 of the '346 patent. Defendants deny the remaining allegations in Paragraph 126.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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%.

ANSWER: Defendants admit that Paragraph 128 recites claim 1 of the '498 patent. Defendants deny the remaining allegations in Paragraph 128.

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%.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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.

ANSWER: Defendants admit that Paragraph 130 recites claim 1 of the '776 patent. Defendants deny the remaining allegations in Paragraph 130.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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.

ANSWER: Defendants admit that Paragraph 132 recites claim 1 of the '341 patent. Defendants deny the remaining allegations in Paragraph 132.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject

of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement 42 U.S.C. § 262(*l*)(3)(C), which included the '474, '346, '498, '776, and '341 patents. Defendants deny the remaining allegations in Paragraph 134.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 135.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 136.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 137.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-137 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 139.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 140.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 141.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '474, '346, '498, '776, and '341 patents. Defendants deny the remaining allegations in Paragraph 142.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '474, '346, '498, '776, and '341 patents are infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 143.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 144.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 145.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 146.

FIFTH COUNT
(PATENT INFRINGEMENT OF THE FIXED DOSE PATENTS)

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

ANSWER: Defendants incorporate their responses to paragraphs 1-146 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 148.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 149.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 150.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 151.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 152.

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.

ANSWER: Defendants admit that Paragraph 153 recites claim 1 of the '184 patent. Defendants deny the remaining allegations in Paragraph 153.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient. Defendants deny the remaining allegations in Paragraph 154.

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.

ANSWER: Defendants admit that Paragraph 155 recites claim 1 of the '234 patent. Defendants deny the remaining allegations in Paragraph 155.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient. Defendants deny the remaining allegations in Paragraph 156.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '184 and '234 patents. Defendants deny the remaining allegations in Paragraph 157.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 158.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 159.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 160.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-160 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 162.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 163.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 164.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '184 and '234 patents. Defendants deny the remaining allegations in Paragraph 165.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning

whether the '184 and '234 patents are infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 166.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 167.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 168.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 169.

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.

ANSWER: Defendants incorporate their responses to paragraphs 1-169 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 171.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 172.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 173.

174. 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 174.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 175.

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/m2 and is increased to 100 mg/m2 if the patient tolerates the initial dose.

ANSWER: Defendants admit that Paragraph 176 recites claim 1 of the '457 patent. Defendants deny the remaining allegations in Paragraph 176.

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/m2 and is increased to 100 mg/m2 if the patient tolerates the initial dose.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 177.

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/m2 and is increased to 100 mg/m2 if the patient tolerates the initial dose.

ANSWER: Defendants admit that Paragraph 178 recites claim 1 of the '457 patent. Defendants deny the remaining allegations in Paragraph 178.

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/m2 and is increased to 100 mg/m2 if the patient tolerates the initial dose.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 179.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '457 and '405 patents. Defendants deny the remaining allegations in Paragraph 180.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 181.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 182.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 183.

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.

ANSWER: Defendants incorporate their responses to paragraphs 1-183 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 185.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA

was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 186.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 187.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '457 and '305 patents. Defendants deny the remaining allegations in Paragraph 188.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '457 and '305 patents are infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 189.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 190.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 191.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 192.

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.

ANSWER: Defendants incorporate their responses to paragraphs 1-192 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 194.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 195.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 196.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 197.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 198.

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/m2 5-FU+90-120 mg/m2 epirubicin+500-600 mg/m2 cyclophosphamide, or of 500-600 mg/m2 5-FU+50 mg/m2 doxorubicin+500-600 mg/m2 cyclophosphamide; or

(ii) 4 cycles of 60 mg/m2 doxorubicin+500-600 mg/m2 cyclophosphamide, or of 90-120 mg/m2 epirubicin+500-600 mg/m2 cyclophosphamide;

(b) following said anthracycline-based chemotherapy, taxane comprising 4 cycles of 75 mg/m2 or 100 mg/m2 docetaxel every 3 weeks or 12 cycles of 80 mg/m2 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.

ANSWER: Defendants admit that Paragraph 199 recites claim 1 of the '189 patent. Defendants deny the remaining allegations in Paragraph 199.

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/m2 5-FU+90-120 mg/m2 epirubicin+500-600 mg/m2 cyclophosphamide, or of 500-600 mg/m2 5-FU+50 mg/m2 doxorubicin+500-600 mg/m2 cyclophosphamide; or (ii) 4 cycles of 60 mg/m2 doxorubicin+500-600 mg/m2 cyclophosphamide, or of 90-120 mg/m2 epirubicin+500-

600 mg/m2 cyclophosphamide; (b) following said anthracycline-based chemotherapy, taxane comprising 4 cycles of 75 mg/m2 or 100 mg/m2 docetaxel every 3 weeks or 12 cycles of 80 mg/m2 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 200.

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/m2 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.

ANSWER: Defendants admit that Paragraph 201 recites claim 1 of the '756 patent. Defendants deny the remaining allegations in Paragraph 201.

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/m2 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 202.

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/m2 and/or 100 mg/m2 docetaxel every 3 weeks or 12 cycles of 80 mg/m2 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.

ANSWER: Defendants admit that Paragraph 203 recites claim 1 of the '529 patent. Defendants deny the remaining allegations in Paragraph 203.

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/m2 and/or 100 mg/m2 docetaxel every 3 weeks or 12 cycles of 80 mg/m2 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 204.

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.

ANSWER: Defendants admit that Paragraph 205 recites claim 1 of the '103 patent. Defendants deny the remaining allegations in Paragraph 205.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 206.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '189, '756, '529, and '103 patents. Defendants deny the remaining allegations in Paragraph 207.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 208.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 209.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 210.

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.

ANSWER: Defendants incorporate their responses to paragraphs 1-210 as if fully set forth herein

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 212.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 213.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 214.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '189, '756, '529, and '103 patents. Defendants deny the remaining allegations in Paragraph 215.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '189, '756, '529, and '103 patents are infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 216.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 217.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 218.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 219.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-219 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United

States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 221.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 222.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 223.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 224.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 225.

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 (dO2) in the pre-harvest cell culture fluid is at least 10%.

ANSWER: Defendants admit that Paragraph 226 recites claim 1 of the '037 patent. Defendants deny the remaining allegations in Paragraph 226.

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%.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 227.

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 (dO2) in the pre-harvest cell culture fluid is at least 10%.

ANSWER: Defendants admit that Paragraph 228 recites claim 1 of the ’294 patent. Defendants deny the remaining allegations in Paragraph 228.

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%.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 229.

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%.

ANSWER: Defendants admit that Paragraph 230 recites claim 1 of the '997 patent. Defendants deny the remaining allegations in Paragraph 230.

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%.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 231.

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.

ANSWER: Defendants admit that Paragraph 232 recites claim 1 of the '080 patent. Defendants deny the remaining allegations in Paragraph 232.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 233.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '037, '294, '997, and '080 patents. Defendants deny the remaining allegations in Paragraph 234.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 235.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 236.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 237.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-237 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 239.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 240.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 241.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '037, '294, '997, and '080 patents. Defendants deny the remaining allegations in Paragraph 242.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '037, '294, '997, and '080 patents are infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 243.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 244.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 245.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 246.

THIRTEENTH COUNT
(PATENT INFRINGEMENT OF THE PERTUZUMAB VARIANTS PATENTS)

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

ANSWER: Defendants incorporate their responses to paragraphs 1-246 as if fully set forth herein

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 248.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 249.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 250.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 251.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 252.

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.

ANSWER: Defendants admit that Paragraph 253 recites claim 1 of the '904 patent. Defendants deny the remaining allegations in Paragraph 253.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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.

ANSWER: Defendants admit that Paragraph 255 recites claim 1 of the '811 patent. Defendants deny the remaining allegations in Paragraph 255.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient and is as described in the Henlius aBLA.

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.

ANSWER: Defendants admit that Paragraph 257 recites claim 1 of the '998 patent. Defendants deny the remaining allegations in Paragraph 257.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that the proposed product that is the subject of the Henlius aBLA is expected to contain pertuzumab as the active pharmaceutical ingredient. Defendants deny the remaining allegations in Paragraph 258.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '904, '811, and '998 patents. Defendants deny the remaining allegations in Paragraph 259.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 260.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 261.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 262.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-262 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 264.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA

was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 265.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 266.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '904, '811, and '998 patents. Defendants deny the remaining allegations in Paragraph 267.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '904, '811, and '998 patents are infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 268.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 269.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 270.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 271.

FIFTEENTH COUNT
(PATENT INFRINGEMENT OF THE '237 PATENT)

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

ANSWER: Defendants incorporate their responses to paragraphs 1-271 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 273.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 274.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 275.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 276.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 277.

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/m2 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.

ANSWER: Defendants admit that Paragraph 278 recites claim 1 of the '237 patent. Defendants deny the remaining allegations in Paragraph 278.

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/m2 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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 279.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '237 patent. Defendants deny the remaining allegations in Paragraph 280.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 281.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 282.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 283.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-284 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 285.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 286.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 287.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '237 patent. Defendants deny the remaining allegations in Paragraph 288.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '237 patent is infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 289.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 290.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 291.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 292.

SEVENTEENTH COUNT
(PATENT INFRINGEMENT OF THE '710 PATENT)

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

ANSWER: Defendants incorporate their responses to paragraphs 1-292 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 294.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 295.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 296.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 297.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 298.

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).

ANSWER: Defendants admit that Paragraph 299 recites claim 1 of the '710 patent. Defendants deny the remaining allegations in Paragraph 299.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 300.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '710 patent. Defendants deny the remaining allegations in Paragraph 301.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 302.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 303.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 304.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-304 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 306.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 307.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 308.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '710 patent. Defendants deny the remaining allegations in Paragraph 309.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning

whether the '710 patent is infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 310.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 311.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 312.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 313.

NINETEENTH COUNT
(PATENT INFRINGEMENT OF THE '975 PATENT)

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

ANSWER: Defendants incorporate their responses to paragraphs 1-313 as if fully set forth herein.

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 315.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants deny the remaining allegations in Paragraph 316.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 317.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 318.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 319.

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.

ANSWER: Defendants admit that Paragraph 320 recites claim 1 of the '975 patent. Defendants deny the remaining allegations in Paragraph 320.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 321.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech provided Defendants with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(C), which included the '975 patent. Defendants deny the remaining allegations in Paragraph 322.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 323.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 324.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 325.

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

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

ANSWER: Defendants incorporate their responses to paragraphs 1-325 as if fully set forth herein

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®.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product, and that the Henlius aBLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Defendants deny the remaining allegations in Paragraph 327.

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.

ANSWER: Defendants admit that Henlius Biotech submitted the Henlius aBLA pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Henlius' proposed pertuzumab product. Defendants further admit that the Henlius aBLA was accepted for review by the FDA on January 28, 2025. Defendants deny the remaining allegations in Paragraph 328.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 329.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Genentech's disclosure pursuant to 42 U.S.C. § 262(l)(3)(A) included the '975 patent. Defendants deny the remaining allegations in Paragraph 330.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that there is an actual controversy concerning whether the '975 patent is infringed, valid, and enforceable. Defendants deny the remaining allegations in Paragraph 331.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 332.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 333.

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.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 334.

RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs are entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. In addition, Defendants do not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Defendants reserve the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

The claims of the Asserted Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or based on other judicially created bases for invalidation.

SECOND DEFENSE

Defendants have not, do not, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Asserted Patents.

THIRD DEFENSE

Defendants have not, do not, and will not induce the infringement of, or contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Asserted Patents.

FOURTH DEFENSE

The claims of the Asserted Patents are barred in whole or in part by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

FIFTH DEFENSE

Plaintiffs are not entitled to preliminary and/or permanent equitable relief.

SIXTH DEFENSE

To the extent the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285. Moreover, Defendants' actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

NINTH DEFENSE

Any additional defenses that discovery may reveal.

RESERVATION OF RIGHTS

As Defendants' investigation is ongoing and discovery has not yet taken place, Defendants are without sufficient information regarding the existence or non-existence of other facts or acts that would constitute a defense to Plaintiffs' claims of patent infringement or that would establish the invalidity and/or unenforceability of the Asserted Patents, including additional prior art or related patents. Defendants hereby give notice that they may assert facts or acts which tend to establish noninfringement, invalidity, unenforceability, or which otherwise constitute a defense under Title 35 of the United States Code as information becomes available to Defendants in sufficient detail to assert such a defense.

DEFENDANTS' COUNTERCLAIMS

For their Counterclaims against Plaintiffs/Counterclaim-Defendants Genentech, Inc. ("Genentech") and Hoffman-LaRoche Inc. ("Hoffman-LaRoche") (collectively, "Plaintiffs"). Defendants/Counterclaim-Plaintiffs Shanghai Henlius Biotech, Inc. ("Henlius Biotech") and Shanghai Henlius Biologics Co., Ltd. ("Henlius Biologics") (collectively, "Henlius") and Organon LLC and Organon & Co. (collectively, "Organon" and together with Henlius, "Defendants"), state as follows:

PARTIES

1. 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.

2. 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.

3. 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.

4. Organon LLC is a limited liability company 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.

5. On information and belief, 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.

6. On information and belief, 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.

NATURE OF THE ACTION

7. Defendants seek declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, et seq., that U.S. Patent No. 7,862,817 ("the '817 patent"), U.S. Patent No. 8,652,474 ("the '474 patent"), U.S. Patent No. 9,181,346 ("the '346 patent"), U.S. Patent No. 11,414,498 ("the '498 patent"), U.S. Patent No. 11,597,776 ("the '776 patent"), U.S. Patent No. 12,110,341 ("the '341 patent"), U.S. Patent No. 7,449,184 ("the '184 patent"), U.S. Patent No. 8,404,234 ("the '234 patent"), U.S. Patent No. 10,689,457 ("the '457 patent"), U.S. Patent No. 11,655,305 ("the '305 patent"), U.S. Patent No. 11,077,189 ("the '189 patent"), U.S. Patent No. 11,638,756 ("the '756 patent"), U.S. Patent No. 11,992,529 ("the '529 patent"), U.S. Patent No. 12,128,103 ("the '103 patent"), U.S. Patent No. 10,808,037 ("the '037 patent"), U.S. Patent No. 11,078,294 ("the '294 patent"), U.S. Patent No. 12,145,997 ("the '997 patent"), U.S. Patent No. 12,173,080 ("the '080 patent"), U.S. Patent No. 9,815,904 ("the '904 patent"), U.S. Patent No. 9,969,811 ("the '811 patent"), U.S. Patent No. 12,415,998 ("the '998 patent"), U.S. Patent No. 10,662,237 ("the '237 patent"), U.S. Patent No. 10,676,710 ("the '710 patent"), and U.S. Patent No. 12,103,975 ("the '975 patent") (the "Asserted Patents") are invalid and/or have not been infringed, are not being infringed, and will not be infringed by the submission of the Henlius aBLA or the manufacture, use, sale, offer for sale, or importation of Henlius's proposed pertuzumab product.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over these Counterclaims pursuant 28 U.S.C. §§ 1331, 1338, 1367(a), 2201, and 2202.

9. This Court has personal jurisdiction over Plaintiffs because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint here.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) for

purposes of this case, and virtue of Plaintiffs' filing of this action in this District.

11. Plaintiffs have filed a Complaint in this District alleging infringement by Defendants of one or more claims of each of the Asserted Patents. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Asserted Patents.

FACTUAL BACKGROUND

12. Upon information and belief, Genentech is the holder of Biologics License Application ("BLA") No. 125409, which purportedly covers Perjeta® (pertuzumab).

13. Upon information and belief, Genentech is an assignee of each of the Asserted Patents.

14. Upon information and belief, Hoffman-La Roche is also an assignee of the '189 patent, the '756 patent, the '529 patent, the '904 patent, the '237 patent, and the '103 patent.

15. Henlius Biotech submitted the Henlius aBLA to the FDA pursuant to 42 U.S.C. § 262(k) to obtain approval to offer to sell, sell, and import Henlius's proposed pertuzumab product in the United States.

16. On January 29, 2025, Defendants sent a letter to Genentech's general counsel providing notice that the Henlius aBLA was submitted to the FDA and accepted for review.

17. On February 11, 2025, pursuant to § 262(l)(2)(A), Defendants produced a copy of the Henlius aBLA to Genentech.

18. On April 3, 2025, Genentech sent notice pursuant to 42 U.S.C. § 262(l)(3)(A) and 35 U.S.C. § 271(e)(2)(C), identifying 47 patents for which Genentech allegedly believed a claim of patent infringement could reasonably be asserted against Defendants ("Genentech's patent list").

19. On May 13, 2025, Defendants provided a detailed statement containing the requisite information under 35 U.S.C. § 262(l)(3)(B) for each of the patents provided on

Genentech's patent list.

20. On July 11, 2025, Genentech provided a detailed statement under 35 U.S.C. § 262 (l)(3)(C) for the Asserted Patents.

21. On July 16, 2025, Defendants informed Genentech that "[f]or the purposes of the patent-exchange provisions of the BPCIA, Henlius and Organon consent to—*i.e.* do not seek to restrict or expand—Genentech's list of patents for which it believes a claim of patent infringement could reasonably be asserted. In particular, should Genentech elect to commence proceedings on any of the patents discussed in its July 11, 2025 letter, Henlius and Organon agree that each of these patents shall be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6), subject to all rights and defenses available to Henlius and Organon to any such claim of infringement, including but not limited to noninfringement defenses, invalidity defenses, unenforceability defenses, standing, and rights under 35 U.S.C. § 285."

22. Plaintiffs filed their Complaint against Defendants on August 14, 2025, alleging infringement of the Asserted Patents.

23. As a consequence of the foregoing, there is an actual and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, as to whether the claims of the '817 patent, the '474 patent, the '346 patent, the '498 patent, the '776 patent, the '341 patent, the '184 patent, the '234 patent, the '457 patent, the '305 patent, the '189 patent, the '756 patent, the '529 patent, the '103 patent, the '037 patent, the '294 patent, the '997 patent, the '080 patent, the '904 patent, the '811 patent, the '998 patent, the '237 patent, the '710 patent, and the '975 patent are invalid and/or unenforceable, and/or whether the products and/or activities described in Henlius's aBLA No. 761450 infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of these patents.

COUNT I
(Declaration of Noninfringement of the ’817 Patent)

24. Defendants re-allege and incorporate the allegations of paragraphs 1–23 as if fully set forth herein.

25. Plaintiffs allege ownership, title, and/or interest to the ’817 patent and have brought claims against Defendants alleging infringement of the ’817 patent.

26. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius’s aBLA and/or manufacture, use, offer for sale, sale, and/or importation into the United States of Henlius’s proposed pertuzumab product infringes, has infringed, and/or will infringe any enforceable claim of the ’817 patent.

27. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

28. According to the records of the U.S. Patent & Trademark Office, the ’817 patent expired on June 1, 2025.

29. Defendants cannot be liable for any alleged infringement of the ’817 patent because Henlius Biotech submitted the Henlius aBLA to obtain FDA approval to offer to sell, sell, and import into the United States Henlius’s proposed pertuzumab product after the expiration of the ’817 patent.

30. The filing of Henlius’s aBLA has not, does not, and will not infringe any enforceable claim of the ’817 patent.

31. The manufacture, use, offer for sale, sale, and/or importation of Henlius’s proposed pertuzumab product has not, does not, and will not infringe any enforceable claim of the ’817 patent.

32. Defendants are entitled to a declaration that the manufacture, use, sale, offer for sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's aBLA, has not infringed, does not infringe, and/or will not infringe any enforceable claim of the '817 patent.

33. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Noninfringement of the Acidic Variant Patents)

34. Defendants re-allege and incorporate the allegations of paragraphs 1–33 as if fully set forth herein.

35. Plaintiffs allege ownership, title, and/or interest to the '474, '346, '498, '776, and '341 patents (the "Acidic Variant Patents") and have brought claims against Defendants alleging infringement of the Acidic Variant Patents.

36. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the Acidic Variant Patents.

37. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

38. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the Acidic Variant Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

39. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed

pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the Acidic Variant Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

40. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the Acidic Variant Patents and are not liable for any alleged infringement.

41. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's aBLA, has not, does not, and will not infringe any valid or enforceable claim of the Acidic Variant Patents.

42. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Invalidity of the Acidic Variant Patents)

43. Defendants re-allege and incorporate the allegations of paragraphs 1–42 as if fully set forth herein.

44. Plaintiffs allege ownership, title, and/or interest to the Acidic Variant Patents and have brought claims against Defendants alleging infringement of the Acidic Variant Patents.

45. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the Acidic Variant Patents, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the Acidic Variant Patents.

46. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

47. One or more of the claims of the Acidic Variant Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

48. The Acidic Variant Patents describe and claim an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

49. The alleged inventions of the Acidic Variant Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Acidic Variant Patents is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Acidic Variant Patents and would have had a reasonable expectation of success in doing so.

50. The subject matter claimed in the Acidic Variant Patents fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

51. Defendants are entitled to a declaration that all claims of the Acidic Variant Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

52. This case is an exceptional one, and Defendants are entitled to an award of their

reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Noninfringement of the Fixed Dose Patents)

53. Defendants re-allege and incorporate the allegations of paragraphs 1–52 as if fully set forth herein.

54. Plaintiffs allege ownership, title, and/or interest to the '184 and '234 patents (the "Fixed Dose Patents") and have brought claims against Defendants alleging infringement of the Fixed Dose Patents.

55. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the Fixed Dose Patents.

56. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

57. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the Fixed Dose Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

58. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the Fixed Dose Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

59. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the Fixed Dose Patents and are not liable for

any alleged infringement.

60. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the Fixed Dose Patents.

61. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V
(Declaration of Invalidity of the Fixed Dose Patents)

62. Defendants re-allege and incorporate the allegations of paragraphs 1–61 as if fully set forth herein.

63. Plaintiffs allege ownership, title, and/or interest to the Fixed Dose Patents and have brought claims against Defendants alleging infringement of the Fixed Dose Patents.

64. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the Fixed Dose Patents, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the Fixed Dose Patents.

65. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

66. One or more of the claims of the Fixed Dose Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

67. The Fixed Dose Patents describe and claim an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and

mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

68. The alleged inventions of the Fixed Dose Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Fixed Dose Patents is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Fixed Dose Patents and would have had a reasonable expectation of success in doing so.

69. The subject matter claimed in the Fixed Dose Patents fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

70. Defendants are entitled to a declaration that all claims of the Fixed Dose Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

71. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Noninfringement of the Metastatic Breast Cancer Indication Patents)

72. Defendants re-allege and incorporate the allegations of paragraphs 1–71 as if fully set forth herein.

73. Plaintiffs allege ownership, title, and/or interest to the '457 and '305 patents (the "Metastatic Breast Cancer Indication Patents") and have brought claims against Defendants

alleging infringement of the Metastatic Breast Cancer Indication Patents.

74. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the Metastatic Breast Cancer Indication Patents.

75. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

76. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the Metastatic Breast Cancer Indication Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

77. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the Metastatic Breast Cancer Indication Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

78. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the Metastatic Breast Cancer Indication Patents and are not liable for any alleged infringement.

79. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the Metastatic Breast Cancer Indication Patents.

80. This case is an exceptional one, and Defendants are entitled to an award of their

reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VII
(Declaration of Invalidity of the Metastatic Breast Cancer Indication Patents)

81. Defendants re-allege and incorporate the allegations of paragraphs 1–80 as if fully set forth herein.

82. Plaintiffs allege ownership, title, and/or interest to the Metastatic Breast Cancer Indication Patents and have brought claims against Defendants alleging infringement of the Metastatic Breast Cancer Indication Patents.

83. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the Metastatic Breast Cancer Indication Patents, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the Metastatic Breast Cancer Indication Patents.

84. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

85. One or more of the claims of the Metastatic Breast Cancer Indication Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

86. The Metastatic Breast Cancer Indication Patents describe and claim an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

87. The alleged inventions of the Metastatic Breast Cancer Indication Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Metastatic Breast Cancer Indication

Patents is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Metastatic Breast Cancer Indication Patents and would have had a reasonable expectation of success in doing so.

88. The subject matter claimed in the Metastatic Breast Cancer Indication Patents fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

89. Defendants are entitled to a declaration that all claims of the Metastatic Breast Cancer Indication Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

90. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
(Declaration of Noninfringement of the Early Breast Cancer Adjuvant Therapy Patents)

91. Defendants re-allege and incorporate the allegations of paragraphs 1–90 as if fully set forth herein.

92. Plaintiffs allege ownership, title, and/or interest to the '189, '756, '529, and '103 patents (the "Early Breast Cancer Adjuvant Therapy Patents") and have brought claims against Defendants alleging infringement of the Early Breast Cancer Adjuvant Therapy Patents.

93. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation

into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the Early Breast Cancer Adjuvant Therapy Patents.

94. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

95. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the Early Breast Cancer Adjuvant Therapy Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

96. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the Early Breast Cancer Adjuvant Therapy Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

97. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the Early Breast Cancer Adjuvant Therapy Patents and are not liable for any alleged infringement.

98. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the Early Breast Cancer Adjuvant Therapy Patents.

99. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IX
(Declaration of Invalidity of the Early Breast Cancer Adjuvant Therapy Patents)

100. Defendants re-allege and incorporate the allegations of paragraphs 1–99 as if fully set forth herein.

101. Plaintiffs allege ownership, title, and/or interest to the Early Breast Cancer Adjuvant Therapy Patents and have brought claims against Defendants alleging infringement of the Early Breast Cancer Adjuvant Therapy Patents.

102. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the Early Breast Cancer Adjuvant Therapy Patents, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the Early Breast Cancer Adjuvant Therapy Patents.

103. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

104. One or more of the claims of the Early Breast Cancer Adjuvant Therapy Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

105. The Early Breast Cancer Adjuvant Therapy Patents describe and claim an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

106. The alleged inventions of the Early Breast Cancer Adjuvant Therapy Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Early Breast Cancer Adjuvant Therapy Patents is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Early Breast Cancer Adjuvant Therapy Patents and would have had a reasonable expectation of success in doing so.

107. The subject matter claimed in the Early Breast Cancer Adjuvant Therapy Patents fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

108. Defendants are entitled to a declaration that all claims of the Early Breast Cancer Adjuvant Therapy Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

109. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT X
(Declaration of Noninfringement of the Disulfide Bond Reduction Patents)

110. Defendants re-allege and incorporate the allegations of paragraphs 1–109 as if fully set forth herein.

111. Plaintiffs allege ownership, title, and/or interest to the '037, '294, and '997 patents (the "Disulfide Bond Reduction Patents") and have brought claims against Defendants alleging infringement of the Disulfide Bond Reduction Patents.

112. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the Disulfide Bond Reduction Patents.

113. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

114. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the Disulfide Bond Reduction Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

115. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the Disulfide Bond Reduction Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

116. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the Disulfide Bond Reduction Patents and are not liable for any alleged infringement.

117. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the Disulfide Bond Reduction Patents.

118. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XI
(Declaration of Invalidity of the Disulfide Bond Reduction Patents)

119. Defendants re-allege and incorporate the allegations of paragraphs 1–118 as if fully set forth herein.

120. Plaintiffs allege ownership, title, and/or interest to the Disulfide Bond Reduction Patents and have brought claims against Defendants alleging infringement of the Disulfide Bond Reduction Patents.

121. There is an actual, substantial, continuing, and justiciable controversy between

Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the Disulfide Bond Reduction Patents, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the Disulfide Bond Reduction Patents.

122. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

123. One or more of the claims of the Disulfide Bond Reduction Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

124. The Disulfide Bond Reduction Patents describe and claim an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

125. The alleged inventions of the Disulfide Bond Reduction Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Disulfide Bond Reduction Patents is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Disulfide Bond Reduction Patents and would have had a reasonable expectation of success in doing so.

126. The subject matter claimed in the Disulfide Bond Reduction Patents fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary

skill in the art to which the claimed subject matter pertains.

127. Defendants are entitled to a declaration that all claims of the Disulfide Bond Reduction Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

128. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XII
(Declaration of Noninfringement of the Pertuzumab Variants Patents)

129. Defendants re-allege and incorporate the allegations of paragraphs 1–128 as if fully set forth herein.

130. Plaintiffs allege ownership, title, and/or interest to the '904, '811, and '998 patents (the "Pertuzumab Variants Patents") and have brought claims against Defendants alleging infringement of the Pertuzumab Variants Patents.

131. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the Pertuzumab Variants Patents.

132. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

133. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the Pertuzumab Variants Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

134. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed

pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the Pertuzumab Variants Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

135. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the Pertuzumab Variants Patents and are not liable for any alleged infringement.

136. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the Pertuzumab Variants Patents.

137. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIII
(Declaration of Invalidity of the Pertuzumab Variants Patents)

138. Defendants re-allege and incorporate the allegations of paragraphs 1–137 as if fully set forth herein.

139. Plaintiffs allege ownership, title, and/or interest to the Pertuzumab Variants Patents and have brought claims against Defendants alleging infringement of the Pertuzumab Variants Patents.

140. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the Pertuzumab Variants Patents, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the Pertuzumab Variants Patents.

141. This controversy is of sufficient immediacy and reality to warrant the issuance of a

declaratory judgment.

142. One or more of the claims of the Pertuzumab Variants Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

143. The Pertuzumab Variants Patents describe and claim an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

144. The alleged inventions of the Pertuzumab Variants Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Pertuzumab Variants Patents is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Pertuzumab Variants Patents and would have had a reasonable expectation of success in doing so.

145. The subject matter claimed in the Pertuzumab Variants Patents fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

146. Defendants are entitled to a declaration that all claims of the Pertuzumab Variants Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

147. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIV
(Declaration of Noninfringement of the '237 Patent)

148. Defendants re-allege and incorporate the allegations of paragraphs 1–147 as if fully set forth herein.

149. Plaintiffs allege ownership, title, and/or interest to the '237 Patent and have brought claims against Defendants alleging infringement of the '237 Patent.

150. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '237 Patent.

151. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

152. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the '237 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

153. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the '237 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

154. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '237 Patent and are not liable for any alleged infringement.

155. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the '237 Patent.

156. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XV
(Declaration of Invalidity of the '237 Patent)

157. Defendants re-allege and incorporate the allegations of paragraphs 1–156 as if fully set forth herein.

158. Plaintiffs allege ownership, title, and/or interest to the '237 Patent and have brought claims against Defendants alleging infringement of the '237 Patent.

159. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the '237 Patent, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the '237 Patent.

160. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

161. One or more of the claims of the '237 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

162. The '237 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

163. The alleged invention of the ’237 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’237 Patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’237 Patent and would have had a reasonable expectation of success in doing so.

164. The subject matter claimed in the ’237 Patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

165. Defendants are entitled to a declaration that all claims of the ’237 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

166. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XVI
(Declaration of Noninfringement of the ’710 Patent)

167. Defendants re-allege and incorporate the allegations of paragraphs 1–166 as if fully set forth herein.

168. Plaintiffs allege ownership, title, and/or interest to the ’710 Patent and have brought claims against Defendants alleging infringement of the ’710 Patent.

169. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of

whether the filing of Henlius's aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius's proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '710 Patent.

170. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

171. The filing of Henlius's aBLA has not, does not, and will not infringe any valid or enforceable claim of the '710 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

172. The manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the '710 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

173. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '710 Patent and are not liable for any alleged infringement.

174. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the '710 Patent.

175. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XVII
(Declaration of Invalidity of the '710 Patent)

176. Defendants re-allege and incorporate the allegations of paragraphs 1–175 as if fully set forth herein.

177. Plaintiffs allege ownership, title, and/or interest to the '710 Patent and have brought claims against Defendants alleging infringement of the '710 Patent.

178. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the '710 Patent, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the '710 Patent.

179. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

180. One or more of the claims of the '710 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

181. The '710 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

182. The alleged invention of the '710 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '710 Patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '710 Patent and would have had a reasonable expectation of success in doing so.

183. The subject matter claimed in the '710 Patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was

made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

184. Defendants are entitled to a declaration that all claims of the ’710 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

185. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XVIII
(Declaration of Noninfringement of the ’975 Patent)

186. Defendants re-allege and incorporate the allegations of paragraphs 1–185 as if fully set forth herein.

187. Plaintiffs allege ownership, title, and/or interest to the ’975 Patent and have brought claims against Defendants alleging infringement of the ’975 Patent.

188. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding, *inter alia*, the issue of whether the filing of Henlius’s aBLA and/or the manufacture, use, offer for sale, and/or importation into the United States of Henlius’s proposed pertuzumab product infringes, has infringed, and/or will infringe any valid or enforceable claim of the ’975 Patent.

189. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

190. The filing of Henlius’s aBLA has not, does not, and will not infringe any valid or enforceable claim of the ’975 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

191. The manufacture, use, offer for sale, sale, and/or importation of Henlius’s proposed

pertuzumab product has not, does not, and will not infringe any valid or enforceable claim of the '975 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

192. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '975 Patent and are not liable for any alleged infringement.

193. Defendants are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Henlius's proposed pertuzumab product, and the submission of Henlius's BLA, has not, does not, and will not infringe any valid or enforceable claim of the '975 Patent.

194. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIX
(Declaration of Invalidity of the '975 Patent)

195. Defendants re-allege and incorporate the allegations of paragraphs 1–194 as if fully set forth herein.

196. Plaintiffs allege ownership, title, and/or interest to the '975 Patent and have brought claims against Defendants alleging infringement of the '975 Patent.

197. There is an actual, substantial, continuing, and justiciable controversy between Defendants, on the one hand, and Plaintiffs, on the other hand, regarding the invalidity of the '975 Patent, based on Plaintiffs' allegation in their Complaint that Defendants have infringed or will infringe the '975 Patent.

198. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

199. One or more of the claims of the '975 Patent are invalid under one or more

provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for patent invalidity.

200. The '975 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

201. The alleged invention of the '975 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '975 Patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '975 Patent and would have had a reasonable expectation of success in doing so.

202. The subject matter claimed in the '975 Patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

203. Defendants are entitled to a declaration that all claims of the '975 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

204. This case is an exceptional one, and Defendants are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request judgment in its favor and against

Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the filing of abbreviated Biologics License Application No. 761450 (the "Henlius aBLA") has not infringed and does not infringe any valid and enforceable claim of the '817 patent, the '474 patent, the '346 patent, the '498 patent, the '776 patent, the '341 patent, the '184 patent, the '234 patent, the '457 patent, the '305 patent, the '189 patent, the '756 patent, the '529 patent, the '103 patent, the '037 patent, the '294 patent, the '997 patent, the '080 patent, the '904 patent, the '811 patent, the '998 patent, the '237 patent, the '710 patent, and the '975 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Henlius's proposed pertuzumab product does not, and would not, if marketed, infringe any valid and enforceable claim of the '817 patent, '474 patent, the '346 patent, the '498 patent, the '776 patent, the '341 patent, the '184 patent, the '234 patent, the '457 patent, the '305 patent, the '189 patent, the '756 patent, the '529 patent, the '103 patent, the '037 patent, the '294 patent, the '997 patent, the '080 patent, the '904 patent, the '811 patent, the '998 patent, the '237 patent, the '710 patent, and the '975 patent;

c. Declaring that the claims of the '474 patent, the '346 patent, the '498 patent, the '776 patent, the '341 patent, the '184 patent, the '234 patent, the '457 patent, the '305 patent, the '189 patent, the '756 patent, the '529 patent, the '103 patent, the '037 patent, the '294 patent, the '997 patent, the '080 patent, the '904 patent, the '811 patent, the '998 patent, the '237 patent, the '710 patent, and the '975 patent are invalid or unenforceable;

d. Declaring this an exceptional case in favor of Defendants and awarding their attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

e. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

Respectfully submitted,

Dated: October 20, 2025

/s/ Rebekah R. Conroy
Rebekah R. Conroy
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: (973) 400-4181
rconroy@stoneconroy.com

OF COUNSEL:
Maureen Rurka (to be admitted *pro hac vice*)
Julia Johnson (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
300 N LaSalle Drive
Chicago, IL 60654
fTelephone: (312) 558-5600
MRurka@winston.com
JMJohnson@winston.com

Attorneys for Defendants Shanghai Henlius Biotech, Inc., Shanghai Henlius Biologics Co., Ltd., Organon LLC, and Organon & Co.

LOCAL CIVIL RULE 11.2 CERTIFICATION

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

Dated: October 20, 2025

/s/ Rebekah R. Conroy

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: October 20, 2025

/s/ Rebekah R. Conroy

CERTIFICATE OF SERVICE

I hereby certify that, on October 20, 2025, the foregoing document described as **DEFENDANT DEFENDANTS SHANGHAI HENLIUS BIOTECH, INC., SHANGHAI HENLIUS BIOLOGICS CO., LTD., ORGANON LLC, AND ORGANON & CO.'S ANSWER, DEFENSES, AND COUNTERCLAIMS'S ANSWER, DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

Keith J. Miller
Michael J. Gesualdo
Bradley A. Suiters
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
Tel: (973) 690-5400

Eric Alan Stone
Naz E. Wehrli
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
565 Fifth Ave, Suite 2900
New York, New York 10017
Tel: (332) 269-0030

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

Dated: October 20, 2025

/s/ Rebekah R. Conroy