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

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

GENENTECH, INC. and HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

BIOCON BIOLOGICS INC., BIOCON BIOLOGICS LTD., BIOCON BIOLOGICS UK LTD., BIOCON BIOLOGICS GERMANY GMBH,

Defendants.

Civil Action No. 26-9585

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and Hoffmann-La Roche Inc. ("Hoffmann-La Roche"), by and through their undersigned attorneys, for their Complaint against Defendants Biocon Biologics Inc., Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH (collectively, "Biocon" or "Defendants"), hereby allege as follows:

NATURE OF THE CASE

1. This is a civil 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 Act of 1934, 28 U.S.C. §§ 2201-2202.

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, Biocon) to rely on the prior licensure and approval status of the innovative biological product that the biosimilar purports to copy, known as the "reference product" (here, Genentech's PERJETA® (pertuzumab)). Genentech is the sponsor of PERJETA® and therefore the "reference product sponsor" or "RPS" under the BPCIA.

3. Genentech is a leading biotechnology company that develops and manufactures innovative medicines, transforming care for patients across a broad range of serious, life-threatening diseases. One such medicine is PERJETA® (pertuzumab), approved by the United States Food and Drug Administration ("FDA") for the treatment of human epidermal growth factor receptor 2 ("HER2")-positive metastatic breast cancer, a particularly aggressive and fast-growing type of breast cancer. PERJETA® is the result of decades of scientific research and more than a billion dollars of investment in research, discovery, development, and manufacturing.

4. Specifically, PERJETA® is used with trastuzumab and chemotherapy to treat HER2-positive breast cancer before surgery in adults with locally advanced, inflammatory, or early-stage breast cancer as part of a complete treatment regimen, and after surgery in adults with HER2-positive early breast cancer with high risk of recurrence. PERJETA® is also approved in combination with trastuzumab and docetaxel in adults with HER2-positive metastatic breast cancer who have not previously received anti-HER2 therapy or chemotherapy for metastatic disease.

5. Genentech holds numerous patents related to PERJETA®, and the manufacture and delivery of biologics like pertuzumab.

6. Defendants plan to sell Bmab1500, a biosimilar copy of PERJETA® (the "Proposed Biocon Pertuzumab Biosimilar"). Defendants submitted abbreviated Biologics License Application ("aBLA") No. 761501 (the "Biocon aBLA") with the FDA seeking approval to market the Proposed Biocon Pertuzumab Biosimilar. But Defendants did not independently develop Bmab1500. Rather, Defendants are seeking regulatory approval based on Genentech's clinical studies and research data for PERJETA®. By submitting their aBLA for Bmab1500, Defendants have infringed Genentech's patents.

THE PARTIES

7. Genentech 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 is a biotechnology company that develops, manufactures, and commercializes medicines to treat patients with serious and life-threatening medical conditions. Genentech employs a large number of scientists who routinely publish in top peer-reviewed journals and are among the leaders in their respective fields. Genentech 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.

8. Hoffmann-La Roche is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 1080 U.S. 202 South, Building 500, Branchburg, NJ 08876. Hoffmann-La Roche is a pharmaceutical company that researches, develops, and manufactures drugs to address unmet medical needs.

9. On information and belief, Biocon Biologics Inc. is a domestic corporation organized and existing under the laws of the state of Delaware, with its principal place of business and headquarters located at 685 Route 202/206, Suite 204, Bridgewater, New Jersey 08807. On information and belief, Biocon Biologics Inc. is a wholly owned subsidiary of Biocon Biologics UK Ltd.

10. On information and belief, Biocon Biologics Ltd. is a foreign company organized and existing under the laws of India, with its principal place of business and headquarters at Biocon House, Ground Floor, Tower-3, Semicon Park, Electronics City, Phase – II, Hosur Road, Bengaluru 560100, Karnataka, India.

11. On information and belief, Biocon Biologics UK Ltd. is a foreign company organized and existing under the laws of the United Kingdom, with its principal place of business at 16 Great Queen Street, Covent Garden, London, WC2B 5AH, United Kingdom. On information and belief, Biocon Biologics UK Ltd. is a wholly owned subsidiary of Biocon Biologics Ltd.

12. On information and belief, Biocon Biologics Germany GmbH is a foreign company organized and existing under the laws of Germany, with its principal place of business and headquarters located at Neue Mainzer Straße 6-10, 60311 Frankfurt am Main, Germany. On information and belief, Biocon Biologics Germany GmbH is a wholly owned subsidiary of Biocon Biologics UK Ltd.

13. On information and belief, Biocon Biologics Inc., acting in concert with the other Defendants, 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.

14. On information and belief, Biocon Biologics Inc., acting in concert with the other Defendants, intends to develop, manufacture, import, market, distribute, offer for sale and/or sell in this Judicial District and throughout the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and, in doing so, will improperly exploit Genentech's intellectual property.

JURISDICTION

15. This is an action for patent infringement 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.

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

17. This Court has personal jurisdiction over Biocon Biologics Inc. because its principal place of business is in New Jersey, and also because it, directly and through its 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. On information and belief, Biocon Biologics Inc.

derives substantial revenue from selling pharmaceutical products throughout the United States, including New Jersey.

18. This Court has personal jurisdiction over each of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH under Fed. R. Civ. P. 4(k) because, on information and belief, each is organized under the laws of a foreign government and because, on information and belief, each maintains continuous and systematic contacts with New Jersey through its collaboration with Biocon Biologics Inc. which has its principal place of business in Bridgewater, New Jersey, and regularly and continuously conducts business within this state. The collaboration by each of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH with Biocon Biologics Inc. includes but is not limited to submission of the Biocon aBLA.

19. Alternatively, should any of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH 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 each entity has sufficient contacts with the United States and with New Jersey that relate to the claims in this case.

20. On information and belief, each of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH, 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.

21. This Court has personal jurisdiction over each of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH because, among other reasons, each such entity itself and through its collaboration with Biocon Biologics Inc., has purposefully availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

22. On information and belief, each of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH collaborated with Biocon Biologics Inc. to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in New Jersey.

23. On information and belief, each of Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH acted in collaboration and in concert with Biocon Biologics Inc. to take substantial steps to prepare for and undertake the filing of the Biocon aBLA and to file the Biocon aBLA, seeking to market the Proposed Biocon Pertuzumab Biosimilar nationwide, including within this Judicial District.

24. 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 FDA approval of the Biocon aBLA, Defendants, acting in collaboration and in concert, will market and sell the Proposed Biocon Pertuzumab Biosimilar, which 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, list the Proposed Biocon Pertuzumab Biosimilar on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursement for sales of the Proposed Biocon Pertuzumab Biosimilar in the State of

New Jersey, either directly or through one or more of Biocon's subsidiaries, agents, and/or alter egos.

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

VENUE

26. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) over Biocon Biologics Ltd. because, *inter alia*, it is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018). On information and belief, Biocon Biologics Ltd. acts and/or will act in concert with Biocon Biologics Inc. to develop, manufacture, import, seek regulatory approval for, market, distribute, and sell the Proposed Biocon Pertuzumab Biosimilar in New Jersey.

27. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) over Biocon Biologics UK Ltd., because, *inter alia*, it is incorporated in the United Kingdom and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction. *Id.* On information and belief, Biocon Biologics UK Ltd. acts and/or will act in concert with Biocon Biologics Inc. to develop, manufacture, import, seek regulatory approval for, market, distribute, and sell the Proposed Biocon Pertuzumab Biosimilar in New Jersey.

28. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) over Biocon Biologics Germany GmbH, because, *inter alia*, it is incorporated in

Germany and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction. *Id.* On information and belief, Biocon Biologics Germany GmbH acts and/or will act in concert with Biocon Biologics Inc. to develop, manufacture, import, seek regulatory approval for, market, distribute, and sell the Proposed Biocon Pertuzumab Biosimilar in New Jersey.

29. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b) over Biocon Biologics Inc. because it has its principal place of business at 685 Route 202/206, Suite 204, Bridgewater, New Jersey 08807 and has systematic and continuous contacts with New Jersey and, in particular, on information and belief, has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar in and from New Jersey, and receiving correspondence with FDA regarding the Biocon aBLA at its office in New Jersey.

BACKGROUND

Genentech's Innovative Biological Product PERJETA® (pertuzumab)

30. Breast cancer is the most common cancer in women in the U.S., and HER2-positive breast cancer accounts for about 20–30% of all breast cancer diagnoses. In 2026, an estimated 385,310 people will be diagnosed with breast cancer in the United States, and approximately one in eight women in the United States will be diagnosed with breast cancer during her lifetime.

31. HER2-positive breast cancer is a particularly aggressive and fast-growing subtype characterized by overexpression of human epidermal growth factor receptor 2 ("HER2") proteins due to HER2 gene amplification. Before the development of HER2-targeted therapies, this subtype was associated with poor outcomes and higher mortality rates compared to other forms of breast cancer.

32. With the development of HER2-targeted agents—principally by Genentech—HER2-positive breast cancer has become a treatable disease, and patient outcomes have improved dramatically.

33. The lives of millions of women suffering from HER2-positive breast cancer changed when Genentech developed HERCEPTIN® (trastuzumab), the first antibody specifically designed to target the HER2 protein. Since FDA approval of HERCEPTIN® in 1998, Genentech has worked diligently to develop new methods of using HERCEPTIN® and to advance targeted therapies for HER2-positive breast cancer.

34. Although HERCEPTIN® represented a breakthrough, it quickly became apparent that additional targeted therapies would be beneficial, particularly for patients with higher-risk early-stage disease.

35. To address this unmet need, Genentech developed PERJETA®, another anti-HER2-antibody-based targeted therapy. PERJETA® contains pertuzumab, an antibody that targets a different epitope on the HER2 protein than trastuzumab. When administered together, trastuzumab and pertuzumab provide complementary mechanisms of action to treat HER2-positive breast cancer.

36. The combination of HERCEPTIN® and PERJETA® has transformed cancer treatment and became the standard of care for HER2-positive breast cancer—a direct result of Genentech's pioneering work since the early 1990s in identifying and developing anti-HER2 antibodies.

37. All told, Genentech has spent billions of dollars over more than two decades to develop life-saving drugs like HERCEPTIN® and PERJETA®.

38. Genentech's groundbreaking work in developing PERJETA® was the product of years of sustained research and innovation. The United States Patent and Trademark Office ("USPTO") recognized Genentech's contributions by granting numerous patents claiming PERJETA®, and its use as well as methods of manufacturing PERJETA® and other biologics. Those patents include: U.S. Patent Nos. 10,689,457, 11,655,305, 11,077,189, 11,638,756, 11,992,529, 12,128,103, 12,527,867, 12,427,193, 11,833,206, 8,652,474, 9,181,346, 11,414,498, 11,597,776, 12,110,341, 9,815,904, 9,969,811, 12,145,998, 10,808,037, 11,078,294, 12,145,997, 12,173,080, 12,103,975, 12,351,641, 10,822,404, 12,152,054, 12,286,619, 12,371,728, 12,479,883 (collectively, the "Asserted Patents"). Hoffmann-La Roche is a co-owner of some of the Asserted Patents.

39. Genentech, Inc. is the sponsor of the Biologics License Application ("BLA") for PERJETA®. Before Genentech introduced PERJETA® to market, Genentech conducted extensive clinical trials and submitted the results of those trials to FDA to demonstrate that PERJETA® is safe, pure, and potent. Genentech invested substantial resources in doing so. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biological product at more than $2 billion, including the costs of failure.

40. Genentech additionally invested extensively in developing methods of manufacturing PERJETA® and other biologic molecules safely, efficiently, and effectively.

41. Prior to the approval of PERJETA®, any other company wishing to market its own version of pertuzumab would have been required to undertake the same extensive effort and investment—conducting its own clinical trials to demonstrate to FDA that its proposed version was also safe, pure, and potent.

Defendants Seek Approval for Bmab1500

42. The BPCIA does not give Defendants a license to infringe Genentech's patents. To the contrary, the BPCIA establishes an intricate and carefully orchestrated set of procedures requiring the biosimilar applicant and the reference product sponsor to engage in a series of information exchanges and good-faith negotiations prior to the filing of a patent infringement lawsuit. These procedures 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).

43. Defendants sought FDA approval for the Proposed Biocon Pertuzumab Biosimilar, their proposed pertuzumab biosimilar, by submitting the Biocon aBLA under the abbreviated licensing pathway of 42 U.S.C. § 262(k). Through the Biocon aBLA, Defendants reference and rely on the approval and licensure of Genentech's PERJETA® in support of their request for FDA approval. On information and belief, FDA accepted the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar for review.

44. On information and belief, the Proposed Biocon Pertuzumab Biosimilar is designed to compete directly with Genentech's PERJETA®.

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

45. On January 20, 2026, Biocon, through its counsel, contacted Genentech's counsel at Groombridge, Wu, Baughman & Stone LLP ("Groombridge") asserting that Biocon recently had submitted for FDA review an aBLA for Genentech's PERJETA®.

46. On January 22, 2026, Genentech, through Groombridge, requested Biocon to provide a copy of Biocon's aBLA and related information under 42 U.S.C. § 262(*l*)(2).

47. On January 22, 2026, Biocon, through its counsel, sent a link for downloading its aBLA to Groombridge.

48. Due to a nationwide Outlook outage on January 22, 2026, Groombridge did not receive the link until the following day.

49. The link provided required a separate request for an account with Biocon's counsel's file-transfer system in order to access the aBLA.

50. Groombridge did not request an account required to access the aBLA until 1:14 PM Eastern Standard Time, February 27, 2026, and therefore did not access the aBLA until after such time.

51. On March 22, 2026, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and 35 U.S.C. § 271(e)(2)(C), Genentech identified 58 patents for which it 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 Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA.

52. On April 17, 2026, Biocon Biologics Inc. provided its detailed statement under 42 U.S.C. § 262(*l*)(3)(B) contesting Biocon's infringement and/or the validity and unenforceability of certain patents.

53. On June 16, 2026, Genentech provided its detailed statement under 42 U.S.C. § 262(*l*)(3)(C) describing, on a claim by claim basis: (a) 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 Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA; and (b) Genentech's response to Biocon's contentions concerning the validity and enforceability of the Asserted Patents as set forth in Biocon's April 17, 2026 statement under 42 U.S.C. § 262(*l*)(3)(B).

54. On July 1, 2026, Biocon Biologics Inc. and Genentech, through their respective counsel, agreed upon the list of patents to be asserted in litigation—the Asserted Patents.

55. Genentech filed this Complaint within the time required under 42 U.S.C. § 262(*l*)(6)—that is, within 30 days after Genentech and Biocon Biologics Inc. reached agreement that the Asserted Patents would be the subject of an action for patent infringement under § 262(*l*)(6).

THE ASSERTED PATENTS

56. Genentech has spent decades and significant resources developing PERJETA®. The USPTO has awarded Genentech numerous patents on inventions related to PERJETA® and various manufacturing methods for antibody production, covering the antibody pertuzumab as well as its use and manufacture.

57. In March 2026, Genentech and Biocon began exchanging information as required by the BPCIA, as detailed *supra* in paragraphs 45–55. The Asserted Patents were included in Genentech's March 22, 2026 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(A) and its June 16, 2026 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

58. 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), an application seeking approval of a biological product, or (ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i). 35 U.S.C. § 271(e)(2)(C)(i)-(ii).

59. The submission of the Biocon 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).

60. If FDA approves the Biocon aBLA and Biocon makes, offers to sell, sells, uses, or imports the Proposed Biocon Pertuzumab Biosimilar within the United States, Biocon will also infringe one or more claims of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

61. This action also arises from Defendants' imminent and actual importation, and imminent commercial manufacture, offer for sale, and sale of that Proposed Biocon Pertuzumab Biosimilar. In the event Defendants import, manufacture, or launch the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the Asserted Patents, Genentech also seeks monetary damages, including lost profits, and any further relief as this Court may deem just and proper.

The Metastatic Breast Cancer Indication Patents

62. U.S. Patent Nos. 10,689,457 ("'457 Patent") and 11,655,305 ("'305 Patent") (collectively, the "Metastatic Breast Cancer Indication Patents") relate to treatment of metastatic breast cancer.

63. 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 1. The listed inventors are Virginia Paton, Anne Blackwood Chirchir, Pam Klein, and Graham Alexander Ross. Genentech and Hoffmann-La Roche are the owners by assignment of the '457 Patent.

64. 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 '305 Patent is attached as Exhibit 2. The listed inventors are Virginia Paton, Anne Blackwood Chirchir, Pam

Klein, and Graham Alexander Ross. Genentech and Hoffmann-La Roche are the owners by assignment of the '305 Patent.

The Early Breast Cancer Adjuvant Treatment Patents

65. 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") relate to the adjuvant treatment of HER2-positive primary breast cancer.

66. 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 3. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech and Hoffmann-La Roche are the owners by assignment of the '189 Patent.

67. 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 4. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech and Hoffmann-La Roche are the owners by assignment of the '756 Patent.

68. 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 5. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech and Hoffmann-La Roche are the owners by assignment of the '529 Patent.

69. The '103 Patent, titled "Adjuvant Treatment of HER2-Positive Breast Cancer," was duly and legally issued by the USPTO on October 29, 2024. A true and correct copy of the '103 Patent is attached as Exhibit 6. The listed inventors are Mark C. Benyunes and Graham Alexander Ross. Genentech and Hoffmann-La Roche are the owners by assignment of the '103 Patent.

The Neoadjuvant Patent

70. U.S. Patent No. 12,527,867 ("'867 Patent" or the "Neoadjuvant Patent"), titled "Uses for and Article of Manufacture Including HER2 Dimerization Inhibitor Pertuzumab," was duly and legally issued by the USPTO on January 20, 2026. A true and correct copy of the '867 Patent is attached as Exhibit 7. The listed inventors are Graham A. Ross and Jayantha Ratnayake. Genentech is the owner by assignment of the '867 Patent.

U.S. Patent No. 12,427,193

71. U.S. Patent No. 12,427,193 ("'193 Patent"), titled "Subcutaneous anti-HER2 Antibody Formulations and Uses Thereof," was duly and legally issued by the USPTO on September 30, 2025. A true and correct copy of the '193 Patent is attached as Exhibit 8. The listed inventors are Michael Adler, Ulla Grauschopf, Hanns-Christian Mahler, and Oliver Boris Stauch. Genentech is the owner by assignment of the '193 Patent.

U.S. Patent No. 11,833,206

72. U.S. Patent No. 11,833,206 ("'206 Patent"), titled "Polysorbate Mixtures Having Modified Fatty Acid Ester Distribution" was duly and legally issued by the USPTO on December 5, 2023. A true and correct copy of the '206 Patent is attached as Exhibit 9. The listed inventors are Sandeep Yadav, Nidhi Doshi, Tamanna Shobha, Anthony Tomlinson, and Amit Srivastava. Genentech is the owner by assignment of the '206 Patent.

The Acidic Variant Patents

73. 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") relate to compositions containing anti-HER2 antibody that binds to domain II of HER2 and its acidic variants, and related methods.

74. 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 10. The listed inventors are Reed J. Harris and Paul A. Motchnik. Genentech is the owner by assignment of the ’474 Patent.

75. 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 11. The listed inventors are Reed J. Harris and Paul A. Motchnik. Genentech is the owner by assignment of the ’346 Patent.

76. 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 12. The listed inventors are Reed J. Harris and Paul A. Motchnik. Genentech is the owner by assignment of the ’498 Patent.

77. 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 13. The listed inventors are Reed J. Harris and Paul A. Motchnik. Genentech is the owner by assignment of the ’776 Patent.

78. 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 14. The listed inventors

are Reed J. Harris and Paul A. Motchnik. Genentech is the owner by assignment of the '341 Patent.

The Pertuzumab Variants Patents

79. U.S. Patent Nos. 9,815,904 ("'904 Patent"), 9,969,811 ("'811 Patent"), and 12,145,998 ("'998 Patent") (collectively, the "Pertuzumab Variants Patents") relate to compositions of variants of pertuzumab and related methods.

80. The '904 Patent, titled "Pertuzumab Variants and Evaluation 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 15. The listed inventors are Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang. Genentech is the owner by assignment of the '904 Patent.

81. The '811 Patent, titled "Pertuzumab Variants and Evaluation 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 16. The listed inventors are Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang. Genentech is the owner by assignment of the '811 Patent.

82. 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 17. The listed inventors are Lynn A. Gennaro, Yung-Hsiang Kao, and Yonghua Zhang. Genentech is the owner by assignment of the '998 Patent.

The Disulfide Bond Reduction Patents

83. 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") relate to prevention of disulfide bond reduction during recombinant production of polypeptides.

84. 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 18. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech is the owner by assignment of the ’037 Patent.

85. 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 19. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech is the owner by assignment of the ’294 Patent.

86. 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 20. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech is the owner by assignment of the ’997 Patent.

87. 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 21. The listed inventors are Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt. Genentech is the owner by assignment of the ’080 Patent.

The Cell Culture Patents

88. U.S. Patent Nos. 12,103,975 (“’975 Patent”) and 12,351,641 (“’641 Patent”) (collectively, the “Cell Culture Patents”) relate to production of proteins in glutamine-free cell culture media.

89. 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 22. The listed inventors are Martin Gawlitzek, Shun Luo, and Christina Teresa Bevilacqua. Genentech is the owner by assignment of the ’975 Patent.

90. The ’641 Patent, titled “Production of Proteins in Glutamine-Free Cell Culture Media” was duly and legally issued by the USPTO on July 8, 2025. A true and correct copy of the ’641 Patent is attached as Exhibit 23. The listed inventors are Martin Gawlitzek, Shun Luo, and Christina Teresa Bevilacqua. Genentech is the owner by assignment of the ’641 Patent.

U.S. Patent No. 10,822,404

91. U.S. Patent No. 10,822,404 (“’404 Patent”), titled “Methods and Compositions Comprising Purified Recombinant Polypeptides,” was duly and legally issued by the USPTO on November 3, 2020. A true and correct copy of the ’404 Patent is attached as Exhibit 24. The listed inventors are X. Christopher Yu, Susan C. Fisher, Atia Naim, Ailen M. Sanchez, Christopher A. Teske, Martin Vanderlaan, Annamarie Amurao, Jayme Franklin, and Corazon Victa. Genentech is the owner by assignment of the ’404 Patent.

U.S. Patent No. 12,152,054

92. U.S. Patent No. 12,152,054 (“’054 Patent”), titled “Methods of Purifying Polypeptides” was duly and legally issued on November 26, 2024. A true and correct copy of the ’054 Patent is attached as Exhibit 25. The listed inventors are Hui F. Liu, Brian David Kelley, Deanna E. Myers, Beth McCooey, and Krista Marie Petty. Genentech is the owner by assignment of the ’054 Patent.

U.S. Patent No. 12,286,619

93. U.S. Patent No. 12,286,619 (“’619 Patent”), titled “Modulating Lactogenic Activity in Mammalian Cells,” was duly and legally issued on April 29, 2025. A true and correct copy of

the ’619 Patent is attached as Exhibit 26. The listed inventors are Shahram Misaghi, Masaru Ken Shiratori, Bradley Richard Snedecor, and Michael W. Laird. Genentech is the owner by assignment of the ’619 Patent.

U.S. Patent No. 12,371,728

94. U.S. Patent No. 12,371,728 (“’728 Patent”), titled “Methods of Protein Production,” was duly and legally issued on July 29, 2025. A true and correct copy of the ’728 Patent is attached as Exhibit 27. The listed inventors are Inn Huam Yuk, Bradley Richard Snedecor, and Dana Christian Andersen. Genentech is the owner by assignment of the ’728 Patent.

U.S. Patent No. 12,479,883

95. U.S. Patent No. 12,479,883 (“’883 Patent”), titled “Methods of Reducing the Enzymatic Hydrolysis Activity Rate in a Composition Obtained from a Purification Platform” was duly and legally issued on November 25, 2025. A true and correct copy of the ’883 Patent is attached as Exhibit 28. The listed inventors are Michael Leiss, Christian Meyer, Alexandra Thomas Morris, Bernhard Spensberger, Yinges Yigzaw, Franziska Edelmann, Roberto Falkenstein, Tobias Graf, Jie Gu, and Jeevan Prabhakar. Genentech and Hoffmann-La Roche are the owners by assignment of the ’883 Patent.

CAUSES OF ACTION

COUNT I
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,689,457)

96. The allegations of paragraphs 1–95 are repeated and incorporated herein by reference.

97. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer.

98. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '457 Patent.

99. Defendants committed an act or acts of infringement with respect to the '457 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

100. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '457 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

101. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

102. The '457 Patent includes five claims, two of which are independent. Claim 1 recites:

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

103. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '457 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer, will actively induce infringement of one or more claims of the '457 Patent under 35 U.S.C. § 271(b), including at least claim 1.

104. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '457 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '457 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading. " *See* 42 U.S.C. § 262(*l*)(1)(F).

105. Defendants have knowledge of or are willfully blind to the '457 Patent, including due to Genentech's disclosure of the '457 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

106. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to a method for the treatment of a human patient with HER2 positive metastatic breast cancer who did not receive either prior chemotherapy or prior anti-HER2 therapy for their metastatic breast cancer, comprising administering to the patient an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein treatment with the combination increases overall survival without increase in cardiac-specific adverse events relative to administration of trastuzumab and docetaxel in the absence of pertuzumab, wherein the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks, the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks, and the docetaxel is administered by intravenous administration every three weeks for at least six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

107. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce

infringement of the ’457 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the ’457 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’457 Patent.

108. On information and belief, Defendants’ active inducement of infringement of the ’457 Patent is and will be willful.

109. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the ’457 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B), preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

110. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’457 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

111. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’457 Patent, will cause and/or has caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,689,457)

112. The allegations of paragraphs 1–111 are repeated and incorporated herein by reference.

113. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A

judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '457 Patent.

114. As set forth in Count I, healthcare providers would directly infringe one or more claims of the '457 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '457 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer.

115. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer.

116. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '457 Patent. On information and belief, Defendants have participated in, directed, controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the

proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

117. Defendants have knowledge of or are willfully blind to the '457 Patent, including due to Genentech's disclosure of the '457 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

118. On information and belief, Defendants' active inducement of infringement of the '457 Patent is and will be willful.

119. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '457 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '457 Patent.

120. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '457 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '457 Patent.

121. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '457 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

122. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '457 Patent. Genentech does not have an adequate remedy at law.

123. Unless Defendants are enjoined from actively inducing infringement of the '457 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

124. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '457 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT III
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,655,305)

125. The allegations of paragraphs 1–124 are repeated and incorporated herein by reference.

126. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer.

127. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '305 Patent.

128. Defendants committed an act or acts of infringement with respect to the '305 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

129. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '305 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

130. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

131. The '305 Patent includes two claims, both of which are independent. Claim 1 recites:

> A method for the treatment of a human patient with HER2-positive metastatic breast cancer who has not received prior anti-HER2 therapy or chemotherapy for metastatic disease, comprising administering to the patient an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein: the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks; the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks; and the docetaxel is administered by intravenous infusion every three weeks for at least

six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

132. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '305 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in patients with HER2-positive metastatic breast cancer, will actively induce infringement of one or more claims of the '305 Patent under 35 U.S.C. § 271(b), including at least claim 1.

133. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '305 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '305 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

134. Biocon Biologics Inc.'s submission of the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar infringed the '305 Patent under 35 U.S.C. § 271(e)(2)(C).

135. Defendants have knowledge of or are willfully blind to the '305 Patent, including due to Genentech's disclosure of the '305 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

136. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to a method for the treatment of a human patient with HER2-positive metastatic breast cancer who has not received prior anti-HER2 therapy or chemotherapy for metastatic disease, comprising administering to the patient an effective amount of a combination of pertuzumab, trastuzumab, and docetaxel, wherein: the pertuzumab is administered by intravenous infusion, at a fixed loading dose of 840 mg, followed by administration of a fixed dose of 420 mg every three weeks; the trastuzumab is administered by intravenous infusion at a loading dose of 8 mg/kg, followed by administration of a dose of 6 mg/kg every three weeks; and the docetaxel is administered by intravenous infusion every three weeks for at least six cycles, wherein the initial dose of docetaxel is 75 mg/m^2 and is increased to 100 mg/m^2 if the patient tolerates the initial dose.

137. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the '305 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the '305 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the '305 Patent.

138. On information and belief, Defendants' active inducement of infringement of the '305 Patent is and will be willful.

139. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the '305 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

140. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '305 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

141. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '305 Patent, will cause and/or has caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT IV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,655,305)

142. The allegations of paragraphs 1–141 are repeated and incorporated herein by reference.

143. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '305 Patent.

144. As set forth in Count III, healthcare providers would directly infringe one or more claims of the '305 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '305 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer.

145. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive metastatic breast cancer.

146. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '305 Patent. On information and belief, Defendants have participated in, directed, controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

147. Defendants have knowledge of or are willfully blind to the '305 Patent, including due to Genentech's disclosure of the '305 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

148. On information and belief, Defendants' active inducement of infringement of the '305 Patent is and will be willful.

149. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '305 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '305 Patent, including at least claim 1.

150. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '305 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '305 Patent.

151. Genentech therefore seeks declaratory judgment that Defendants actively induce infringement of one or more claims of the '305 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

152. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '305 Patent. Genentech does not have an adequate remedy at law.

153. Unless Defendants are enjoined from actively inducing infringement of the '305 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

154. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '305 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT V
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,077,189)

155. The allegations of paragraphs 1–154 are repeated and incorporated herein by reference.

156. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence.

157. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '189 Patent.

158. Defendants committed an act or acts of infringement with respect to the '189 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the

commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

159. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '189 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

160. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

161. The '189 Patent includes four claims, one of which is independent. Claim 1 recites:

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

> wherein said IDFS at 3 years from initial administration in said patients is increased compared to patients to whom anthracycline-based chemotherapy, taxane, and trastuzumab without pertuzumab are administered, wherein the cardiac toxicity is a LVEF decline ≥10 points from baseline and a drop to less than 50%, and wherein said high risk patients are node positive or hormone receptor negative.

162. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '189 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence, will actively induce infringement of one or more claims of the '189 Patent under 35 U.S.C. § 271(b), including at least claim 1.

163. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '189 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '189 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

164. Biocon Biologics Inc.'s submission of the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar infringed the '189 Patent under 35 U.S.C. § 271(e)(2)(C).

165. Defendants have knowledge of or are willfully blind to the '189 Patent, including due to Genentech's disclosure of the '189 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

166. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to 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.

167. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the '189 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the '189 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the '189 Patent.

168. On information and belief, Defendants' active inducement of infringement of the '189 Patent is and will be willful.

169. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the '189 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

170. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '189 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

171. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '189 Patent, will cause and/or has

caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT VI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,077,189)

172. The allegations of paragraphs 1–171 are repeated and incorporated herein by reference.

173. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '189 Patent.

174. As set forth in Count V, healthcare providers would directly infringe one or more claims of the '189 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '189 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence.

175. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with

proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence.

176. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '189 Patent. On information and belief, Defendants have participated in, directed, controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

177. Defendants have knowledge of or are willfully blind to the '189 Patent, including due to Genentech's disclosure of the '189 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

178. On information and belief, Defendants' active inducement of infringement of the '189 Patent is and will be willful.

179. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '189 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '189 Patent, including at least claim 1.

180. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '189 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within

the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon Biologics Inc.'s proposed labeling, prior to the expiration of the '189 Patent.

181. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '189 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

182. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '189 Patent. Genentech does not have an adequate remedy at law.

183. Unless Defendants are enjoined from actively inducing infringement of the '189 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

184. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '189 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT VII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,638,756)

185. The allegations of paragraphs 1–184 are repeated and incorporated herein by reference.

186. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence.

187. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '756 Patent.

188. Defendants committed an act or acts of infringement with respect to the '756 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

189. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '756 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

190. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

191. The ’756 Patent includes fifteen claims, two of which are independent. Claim 1 recites:

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

192. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon’s proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the ’756 Patent, including at least claim 1. On information and belief, Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence, will actively induce infringement of one or more claims of the ’756 Patent under 35 U.S.C. § 271(b), including at least claim 1.

193. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '756 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '756 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar biological product that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

194. Biocon Biologics Inc.'s submission of the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar infringed the '756 Patent under 35 U.S.C. § 271(e)(2)(C).

195. Defendants have knowledge of or are willfully blind to the '756 Patent, including due to Genentech's disclosure of the '756 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

196. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to a method of increasing invasive disease free survival (IDFS) at 3 years in HER2-positive early breast cancer patients without increase in cardiac toxicity, wherein the patients have a high risk of cancer recurrence, have a baseline left ventricular ejection fraction (LVEF) ≥55%, and have not received prior anti-HER2 therapy, comprising administering to said patients, following surgery, pertuzumab, trastuzumab, and non-anthracycline containing chemotherapy, wherein the non-anthracycline containing chemotherapy comprises 6 cycles every 3 weeks of 75 mg/m^2 docetaxel

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

197. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the ’756 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the ’756 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’756 Patent.

198. On information and belief, Defendants’ active inducement of infringement of the ’756 Patent is and will be willful.

199. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the ’756 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

200. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '756 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

201. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '756 Patent, will cause and/or has caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT VIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,638,756)

202. The allegations of paragraphs 1–201 are repeated and incorporated herein by reference.

203. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '756 Patent.

204. As set forth in Count VII, healthcare providers would directly infringe one or more claims of the '756 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '756 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling

that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence.

205. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer, including in patients at high risk of cancer recurrence.

206. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '756 Patent. On information and belief, Defendants have participated in, directed, controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

207. Defendants have knowledge of or are willfully blind to the '756 Patent, including due to Genentech's disclosure of the '756 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

208. On information and belief, Defendants' active inducement of infringement of the '756 Patent is and will be willful.

209. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import

the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '756 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '756 Patent, including at least claim 1.

210. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '756 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '756 Patent.

211. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '756 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

212. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '756 Patent. Genentech does not have an adequate remedy at law.

213. Unless Defendants are enjoined from actively inducing infringement of the '756 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

214. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '756 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT IX
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,992,529)

215. The allegations of paragraphs 1–214 are repeated and incorporated herein by reference.

216. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative.

217. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '529 Patent.

218. Defendants committed an act or acts of infringement with respect to the '529 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

219. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with

Biocon's proposed labeling, will infringe one or more claims of the '529 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

220. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

221. The '529 Patent includes eleven claims, one of which is independent. Claim 1 recites:

> A method of adjuvant therapy for increasing invasive disease free survival (IDFS) at 3 years in patients with HER2-positive, node positive or hormone receptor negative, early breast cancer, comprising administering to said patients, following surgery:
>
> (a) anthracycline-based chemotherapy comprising:
>
> (i) 3 or 4 cycles of 5-fluorouracil+epirubicin+cyclophosphamide (FEC) or 5-fluorouracil+doxorubicin+cyclophosphamide (FAC); or
>
> (ii) 4 cycles of doxorubicin+cyclophosphamide (AC) or epirubicin+cyclophosphamide (EC);
>
> (b) following said anthracycline-based chemotherapy, pertuzumab, trastuzumab, and taxane-based chemotherapy, wherein:
>
> (i) pertuzumab and trastuzumab are each administered intravenously starting on Day 1 of a first taxane-containing cycle and administered for 52 weeks;
>
> (ii) an initial dose of pertuzumab is 840 mg followed every 3 weeks by 420 mg pertuzumab;
>
> (iii) an initial dose of trastuzumab is 8 mg/kg followed every 3 weeks by 6 mg/kg trastuzumab; and
>
> (iv) said taxane-based chemotherapy comprises 3 or 4 cycles of 75 mg/m^2 and/or 100 mg/m^2 docetaxel every 3 weeks or 12 cycles of 80 mg/m^2 paclitaxel every week; and

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

222. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '529 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative, will actively induce infringement of one or more claims of the '529 Patent under 35 U.S.C. § 271(b), including at least claim 1.

223. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '529 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '529 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

224. Biocon Biologics Inc.'s submission of the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar infringed the '529 Patent under 35 U.S.C. § 271(e)(2)(C).

225. Defendants have knowledge of or are willfully blind to the ’529 Patent, including due to Genentech’s disclosure of the ’529 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

226. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to 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..

227. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce

infringement of the ’529 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the ’529 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’529 Patent.

228. On information and belief, Defendants’ active inducement of infringement of the ’529 Patent is and will be willful.

229. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the ’529 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

230. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’529 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

231. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’529 Patent, will cause and/or has caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT X
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,992,529)

232. The allegations of paragraphs 1–231 are repeated and incorporated herein by reference.

233. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A

judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '529 Patent.

234. As set forth in Count IX, healthcare providers would directly infringe one or more claims of the '529 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '529 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative .

235. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative.

236. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '529 Patent. On information and belief, Defendants have participated in, directed,

controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

237. Defendants have knowledge of or are willfully blind to the '529 Patent, including due to Genentech's disclosure of the '529 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

238. On information and belief, Defendants' active inducement of infringement of the '529 Patent is and will be willful.

239. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '529 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants actively induce infringement of one or more claims of the '529 Patent, including at least claim 1.

240. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '529 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '529 Patent.

241. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '529 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

242. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '529 Patent. Genentech does not have an adequate remedy at law.

243. Unless Defendants are enjoined from actively inducing infringement of the '529 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

244. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '529 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XI
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,128,103)

245. The allegations of paragraphs 1–244 are repeated and incorporated herein by reference.

246. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative.

247. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '103 Patent.

248. Defendants committed an act or acts of infringement with respect to the '103 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

249. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '103 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

250. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

251. The '103 Patent includes twenty-five claims, two of which are independent. Claim 1 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 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/m^2 or 100 mg/m^2 docetaxel every 3 weeks or 12 cycles of 80 mg/m^2 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.

252. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '103 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative, will actively induce infringement of one or more claims of the '103 Patent under 35 U.S.C. § 271(b), including at least claim 1.

253. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '103 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '103 Patent will be infringed by the commercial

marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

254. Biocon Biologics Inc.'s submission of the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar infringed the '103 Patent under 35 U.S.C. § 271(e)(2)(C).

255. Defendants have knowledge of or are willfully blind to the '103 Patent, including due to Genentech's disclosure of the '103 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

256. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar 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 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 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.

257. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the '103 Patent upon FDA approval and will do so with specific intent to induce infringement of the '103 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the '103 Patent.

258. On information and belief, Defendants' active inducement of infringement of the '103 Patent is and will be willful.

259. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the '103 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

260. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '103 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

261. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '103 Patent, will cause and/or has caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT XII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,128,103)

262. The allegations of paragraphs 1–261 are repeated and incorporated herein by reference.

263. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '103 Patent.

264. As set forth in Count XI, healthcare providers would directly infringe one or more claims of the '103 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '103 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative.

265. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in adjuvant treatment regimens for HER2-positive early breast cancer that is node positive or hormone receptor negative.

266. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval and prior to the expiration of the '103 Patent. On information and belief, Defendants have participated in, directed, controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

267. Defendants have knowledge of or are willfully blind to the '103 Patent, including due to Genentech's disclosure of the '103 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

268. On information and belief, Defendants' active inducement of infringement of the '103 Patent is and will be willful.

269. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '103 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe and actively induce infringement of one or more claims of the '103 Patent, including at least claim 1.

270. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '103 Patent, literally or under the doctrine of equivalents, including at least claim 1, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '103 Patent.

271. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '103 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

272. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '103 Patent. Genentech does not have an adequate remedy at law.

273. Unless Defendants are enjoined from actively inducing infringement of the '103 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

274. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '103 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XIII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,527,867)

275. The allegations of paragraphs 1–274 are repeated and incorporated herein by reference.

276. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in neoadjuvant treatment regimens for HER2-positive breast cancer.

277. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '867 Patent.

278. Defendants committed an act or acts of infringement with respect to the '867 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of the Proposed Biocon Pertuzumab Biosimilar.

279. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '867 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

280. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted

in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

281. The ’867 Patent includes thirteen claims, four of which are independent. Claim 1 recites:

> A method of achieving a pathological complete response in a human patient with HER2-positive, estrogen receptor-negative and progesterone receptor-negative breast cancer comprising administering 6 cycles of Pertuzumab, Trastuzumab, Docetaxel, and Carboplatin as a neoadjuvant therapy to the patient every 3 weeks prior to surgery in order to achieve the pathological complete response, wherein:
>
> (a) the Docetaxel dose is 75 mg/m2 for all 6 cycles;
>
> (b) the Carboplatin dose is area under the curve equals 6 (AUC6) using Calvert’s Formula;
>
> (c) the Trastuzumab is a monoclonal antibody comprising the light chain amino acid sequence in SEQ ID NO: 13 and the heavy chain amino acid sequence in SEQ ID NO: 14, and the Trastuzumab dose is 8 mg/kg on day 1 of a first treatment and 6 mg/kg every 3 weeks thereafter;
>
> (d) the Pertuzumab is a monoclonal antibody comprising the light chain amino acid sequence in SEQ ID NO: 11 and the heavy chain amino acid sequence in SEQ ID NO: 12, and the Pertuzumab dose is 840 mg on day 1 of a first treatment and 420 mg every 3 weeks thereafter;
>
> (e) the Pertuzumab, Trastuzumab, Docetaxel, and Carboplatin are administered intravenously to the patient on day 1 of each cycle for all 6 cycles;
>
> (f) the HER2-positive breast cancer has HER2 protein overexpression or HER2 gene amplification; and
>
> (g) the HER2-positive breast cancer is early-stage and > 2 cm in diameter.

282. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon’s proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the ’867 Patent, including at least claim 1. On

information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in neoadjuvant treatment regimens for HER2-positive breast cancer, will actively induce infringement of one or more claims of the '867 Patent under 35 U.S.C. § 271(b), including at least claim 1.

283. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '867 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '867 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

284. Biocon Biologics Inc.'s submission of the Biocon aBLA for the Proposed Biocon Pertuzumab Biosimilar infringed the '867 Patent under 35 U.S.C. § 271(e)(2)(C).

285. Defendants have knowledge of or are willfully blind to the '867 Patent, including due to Genentech's disclosure of the '867 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

286. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in a method of

achieving a pathological complete response in a human patient with HER2-positive, estrogen receptor-negative and progesterone receptor-negative breast cancer comprising administering 6 cycles of Pertuzumab, Trastuzumab, Docetaxel, and Carboplatin as a neoadjuvant therapy to the patient every 3 weeks prior to surgery in order to achieve the pathological complete response, wherein: (a) the Docetaxel dose is 75 mg/m2 for all 6 cycles; (b) the Carboplatin dose is area under the curve equals 6 (AUC6) using Calvert's Formula; (c) the Trastuzumab is a monoclonal antibody comprising the light chain amino acid sequence in SEQ ID NO: 13 and the heavy chain amino acid sequence in SEQ ID NO: 14, and the Trastuzumab dose is 8 mg/kg on day 1 of a first treatment and 6 mg/kg every 3 weeks thereafter; (d) the Pertuzumab is a monoclonal antibody comprising the light chain amino acid sequence in SEQ ID NO: 11 and the heavy chain amino acid sequence in SEQ ID NO: 12, and the Pertuzumab dose is 840 mg on day 1 of a first treatment and 420 mg every 3 weeks thereafter; (e) the Pertuzumab, Trastuzumab, Docetaxel, and Carboplatin are administered intravenously to the patient on day 1 of each cycle for all 6 cycles; (f) the HER2-positive breast cancer has HER2 protein overexpression or HER2 gene amplification; and (g) the HER2-positive breast cancer is early-stage and >2 cm in diameter.

287. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the ’867 Patent upon FDA approval and will do so with specific intent to induce infringement of the ’867 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’867 Patent.

288. On information and belief, Defendants’ active inducement of infringement of the ’867 Patent is and will be willful.

289. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the '867 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

290. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '867 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

291. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '867 Patent, will cause and/or has caused injury to Genentech, entitling Genentech to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

COUNT XIV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,527,867)

292. The allegations of paragraphs 1–291 are repeated and incorporated herein by reference.

293. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '867 Patent.

294. As set forth in Count XIII, healthcare providers would directly infringe one or more claims of the '867 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '867 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in neoadjuvant treatment regimens for HER2-positive breast cancer.

295. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in neoadjuvant treatment regimens for HER2-positive breast cancer.

296. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval and prior to the expiration of the '867 Patent. On information and belief, Defendants have participated in, directed, controlled, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

297. Defendants have knowledge of or are willfully blind to the '867 Patent, including due to Genentech's disclosure of the '867 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

298. On information and belief, Defendants' active inducement of infringement of the '867 Patent is and will be willful.

299. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '867 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '867 Patent, including at least claim 1.

300. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '867 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '867 Patent.

301. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '867 Patent, including at least claim 1, under 35 U.S.C. § 271(b).

302. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '867 Patent. Genentech does not have an adequate remedy at law.

303. Unless Defendants are enjoined from actively inducing infringement of the '867 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

304. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '867 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XV
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,427,193)

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

306. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive breast cancer.

307. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '193 Patent.

308. Defendants committed an act or acts of infringement with respect to the '193 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or

importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '193 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

309. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

310. The '193 Patent includes four claims, two of which are independent. Claim 1 recites:

> A method of treating HER2-positive breast cancer in a patient comprising administering a highly concentrated, stable pharmaceutical formulation of Trastuzumab to the patient, wherein the Trastuzumab formulation comprises 120 mg/mL Trastuzumab, 20 mM L-histidine/HCl pH 5.5, 210 mM α,α-trehalose dihydrate, 10 mM methionine, 0.04% polysorbate 20, and 2000 U/mL hyaluronidase, and is administered subcutaneously, and wherein the method further comprises administering Pertuzumab to the patient.

311. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '193 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive breast cancer, will actively induce infringement of one or more claims of the '193 Patent under 35 U.S.C. § 271(b), including at least claim 1.

312. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '193 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '193 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

313. Defendants have knowledge of or are willfully blind to the '193 Patent, including due to Genentech's disclosure of the '193 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

314. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to a method of treating HER2-positive breast cancer in a patient comprising administering a highly concentrated, stable pharmaceutical formulation of Trastuzumab to the patient, wherein the Trastuzumab formulation comprises 120 mg/mL Trastuzumab, 20 mM L-histidine/HCl pH 5.5, 210 mM α,α-trehalose dihydrate, 10 mM methionine, 0.04% polysorbate 20, and 2000 U/mL hyaluronidase, and is administered subcutaneously, and wherein the method further comprises administering Pertuzumab to the patient.

315. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce

infringement of the ’193 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the ’193 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’193 Patent.

316. On information and belief, Defendants’ active inducement of infringement of the ’193 Patent is and will be willful.

317. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the ’193 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

318. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’193 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

319. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’193 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).

COUNT XVI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,427,193)

320. The allegations of paragraphs 1–319 are repeated and incorporated herein by reference.

321. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A

judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '193 Patent.

322. As set forth in Count XV, healthcare providers would directly infringe one or more claims of the '193 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '193 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive breast cancer.

323. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive breast cancer.

324. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '193 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon

aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

325. Defendants have knowledge of or are willfully blind to the '193 Patent, including due to Genentech's disclosure of the '193 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

326. On information and belief, Defendants' active inducement of infringement of the '193 Patent is and will be willful.

327. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '193 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '193 Patent.

328. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '193 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '193 Patent.

329. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '193 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b).

330. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '193 Patent. Genentech does not have an adequate remedy at law.

331. Unless Defendants are enjoined from actively inducing infringement of the '193 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

332. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '193 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XVII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,833,206)

333. The allegations of paragraphs 1–332 are repeated and incorporated herein by reference.

334. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to the FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

335. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '206 Patent.

336. Defendants committed an act or acts of infringement with respect to the '206 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

337. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '206 Patent under 35 U.S.C. §§ 271(a)-(c), literally or under the doctrine of equivalents.

338. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

339. The '206 Patent includes twenty-nine claims, two of which are independent. Claim 1 recites:

> A polysorbate 20 composition comprising fatty acid esters comprising 1.0% or less caproate, greater than or equal to 2.6% and less than or equal to 6.6% caprylate, greater than or equal to 2.4% and less than or equal to 6.4% caprate, greater than or equal to 55.0% and less than or equal to 60.0% laurate, greater than or equal to 14.1% and less than or equal to 18.1% myristate, greater than or equal to 7.0% and less than or equal to 10.9% palmitate, and less than or equal to 2.0% stearate.

340. Based on confidential information disclosed to Genentech by Biocon pursuant to 42 U.S.C. § 262(*l*)(2), Biocon's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '206 Patent is an act of infringement of one

or more of the claims of the '206 Patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

341. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe, actively induce infringement by others, or contribute to the infringement by others of at least claim 1 of the '206 Patent under 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents.

342. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '206 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '206 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

343. Defendants have knowledge of or are willfully blind to the '206 Patent, including due to Genentech's disclosure of the '206 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

344. On information and belief, Defendants' infringement, active inducement of infringement, and contributory infringement of the '206 Patent are and will be willful.

345. Genentech will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to the infringement of one or more claims of the '206 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

346. To the extent Biocon commercializes its product prior to the expiration of the '206 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

347. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '206 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).

COUNT XVIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,833,206)

348. The allegations of paragraphs 1–347 are repeated and incorporated herein by reference.

349. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. §§ 271(a), (b), and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use,

offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '206 Patent.

350. As set forth in Count XVII, Defendants would infringe the '206 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '206 Patent.

351. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

352. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '206 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

353. Defendants have knowledge of or are willfully blind to the '206 Patent, including due to Genentech's disclosure of the '206 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

354. On information and belief, Defendants' infringement, active inducement of infringement, and contributory infringement of the '206 Patent are and will be willful.

355. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import

the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’206 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the ’206 Patent.

356. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’206 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

357. Genentech therefore seeks declaratory judgment that Defendants will infringe, actively induce infringement of, or contributorily infringe one or more claims of the ’206 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

358. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’206 Patent. Genentech does not have an adequate remedy at law.

359. Unless Defendants are enjoined from infringing, actively inducing infringement, or contributorily infringing the ’206 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

360. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’206 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XIX
(PATENT INFRINGEMENT OF U.S. PATENT NO. 8,652,474)

361. The allegations of paragraphs 1–360 are repeated and incorporated herein by reference.

362. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

363. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '474 Patent.

364. Defendants committed an act or acts of infringement with respect to the '474 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

365. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '474 Patent under 35 U.S.C. §§ 271(a)-(c), literally or under the doctrine of equivalents.

366. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted

in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

367. The ’474 Patent includes sixteen claims, four of which are independent. Claim 1 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.

368. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the ’474 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

369. Based on confidential information disclosed to Genentech by Biocon pursuant to 42 U.S.C. § 262(*l*)(2), Biocon’s submission of its aBLA to obtain approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’474 Patent is an act of infringement of one or more of the claims of the ’474 Patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

370. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon’s commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe, actively induce infringement by others, or

contribute to the infringement by others of at least claim 1 of the '474 patent under 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents.

371. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '474 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '474 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

372. Defendants have knowledge of or are willfully blind to the '474 Patent, including due to Genentech's disclosure of the '474 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

373. On information and belief, Defendants' infringement, active inducement of infringement, and contributory infringement of the '474 Patent are and will be willful.

374. Genentech will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to infringement of one or more claims of the '474 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

375. To the extent Biocon commercializes the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '474 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

376. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '474 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).

COUNT XX
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,652,474)

377. The allegations of paragraphs 1–376 are repeated and incorporated herein by reference.

378. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. §§ 271(a), (b), and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '474 Patent.

379. As set forth in Count XIX, Defendants would infringe the '474 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '474 Patent.

380. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

381. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '474 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

382. Defendants have knowledge of or are willfully blind to the '474 Patent, including due to Genentech's disclosure of the '474 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

383. On information and belief, Defendants' infringement, active inducement of infringement, and contributory infringement of the '474 Patent are and will be willful.

384. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '474 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '474 Patent.

385. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '474 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

386. Genentech therefore seeks declaratory judgment that Defendants will infringe, actively induce infringement of, or contributorily infringe one or more claims of the '474 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

387. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '474 Patent. Genentech does not have an adequate remedy at law.

388. Unless Defendants are enjoined from infringing, actively inducing infringement, or contributorily infringing the '474 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

389. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '474 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXI
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,181,346)

390. The allegations of paragraphs 1–389 are repeated and incorporated herein by reference.

391. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct

and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer.

392. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '346 Patent.

393. Defendants committed an act or acts of infringement with respect to the '346 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

394. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '346 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

395. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

396. The '346 Patent includes twenty-six claims, three of which are independent. Claim 1 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.

397. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '346 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer, will actively induce infringement of one or more claims of the '346 Patent under 35 U.S.C. § 271(b), including at least claim 1.

398. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '346 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '346 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

399. Defendants have knowledge of or are willfully blind to the '346 Patent, including due to Genentech's disclosure of the '346 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

400. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to 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..

401. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the ’346 Patent upon FDA approval and will do so with specific intent to induce infringement of the ’346 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’346 Patent.

402. On information and belief, Defendants’ active inducement of infringement of the ’346 Patent is and will be willful.

403. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the ’346 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

404. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '346 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

405. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '346 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).

COUNT XXII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,181,346)

406. The allegations of paragraphs 1–405 are repeated and incorporated herein by reference.

407. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '346 Patent.

408. As set forth in Count XXI, healthcare providers would directly infringe one or more claims of the '346 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '346 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling

that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer.

409. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer.

410. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '346 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned U.S. launch of the Proposed Biocon Pertuzumab Biosimilar.

411. Defendants have knowledge of or are willfully blind to the '346 Patent, including due to Genentech's disclosure of the '346 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

412. On information and belief, Defendants' active inducement of infringement of the '346 Patent is and will be willful.

413. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '346 Patent creates an

actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the ’346 Patent.

414. Genentech is entitled to a declaratory judgment that Biocon will actively induce infringement of one or more claims of the ’346 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon’s proposed labeling, prior to the expiration of the ’346 Patent.

415. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the ’346 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b).

416. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’346 Patent. Genentech does not have an adequate remedy at law.

417. Unless Defendants are enjoined from actively inducing infringement of the ’346 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

418. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’346 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXIII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,414,498)

419. The allegations of paragraphs 1–418 are repeated and incorporated herein by reference.

420. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

421. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '498 Patent.

422. Defendants committed an act or acts of infringement with respect to the '498 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '498 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

423. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

424. The ’498 Patent includes thirty-one claims, two of which are independent. Claim 1 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%.

425. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the ’498 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

426. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon’s commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the ’498 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

427. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the ’498 Patent, on a claim by claim basis, the factual and legal bases of Genentech’s opinion that the ’498 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech’s detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

428. Defendants have knowledge of or are willfully blind to the '498 Patent, including due to Genentech's disclosure of the '498 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

429. On information and belief, Defendants' infringement of the '498 Patent is and will be willful.

430. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '498 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

431. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '498 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

432. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '498 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).

COUNT XXIV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,414,498)

433. The allegations of paragraphs 1–432 are repeated and incorporated herein by reference.

434. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '498 Patent.

435. As set forth in Count XXII, Biocon would infringe the '498 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '498 Patent.

436. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

437. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '498 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

438. Defendants have knowledge of or are willfully blind to the '498 Patent, including due to Genentech's disclosure of the '498 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

439. On information and belief, Defendants' infringement of the '498 Patent is and will be willful.

440. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '498 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '498 Patent.

441. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '498 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

442. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '498 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

443. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '498 Patent. Genentech does not have an adequate remedy at law.

444. Unless Defendants are enjoined from infringing the '498 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

445. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the

expiration of the ’498 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXV
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,597,776)

446. The allegations of paragraphs 1–445 are repeated and incorporated herein by reference.

447. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

448. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’776 Patent.

449. Defendants committed an act or acts of infringement with respect to the ’776 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the ’776 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

450. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted

in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

451. The ’776 Patent includes thirty claims, four of which are independent. Claim 1 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.

452. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the ’776 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

453. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon’s commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the ’776 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

454. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the ’776 Patent, on a claim by claim basis, the factual and legal bases of Genentech’s opinion that the ’776 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech’s detailed statement includes, refers to, and relies on confidential information that

Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

455. Defendants have knowledge of or are willfully blind to the '776 Patent, including due to Genentech's disclosure of the '776 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

456. On information and belief, Defendants' infringement of the '776 Patent is and will be willful.

457. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '776 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

458. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '776 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

459. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '776 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).

COUNT XXVI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,597,776)

460. The allegations of paragraphs 1–459 are repeated and incorporated herein by reference.

461. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '776 Patent.

462. As set forth in Count XXV, Defendants would infringe the '776 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '776 Patent.

463. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

464. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '776 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

465. Defendants have knowledge of or are willfully blind to the '776 Patent, including due to Genentech's disclosure of the '776 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

466. On information and belief, Defendants' infringement of the '776 Patent is and will be willful.

467. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '776 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '776 Patent.

468. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '776 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

469. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '776 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

470. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '776 Patent. Genentech does not have an adequate remedy at law.

471. Unless Defendants are enjoined from infringing the ’776 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

472. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’776 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXVII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,110,341)

473. The allegations of paragraphs 1–472 are repeated and incorporated herein by reference.

474. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer.

475. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’341 Patent.

476. Defendants committed an act or acts of infringement with respect to the ’341 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants,

submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

477. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '341 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

478. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

479. The '341 Patent includes thirty claims, four of which are independent. Claim 1 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.

480. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '341 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling

that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer, will actively induce infringement of one or more claims of the '341 Patent under 35 U.S.C. § 271(b), including at least claim 1.

481. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '341 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '341 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

482. Defendants have knowledge of or are willfully blind to the '341 Patent, including due to Genentech's disclosure of the '341 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

483. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar, in 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.

484. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the ’341 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the ’341 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the ’341 Patent.

485. On information and belief, Defendants’ active inducement of infringement of the ’341 Patent is and will be willful.

486. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement of one or more claims of the ’341 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

487. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’341 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

488. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’341 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).

COUNT XXVIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,110,341)

489. The allegations of paragraphs 1–488 are repeated and incorporated herein by reference.

490. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271((b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '341 Patent.

491. As set forth in Count XXVII, healthcare providers would directly infringe one or more claims of the '341 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '341 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer.

492. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for HER2-positive cancer.

493. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '341 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

494. Defendants have knowledge of or are willfully blind to the '341 Patent, including due to Genentech's disclosure of the '341 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

495. On information and belief, Defendants' active inducement of infringement of the '341 Patent will be willful.

496. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '341 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the '341 Patent.

497. Genentech is entitled to a declaratory judgment that Defendants will actively induce infringement of one or more claims of the '341 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab

Biosimilar, including through Biocon's proposed labeling, prior to the expiration of the '341 Patent.

498. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the '341 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b).

499. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '341 Patent. Genentech does not have an adequate remedy at law.

500. Unless Defendants are enjoined from actively inducing infringement, of the '341 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

501. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '341 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXIX
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,815,904)

502. The allegations of paragraphs 1–501 are repeated and incorporated herein by reference.

503. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use,

offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

504. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '904 Patent.

505. Defendants committed an act or acts of infringement with respect to the '904 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '904 Patent under 35 U.S.C. §§ 271(a)-(c), literally or under the doctrine of equivalents.

506. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

507. The '904 Patent includes fifteen claims, three of which are independent. Claim 1 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.

508. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or

more claims of the '904 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

509. Based on confidential information disclosed to Genentech by Biocon pursuant to 42 U.S.C. § 262(*l*)(2), Biocon's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '904 Patent is an act of infringement of one or more of the claims of the '904 Patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

510. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the composition, indications, dosage, and methods of use for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe, actively induce infringement by others, or contribute to the infringement by others of at least claim 1 of the '904 Patent under 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents.

511. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '904 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '904 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

512. Defendants have knowledge of or are willfully blind to the '904 Patent, including due to Genentech's disclosure of the '904 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

513. On information and belief, Defendants' infringement, active inducement of infringement, and contributory infringement of the '904 Patent are and will be willful.

514. Genentech will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to infringement of one or more claims of the '904 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

515. To the extent Biocon commercializes the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '904 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

516. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '904 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).

COUNT XXX
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,815,904)

517. The allegations of paragraphs 1–516 are repeated and incorporated herein by reference.

518. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. §§ 271(a), (b), and/or (c). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '904 Patent.

519. As set forth in Count XXIX, Defendants would infringe the '904 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '904 Patent.

520. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

521. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '904 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned U.S. launch of the Proposed Biocon Pertuzumab Biosimilar.

522. Defendants have knowledge of or are willfully blind to the '904 Patent, including due to Genentech's disclosure of the '904 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

523. On information and belief, Defendants' infringement, active inducement of infringement, and contributory infringement of the '904 Patent are and will be willful.

524. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '904 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '904 Patent.

525. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '904 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

526. Genentech therefore seeks declaratory judgment that Defendants will infringe, actively induce infringement of, or contributorily infringe one or more claims of the '904 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

527. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '904 Patent. Genentech does not have an adequate remedy at law.

528. Unless Defendants are enjoined from infringing, actively inducing infringement, or contributorily infringing the ’904 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

529. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’904 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXXI
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,969,811)

530. The allegations of paragraphs 1–529 are repeated and incorporated herein by reference.

531. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for cancer.

532. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’811 Patent.

533. Defendants committed an act or acts of infringement with respect to the ’811 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., acting in concert with the other

Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

534. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including use in accordance with Biocon's proposed labeling, will infringe one or more claims of the '811 Patent under 35 U.S.C. § 271(b), literally or under the doctrine of equivalents.

535. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

536. The '811 Patent includes two claims, one of which is independent. Claim 1 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.

537. On information and belief, healthcare providers using the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling will administer the Proposed Biocon Pertuzumab Biosimilar in a manner that directly infringes, literally or under the doctrine of equivalents, one or more claims of the '811 Patent, including at least claim 1. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, including through proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab

Biosimilar in treatment regimens for cancer, will actively induce infringement of one or more claims of the '811 Patent under 35 U.S.C. § 271(b), including at least claim 1.

538. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '811 Patent, on a claim-by-claim basis, the factual and legal bases of Genentech's opinion that the '811 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

539. Defendants have knowledge of or are willfully blind to the '811 Patent, including due to Genentech's disclosure of the '811 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

540. On information and belief, Defendants plan to, intend to, and will sell the Proposed Biocon Pertuzumab Biosimilar with instructions and labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar according to 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.

541. By knowingly including the aforementioned instructions and labeling with the Proposed Biocon Pertuzumab Biosimilar, Defendants plan to, intend to, and will actively induce infringement of the '811 Patent upon FDA approval of the Biocon aBLA and will do so with specific intent to induce infringement of the '811 Patent in violation of 35 U.S.C. § 271(b), causing patients and healthcare providers to infringe the '811 Patent. .

542. On information and belief, Defendants' active inducement of infringement of the '811 Patent is and will be willful.

543. Genentech will be irreparably harmed if Defendants are not enjoined from actively inducing infringement one or more claims of the '811 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

544. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '811 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

545. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '811 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).

COUNT XXXII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,969,811)

546. The allegations of paragraphs 1–545 are repeated and incorporated herein by reference.

547. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(b). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '811 Patent.

548. As set forth in Count XXXI, healthcare providers would directly infringe one or more claims of the '811 Patent, literally or under the doctrine of equivalents, if they administer the Proposed Biocon Pertuzumab Biosimilar in accordance with Biocon's proposed labeling prior to the expiration of the '811 Patent. On information and belief, Defendants would actively induce that direct infringement by commercially manufacturing, using, offering to sell, selling, marketing, distributing, and/or importing the Proposed Biocon Pertuzumab Biosimilar with proposed labeling that instructs and encourages healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for cancer.

549. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®, including with proposed labeling that will instruct and encourage healthcare providers to administer the Proposed Biocon Pertuzumab Biosimilar in treatment regimens for cancer.

550. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '811 Patent. On information and belief, Defendants have participated in, directed,

controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, the proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

551. Defendants have knowledge of or are willfully blind to the ’811 Patent, including due to Genentech’s disclosure of the ’811 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

552. On information and belief, Defendants’ active inducement of infringement of the ’811 Patent is and will be willful.

553. Defendants’ submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’811 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will actively induce infringement of one or more claims of the ’811 Patent.

554. Genentech is entitled to a declaratory judgment that Defendants actively induce infringement of one or more claims of the ’811 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar, including through Biocon’s proposed labeling, prior to the expiration of the ’811 Patent.

555. Genentech therefore seeks declaratory judgment that Defendants will actively induce infringement of one or more claims of the ’811 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271 (b).

556. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’811 Patent. Genentech does not have an adequate remedy at law.

557. Unless Defendants are enjoined from actively inducing infringement of the ’811 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

558. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’811 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXXIII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,145,998)

559. The allegations of paragraphs 1–558 are repeated and incorporated herein by reference.

560. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

561. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’998 Patent.

562. Defendants committed an act or acts of infringement with respect to the ’998 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc. submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the ’998 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

563. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

564. The ’998 Patent includes three claims, one of which is independent. Claim 1 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.

565. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the '998 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

566. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '998 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '998 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '998 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

567. Defendants have knowledge of or are willfully blind to the '998 Patent, including due to Genentech's disclosure of the '998 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

568. On information and belief, Defendants' infringement of the '998 Patent is and will be willful.

569. Genentech will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to infringement of one or more claims of the '998 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

570. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '998 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

571. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '998 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).

COUNT XXXIV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,145,998)

572. The allegations of paragraphs 1–571 are repeated and incorporated herein by reference.

573. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for

sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the ’998 Patent.

574. As set forth in Count XXXIII, Defendants would infringe the ’998 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the ’998 Patent.

575. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

576. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the ’998 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon’s proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

577. Defendants have knowledge of or are willfully blind to the ’998 Patent, including due to Genentech’s disclosure of the ’998 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

578. On information and belief, Defendants’ infringement of the ’998 Patent is and will be willful.

579. Defendants’ submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import

the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '998 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '998 Patent.

580. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '998 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

581. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '998 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

582. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '998 Patent. Genentech does not have an adequate remedy at law.

583. Unless Defendants are enjoined from infringing the '998 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

584. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '998 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXXV
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,808,037)

585. The allegations of paragraphs 1–584 are repeated and incorporated herein by reference.

586. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

587. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '037 Patent.

588. Defendants committed an act or acts of infringement with respect to the '037 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

589. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '037 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

590. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted

in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

591. The '037 Patent includes nine claims, one of which is independent. Claim 1 recites:

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

592. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the '037 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

593. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '037 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

594. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '037 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '037 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA.

Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

595. Defendants have knowledge of or are willfully blind to the '037 Patent, including due to Genentech's disclosure of the '037 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

596. On information and belief, Defendants' infringement of the '037 Patent is and will be willful.

597. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '037 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

598. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '037 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

599. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '037 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).

COUNT XXXVI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,808,037)

600. The allegations of paragraphs 1–599 are repeated and incorporated herein by reference.

601. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '037 Patent.

602. As set forth in Count XXXV, Defendants would infringe the '037 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '037 Patent.

603. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

604. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '037 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

605. Defendants have knowledge of or are willfully blind to the '037 Patent, including due to Genentech's disclosure of the '037 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

606. On information and belief, Defendants' infringement of the '037 Patent is and will be willful.

607. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '037 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '037 Patent.

608. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '037 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

609. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '037 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

610. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '037 Patent. Genentech does not have an adequate remedy at law.

611. Unless Defendants are enjoined from infringing the ’037 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

612. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’037 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXXVII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 11,078,294)

613. The allegations of paragraphs 1–612 are repeated and incorporated herein by reference.

614. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

615. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’294 Patent.

616. Defendants committed an act or acts of infringement with respect to the ’294 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon

Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '294 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

617. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

618. The '294 Patent includes eight claims, one of which is independent. Claim 1 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, and wherein the air sparging is continued until the amount of dissolved oxygen (dO_2) in the pre-harvest cell culture fluid is at least 10%.

619. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '294 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

620. On information and belief, the Proposed Biocon Pertuzumab Biosimilar does not have a substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '294 Patent immediately and imminently upon approval

of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA in violation of 35 U.S.C. § 271(c).

621. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '294 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion the '294 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

622. Defendants have knowledge of or are willfully blind to the '294 Patent, including due to Genentech's disclosure of the '294 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

623. On information and belief, Defendants' infringement of the '294 Patent is and will be willful.

624. Genentech will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to infringement of one or more claims of the '294 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

625. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '294 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

626. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '294 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).

COUNT XXXVIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,078,294)

627. The allegations of paragraphs 1–626 are repeated and incorporated herein by reference.

628. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '294 Patent.

629. As set forth in Count XXXVII, Defendants would infringe the '294 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '294 Patent.

630. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

631. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '294 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

632. Defendants have knowledge of or are willfully blind to the '294 Patent, including due to Genentech's disclosure of the '294 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

633. On information and belief, Defendants' infringement of the '294 Patent is and will be willful.

634. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '294 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '294 Patent.

635. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '294 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

636. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the ’294 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

637. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’294 Patent. Genentech does not have an adequate remedy at law.

638. Unless Defendants are enjoined from infringing the ’294 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

639. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’294 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XXXIX
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,145,997)

640. The allegations of paragraphs 1–639 are repeated and incorporated herein by reference.

641. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

642. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '997 Patent.

643. Defendants committed an act or acts of infringement with respect to the '997 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '997 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

644. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

645. The '997 Patent includes eight claims, one of which is independent. Claim 1 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%.

646. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the '997 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

647. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '997 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

648. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '997 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '997 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

649. Defendants have knowledge of or are willfully blind to the '997 Patent, including due to Genentech's disclosure of the '997 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

650. On information and belief, Defendants' infringement of the '997 Patent is and will be willful.

651. Genentech will be irreparably harmed if Defendants are not enjoined from infringing, actively inducing, or contributing to infringement of one or more claims of the '997

Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

652. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '997 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

653. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '997 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).

COUNT XL
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,145,997)

654. The allegations of paragraphs 1–653 are repeated and incorporated herein by reference.

655. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '997 Patent.

656. As set forth in Count XXXIX, Defendants would infringe the '997 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '997 Patent.

657. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

658. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '997 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

659. Defendants have knowledge of or are willfully blind to the '997 Patent, including due to Genentech's disclosure of the '997 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

660. On information and belief, Defendants' infringement of the '997 Patent is and will be willful.

661. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '997 Patent creates an

actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the ’997 Patent.

662. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’997 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

663. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the ’997 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

664. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’997 Patent. Genentech does not have an adequate remedy at law.

665. Unless Defendants are enjoined from infringing the ’997 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

666. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’997 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XLI
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,173,080)

667. The allegations of paragraphs 1–666 are repeated and incorporated herein by reference.

668. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

669. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '080 Patent.

670. Defendants committed an act or acts of infringement with respect to the '080 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '080 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

671. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

672. The '080 Patent includes ten claims, two of which are independent. Claim 1 recites:

673. 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.On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the '080 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

674. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '080 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

675. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '080 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '080 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

676. Defendants have knowledge of or are willfully blind to the '080 Patent, including due to Genentech's disclosure of the '080 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

677. On information and belief, Defendants' infringement of the '080 Patent is and will be willful.

678. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '080 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

679. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '080 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

680. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '080 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).

COUNT XLII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,173,080)

681. The allegations of paragraphs 1–680 are repeated and incorporated herein by reference.

682. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '080 Patent.

683. As set forth in Count XLI, Defendants would infringe the '080 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '080 Patent.

684. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

685. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '080 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

686. Defendants have knowledge of or are willfully blind to the '080 Patent, including due to Genentech's disclosure of the '080 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

687. On information and belief, Defendants' infringement of the '080 Patent is and will be willful.

688. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '080 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '080 Patent.

689. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '080 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

690. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '080 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

691. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '080 Patent. Genentech does not have an adequate remedy at law.

692. Unless Defendants are enjoined from infringing the '080 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

693. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the

expiration of the ’080 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XLIII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,103,975)

694. The allegations of paragraphs 1–693 are repeated and incorporated herein by reference.

695. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to the FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

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

697. Defendants committed an act or acts of infringement with respect to the ’975 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

698. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the ’975 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

699. On information and belief Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

700. The '975 Patent includes twenty-two claims, one of which is independent. Claim 1 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.

701. On information and belief, the manufacture of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more claims of the '975 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

702. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '975 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

703. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon 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 the '975 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA.

Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

704. Defendants have knowledge of or are willfully blind to the '975 Patent, including due to Genentech's disclosure of the '975 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

705. On information and belief, Defendants' infringement of the '975 Patent is and will be willful.

706. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '975 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

707. To the extent Defendants commercialize its product prior to the expiration of the '975 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

708. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon 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).

COUNT XLIV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,103,975)

709. The allegations of paragraphs 1–708 are repeated and incorporated herein by reference.

710. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '975 Patent.

711. As set forth in Count XLIII, Defendants would infringe the '975 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '975 Patent.

712. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

713. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '975 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

714. Defendants have knowledge of or are willfully blind to the ’975 Patent, including due to Genentech’s disclosure of the ’975 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

715. On information and belief, Defendants’ infringement of the ’975 Patent is and will be willful.

716. Defendants’ submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’975 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the ’975 Patent.

717. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’975 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

718. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the ’975 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

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

720. Unless Defendants are enjoined from infringing the ’975 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

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

COUNT XLV
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,351,641)

722. The allegations of paragraphs 1–721 are repeated and incorporated herein by reference.

723. On information and belief, by submitting the Biocon aBLA to the FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

724. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’641 Patent.

725. Defendants committed an act or acts of infringement with respect to the ’641 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the

commercial manufacture, use, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

726. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '641 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

727. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

728. The '641 Patent includes thirty claims, four of which are independent. Claim 1 recites:

> A process for producing a therapeutic IgG antibody in a Chinese hamster ovary (CHO) host cell expressing said therapeutic IgG antibody, wherein the process comprises culturing the CHO host cell in a production phase culture medium that is essentially free of glutamine, wherein the production phase culture medium comprises asparagine provided at a concentration in the range of 2.5 mM to 15 mM, wherein the therapeutic IgG antibody is pertuzumab.

729. On information and belief, the manufacture of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more of the claims of the '641 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

730. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries,

and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '641 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

731. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '641 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '641 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

732. Defendants have knowledge of or are willfully blind to the '641 Patent, including due to Genentech's disclosure of the '641 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

733. On information and belief, Defendants' infringement of the '641 Patent is and will be willful.

734. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '641 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

735. To the extent Defendants commercialize its product prior to the expiration of the '641 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

736. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '641 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).

COUNT XLVI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,351,641)

737. The allegations of paragraphs 1–736 are repeated and incorporated herein by reference.

738. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '641 Patent.

739. As set forth in Count XLV, Defendants would infringe the '641 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '641 Patent.

740. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

741. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the

expiration of the ’641 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon’s proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

742. Defendants have knowledge of or are willfully blind to the ’641 Patent, including due to Genentech’s disclosure of the ’641 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

743. On information and belief, Defendants’ infringement of the ’641 Patent is and will be willful.

744. Defendants’ submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’641 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the ’641 Patent.

745. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’641 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

746. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the ’641 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

747. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Biocon from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '641 Patent. Genentech does not have an adequate remedy at law.

748. Unless Defendants are enjoined from infringing the '641 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

749. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '641 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284

COUNT XLVII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,822,404)

750. The allegations of paragraphs 1–749 are repeated and incorporated herein by reference.

751. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

752. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '404 Patent.

753. Defendants committed an act or acts of infringement with respect to the '404 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

754. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '404 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

755. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

756. The '404 Patent includes twenty-eight claims, one of which is independent. Claim 1 recites:

> A method of purifying a recombinant antibody produced in Chinese hamster ovary host cells and having phospholipase B-like 2 (PLBL2) levels greater than 100 ng/mg, wherein the method comprises performing a hydrophobic interaction chromatography (HIC) step and provides a purified preparation comprising the recombinant antibody and a residual amount of hamster PLBL2, and wherein the residual amount of hamster PLBL2 is less than 20 ng/mg.

757. On information and belief, the manufacture of Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more of the claims of the '404 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

758. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential

information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '404 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

759. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '404 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '404 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon provided to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). Genentech is not permitted to include confidential information provided by Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

760. Defendants have knowledge of or are willfully blind to the '404 Patent, including due to Genentech's disclosure of the '404 Patent under 42 U.S.C. § 262(*l*)(3)(A); Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

761. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '404 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

762. To the extent Defendants commercialize its product prior to the expiration of the '404 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

763. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '404 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).

COUNT XLVIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,822,404)

764. The allegations of paragraphs 1–763 are repeated and incorporated herein by reference.

765. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '404 Patent.

766. As set forth in Count XLVII, Defendants would infringe the '404 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '404 Patent.

767. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

768. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the

expiration of the '404 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

769. Defendants have knowledge of or are willfully blind to the '404 Patent, including due to Genentech's disclosure of the '404 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

770. On information and belief, Defendants' infringement of the '404 Patent is and will be willful.

771. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '404 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '404 Patent.

772. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '404 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

773. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '404 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

774. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '404 Patent. Genentech does not have an adequate remedy at law.

775. Unless Defendants are enjoined from infringing the '404 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

776. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '404 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT XLIX
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,152,054)

777. The allegations of paragraphs 1–776 are repeated and incorporated herein by reference.

778. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

779. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '054 Patent.

780. Defendants committed an act or acts of infringement with respect to the ’054 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

781. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the ’054 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

782. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

783. The ’054 Patent includes twenty-seven claims, one of which is independent. Claim 1 of the ’054 Patent recites:

> A method for purifying an antibody or immunoadhesin from a composition comprising the antibody or immunoadhesin and at least one contaminant, wherein the method comprises either (i) or (ii):
>
> (i) sequential steps of (a) loading the composition onto a cation exchange material at a loading density of greater than about 150 g/L of cation exchange material; and (b) loading a composition recovered from the cation exchange material as an unbound fraction onto a mixed mode material; or
>
> (ii) sequential steps of (a) loading the composition onto a mixed mode material; and (b) loading a composition recovered from mixed mode material as an unbound fraction onto a cation exchange material at a loading density of greater than about 150 g/L of cation exchange material;
>
> wherein the cation exchange material is resin particles.

784. On information and belief, the manufacture of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more of the claims of the '054 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

785. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '054 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

786. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '054 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '054 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

787. Defendants have knowledge of or are willfully blind to the '054 Patent, including due to Genentech's disclosure of the '054 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

788. On information and belief, Defendants' infringement of the '054 Patent is and will be willful.

789. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '054 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

790. To the extent Defendants commercializes its product prior to the expiration of the '054 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

791. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '054 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).

COUNT L
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,152,054)

792. The allegations of paragraphs 1–791 are repeated and incorporated herein by reference.

793. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '054 Patent.

794. As set forth in Count XLIX, Defendants would infringe the ’054 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the ’054 Patent.

795. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

796. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the ’054 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon’s proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

797. Defendants have knowledge of or are willfully blind to the ’054 Patent, including due to Genentech’s disclosure of the ’054 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

798. On information and belief, Defendants’ infringement of the ’054 Patent is and will be willful.

799. Defendants’ submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’054 Patent creates an

actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the ’054 Patent.

800. Genentech is entitled to a declaratory judgment that Biocon will infringe one or more claims of the ’054 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

801. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the ’054 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

802. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’054 Patent. Genentech does not have an adequate remedy at law.

803. Unless Defendants are enjoined from infringing the ’054 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

804. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’054 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT LI
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,286,619)

805. The allegations of paragraphs 1–804 are repeated and incorporated herein by reference.

806. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

807. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '619 Patent.

808. Defendants committed an act or acts of infringement with respect to the '619 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

809. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the '619 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

810. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

811. The '619 Patent includes nineteen claims, two of which are independent. Claim 10 depends from claim 1 and recites:

> 1. A mammalian cell having reduced or eliminated lactogenic activity, wherein the cell comprises an exogenous nucleic acid sequence encoding a product of interest, wherein the expression of a pyruvate kinase muscle (PKM) polypeptide isoform in the cell is knocked down or knocked out, and wherein the PKM polypeptide isoform comprises a PKM-1 polypeptide isoform or a PKM-2 polypeptide isoform; wherein the cell is a CHO cell.
>
> 10. A method of producing a product of interest, comprising culturing the mammalian cell of claim 1, wherein the mammalian cell expresses the product of interest.

812. On information and belief, the manufacture of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more of the claims of the '619 Patent, including at least claim 10, either literally or under the doctrine of equivalents.

813. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 10 of the '619 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

814. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '619 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '619 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

815. Defendants have knowledge of or are willfully blind to the '619 Patent, including due to Genentech's disclosure of the '619 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

816. On information and belief, Defendants' infringement of the '619 Patent is and will be willful.

817. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '619 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

818. To the extent Defendants commercialize its product prior to the expiration of the '619 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

819. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '619 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).

COUNT LII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,286,619)

820. The allegations of paragraphs 1–819 are repeated and incorporated herein by reference.

821. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '619 Patent.

822. As set forth in Count LI, Biocon would infringe the '619 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '619 Patent.

823. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

824. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '619 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

825. Defendants have knowledge of or are willfully blind to the '619 Patent, including due to Genentech's disclosure of the '619 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

826. On information and belief, Defendants' infringement of the '619 Patent is and will be willful.

827. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '619 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '619 Patent.

828. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '619 Patent, including at least claim 10, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

829. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '619 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

830. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '619 Patent. Genentech does not have an adequate remedy at law.

831. Unless Defendants are enjoined from infringing the '619 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

832. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the

expiration of the ’619 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT LIII
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,371,728)

833. The allegations of paragraphs 1–832 are repeated and incorporated herein by reference.

834. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech’s PERJETA®.

835. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the ’728 Patent.

836. Defendants committed an act or acts of infringement with respect to the ’728 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

837. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the ’728 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

838. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

839. The '728 Patent includes twenty claims, one of which is independent. Claim 1 recites:

> A method of producing a polypeptide with reduced glycation comprising:
>
> (a) culturing host cells expressing the polypeptide in a cell growth phase,
>
> (b) thereafter culturing the cells in a polypeptide production phase in a cell culture medium comprising at least one reducing sugar in which the total reducing sugar concentration is maintained between about 2 g/L and about 5 g/L by fed batch cell culturing with a continuous reducing sugar feed or a continuous nutrient feed comprising at least one reducing sugar, and
>
> (c) thereafter harvesting the polypeptide from the cell culture.

840. On information and belief, the manufacture of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more of the claims of the '728 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

841. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '728 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

842. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '728 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '728 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA under 35 U.S.C. § 271(g). Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

843. Defendants have knowledge of or are willfully blind to the '728 Patent, including due to Genentech's disclosure of the '728 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

844. On information and belief, Defendants' infringement of the '728 Patent is and will be willful.

845. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '728 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

846. To the extent Defendants commercialize the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '728 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

847. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '728 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).

COUNT LIV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,371,728)

848. The allegations of paragraphs 1–847 are repeated and incorporated herein by reference.

849. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '728 Patent.

850. As set forth in Count LIII, Biocon would infringe the '728 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '728 Patent.

851. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

852. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the

expiration of the '728 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

853. Defendants have knowledge of or are willfully blind to the '728 Patent, including due to Genentech's disclosure of the '728 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

854. On information and belief, Defendants' infringement of the '728 Patent is and will be willful.

855. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '728 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '728 Patent.

856. Genentech is entitled to a declaratory judgment that Biocon will infringe one or more claims of the '728 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

857. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '728 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

858. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Biocon from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '728 Patent. Genentech does not have an adequate remedy at law.

859. Unless Defendants are enjoined from infringing the '728 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Biocon.

860. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '728 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

COUNT LV
(PATENT INFRINGEMENT OF U.S. PATENT NO. 12,479,883)

861. The allegations of paragraphs 1–860 are repeated and incorporated herein by reference.

862. On information and belief, by submitting the Biocon aBLA to FDA, and/or by participating in, causing, directing, controlling, and/or acting in concert with Biocon Biologics Inc. in submitting the Biocon aBLA to FDA, Defendants 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, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

863. On information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '883 Patent.

864. Defendants committed an act or acts of infringement with respect to the ’883 Patent under 35 U.S.C. § 271(e)(2)(C) when Biocon Biologics Inc., in concert with the other Defendants, submitted the Biocon aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar.

865. On information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar will infringe one or more claims of the ’883 Patent under 35 U.S.C. § 271(g), literally or under the doctrine of equivalents.

866. On information and belief, Biocon Biologics Ltd., Biocon Biologics UK Ltd., and Biocon Biologics Germany GmbH have participated in, caused, directed, controlled, and/or acted in concert with Biocon Biologics Inc. in connection with the Biocon aBLA and the planned commercial launch of the Proposed Biocon Pertuzumab Biosimilar.

867. The ’883 Patent includes eighteen claims, one of which is independent. Claim 1 recites:

> A method of reducing an enzymatic hydrolysis activity rate of a composition obtained from a purification platform, the method comprising subjecting a sample to the purification platform comprising, in order:
>
> (a) a capture step comprising processing via affinity chromatography; and
>
> (b) a purification step comprising processing via a chromatography selected from the group consisting of a HIC, a cation exchange chromatography, and a multimodal chromatography, wherein the purification platform further comprises one or more depth filtration steps, wherein the one or more depth filtration steps are performed at any one or more of: prior to the capture step; after the capture step; or after the capture step and prior to the purification step, wherein each depth filtration step comprises processing via a depth filter, and wherein the depth filter comprises materials selected from the group consisting of: (i) a silica filter aid and a polyacrylic fiber pulp; and (ii) cellulose fibers, diatomaceous earth, and perlite, wherein the depth filter comprising the cellulose fibers, diatomaceous earth, and perlite comprises two layers, wherein each

> layer comprises a cellular filter matrix impregnated with a filter aid comprising one or more of diatomaceous earth or perlite, and wherein each layer further comprises a resin binder, thereby reducing the enzymatic hydrolysis activity rate of the composition as compared to purification of the sample using the same purification platform without the one or more depth filtration steps.

868. On information and belief, the manufacture of the Proposed Biocon Pertuzumab Biosimilar is covered by and will infringe one or more of the claims of the '883 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

869. Biocon has provided information to Genentech pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration for the Proposed Biocon Pertuzumab Biosimilar. Based on this confidential information, Biocon's commercial manufacture, use, sale, offer for sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claim 1 of the '883 Patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents.

870. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech has provided Biocon with a detailed statement describing with respect to the '883 Patent, on a claim by claim basis, the factual and legal bases of Genentech's opinion that the '883 Patent will be infringed by the commercial marketing of the Proposed Biocon Pertuzumab Biosimilar that is the subject of the Biocon aBLA. Genentech's detailed statement includes, refers to, and relies on confidential information that Biocon 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 Biocon "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

871. Defendants have knowledge of or are willfully blind to the ’883 Patent, including due to Genentech’s disclosure of the ’883 Patent under 42 U.S.C. § 262(*l*)(3)(A), Genentech’s detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

872. On information and belief, Defendants’ infringement of the ’883 Patent is and will be willful.

873. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’883 Patent. Genentech is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Proposed Biocon Pertuzumab Biosimilar. Genentech does not have an adequate remedy at law.

874. To the extent Defendants commercialize its product prior to the expiration of the ’883 Patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

875. The submission of the Biocon aBLA to FDA, and the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the ’883 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).

COUNT LVI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,479,883)

876. The allegations of paragraphs 1-875 are repeated and incorporated herein by reference.

877. This declaratory judgment action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the patent laws of the United States, including 35 U.S.C. § 271(g). A judicial determination of infringement is necessary and appropriate to resolve the controversy

between the parties concerning Defendants' threatened commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Biocon Pertuzumab Biosimilar before expiration of the '883 Patent.

878. As set forth in Count LV, Defendants would infringe the '883 Patent, literally or under the doctrine of equivalents, if the Proposed Biocon Pertuzumab Biosimilar is used, offered for sale, sold, or imported into the United States prior to the expiration of the '883 Patent.

879. On information and belief, Defendants 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 Biocon Pertuzumab Biosimilar, a proposed biosimilar version of Genentech's PERJETA®.

880. On information and belief, Defendants intend to, and will, commercially manufacture, use, offer to sell, sell, market, distribute, and/or import into the United States the Proposed Biocon Pertuzumab Biosimilar upon FDA approval of the Biocon aBLA and prior to the expiration of the '883 Patent. On information and belief, Defendants have participated in, directed, controlled, contributed to, and/or acted in concert with one another in connection with the Biocon aBLA, Biocon's proposed labeling, and the planned United States launch of the Proposed Biocon Pertuzumab Biosimilar.

881. Defendants have knowledge of or are willfully blind to the '883 Patent, including due to Genentech's disclosure of the '883 Patent pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

882. On information and belief, Defendants' infringement of the '883 Patent is and will be willful.

883. Defendants' submission of the Biocon aBLA, their pursuit of FDA approval of the Biocon aBLA, and their intent to commercially manufacture, use, offer for sale, sell, and/or import the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '883 Patent creates an actual, immediate, and real controversy between the parties concerning whether Defendants will infringe one or more claims of the '883 Patent.

884. Genentech is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '883 Patent, including at least claim 1, literally or under the doctrine of equivalents, by commercially manufacturing, using, offering to sell, selling within the United States, and/or importing into the United States the Proposed Biocon Pertuzumab Biosimilar.

885. Genentech therefore seeks declaratory judgment that Defendants will infringe one or more claims of the '883 Patent, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(g).

886. Genentech is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Biocon from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Biocon Pertuzumab Biosimilar prior to the expiration of the '883 Patent. Genentech does not have an adequate remedy at law.

887. Unless Defendants are enjoined from infringing the '883 Patent, Genentech will suffer substantial and irreparable harm. Genentech does not have an adequate remedy at law to redress the infringement by Defendants.

888. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Biocon Pertuzumab Biosimilar before the expiration of the '883 Patent will cause injury to Genentech, entitling Genentech to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

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

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

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

C. a judgment declaring that each of the Defendants will infringe directly, or contribute to or induce the infringement of, one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c), and/or (g) by engaging in the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Biocon aBLA;

D. a judgment that Defendants' infringement of the Asserted Patents was and will continue to be willful;

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

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

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

DEMAND FOR A JURY TRIAL

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

Dated: July 29, 2026

By: */s/ Charles H. Chevalier*

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