

February 27, 2026

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VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W., Room 112
Washington, DC 20436

Re: *Certain Pertuzumab Biosimilars, Including Those Made by Certain Methods of Manufacturing, the Active Ingredient Thereof, and Products Containing the Same*
Inv. No. 337-TA-_____

Dear Secretary Barton:

On behalf of Complainant Genentech, Inc. (“Genentech”), I enclose for filing the following documents in support of Genentech’s request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Pursuant to the Commission Rules of Practice and Procedure, a request for confidential treatment of Confidential Exhibit Nos. 23, 29, 43–48, and 59–68 is included with this filing.

Genentech submits the following documents for filing:

1. One (1) electronic copy of Genentech’s Confidential Verified Complaint, Genentech’s Public Verified Complaint, and the Public Interest Statement, pursuant to Commission Rules 210.8(a)(1)(i), 210.8(b), and 210.12(a);
2. One (1) electronic copy of the public exhibits to the Verified Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9), including:
 - a. One (1) electronic copy of each of the certified versions of United States Patent Nos. 8,652,474 (“the ’474 Patent”), 11,597,776 (“the ’776 Patent”), 12,145,997 (“the ’997 Patent”), and 12,173,080 (“the ’080 Patent”), cited respectively as

Exhibits 1–4 to the Verified Complaint, pursuant to Commission Rule 210.12(a)(9)(i);¹ and

- b. One (1) electronic copy of each of the certified versions of the assignments for the '474 Patent, the '776 Patent, the '997 Patent, and the '080 Patent, cited respectively as Exhibits 5–8 to the Verified Complaint, pursuant to Commission Rule 210.12(a)(9)(ii);
3. One (1) electronic copy of each of the certified versions of the prosecution history for the '474 Patent, the '776 Patent, the '997 Patent, and the '080 Patent, which are included as Appendixes A, B, C, and D to the Verified Complaint, pursuant to Commission Rule 210.12(c)(1);
4. One (1) electronic copy of each of the prosecution histories for priority applications for the '474 Patent, the '776 Patent, the '997 Patent, and the '080 Patent, which are included as Appendixes E, F, G, and H to the Verified Complaint, pursuant to Commission Rule 210.12(c)(2);
5. One (1) electronic copy of Confidential Exhibit Nos. 23, 29, 43–48, and 59–68 to the Verified Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii);
6. One (1) electronic copy of public, redacted versions of Exhibit Nos. 23, 29, 43–48, and 59–68 to the Verified Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii); and
7. A letter requesting confidential treatment of the information contained in Confidential Exhibit Nos. 23, 29, 43–48, and 59–68, pursuant to Commission Rules 201.6(b) and 210.5(d).

The requisite paper copies and electronic form of the above will be delivered to the Secretary pursuant to 19 C.F.R. § 210.8(a).

Please contact me if you have any questions regarding this request, or if this request is not granted in full. Thank you for your attention to this matter.

¹ To the extent that certified copies of the Asserted Patents, prosecution histories, and assignments are not included, they have been ordered and will be promptly submitted to the Commission once they arrive.

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Respectfully submitted,

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/s/ Mark G. Davis

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The Honorable Lisa R. Barton
Secretary to the Commission
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Re: *Certain Pertuzumab Biosimilars, Including Those Made by Certain Methods of Manufacturing, the Active Ingredient Thereof, and Products Containing the Same*
Inv. No. 337-TA-_____

Dear Secretary Barton:

In accordance with Commission Rules 201.6(b) and 210.5, Genentech, Inc. requests confidential treatment of Confidential Business Information contained in the Confidential Complaint, as well as Confidential Exhibit Nos. 23, 29, 43–48, and 59–68 to the Complaint under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, filed concurrently herewith.

Confidential Exhibit 23 contains proprietary licensing information. Confidential Exhibits 29 and 46–48 are domestic industry claim charts and Confidential Exhibits 43–44 are infringement claim charts which disclose information which is proprietary to Genentech. Confidential Exhibit 45 contains information regarding Genentech’s confidential economic data related to Genentech’s domestic investments in activities that relate to support of PERJETA[®]. Confidential Exhibits 59–68 contain information regarding Genentech’s confidential research, development, and manufacture of PERJETA[®]. The redacted portions of Genentech’s Complaint discuss and/or quote the confidential information contained in the Confidential Exhibits discussed above.

Specifically, Genentech requests that certain portions of Exhibits 23, 29, 43–48, and 59–68 be kept confidential, and is filing both confidential and public (redacted) versions of these documents.

The information described above qualifies as confidential business information pursuant to Rule 201.6(a) because:

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1. It is not publicly available;
2. Unauthorized disclosure of such information could cause substantial harm to the competitive position of Genentech; and/or
3. The disclosure of such information could impair the Commission's ability to obtain information necessary to perform its statutory function.

Please contact me if you have any questions regarding this request, or if this request is not granted in full. Thank you for your attention to this matter.

Respectfully submitted,

JENNER & BLOCK LLP

/s/ Mark G. Davis

Mark G. Davis

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

In the matter of

CERTAIN PERTUZUMAB BIOSIMILARS,
INCLUDING THOSE MADE BY CERTAIN
METHODS OF MANUFACTURING, THE
ACTIVE INGREDIENT THEREOF, AND
PRODUCTS CONTAINING THE SAME

INVESTIGATION NO. 337-TA-_____

STATEMENT REGARDING THE PUBLIC INTEREST

Complainant Genentech, Inc. submits this Statement Regarding the Public Interest pursuant to Commission Rule 210.8(b). As set forth in the Complaint, upon information and belief, proposed respondents Biocon Ltd.'s, Biocon Biologics Ltd.'s, Biocon Biologics UK PLC's, and Biocon Biologics Inc.'s (collectively, "Biocon" or "Proposed Respondents") pertuzumab biosimilar candidate BMAB 1500/PERT-IJS infringes Genentech's patents covering PERJETA[®] (pertuzumab) and methods of its manufacture. Genentech's development of PERJETA[®] and its method of manufacture took decades of work and over one billion dollars in U.S. investments. Rather than taking a license, Biocon chose to infringe Genentech's patented technology.

Granting relief in this investigation would advance multiple public interest issues identified as crucial by the administration, as well as the traditional public interest issues of public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and the effect on United States consumers. As the Commission has recognized, the "public interest favors the protection of intellectual property rights by excluding infringing products."¹ The public interest also favors the protection of U.S.

¹ *Certain Light-Based Physiological Measurement Devices & Components Thereof*, Inv. No. 337-TA-1276, Comm'n Op. at 13 (Jan. 3, 2024).

jobs and competitive conditions in the U.S. economy. Genentech not only researched and developed its patented technology in the United States, but it also established its supply chain for PERJETA[®] in the United States. The U.S. manufacture of PERJETA[®] continues today and Genentech has no plans to transfer manufacture abroad. Genentech's U.S. efforts have included the work of numerous Genentech employees, including scientists, engineers, quality specialists, regulatory affairs professionals, and operations staff. Protecting American companies, such as Genentech, from unfair imports is important because unfair imports hinder the efforts of American companies both to manufacture in the United States and to pay for research into new innovative products and methods of manufacture. Conversely, the issuance of relief in this matter would have no adverse public interest effects because Biocon chose to begin commercialization efforts before obtaining FDA approval. An exclusion order would therefore merely maintain the status quo. Accordingly, the applicable public interest factors strongly favor granting relief in this matter.

I. FAILING TO GRANT THE REQUESTED RELIEF COULD HAVE ADVERSE EFFECTS ON COMPETITIVE CONDITIONS IN THE UNITED STATES ECONOMY.

The issuance of an exclusion order would help protect competitive conditions in the United States. The White House has declared a national emergency to increase the competitive edge of the United States and to reduce the trade deficit.² Increasing domestic manufacturing is critical both to the effort to address this emergency and to bolster U.S. national security.³ As the White House noted in its fact sheet regarding this national emergency, U.S. manufacturing output as a share of global manufacturing output has decreased from 28.4% in 2001 to 17.4% in 2025.⁴ This

² The White House, *Fact Sheet: President Donald J. Trump Declares National Emergency to Increase our Competitive Edge, Protect our Sovereignty, and Strengthen our National and Economic Security* (April 2, 2025), <https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-declares-national-emergency-to-increase-our-competitive-edge-protect-our-sovereignty-and-strengthen-our-national-and-economic-security/>.

³ *Id.*

⁴ *Id.*

decline in manufacturing output has in turn reduced U.S. manufacturing capacity. The fact sheet also noted that the need to protect manufacturing capability is “particularly acute” in industries such as pharmaceuticals, “where loss of capacity could permanently weaken U.S. competitiveness.”⁵

Allowing Genentech to level the playing field by ensuring competitors honor Genentech’s patent rights is crucial. Recent studies have shown that nearly 90% of sites manufacturing active pharmaceutical ingredients (API) for pharmaceutical products intended for domestic U.S. consumption are located overseas.⁶ This has led to concerns about supply issues due to various factors such as pandemics, weather events, and the international trade policies of the countries where the drugs are made.⁷ Genentech’s manufacture of PERJETA[®] in the United States avoids the issues described above relating to U.S. competitiveness and national security and provides jobs for American workers. Accordingly, the applicable public interest factors all weigh strongly in Genentech’s favor.

II. THE REQUESTED REMEDIAL ORDERS RAISE NO PUBLIC HEALTH, SAFETY, OR WELFARE CONCERNS.

Issuing the requested relief will not adversely affect public health, safety, or welfare in the U.S. for several reasons. First, patients will continue to have access to all FDA-approved treatments available today, including PERJETA[®]. BMAB 1500/PERT-IJS is not approved for commercial sale in the United States, so U.S. patients will not be affected by this action. Second, the safety and efficacy of PERJETA[®] is well-established and the introduction of a biosimilar would do nothing to increase the safety and efficacy of any of the treatments available to cancer patients.

⁵ *Id.*

⁶ Yashna Shivdasani, *The Geography of Prescription Pharmaceuticals Supplied to the USA: Levels, Trends, and Implications*, 8 J.L. & BIOSCIENCES 1, 5 (2021).

⁷ *Id.* at 3.

III. GRANTING RELIEF IN THIS INVESTIGATION WILL NOT ADVERSELY AFFECT PRODUCTION IN THE UNITED STATES.

PERJETA[®] is the only pertuzumab or pertuzumab-biosimilar manufactured in the United States and, on information and belief, Biocon has no plans to make its infringing biosimilar in the United States even after it obtains FDA approval. Accordingly, far from adversely affecting the domestic manufacture of pertuzumab, granting relief in this investigation would help ensure that PERJETA[®] continues to be manufactured in the United States and protect Genentech's ongoing U.S. investments related to PERJETA[®] that already total over one billion dollars.

IV. GENENTECH HAS THE CAPACITY TO MEET THE ONGOING DEMAND FOR PERJETA[®].

There are no concerns regarding Genentech's ability to meet the ongoing demand for PERJETA[®]. Genentech has not had any supply issues for well over ten years and has demonstrated its ability to increase production to match any increase in demand for PERJETA[®].

There is also no worry that Genentech will be unable to fill the demand for BMAB 1500/PERT-IJS for the simple reason that there is no commercial demand for BMAB 1500/PERT-IJS. BMAB 1500/PERT-IJS has not been approved for commercial sale in the United States. Therefore, there is no material volume of excluded articles that would need to be replaced.

V. THE REQUESTED RELIEF WOULD NOT ADVERSELY IMPACT CONSUMERS.

For the reasons discussed above, the requested remedy will have no material adverse impact on consumers. BMAB 1500/PERT-IJS is not currently approved for sale in the United States. Consumers will also continue to have access to PERJETA[®]. Finally, granting the

requested relief would likely have a positive effect on consumers by protecting U.S. competitiveness, manufacturing capacity, security, and jobs.

In sum, no public interest considerations preclude the issuance of the proposed remedies here.

Dated: February 27, 2026

Respectfully submitted,

By: */s/ Mark G. Davis*

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PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

In the Matter of

**CERTAIN PERTUZUMAB BIOSIMILARS,
INCLUDING THOSE MADE BY
CERTAIN METHODS OF
MANUFACTURING, THE ACTIVE
INGREDIENT THEREOF, AND
PRODUCTS CONTAINING THE SAME**

Investigation No. 337-TA-_____

**VERIFIED COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS
AMENDED**

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4.	Copy of U.S. Patent No. 12,173,080
5.	Copy of Recorded Assignments for U.S. Patent No. 8,652,474
6.	Copy of Recorded Assignments for U.S. Patent No. 11,597,776
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14.	PERJETA® Prescribing Information (June 2025)
15.	Biocon Biologics to Expand Biosimilar Oncology Portfolio (Press Release)
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34.	FDA Guidance for Industry (October 2025)
35.	Infringement Chart for U.S. Patent No. 8,652,474 by Biocon
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40.	Biocon Biologics Receives EU GMP Certification for Multiple Biosimilars Manufacturing Facilities in Bengaluru Expands Manufacturing Capacity (Press Release)
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B.	Copy of Prosecution History for U.S. Patent No. 11,597,776
C.	Copy of Prosecution History for U.S. Patent No. 12,145,997
D.	Copy of Prosecution History for U.S. Patent No. 12,173,080
E.	Copy of Prosecution History for Priority Applications for U.S. Patent No. 8,652,474
F.	Copy of Prosecution History for Priority Applications for U.S. Patent No. 11,597,776
G.	Copy of Prosecution History for Priority Applications for U.S. Patent No. 12,145,997
H.	Copy of Prosecution History for Priority Applications for U.S. Patent No. 12,173,080

PUBLIC VERSION**I. INTRODUCTION**

1.1. This Complaint challenges the commercial-scale importation into the United States of infringing pertuzumab biosimilar product by Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics Inc. Biocon Biologics International Ltd., and Biocon Biologics UK PLC (collectively, “Biocon” or “Proposed Respondents”), in violation of Section 337 of the Tariff Act of 1930. Although Biocon has not yet obtained FDA approval to commercially market its biosimilar product, it has already imported substantial quantities of infringing product into the United States in preparation for commercial launch. Such importation and stockpiling fall outside the safe harbor protection of 35 U.S.C. § 271(e)(1) and constitute unfair acts under Section 337.

1.2. Genentech, Inc. (“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 discovery, development, and manufacturing. Moreover, at a time when U.S. manufacturing of pharmaceuticals is rare, PERJETA[®] continues to be manufactured in the United States.

1.3. Genentech’s innovations relating to PERJETA[®] are protected by numerous patents, including U.S. Patent Nos. 8,652,474 (“the ’474 Patent”), 11,597,776 (“the ’776 Patent”), 12,145,997 (“the ’997 Patent”), and 12,173,080 (“the ’080 Patent”) (collectively, the “Asserted Patents”). These patents cover both patented pertuzumab compositions and patented methods of manufacturing those compositions, including methods that prevent disulfide bond reduction and ensure consistent, high-quality antibody production.

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1.4. On information and belief, Biocon is seeking FDA approval to market a purported biosimilar version of PERJETA[®] by submitting an abbreviated Biologics License Application (“aBLA”) that relies on Genentech’s prior scientific and clinical work. Biocon refers to its biosimilar pertuzumab product as BMAB 1500 and/or PERT-IJS. **Exhibit 9; Exhibit 10; Exhibit 11.** For clarity, this Complaint refers to the product as “BMAB 1500/PERT-IJS.”

1.5. Although BMAB 1500/PERT-IJS has not yet been approved for commercial sale in the United States, Biocon has already imported large, commercial-scale quantities of infringing product into the United States from India. Upon information and belief, these imports are not associated with any active U.S. clinical trials and are inconsistent with any legitimate research or regulatory purpose. Instead, the quantity, timing, and circumstances demonstrate stockpiling in anticipation of commercial launch.

1.6. On information and belief, BMAB 1500/PERT-IJS infringes the Asserted Patents because it comprises patented pertuzumab compositions and is manufactured in India using Genentech’s patented processes, including (1) processes to produce the patented compositions; and (2) processes that prevent the reduction of disulfide bonds, thereby increasing the yield of desired antibodies. On information and belief, Biocon’s importation of BMAB 1500/PERT-IJS infringes the following claims of the Asserted Patents:

U.S. Patent No.	Asserted Claims¹
8,652,474	1, 4, 6, 11-12, 15
11,597,776	1-4, 7, 13-14, 17-19, 21, 25-27
12,145,997	1-7
12,173,080	1-3, 5-7, 9, 10

¹ Bolded claim numbers designate independent claims.

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1.7. The Asserted Patents belong to two patent families. The '474 and '776 Patents share a common specification (“the Harris Patent Family”), and the '997 and '080 Patents also share (a different) common specification (“the Kao Patent Family”). Certified copies of the Asserted Patents are included as **Exhibits 1-4**. Genentech is the assignee of the Asserted Patents and holds all rights, title, and interest in and to the Asserted Patents. Certified copies of the Assignment Records for each of the Asserted Patents are included as **Exhibits 5-8**.

1.8. Genentech has a robust domestic industry in the United States that practices the Asserted Patents including substantial investments in research and development, manufacturing, engineering, clinical testing, and commercialization of PERJETA[®]. Those investments satisfy both the economic and technical prongs of the domestic industry requirement.

1.9. Genentech respectfully requests that the United States International Trade Commission institute an investigation under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into sale for importation, importation, and sale after importation by Biocon.

1.10. Genentech requests institution of this Investigation to protect its rights and halt Biocon’s unfair methods of competition and unfair acts involving the sale for importation, importation, and/or sale after importation of articles that infringe the Asserted Patents.

1.11. Genentech seeks a limited exclusion order—extending only through expiry of the latest expiring Asserted Patent—barring from entry into the United States infringing pertuzumab biosimilars, components thereof, and products containing the same manufactured, sold, or imported by or on behalf of, Biocon. Genentech also seeks cease and desist orders prohibiting importation, sale after importation, distribution, offering for sale, promoting, marketing, advertising, testing, demonstrating, warehousing inventory for distribution, solicitation of sales, using, transferring, and other commercial activity relating to infringing pertuzumab biosimilars

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and products containing the same. Genentech further seeks imposition of a bond during the Presidential Review Period pursuant to 19 U.S.C. § 1337(j).

II. BACKGROUND**A. Genentech's Innovative Biologic Product PERJETA[®] (pertuzumab)**

2.1. Breast cancer is the most common cancer in women in the United States. HER2-positive breast cancer accounts for approximately 20-30% of human breast cancers. **Exhibit 12.** 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. **Exhibit 13.**

2.2. HER2-positive breast cancer is particularly aggressive and fast-growing. This subtype of breast cancer is characterized by overexpression of HER2 proteins due to HER2 gene amplification.

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

2.4. Genentech manufactures, markets, and sells PERJETA[®], a treatment for HER2-positive breast cancer that uses pertuzumab as its active ingredient. Pertuzumab is a recombinant humanized monoclonal antibody that targets and binds to the extracellular dimerization domain (Subdomain II) of the HER2 protein on cancer cells, which inhibits the cancer cells' growth and spread. **Exhibit 14** at 22. Pertuzumab is the only approved antibody that targets the Subdomain II of the HER2 protein on cancer cells.

PUBLIC VERSION**B. Biocon Has Sought Approval to Market a Proposed Biosimilar Version of PERJETA[®] and Is Preparing for Launch by Importing the Infringing Product**

2.5. Biocon has publicly announced plans to enter the U.S. market with a biosimilar version of PERJETA[®]. **Exhibit 15.** Under FDA standards, to be considered biosimilar to PERJETA[®], Biocon's BMAB 1500/PERT-IJS must have no clinically meaningful differences in safety, purity, or potency compared to PERJETA[®]. **Exhibit 16.**

2.6. According to Biocon's press releases, Biocon has applied for FDA approval of its purported pertuzumab biosimilar by filing an aBLA with the FDA under 42 U.S.C. § 262(k), which permits Biocon to rely on PERJETA[®]'s licensure. **Exhibit 15.** That application should include laboratory and clinical data addressing the similarity or identity of the molecular structure and purity of BMAB 1500/PERT-IJS. The uses of Biocon's BMAB 1500/PERT-IJS must match the dosages and strengths for which PERJETA[®] is already FDA-approved, including protocols for treating HER2-positive breast cancer.

2.7. Based on the timing of Biocon's regulatory submission for BMAB1500/PERT-IJS, it is expected to receive regulatory approval before the end of 2026.

2.8. As set forth below, even though BMAB 1500/PERT-IJS has not yet been approved for marketing by the FDA, importation records show that Biocon has imported large, commercial quantities of the product into the United States. **Exhibit 17; Exhibit 18.** While some activities, such as research that generates data for FDA submissions, may fall within the patent infringement safe harbor of 35 USC § 271(e)(1), importation for stockpiling prior to commercial approval is not protected and gives rise to patent infringement liability.

2.9. Further, on information and belief, Biocon is not currently conducting active research involving pertuzumab within the United States and was not conducting any such research when it imported commercial quantities of its biosimilar BMAB 1500/PERT-IJS product. As such,

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Biocon's importation is not protected by the safe harbor and is instead intended for stockpiling in preparation for commercial launch.

III. PARTIES**A. Complainant**

3.1. Genentech is a Delaware corporation with its principal place of business at 1 DNA Way, South San Francisco, CA 94080. As a biotechnology company, Genentech develops, manufactures, and commercializes medicines for serious and life-threatening medical conditions. Genentech's team of scientists—recognized leaders who routinely publish in top peer-reviewed journals—have produced a portfolio of numerous FDA-approved pharmaceutical and biologic therapies for conditions including cancer, heart attack, stroke, rheumatoid arthritis, and respiratory disease. Genentech's sustained investment in research has resulted in more than forty marketed medicines and thirty-nine FDA Breakthrough Therapy designations.

B. Proposed Respondents

3.2. On information and belief, Proposed Respondent Biocon Ltd. is an Indian limited company headquartered at 20th KM, Hosur Road, Electronic City, Bengaluru 560100, Karnataka, India. Biocon Ltd. is listed as the manufacturer of the BMAB 1500/PERT-IJS shipment that was imported into the United States. **Exhibit 17**.

3.3. On information and belief, Proposed Respondent Biocon Biologics Ltd. is an Indian limited company headquartered at Biocon House, Semicon Park, Hosur Road, Electronics City Phase II, Bengaluru 560100, Karnataka, India. On information and belief, Biocon Biologics Ltd. is the dedicated biosimilars arm for Biocon Ltd. and is in the process of becoming a wholly owned subsidiary of Biocon Ltd. **Exhibit 19; Exhibit 20** at 46, 189. Biocon Biologics Ltd. submitted the aBLA for its pertuzumab biosimilar product, BMAB 1500/PERT-IJS, to the FDA. **Exhibit 15**. On information and belief, Biocon Biologics Ltd. acts in concert with Biocon Ltd., Biocon Biologics

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Inc., Biocon Biologics International Ltd., and Biocon Biologics UK PLC to develop, manufacture, import, seek regulatory approval for, market, distribute, and sell BMAB 1500/PERT-IJS in the United States.

3.4. On information and belief, Proposed Respondent Biocon Biologics Inc. is a Delaware corporation with its principal place of business at 245 Main St, 2nd floor, Cambridge, Massachusetts 02142. On information and belief, Biocon Biologics Inc. is a wholly owned subsidiary of Biocon Biologics UK PLC established to undertake all activities, such as commercialization and distribution, relating to biologic products imported into the United States. **Exhibit 20** at 190. On information and belief, Biocon Biologics Inc. acts in concert with Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics International Ltd., and Biocon Biologics UK PLC to import, commercialize, and distribute BMAB 1500/PERT-IJS for use in the United States.

3.5. On information and belief, Proposed Respondent Biocon Biologics International Ltd. is a foreign corporation organized and existing under the laws of the United Kingdom, with its principal place of business at 16 Great Queen Street, Covent Garden, London, United Kingdom, WC2B 5AH. On information and belief, Biocon Biologics International Ltd. is a wholly owned subsidiary of Biocon Biologics Ltd. and is identified under its old name, Biocon Biologics UK Ltd., as a sponsor of the clinical development of BMAB 1500/PERT-IJS. **Exhibit 20** at 189; **Exhibit 21**. On information and belief, Biocon Biologics International Ltd. acts in concert with Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics Inc., and Biocon Biologics UK PLC to seek regulatory approval for and import BMAB 1500/PERT-IJS for use in the United States.

3.6. On information and belief, Proposed Respondent Biocon Biologics UK PLC is a foreign corporation organized and existing under the laws of the United Kingdom, with its principal place of business at 16 Great Queen Street, Covent Garden, London, United Kingdom,

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WC2B 5AH. On information and belief, Biocon Biologics UK PLC is a wholly owned subsidiary of Biocon Biologics Ltd. and is identified under its old name, Biosimilars Newco Ltd., as involved in the biosimilars business of Biocon Ltd. and Biocon Biologics Ltd.'s trastuzumab, bevacizumab, pegfilgrastim, glargine, aspart, and ustekinumab products "across the globe." **Exhibit 20** at 189. On information and belief, Biocon Biologics UK PLC acts in concert with Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics Inc., and Biocon Biologics International Ltd. to seek regulatory approval for and import BMAB 1500/PERT-IJS for use in the United States.

3.7. On information and belief, Biocon Ltd. is the ultimate parent entity of the Biocon corporate group, and all other entities identified as Proposed Respondents in this Complaint are each in the process of becoming direct or indirect wholly owned subsidiaries of Biocon Ltd. and are subject to Biocon Ltd.'s ownership, direction, and control. *Id.* at 187. On information and belief, at all relevant times, Biocon Ltd. exercised control over the policies, finances, and operations of its wholly owned subsidiaries, and those entities acted at the direction of, under the control of, and/or in concert with Biocon Ltd. Accordingly, Biocon Ltd. and its wholly owned subsidiaries operate as a single enterprise for purposes of the acts alleged herein.

3.8. On information and belief, Biocon develops, manufactures, tests, and/or imports into the United States pharmaceutical products including pertuzumab biosimilars, the active ingredient thereof, and products containing the same, including those made by certain methods of manufacturing. On information and belief, the primary nature of Biocon's business is designing, developing, manufacturing, and selling pharmaceutical products.

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

4.1. Pursuant to 19 C.F.R. § 210.12(a)(12), the category of products accused are certain pertuzumab biosimilars, the active ingredient thereof, and injectors, syringes, vials, bags, bottles, cartridges, carboys, and/or containers containing the finished BMAB1500/PERT-IJS injection

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product ready for patient use or the bulk pertuzumab drug substance of BMAB1500/PERT-IJS made by the methods of manufacturing claimed in the Asserted Claims of the Asserted Patents. These products include certain exemplary Biocon products (“Accused Products”) that practice the technology claimed by the Asserted Patents.

4.2. On information and belief, the Accused Products are manufactured abroad and imported into the United States by or on behalf of Biocon. Without discovery, Genentech cannot exhaustively identify all Biocon products imported, sold for importation, and/or sold after importation into the United States that infringe the Asserted Patents. Genentech reserves its right to supplement its allegations, to further amend this Complaint, and to add respondents and accused products in the future if appropriate based on discovery received during the Investigation.

V. THE ASSERTED PATENTS AND NON-TECHNICAL DESCRIPTION OF THE INVENTIONS²

5.1. Genentech has spent decades and significant resources developing PERJETA[®]. In recognition of Genentech’s innovations, the USPTO has awarded Genentech numerous patents on inventions related to PERJETA[®] and various manufacturing methods for antibody production. These patents cover the compositions and manufacture of pertuzumab.

A. Harris Patent Family**1. U.S. Patent No. 8,652,474****(a) Identification of the Patent and Ownership by Genentech**

5.2. The USPTO, after full and fair examination, duly and legally issued U.S. Patent No. 8,652,474, titled “Composition Comprising Antibody that Binds to Domain II of HER2 and

² All non-technical descriptions of the Asserted Patents are for the purposes of providing general information only and should not be interpreted as a representation regarding the scope or applicability of any patent, or the requirements or meaning of any patent claims.

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Acidic Variants Thereof,” to inventors Reed J. Harris and Paul A. Motchnik on February 18, 2014.

Exhibit 1. The '474 Patent issued from Application No. 12/361,180. *Id.* The '474 Patent claims priority to Provisional Application No. 61/024,825, filed on January 30, 2008. *Id.*

5.3. The '474 Patent has 4 independent claims and 12 dependent claims. *Id.* Genentech is asserting claims 1, 4, 6, 11-12, and 15 of the '474 Patent in this Investigation. Further investigation and discovery may lead to the assertion of additional claims.

5.4. The Asserted Claims of the '474 Patent are valid, enforceable, and currently in full force and effect until the expiration of the '474 Patent on September 28, 2031. Genentech holds all rights, title, and interest in the '474 Patent with full rights to enforce the same. **Exhibit 5.**

5.5. Pursuant to Commission Rule 210.12(c), copies of the certified prosecution history of the '474 Patent have been submitted with this Complaint as **Appendix A.** Pursuant to Commission Rule 210.12(c), the prosecution histories for any priority applications for the '474 Patent also have been submitted with this Complaint as **Appendix E.**

(b) Non-Technical Description of the Patent

5.6. The '474 Patent generally relates to a pharmaceutical composition comprising a HER2 antibody and one or more of its acidic variants.

5.7. Therapeutic antibodies are typically produced by living cells, which could potentially generate different forms of the same antibody with variations in the antibody sequence or structure. These forms, called antibody variants, could differ in potency, pharmacokinetics, and purity (monomer content). Through its research, Genentech unexpectedly discovered that certain variants are present in pertuzumab compositions and that those variants are present as manageable quality attributes rather than disqualifying impurities. The invention claimed in the '474 Patent reduces unnecessary over-purification and product discard, improves yield and cost efficiency, and ensures consistent results between batches.

PUBLIC VERSION**(c) Foreign and Domestic Counterparts to the Patent**

5.8. The foreign patents and foreign or domestic patent applications corresponding to the '474 Patent, including any denied, abandoned, or withdrawn applications, are listed in **Exhibit 22**. No other foreign patents or foreign or domestic patent applications corresponding to the '474 Patent are known to Genentech at this time.

(d) Licenses

5.9. Pursuant to Commission Rule 210.12(a)(9)(iii), the licensed entities for the '474 Patent are listed in **Confidential Exhibit 23** to this Complaint. There are no other licensed entities to the '474 Patent other than those listed in **Confidential Exhibit 23**.

2. U.S. Patent No. 11,597,776**(a) Identification of the Patent and Ownership by Genentech**

5.10. The USPTO, after full and fair examination, duly and legally issued U.S. Patent No. 11,597,776, titled "Composition Comprising Antibody that Binds to Domain II of HER2 and Acidic Variants Thereof," to inventors Reed J. Harris and Paul A. Motchnik on March 7, 2023. **Exhibit 2**. The '776 Patent issued from Application No. 17/815,535, which is a division of Application No. 16/503,364, now U.S. Patent No. 11,414,498, which is a division of Application No. 15/450,509, which is a continuation of Application No. 14/162,255, which is a division of Application No. 12/361,180, which is now the '474 Patent. *Id.* The '776 Patent claims priority to Provisional Application No. 61/024,825, filed on January 30, 2008. *Id.*

5.11. The '776 Patent has 4 independent claims and 26 dependent claims. *Id.* Genentech is asserting claims 1-4, 7, 13-14, 17-19, 21, and 25-27 of the '776 Patent in this Investigation. Further investigation and discovery may lead to the assertion of additional claims.

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5.12. The Asserted Claims of the '776 Patent are valid, enforceable, and currently in full force and effect until the expiration of the '776 Patent on January 28, 2029. Genentech holds all rights, title, and interest in the '776 Patent with full rights to enforce the same. **Exhibit 6**.

5.13. Pursuant to Commission Rule 210.12(c), copies of the certified prosecution history of the '776 Patent have been submitted with this Complaint as **Appendix B**. Pursuant to Commission Rule 210.12(c), the prosecution histories for any priority applications for the '776 Patent also have been submitted with this Complaint as **Appendix F**.

(b) Non-Technical Description of the Patent

5.14. The '776 Patent generally relates to methods of making a pharmaceutical composition comprising pertuzumab and one or more of its acidic variants. More specifically, the inventions claimed in the '776 Patent provide methods of making a pharmaceutical composition comprising the pertuzumab variant compositions as described above in the context of the '474 Patent.

(c) Foreign and Domestic Counterparts to the Patent

5.15. The foreign patents and foreign or domestic patent applications corresponding to the '776 Patent, including any denied, abandoned, or withdrawn applications, are listed in **Exhibit 22**. No other foreign patents or foreign or domestic patent applications corresponding to the '776 Patent are known to Genentech at this time.

(d) Licenses

5.16. Pursuant to Commission Rule 210.12(a)(9)(iii), the licensed entities for the '776 Patent are listed in **Confidential Exhibit 23** to this Complaint. There are no other licensed entities to the '776 Patent other than those listed in **Confidential Exhibit 23**.

PUBLIC VERSION**B. Kao Patent Family****1. U.S. Patent No. 12,145,997****(a) Identification of the Patent and Ownership by Genentech**

5.17. The USPTO, after full and fair examination, duly and legally issued U.S. Patent No. 12,145,997, titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” to inventors Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt on November 19, 2024. **Exhibit 3.** The ’997 Patent issued from Application No. 18/648,209, which is a division of Application No. 18/194,471, which is a continuation of Application No. 17/087,313, now U.S. Patent No. 11,639,395, which is a continuation of Application No. 16/847,317, now U.S. Patent No. 10,906,986, which is a continuation of Application No. 16/240,592, now U.S. Patent No. 10,759,866, which is a continuation of Application No. 15/488,917, which is a division of Application No. 14/043,758, which is a division of Application No. 13/354,223, now U.S. Patent No. 8,574,869, which is a continuation of Application No. 12/217,745. *Id.* The ’997 Patent claims priority to Provisional Application No. 60/948,677, filed on July 9, 2007. *Id.*

5.18. The ’997 Patent has 1 independent claim and 7 dependent claims. *Id.* Genentech is asserting claims 1-7 of the ’997 Patent in this Investigation. Further investigation and discovery may lead to the assertion of additional claims.

5.19. The Asserted Claims of the ’997 Patent are valid, enforceable, and currently in full force and effect until the expiration of the ’997 Patent on July 8, 2028. Genentech holds all rights, title, and interest in the ’997 Patent with full rights to enforce the same. **Exhibit 7.**

5.20. Pursuant to Commission Rule 210.12(c), copies of the certified prosecution history of the ’997 Patent have been submitted with this Complaint as **Appendix C.** Pursuant to

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Commission Rule 210.12(c), the prosecution histories for any priority applications for the '997 Patent also have been submitted with this Complaint as **Appendix G**.

(b) Non-Technical Description of the Patent

5.21. The '997 Patent generally relates to methods for preventing reduction of disulfide bonds during the antibody manufacturing process by sparging pre-harvest or harvested cell culture fluid with air following a production phase of a cell culture.

5.22. Genentech's development of the claimed technology began in the mid-2000s when Genentech began seeing significant and unexpected reductions in yield when scaling up production of antibodies. Upon extensive investigation, Genentech determined this reduction in yield was caused by biochemical processes occurring during the manufacturing process that reduced, or broke, the disulfide bonds holding together the multiple polypeptide chains that make up an antibody. Through extensive research, the inventors discovered that the increase in disulfide bond reduction was caused in part by the activity of reducing enzymes released by the host cells. The inventors discovered that they could address this problem by sparging the cell culture fluid with air following the production phase of the cell culture process in the ways claimed in the '997 Patent. Genentech uses the claimed methods to produce higher yields of pertuzumab, which is used in PERJETA[®] to treat HER2-positive breast cancer.

(c) Foreign and Domestic Counterparts to the Patent

5.23. The foreign patents and foreign or domestic patent applications corresponding to the '997 Patent, including any denied, abandoned, or withdrawn applications, are listed in **Exhibit 22**. No other foreign patents or foreign or domestic patent applications corresponding to the '997 Patent are known to Genentech at this time.

PUBLIC VERSION**(d) Licenses**

5.24. Pursuant to Commission Rule 210.12(a)(9)(iii), the licensed entities for the '997 Patent are listed in **Confidential Exhibit 23** to this Complaint. There are no other licensed entities to the '997 Patent other than those listed in **Confidential Exhibit 23**.

2. U.S. Patent No. 12,173,080**(a) Identification of the Patent and Ownership by Genentech**

5.25. The USPTO, after full and fair examination, duly and legally issued U.S. Patent No. 12,173,080, titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," to inventors Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt on December 24, 2024. **Exhibit 4**. The '080 Patent issued from Application No. 18/824,681, which is a division of Application No. 18/648,209, which is a division of Application No. 18/194,471, now U.S. Patent No. 12,098,211, which is a continuation of Application No. 17/087,313, now U.S. Patent No. 11,639,395, which is a continuation of Application No. 16/847,317, now U.S. Patent No. 10,906,986, which is a continuation of Application No. 16/240,592, now U.S. Patent No. 10,759,866, which is a continuation of Application No. 15/488,917, which is a division of Application No. 14/043,758, which is a division of Application No. 13/354,223, now U.S. Patent No. 8,574,869, which is a continuation of Application No. 12/217,745. *Id.* The '080 Patent claims priority to Provisional Application No. 60/948,677, filed on July 9, 2007. *Id.*

5.26. The '080 Patent has 2 independent claims and 8 dependent claims. *Id.* Genentech is asserting claims 1-3, 5-7, 9, and 10 of the '080 Patent in this Investigation. Further investigation and discovery may lead to the assertion of additional claims.

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5.27. The Asserted Claims of the '080 Patent are valid, enforceable, and currently in full force and effect until the expiration of the '080 Patent on July 8, 2028. Genentech holds all rights, title, and interest in the '080 Patent with full rights to enforce the same. **Exhibit 8**.

5.28. Pursuant to Commission Rule 210.12(c), copies of the certified prosecution history of the '080 Patent have been submitted with this Complaint as **Appendix D**. Pursuant to Commission Rule 210.12(c), the prosecution histories for any priority applications for the '080 Patent also have been submitted with this Complaint as **Appendix H**.

(b) Non-Technical Description of the Patent

5.29. The '080 Patent generally relates to methods for preventing reduction of disulfide bonds during a pertuzumab antibody manufacturing process by inhibiting the antibody reduction machinery in pre-harvest or harvested cell culture fluid following completion of a cell culture process. The claimed technology resulted from Genentech's discovery as described above in the context of the '997 Patent.

(c) Foreign and Domestic Counterparts to the Patent

5.30. The foreign patents and foreign or domestic patent applications corresponding to the '080 Patent, including any denied, abandoned, or withdrawn applications, are listed in **Exhibit 22**. No other foreign patents or foreign or domestic patent applications corresponding to the '080 Patent are known to Genentech at this time.

(d) Licenses

5.31. Pursuant to Commission Rule 210.12(a)(9)(iii), the licensed entities for the '080 Patent are listed in **Confidential Exhibit 23** to this Complaint. There are no other licensed entities to the '080 Patent other than those listed in **Confidential Exhibit 23**.

PUBLIC VERSION**VI. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS**

6.1. Biocon has developed BMAB 1500/PERT-IJS, a product that it purports to be biosimilar to PERJETA[®]. On information and belief, Biocon purports that BMAB 1500/PERT-IJS contains the same antibody—pertuzumab—that is the active ingredient in PERJETA[®]. On information and belief, Biocon is manufacturing BMAB 1500/PERT-IJS in India. **Exhibit 17.**

6.2. Although Biocon has not yet received FDA approval to market BMAB 1500/PERT-IJS, it has already committed unlawful and unfair acts as described below. Furthermore, on information and belief based on FDA's past review of biosimilar applications, Biocon could receive FDA approval to market BMAB 1500/PERT-IJS by the end of 2026.

A. Specific Instances of Unfair Importation and Sale

6.3. On information and belief, Biocon has imported commercial quantities of its PERJETA[®] biosimilar, BMAB 1500/PERT-IJS, which it intends to market to healthcare providers as a substitute for PERJETA[®] upon receiving FDA approval. On information and belief, Proposed Respondent Biocon Ltd. manufactures BMAB 1500/PERT-IJS in its facilities at Sez Plot No. 2, 3, 4 & 5 Phase IV, Bommasandra Post, Bengaluru, India. **Exhibit 17.** On information and belief, BMAB 1500/PERT-IJS is then imported into the United States.

6.4. On information and belief, Proposed Respondent Biocon Biologics Ltd. submitted the aBLA for its pertuzumab biosimilar product, BMAB 1500/PERT-IJS, to the FDA. **Exhibit 15.** On information and belief, Proposed Respondent Biocon Biologics Ltd. acts in concert with Proposed Respondents Biocon Ltd., Biocon Biologics Inc., Biocon Biologics International Ltd., and Biocon Biologics UK PLC to develop, manufacture, import, seek regulatory approval for, market, distribute, and sell BMAB 1500/PERT-IJS in the United States.

6.5. On information and belief, Biocon Biologics Inc. is a wholly owned subsidiary of Biocon Biologics UK PLC established to undertake all activities, such as commercialization and

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distribution, relating to biologic products imported into the United States. **Exhibit 20** at 190. On information and belief, Biocon Biologics Inc. acts in concert with Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics International Ltd., and Biocon Biologics UK PLC to import, commercialize, and distribute BMAB 1500/PERT-IJS for use in the United States.

6.6. On information and belief, Biocon Biologics International Ltd. is a wholly owned subsidiary of Biocon Biologics Ltd. and is identified under its old name, Biocon Biologics UK Ltd., as a sponsor of the clinical development of BMAB 1500/PERT-IJS. **Exhibit 20** at 189; **Exhibit 21**. On information and belief, Biocon Biologics International Ltd. acts in concert with Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics Inc., and Biocon Biologics UK PLC to seek regulatory approval for and import BMAB 1500/PERT-IJS for use in the United States.

6.7. On information and belief, Biocon Biologics UK PLC is a wholly owned subsidiary of Biocon Biologics Ltd. and is identified under its old name, Biosimilars Newco Ltd., as involved in the biosimilars business of Biocon Ltd. and Biocon Biologics Ltd.'s trastuzumab, bevacizumab, pegfilgrastim, glargine, aspart, and ustekinumab products "across the globe." **Exhibit 20** at 189. On information and belief, Biocon Biologics UK PLC acts in concert with Biocon Ltd., Biocon Biologics Ltd., Biocon Biologics Inc., and Biocon Biologics International Ltd. to seek regulatory approval for and import BMAB 1500/PERT-IJS for use in the United States.

6.8. On information and belief, Biocon Ltd. is the ultimate parent entity of the Biocon corporate group, and all other entities identified as Proposed Respondents in this Complaint are each in the process of becoming direct or indirect wholly owned subsidiaries of Biocon Ltd. and are subject to Biocon Ltd.'s ownership, direction, and control. *Id.* at 187. On information and belief, at all relevant times, Biocon Ltd. exercised control over the policies, finances, and operations of its wholly owned subsidiaries, and those entities acted at the direction of, under the

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control of, and/or in concert with Biocon Ltd. Accordingly, Biocon Ltd. and its wholly owned subsidiaries operate as a single enterprise for purposes of the acts alleged herein.

6.9. On information and belief, Biocon has imported BMAB 1500/PERT-IJS into the United States at commercial-scale. For example, according to FDA databases, Shipment ID 101-3285473-9/10003-1 arrived in the United States from India on October 18, 2025. **Exhibit 17**. The Import Trade Auxiliary Communications System (“ITACS”) Product Description is “BMAB 1500.” **Exhibit 18**. The FDA’s Imports Entry Database identifies Shipment ID 101-3285473-9/10003-1 as manufactured by “Biocon Limited” and the Product Code Description is “Pertuzumab.” **Exhibit 17**. The key shipment information contained in **Exhibits 17** and **18** is summarized in the table below:

Shipment ID	Arrival Date	Manufacturer	Country of Origin	Product Code	FDA Product Code Description	ITACS Product Description	ITACS Quantity
101-3285473-9/10003-1	10/18/2025	Biocon Limited	India	58DIP46	Pertuzumab	BMAB 1500	Total: 17820.0 Pieces

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6.10. A record view from FDA’s database for the shipment is set forth below:

Record View

Shipment ID:	101-3285473-9/10003/1
Arrival Date:	10/18/2025
Submission Date:	10/20/2025
Port of Entry Division:	Division of Southeast Imports
Country of Origin:	India
Product Code:	58DIP46
Product Code Description:	PERTUZUMAB
Manufacturer FEI Number:	3010164491
Manufacturer Legal Name:	Biocon Limited
Manufacturer Line1 Address:	Sez Plot No. 2,3, 4 & 5 Phase Iv, Bommasandra Post
Manufacturer Line2 Address:	Bommasandra-Jigani Link Road
Manufacturer City Name:	Bengaluru
Manufacturer Country:	India
Filer FEI Number:	1000525397
Filer Legal Name:	Kuehne + Nagel Inc
Filer Line1 Address:	7297 Conway Rd Ste 100
Filer Line2 Address:	
Filer City Name:	Orlando
Filer State Code:	FL
Filer County Code:	95
Filer Zip Code:	32812-3853
Filer Country:	United States
Final Disposition:	MPro Issued
Final Disposition Date:	10/20/2025
Product Category:	

Exhibit 17.

6.11. The above import came from the entity registered under FDA Establishment Identifier (“FEI”) number 3010164491, which is assigned to Biocon Limited. **Exhibit 24.** This shipment reflects the importation of substantial quantities of Accused Products—over 17,800

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pieces. **Exhibit 18.** The record from FDA's ITACS database reflecting the quantity of BMAB 1500/PERT-IJS imported is reproduced below:

Select	Entry/CBP-FDA[Suffix]	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date
<input type="checkbox"/>	101-3285473-9/10003-1	BMAB 1500	58DIP46	Total: 17820.0 Pieces (17820.0 Pieces)	India	May Proceed Without FDA Examination	10/20/2025	Document Submitted	10/20/2025

Id.

6.12. On information and belief, this shipment is not related to clinical trials seeking approval of BMAB 1500/PERT-IJS because, *inter alia*, (1) Biocon's Phase 1 trial was completed before BMAB 1500/PERT-IJS was imported; and (2) Biocon's Phase 3 trial never included any sites within the United States. **Exhibit 25; Exhibit 21.** Genentech is unaware of any clinical trials for Biocon's BMAB 1500/PERT-IJS that were active at the time of Biocon's importation. Instead, on information and belief, the imported quantity of BMAB 1500/PERT-IJS is intended to be stockpiled in anticipation of providing product to supply the U.S. commercial market. As described above, such stockpiling constitutes patent infringement and is not protected by any safe harbor.

6.13. Further, Biocon announced that it submitted its biosimilar application to the FDA, signaling its intent to commercially market its BMAB 1500/PERT-IJS in the United States. **Exhibit 15.** As such, on information and belief, Biocon's actions constitute an importation into the United States of a patented product made by a patented process and not protected by the safe harbor.

6.14. On information and belief, Biocon caused the importation of BMAB 1500/PERT-IJS. Because it has not been FDA-approved for commercial sale to the public, any importation of BMAB 1500/PERT-IJS must be directly ordered by and for Biocon.

PUBLIC VERSION**B. The Accused Products and Proposed Respondents' Act of Infringement**

6.15. Based on available information after a reasonable investigation, Biocon's BMAB 1500/PERT-IJS infringes the Asserted Claims of the Asserted Patents literally or under the doctrine of equivalents.

1. Infringement of U.S. Patent No. 8,652,474

6.16. On information and belief, Biocon imports into the United States Accused Products that infringe the '474 Patent, literally or under the doctrine of equivalents. Biocon's acts constitute direct infringement under 35 U.S.C. § 271(a).

6.17. On information and belief, Biocon's BMAB 1500/PERT-IJS directly infringes at least claims 1, 4, 6, 11-12, and 15 of the '474 Patent as the composition of BMAB 1500/PERT-IJS meets each element of those claims.

6.18. For example, claim 1 of the '474 Patent recites a "composition comprising a main species HER2 antibody that binds to domain II of HER2 and comprises variable light and variable heavy amino acid sequences in SEQ ID Nos. 3 and 4, respectively, and acidic variants thereof comprising disulfide reduced variant and non-reducible variant of the main species antibody."

6.19. On information and belief, BMAB 1500/PERT-IJS comprises a composition comprising pertuzumab, a main species HER2 antibody that binds to domain II of HER2. **Exhibit 14** at 22; **Exhibit 15**; **Exhibit 25**; **Exhibit 21**.

6.20. As indicated by regulatory guidelines and Biocon's practice in developing biosimilar antibodies, on information and belief, the pertuzumab antibody in BMAB 1500/PERT-IJS comprises the same amino acid sequence as the pertuzumab in PERJETA[®], including the variable light and variable heavy sequences comprising SEQ ID Nos. 3 and 4, respectively. The statutes governing biosimilar approval define "biosimilar" or "biosimilarity" as requiring that "the biological product [be] highly similar to the reference product notwithstanding minor differences

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in clinically inactive components,” with “no clinically meaningful differences” in safety, purity, and potency. 42 U.S.C. § 262(i)(2). The FDA has implemented that statutory requirement by issuing multiple regulatory guidelines directing biosimilar sponsors to use carefully controlled manufacturing processes and rigorous comparative analytical assessment (“CAA”) to demonstrate that the proposed biosimilar product closely matches the reference product’s structural and functional “fingerprint.” The FDA therefore expects the amino acid sequence of the proposed biosimilar product to be the same as that of the reference product. **Exhibit 26** at 9. Consistently, Biocon’s other biosimilar monoclonal antibodies have an identical amino acid sequence to the reference product. **Exhibit 27** at 22; **Exhibit 28** at 17.

6.21. On information and belief, evidence will show that BMAB 1500/PERT-IJS is more likely than not to comprise a composition comprising acidic variants of pertuzumab, including disulfide reduced variants and non-reducible variants. As shown in the accompanying Exemplary Chart of Genentech’s Practice of U.S. Patent No. 8,652,474 (**Confidential Exhibit 29**), PERJETA[®] comprises these claimed variants of pertuzumab. On information and belief, evidence will show that it is more likely than not that Biocon monitors and controls the variant profile of BMAB 1500/PERT-IJS to match that of the reference product PERJETA[®]. On information and belief, Biocon does so to support a claim of biosimilarity to PERJETA[®] and obtain FDA approval of BMAB 1500/PERT-IJS. The FDA’s guidance for biosimilar products instructs manufacturers to demonstrate biosimilarity to the reference product by comprehensively characterizing the profile of antibody variants. **Exhibit 30** at 3; **Exhibit 26** at 11; **Exhibit 31** at 9.

6.22. Consistently, Biocon’s patent describing pharmaceutical formulations of pertuzumab discloses monitoring and controlling the levels of antibody variants. **Exhibit 32**. Indeed, on information and belief, Biocon uses a contract research organization, Kymos Group, as

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a batch release site to confirm the level of antibody variants in its biosimilar products. **Exhibit 33**. Based on the regulatory guidance, Biocon's disclosures in its patent, and Biocon's practice in developing biosimilar antibodies, the evidence will show it is more likely than not that Biocon likewise controls the variant profile of BMAB 1500/PERT-IJS to match that of PERJETA[®].

6.23. Further, on information and belief, Biocon submitted its aBLA for BMAB 1500/PERT-IJS without completing a Phase III clinical trial because it has received a so-called "Phase III waiver" from the FDA. A Phase III waiver permits a biosimilar to submit an aBLA application without Phase III clinical trial data which, on information and belief, Biocon has done here. Before granting a Phase III waiver, the FDA evaluates whether the biosimilar manufacturer has provided a comprehensive CAA demonstrating analytically that the proposed biosimilar is highly similar to the reference product. **Exhibit 34** at 4. Related FDA guidance for CAA instructs characterizing and matching antibody variants in the reference product—matching the reference product "fingerprint"—and in particular, determination of "the number and positions of any free sulfhydryl groups and/or disulfide bridges." **Exhibit 30** at 18. Thus, on information and belief, Biocon has generated CAA data to support its representation to the FDA that BMAB 1500/PERT-IJS is analytically similar to PERJETA[®], including in the claimed variants of pertuzumab.

6.24. The above facts support that evidence will show that BMAB 1500/PERT-IJS is more likely than not to contain acidic variants, including disulfide reduced variants and non-reducible variants, of pertuzumab.

6.25. An exemplary claim chart demonstrating how the composition of BMAB 1500/PERT-IJS infringes the independent Asserted Claims of the '474 Patent is attached to the Complaint as **Exhibit 35**.

PUBLIC VERSION**2. Infringement of U.S. Patent No. 11,597,776**

6.26. On information and belief, Biocon imports into the United States Accused Products made by a process that infringes the '776 Patent, literally or under the doctrine of equivalents. Biocon's acts constitute direct infringement under 35 U.S.C. § 271(g).

6.27. On information and belief, Biocon's BMAB 1500/PERT-IJS directly infringes at least claims 1-4, 7, 13-14, 17-19, 21, and 25-27 of the '776 Patent as the process used to produce BMAB 1500/PERT-IJS includes a step that meets each and every element of those claims.

6.28. For example, claim 1 of the '776 Patent recites a "method of making a pharmaceutical formulation comprising combining: (i) a composition comprising: (a) a main species HER2 antibody comprising light chain and heavy chain amino acid sequences set forth in SEQ ID Nos. 15 and 16, respectively; and (b) acidic variants of the main species antibody, comprising a disulfide reduced variant, with: (ii) a pharmaceutically acceptable carrier."

6.29. As shown above with respect to the '474 Patent, on information and belief, evidence will show that BMAB 1500/PERT-IJS is more likely than not to comprise a composition comprising pertuzumab and acidic variants of pertuzumab, including disulfide reduced variants. For the same reasons stated above for the '474 Patent, on information and belief, the pertuzumab antibody in BMAB 1500/PERT-IJS comprises the same amino acid sequence as the pertuzumab in PERJETA[®], *i.e.*, light chain and heavy chain amino acid sequences set forth in SEQ ID Nos. 15 and 16, respectively.

6.30. On information and belief, BMAB 1500/PERT-IJS is made by a process comprising a method of making a pharmaceutical formulation comprising combining the above composition with a pharmaceutically acceptable carrier. Biocon's press releases and published clinical trial information indicate that BMAB 1500/PERT-IJS comprises a pharmaceutical formulation. **Exhibit 15; Exhibit 25; Exhibit 21.** On information and belief, Biocon described its

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pharmaceutical formulation for BMAB 1500/PERT-IJS in an issued patent. **Exhibit 32.** The Biocon patent discloses “a method of making a pharmaceutical formulation comprising preparing the formulation as described herein,” including exemplary processes comprising mixing the antibody with pharmaceutically acceptable carriers including sorbitol and polyethylene glycol. *Id.* at 20:43-45, 20:60-67.

6.31. The above facts support that evidence will show that BMAB 1500/PERT-IJS is more likely than not made by a process that practices the claimed methods of the '776 Patent.

6.32. An exemplary claim chart demonstrating how the process of producing BMAB 1500/PERT-IJS infringes the independent Asserted Claims of the '776 Patent is attached to the Complaint as **Exhibit 36.**

3. Infringement of U.S. Patent No. 12,145,997

6.33. On information and belief, Biocon imports into the United States Accused Products made by a process that infringes the '997 Patent, literally or under the doctrine of equivalents. Biocon's acts constitute direct infringement under 35 U.S.C. § 271(g).

6.34. On information and belief, Biocon's BMAB 1500/PERT-IJS directly infringes at least claims 1-7 of the '997 Patent as the process used to produce BMAB 1500/PERT-IJS includes a step that meets each and every element of those claims.

6.35. For example, claim 1 of the '997 Patent recites a “method for the prevention of the reduction of a disulfide bond in a human epidermal growth factor receptor 2 (HER2) antibody expressed in a recombinant Chinese Hamster Ovary (CHO) host cell, comprising, following a production phase of a cell culture, sparging the pre-harvest cell culture fluid (CCF) or harvested culture fluid (HCCF) of said recombinant CHO host cell with air, wherein the amount of dissolved oxygen (dO₂) in the CCF or HCCF is at least 10%.”

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6.36. On information and belief, BMAB 1500/PERT-IJS is expressed in a recombinant CHO host cell, as claimed. Biocon claims to have a “consistent and scalable mammalian CHO and NSO cell-based expression platform” for making “biosimilar monoclonal antibodies.” **Exhibit 37**. Based on Biocon’s statements to the European Medicines Agency, Biocon uses this CHO cell-based expression platform to make a biosimilar of another HER2 antibody, trastuzumab, at its Bengaluru facility in India. *See, e.g., Exhibit 28* at 12. On information and belief, Biocon makes BMAB 1500/PERT-IJS using the same CHO cell-based expression platform at the same Bengaluru facility in India as its trastuzumab biosimilar product. As such, on information and belief, the evidence will show it is more likely than not that Biocon expresses BMAB 1500/PERT-IJS in a recombinant CHO host cell.

6.37. Further, on information and belief, evidence will show that it is more likely than not that BMAB 1500/PERT-IJS is made by a process comprising sparging the pre-harvest CCF or HCCF with air, as claimed. On information and belief, Biocon monitors and controls the level of disulfide bond reduction to support a claim of biosimilarity to PERJETA[®] and to obtain FDA approval for BMAB 1500/PERT-IJS. Biocon has submitted an abbreviated Biologics aBLA to the FDA seeking approval for commercializing BMAB 1500/PERT-IJS in the United States. **Exhibit 15**. The FDA’s guidance for CAA of biosimilar products specifically instructs biosimilars to address variants of the reference product. *See, e.g., Exhibit 26* at 11; **Exhibit 31** at 9. As such, on information and belief, evidence will show that it is more likely than not that Biocon monitors and controls the levels of variants, including disulfide reduced variants in its biosimilar.

6.38. Biocon’s patents also disclose monitoring and controlling disulfide bond reduction in BMAB 1500/PERT-IJS. On information and belief, Biocon described its pharmaceutical formulation for BMAB 1500/PERT-IJS in an issued patent. **Exhibit 32**. That Biocon patent

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the extent of disulfide bond reduction in BMAB 1500/PERT-IJS and employs a method to prevent it.

6.41. Moreover, on information and belief, the amount of dissolved oxygen (dO₂) in the pre-harvest CCF or HCCF of the Biocon process is likely to be at least 10%, as claimed in the '997 Patent. The widespread adoption of the now industry standard methods claimed in the '997 Patent—air sparging to prevent antibody reduction—indicates that it is more likely than not that Biocon is using the claimed methods. **Exhibit 41**. For example, there are different methods for preventing antibody reduction, such as adding copper sulfate, adding EDTA, or air sparging but air sparging has become the “preferred method” in the industry for preventing antibody reduction. *Id.* at 2, 3 (Table 1). That is because it has been shown to be a “robust and universal mitigation strategy to prevent [antibody] reduction,” without compromising product quality. **Exhibit 42** at 740. This recognition and praise for the benefits of the claimed methods over alternative methods of preventing reduction further indicate that, on information and belief, the evidence will show it is more likely than not that Biocon is using the claimed methods.

6.42. An exemplary claim chart demonstrating how the process of producing BMAB 1500/PERT-IJS infringes the independent Asserted Claims of the '997 Patent is attached to the Complaint as **Exhibit 43**.

4. Infringement of U.S. Patent No. 12,173,080

6.43. On information and belief, Biocon imports into the United States Accused Products made by a process that infringes the '080 Patent, literally or under the doctrine of equivalents. Biocon's acts constitute direct infringement under 35 U.S.C. § 271(g).

6.44. On information and belief, Biocon's BMAB 1500/PERT-IJS directly infringes at least claims 1-3, 5-7, 9, and 10 of the '080 Patent as the process used to produce BMAB 1500/PERT-IJS includes a step that meets each and every element of those claims.

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6.45. Claim 1 of the '080 Patent recites a “method for the prevention of the reduction of a disulfide bond in an IgG1 monoclonal antibody that binds to HER2 expressed by a recombinant Chinese Hamster Ovary (CHO) host cell, comprising supplementing pre-harvest cell culture fluid or harvested cell culture fluid of the recombinant CHO host cell with a thioredoxin inhibitor, wherein the thioredoxin inhibitor is added in an amount effective to prevent disulfide bond reduction of the antibody that binds to HER2 following completion of a cell culture process, and wherein the antibody that binds to HER2 comprises a light chain variable domain amino acid sequence set forth in SEQ ID NO: 16 and a heavy chain variable domain amino acid sequence set forth in SEQ ID NO: 17.”

6.46. As shown above with respect to the '997 Patent, on information and belief, BMAB 1500/PERT-IJS is expressed in a recombinant CHO host cell. Further, under the proper construction of the relevant terms, on information and belief, evidence will show that it is more likely than not that BMAB 1500/PERT-IJS is manufactured using a thioredoxin inhibitor because, as described above for the '997 Patent, Biocon likely uses air sparging following completion of a cell culture process to prevent reduction of disulfide bonds.

6.47. For the same reasons stated above for the '997 Patent, on information and belief, the pertuzumab antibody in BMAB 1500/PERT-IJS comprises the same amino acid sequence as the pertuzumab in PERJETA[®], *i.e.*, light chain and heavy chain variable domain amino acid sequences set forth in SEQ ID Nos. 16 and 17, respectively.

6.48. An exemplary claim chart demonstrating how the process of producing BMAB 1500/PERT-IJS infringes the independent Asserted Claims of the '080 Patent is attached to the Complaint as **Exhibit 44**.

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6.49. Genentech has not yet had the benefit of discovery, and thus this identification of types of products is not intended to limit the scope of the investigation. Any remedy should extend to all infringing products.

VII. HARMONIZED TARIFF SCHEDULE ITEM NUMBERS

7.1. On information and belief, the Harmonized Tariff Schedule of the United States item numbers under which the pertuzumab biosimilars and products containing the same may be imported into the United States may be at least HTSUS 3002.13.00.10 (immunological products, monoclonal antibodies), 3002.14.00.10 (immunological products, monoclonal antibodies), 3002.15.00.11 (immunological products, monoclonal antibodies), 3002.49.00 (vaccines, toxins, cultures of micro-organisms; other), and/or 3002.51.00 (cell therapy products). These classifications are intended for illustration only and are not intended to be restrictive of the Accused Products or of products subject to the relief requested.

VIII. THE DOMESTIC INDUSTRY

8.1. In accordance with Section 337(a)(2) and (a)(3), a domestic industry exists in the United States in connection with the Asserted Patents by virtue of Genentech's significant U.S. investments in the manufacture, engineering, discovery, and research and development of the Asserted Patents.

8.2. At a time when many pharmaceutical are developed and manufactured abroad, PERJETA[®] is made in the United States and Genentech's domestic investments include research, development, clinical trials, testing, manufacturing, supply chain management, packaging, warehousing, distribution, marketing, and commercialization, among other activities, related to PERJETA[®] ("Domestic Industry Product"), which has been sold in the United States since 2012. The Asserted Patents are practiced by the Domestic Industry Product, and the Domestic Industry Product is protected by the Asserted Patents.

PUBLIC VERSION**A. The Economic Prong of the Domestic Industry Requirement Is Satisfied**

8.3. Genentech has made substantial investments over many years in research, development, clinical testing, manufacturing, and commercialization that are designed to exploit the Asserted Patents. Those investments continue today, including most notably the manufacture of PERJETA[®] in the United States.

8.4. For example, the inventions described and claimed in the Asserted Patents were made possible through significant research and development efforts in the United States. Genentech's pharmaceutical and technical development teams dedicated substantial resources to the initial development of PERJETA[®] and to refining its manufacturing process by developing its Version 2.0 process. The original development of PERJETA[®] began in the early 2000s, with major R&D expenditures occurring throughout the decade leading up to its FDA approval in 2012.

Exhibit 45.

8.5. Genentech has also devoted substantial investments to developing and using the Version 2.0 manufacturing process, which was designed to increase production yield. For example, Genentech's investments included creating an entirely new cell line to comply with FDA post-marketing commitments. *Id.* Further substantial expenditures were required to implement the Version 2.0 manufacturing process in the United States. *Id.*

8.6. Genentech's financial systems confirm that substantial sums were spent on R&D efforts associated with PERJETA[®] in the United States. These investments in research and development were made at multiple U.S.-based research facilities and involved a dedicated workforce, including full-time scientists, engineers, and regulatory experts. *Id.*

8.7. Genentech has also made substantial investments in clinical trials related to the Asserted Patents and PERJETA[®]. The clinical trials for PERJETA[®] were multinational but involved significant U.S.-based expenditures, including over a decade of clinical research and trial

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execution in the U.S. and large-scale investments in U.S. clinical trial sites, personnel, and clinical trial subject testing. Those U.S. based investments are set forth in *Id.*

8.8. Financial records also confirm that substantial U.S.-based clinical trial spending took place to demonstrate the efficacy and safety of PERJETA[®] for FDA approval. *Id.*

8.9. The manufacturing of PERJETA[®] has been a cornerstone of Genentech’s U.S. operations. The PERJETA[®] drug substance continues to be manufactured at the Vacaville, California facility. [REDACTED]

[REDACTED] *Id.* Additionally, Genentech uses the PERJETA[®] drug substance made in Vacaville to make the PERJETA[®] drug product at its Hillsboro, Oregon facility.

8.10. Genentech has made and continues to make significant employment and financial investments in the U.S. in support of PERJETA[®]. Hundreds of U.S.-based employees have been involved in the development, regulatory, and manufacturing processes related to PERJETA[®]. Financial records confirm substantial employment of labor and capital specifically allocated to PERJETA[®]-related projects. *Id.*

B. The Technical Prong of the Domestic Industry Requirement Is Satisfied

8.11. Claim charts and explanatory information for products and processes that practice at least one valid asserted claim of the Asserted Patents accompany this Complaint. Genentech currently asserts that PERJETA[®] practices at least the following asserted claims:

U.S. Patent No.	Domestic Industry Asserted Claims
8,652,474	1, 4, 6, 11-12, 15
11,597,776	1-4, 7, 13-14, 17-19, 21, 25-27
12,145,997	1-7
12,173,080	1-3, 5-7, 9, 10

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8.12. **Confidential Exhibit 29** includes an exemplary claim chart that discloses how PERJETA[®] practices at least one claim of the '474 Patent.

8.13. **Confidential Exhibit 46** includes an exemplary claim chart that discloses how PERJETA[®] practices at least one claim of the '776 Patent.

8.14. **Confidential Exhibit 47** includes an exemplary claim chart that discloses how PERJETA[®] practices at least one claim of the '997 Patent.

8.15. **Confidential Exhibit 48** includes an exemplary claim chart that discloses how PERJETA[®] practices at least one claim of the '080 Patent.

IX. RELATED LITIGATION

9.1. The Asserted Patents (the '474, '776, '997, and '080 Patents) were the subject of a civil action in the United States District Court for the District of New Jersey, 2:25-cv-14648, filed on August 14, 2025, by Genentech and Hoffman-La Roche Inc. naming Shanghai Henlius Biotech, Inc.; Shanghai Henlius Biologics Co., Ltd.; Organon LLC; and Organon & Co. as Defendants. On January 30, 2026, the action was dismissed with prejudice following a joint stipulation by the parties.

9.2. Other members of the '997 and '080 Patents' family have previously been asserted by Genentech are listed in **Exhibit 49**.

9.3. No other court, agency or arbitration litigations related to the asserted patents are known to Genentech at this time.

X. RELIEF REQUESTED

10.1. WHEREFORE, by reason of the foregoing, Genentech respectfully requests that the Commission:

- (a) Institute an Investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(B)(i) and (b)(1) with respect to violations of

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Section 337 based upon the sale for importation, importation, and/or sale after importation in the United States by the Proposed Respondents of pertuzumab biosimilars and products containing the same that infringe one or more of the Asserted Claims of the Asserted Patents;

(b) Schedule and conduct a hearing on the unlawful acts and, following the hearing, determine that there has been a violation of Section 337 based on said unlawful acts;

(c) Issue a permanent limited exclusion order under 19 U.S.C. § 1337(d)(1)—extending only through expiration of the last Asserted Patent—barring from entry into the United States all infringing pertuzumab biosimilars, including BMAB 1500/PERT-IJS, and products containing the same manufactured by or on behalf of, or sold for importation, imported, and/or sold after importation by or on behalf of, each of the Proposed Respondents or their affiliates, except for imports that Proposed Respondents certify will be used only in clinical trials and will not be offered for commercial sale;

(d) Issue permanent cease and desist orders, under 19 U.S.C. § 1337(f), prohibiting each Proposed Respondent and its subsidiaries, related companies, distributors, and agents from at least using, importing, selling, offering for sale, selling for importation, transferring, distributing warehousing inventory for distribution, making, assembling, advertising, marketing, demonstrating, and testing the Accused Products, except for imports that Proposed Respondents certify will be used only in clinical trials and will not be offered for commercial sale;

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(e) Impose a bond upon the Proposed Respondents who continue to import infringing articles, including pertuzumab biosimilars and products containing the same, during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(j); and

(f) Grant such other and further relief as the Commission deems just and proper based on the facts determined by the Investigation and the authority of the Commission.

Dated: February 27, 2026

Respectfully Submitted,

/s/ Michael A. Morin

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VERIFICATION

I, Michael Laird, declare in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury, that the following statements are true:

1. I am Vice President, Global MSAT Drug Substance Biologics Technology Innovation and Commercial Products Support of Genentech, Inc., and I am duly authorized to verify this Complaint under Section 337 of the Tariff Act of 1930, as Amended (“Complaint”);

2. I have read the Complaint and am aware of its contents;

3. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, (a) the claims and other legal contentions in the Complaint are warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law, and (b) the allegations and other factual contentions in the Complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and

4. The Complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the Investigation or related proceedings.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

DocuSigned by:
Michael Laird
F2E358AACB51446...

Michael Laird