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11 REDACTED VERSION OF DOCUMENT
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12
13 UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
14

15 CELLTRION, INC., CELLTRION
HEALTHCARE, CO. LTD., TEVA
16 PHARMACEUTICALS INTERNATIONAL
GMGH, and
17 TEVA PHARMACEUTICALS USA, INC.

18 Plaintiffs,

19 v.

20 GENENTECH, INC., HOFFMANN LA-
ROCHE INC. and CITY OF
21 HOPE,

22 Defendants.

Case No. 3:18-cv-274

**COMPLAINT FOR
DECLARATORY JUDGMENT OF
PATENT NON-INFRINGEMENT,
INVALIDITY, AND/OR
UNENFORCEABILITY**

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1 Plaintiffs Celltrion, Inc. (“Celltrion Inc.”), Celltrion Healthcare, Co. Ltd. (“Celltrion
2 Healthcare”) (collectively “Celltrion”), Teva Pharmaceuticals International GmbH (“TPIG”), and
3 Teva Pharmaceuticals USA, Inc. (“Teva USA”) (collectively “Teva”) (collectively with Celltrion,
4 Celltrion Healthcare, and TPIG, “Plaintiffs”) bring this action for declaratory judgment of patent
5 non-infringement, invalidity and unenforceability against Defendants Genentech, Inc.
6 (“Genentech”), Hoffmann-La Roche Inc. (“Roche”) and City of Hope. This is a case to protect
7 Celltrion and Teva’s efforts to bring more affordable drugs to market. Celltrion and Teva have
8 developed technology to manufacture antibodies known to be effective in treating several types of
9 cancer and other serious diseases, and have sought FDA approval to market a product containing
10 these antibodies. Genentech has claimed that forty patents will be infringed by Celltrion and
11 Teva. Rather than focusing their assertion, Defendants have rested on a complex series of patents
12 from two dozen patent families. As Celltrion has already demonstrated to Genentech, these
13 allegations are wrong and the panoply of vague allegations are simply intended to interfere with
14 Celltrion and Teva’s entry into the market. This case seeks to clear the underbrush of Defendants’
15 allegations to ensure that Celltrion and Teva’s biosimilar product can help millions of people facing
16 life-threatening diseases today.

17 NATURE OF THE CASE

18 1. This is an action for declaratory judgment of non-infringement, invalidity, and
19 unenforceability relating to the following patents:

- 20 (i) U.S. Patent No. 6,331,415 (“the ’415 patent”);
- 21 (ii) U.S. Patent No. 6,339,142 (“the ’142 patent”)
- 22 (iii) U.S. Patent No. 6,407,213 (“the ’213 patent”)
- 23 (iv) U.S. Patent No. 6,417,335 (“the ’335 patent”);
- 24 (v) U.S. Patent No. 6,489,447 (“the ’447 patent”);
- 25 (vi) U.S. Patent No. 6,586,206 (“the ’206 patent”);
- 26 (vii) U.S. Patent No. 6,610,516 (“the ’516 patent”);
- 27 (viii) U.S. Patent No. 6,620,918 (“the ’918 patent”);

- 1 (ix) U.S. Patent No. 6,627,196 (“the ’196 patent”)
- 2 (x) U.S. Patent No. 6,716,602 (“the ’602 patent”);
- 3 (xi) U.S. Patent No. 7,371,379 (“the ’379 patent”)
- 4 (xii) U.S. Patent No. 7,390,660 (“the ’660 patent”);
- 5 (xiii) U.S. Patent No. 7,449,184 (“the ’184 patent”)
- 6 (xiv) U.S. Patent No. 7,485,704 (“the ’704 patent”);
- 7 (xv) U.S. Patent No. 7,501,122 (“the ’122 patent”);
- 8 (xvi) U.S. Patent No. 7,807,799 (“the ’799 patent”);
- 9 (xvii) U.S. Patent No. 7,846,441 (“the ’441 patent”);
- 10 (xviii) U.S. Patent No. 7,892,549 (“the ’549 patent”);
- 11 (xix) U.S. Patent No. 7,923,221 (“the ’221 patent”);
- 12 (xx) U.S. Patent No. 7,993,834 (“the ’834 patent”);
- 13 (xxi) U.S. Patent No. 8,076,066 (“the ’066 patent”);
- 14 (xxii) U.S. Patent No. 8,357,301 (“the ’301 patent”);
- 15 (xxiii) U.S. Patent No. 8,425,908 (“the ’908 patent”);
- 16 (xxiv) U.S. Patent No. 8,440,402 (“the ’402 patent”);
- 17 (xxv) U.S. Patent No. 8,460,895 (“the ’895 patent”);
- 18 (xxvi) U.S. Patent No. 8,512,983 (“the ’983 patent”);
- 19 (xxvii) U.S. Patent No. 8,574,869 (“the ’869 patent”);
- 20 (xxviii) U.S. Patent No. 8,633,302 (“the ’302 patent”);
- 21 (xxix) U.S. Patent No. 8,691,232 (“the ’232 patent”);
- 22 (xxx) U.S. Patent No. 8,771,988 (“the ’988 patent”);
- 23 (xxxii) U.S. Patent No. 8,822,655 (“the ’655 patent”);
- 24 (xxxiii) U.S. Patent No. 9,047,438 (“the ’438 patent”);
- 25 (xxxiv) U.S. Patent No. 9,080,183 (“the ’183 patent”);
- 26 (xxxv) U.S. Patent No. 9,249,218 (“the ’218 patent”);
- 27 (xxxvi) U.S. Patent No. 9,428,548 (“the ’548 patent”);

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1 (xxxvi) U.S. Patent No. 9,428,766 (“the ’766 patent”);

2 (xxxvii) U.S. Patent No. 9,487,809 (“the ’809 patent”); and

3 (xxxviii) U.S. Patent No. 9,714,293 (“the ’293 patent”) (collectively, “the patents-in-suit”).

4 2. According to Genentech, the patents-in-suit relate to an antibody product called
5 trastuzumab, which Genentech markets under the brand name Herceptin®. Herceptin® is
6 approved by the FDA for the treatment of HER2 overexpressing breast cancer, and HER2-
7 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

8 3. On information and belief, Roche is an owner of certain patents-in-suit, and has
9 provided Genentech with the rights to enforce certain of the patents-in-suit.

10 4. On information and belief, each patent-in-suit is owned by at least one of
11 Genentech, Roche, or City of Hope.

12 5. A substantial controversy exists between Plaintiffs, on the one hand, and
13 Genentech, Roche, and City of Hope, on the other hand, in which the parties have adverse legal
14 interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.
15 Celltrion Healthcare, Celltrion Inc., and TPIG entered into a business collaboration agreement to
16 commercialize CT-P6, a biosimilar to Herzuma®. Celltrion Inc. submitted an Abbreviated
17 Biologics License Application (“aBLA”) to the FDA under 42 U.S.C. § 262(k) of the Biologics
18 Price Competition and Innovation Act of 2009 (the “BPCIA”) for licensure of a trastuzumab
19 biological product (hereinafter, “biosimilar product,” “CT-P6,” or “Herzuma®”) that is highly
20 similar to Herceptin®. Teva USA will sell and distribute the CT-P6 product in the United States.
21 The FDA accepted Celltrion Inc.’s biosimilar application on July 28, 2017. Celltrion Inc. provided
22 Genentech with a copy of its aBLA and other detailed information regarding the manufacturing
23 processes used to make Herzuma® and, in response, Genentech identified the patents which
24 Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use,
25 offer for sale, or sell in the United States, or import into the United States, the biosimilar product.
26 Celltrion Inc. then provided Genentech with a detailed statement regarding the invalidity,
27 unenforceability, and/or non-infringement of the patents that Genentech identified, along with
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1 citations to the aBLA and other manufacturing information that Celltrion produced to Genentech.
2 In response, Genentech provided Plaintiffs with a statement purporting to contain the factual and
3 legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the
4 commercial marketing of the biosimilar product.

5 6. Pursuant to 42 U.S.C. § 262(l)(8)(A) [REDACTED], Celltrion Inc. provided
6 Genentech with notice that the first commercial marketing of Herzuma® will commence no earlier
7 than 180 days from the date of the notice.

8 **PARTIES**

9 7. Celltrion Inc. is a corporation organized and existing under the laws of the
10 Republic of Korea, with a place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-840,
11 South Korea.

12 8. Celltrion Healthcare, Co. Ltd. is a corporation organized under the laws of the
13 Republic of Korea, having its place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-
14 840, South Korea.

15 9. Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a place of business
16 at 1090 Horsham Road, North Wales, PA 19454-1090.

17 10. TPIG is a limited liability company organized and existing under the laws of
18 Switzerland, having its corporate offices and a place of business at Schlüsselstrasse 12, Jona (SG)
19 8645, Switzerland.

20 11. On information and belief, Defendant Genentech, Inc. is a corporation with its
21 principal place of business in this District at 1 DNA Way, South San Francisco, CA 94080.

22 12. On information and belief, Defendant City of Hope is a not-for-profit organization
23 organized and existing under the laws of California, having its principal place of business at 1500
24 East Duarte Road, Duarte, California 91010.

25 13. On information and belief, Defendant Hoffmann La-Roche Inc. is a company
26 organized and existing under the laws of the State of New Jersey with its principal place of
27 business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

JURISDICTION AND VENUE

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2 14. This is a declaratory judgment action arising under the patent laws of the United
3 States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28
4 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act,
5 28 U.S.C. §§ 2201 and 2202.

6 15. Celltrion Inc. provided to Genentech the aBLA required under 42 U.S.C. §
7 262(l)(2)(A), and also provided additional manufacturing information to Genentech. In response,
8 Genentech identified the patents-in-suit pursuant to 42 U.S.C. § 262(l)(3)(A), which Genentech
9 alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for
10 sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion
11 Inc. provided Genentech with a detailed statement why Plaintiffs will not infringe any of the
12 patents-in-suit. Genentech then provided Plaintiffs with a statement purporting to contain the
13 factual and legal basis of Genentech’s opinion that some of the patents-in-suit would be infringed
14 by the commercial marketing of Celltrion’s biosimilar product.

15 16. On [REDACTED], Celltrion provided notice of commercial marketing to
16 Genentech pursuant to 42 U.S.C. § 262(l)(8)(A).

17 17. The Court has personal jurisdiction over Genentech because Genentech has its
18 headquarters and principal place of business in the State of California, in this District. On
19 information and belief, Genentech’s South San Francisco campus is its headquarters for its
20 pharmaceutical operations in the United States. Genentech also maintains multiple other facilities
21 in California, including a biotech manufacturing and clinical operations complex in Oceanside,
22 California, and a biotechnology manufacturing plant in Vacaville, California.

23 18. Upon information and belief, Genentech markets, distributes and sells
24 pharmaceutical products, including Herceptin®, in California, including in this District.
25 Genentech’s continuous and systematic corporate operations within California are so substantial
26 and of such a nature to justify suit against it on causes of action arising from dealings entirely
27 distinct from those activities.

1 19. The Court also has personal jurisdiction over Genentech because, among other
2 reasons, Genentech's activities in California gave rise to this action. For example, Genentech,
3 which is located in this District, directed its counsel to send Plaintiffs' counsel (i) correspondence
4 related to the BPCIA exchanges described above, (ii) a list of patents that it purports could
5 reasonably be asserted against Plaintiffs, and (iii) a statement that purports to describe, among
6 other things, the factual and legal basis of Genentech's opinion that patents that it owns, or for
7 which it is an exclusive licensee, will be infringed by the commercial marketing of the biosimilar
8 product, all within this District and the State of California.

9 20. The Court has personal jurisdiction over City of Hope because, among other
10 reasons, upon information and belief, it is organized under the laws of the State of California and
11 has its principal place of business in California. Upon information and belief, City of Hope is the
12 co-owner of one or more patents-in-suit. City of Hope also maintains a place of business for
13 fundraising and development in this District at 55 Hawthorne Street, Ste. 450, San Francisco,
14 California 94105.

15 21. This Court also has personal jurisdiction over City of Hope because City of Hope
16 has purposefully directed various activities at this District which gave rise to this action. For
17 example, on information and belief, City of Hope collaborated with San-Francisco-based
18 Genentech to research and/or develop the subject matter of certain patents-in-suit and/or entered
19 into contractual agreements with San-Francisco-based Genentech regarding certain patents-in-suit.
20 In addition, on information and belief, City of Hope has knowingly consented to and/or
21 collaborated with San-Francisco-based Genentech's enforcement actions regarding one or more of
22 the patents-in-suit.

23 22. The Court has personal jurisdiction over Roche because, upon information and belief,
24 Roche researches, manufactures, and markets branded drug products, and continuously and
25 systematically conducts business throughout the United States, including in California. Roche is
26 licensed to do business in the State of California. Roche's headquarters for commercial operations
27 are in this District at 1 DNA Way, South San Francisco, CA 94080. Roche's continuous and
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1 systematic corporate operations within California are so substantial and of such a nature to justify
2 suit against it on causes of action arising from dealings entirely distinct from those activities.

3 23. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, among
4 other reasons, Genentech, City of Hope, and Roche all reside and are subject to personal
5 jurisdiction in this District for purposes of this action as set forth above. In addition, venue is
6 proper in this district because a substantial part of the events that gave rise to this action occurred
7 in this District. For example, on information and belief, one or more of Genentech, City of Hope,
8 and Roche collaborated in this District regarding research and/or development of the subject matter
9 of certain patents-in-suit and/or entered into contractual agreements with San Francisco-based
10 Genentech regarding certain patents-in-suit. In addition, on information and belief, one or more of
11 City of Hope and Roche have knowingly consented to and/or collaborated with San-Francisco-
12 based Genentech's enforcement actions regarding one or more of the patents-in-suit. Moreover,
13 Genentech, which is located in this District, has directed certain activities at Plaintiffs' counsel
14 relating to the enforcement of the patents-in-suit, including the transmission of (i) correspondence
15 related to the BPCIA exchanges described above, (ii) a list identifying the patents-in-suit among
16 those patents that Genentech believes could reasonably be asserted against Plaintiffs following the
17 submission of their subsection (k) application, and (iii) a statement that purports to describe
18 Genentech's opinions regarding the infringement, validity, and enforceability of the patents-in-suit.
19 Furthermore, Genentech and City of Hope have litigated in this District at least 11 separate actions
20 relating to one or more of the patents-in-suit, including those having civil action numbers 5-15-cv-
21 01238; 3-13-cv-02045; 4-13-cv-00919; 4-11-cv-02410; 3-11-cv-01925; 5-10-cv-04255; 5-10-cv-
22 02037; 3-10-cv-00675; 3-09-cv-04919; 5-08-cv-05590; 3-08-cv-04909; 4-04-cv-05429; 3-04-cv-
23 01910; 3-03-cv-01603; 3-01-cv-03560; 5-01-cv-20434; 3-98-cv-03926.

24 **FACTUAL BACKGROUND**

25 24. Celltrion was founded in 2002 with the mission of developing and supplying
26 medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases.
27 Such patients previously had limited access to advanced therapeutics such as biologic drugs due to
28

1 their high cost and relative shortage of availability. Celltrion develops, manufactures, and
2 distributes biosimilars and novel biologics to introduce competition in the pharmaceutical market
3 for antibody biologics, to offer alternative solutions for previously limited, high-cost therapies.
4 Because of their complexity, biologic drugs require substantially more effort, monetary resources
5 and technical expertise to develop than traditional drugs that are synthesized chemically.

6 25. Over the last 15 years, Celltrion has made significant investments in human
7 resources, facilities, and technology to become a global leader in biologics. Celltrion spear-headed
8 global efforts to produce a biosimilar version of monoclonal antibody biologics, and received
9 marketing approval for the world's first biosimilar monoclonal antibody in 2012. In 2014,
10 Celltrion achieved another global first, and obtained approval for a biosimilar oncology
11 monoclonal antibody. Celltrion has since introduced other biosimilars for the treatment of various
12 types of cancer and autoimmune diseases in Europe, Korea, and Canada. Since its founding,
13 Celltrion has devoted itself to improving patient access to advanced and novel therapeutics for the
14 treatment of life-altering and life-threatening diseases. Celltrion has invested in major cell lines
15 and core technologies to develop biosimilars and novel drugs and vaccines.

16 26. Celltrion has devoted significant time, effort, and substantial monetary resources
17 to the development of Herzuma®. With its deep experience in biologics development and
18 manufacturing, Celltrion designed the manufacturing process and process controls that have been
19 and will be used to make Herzuma®, including, among other things, developing the cell culture,
20 harvest, and numerous purification steps to manufacture and purify the Herzuma® antibody.
21 Celltrion also conducted numerous clinical studies in which it successfully tested Herzuma® in
22 humans. In the end, Celltrion generated comprehensive analytical, pharmacokinetic,
23 pharmacodynamics, and clinical data that was submitted to the FDA as part of the FDA-approval
24 process.

25 27. In 2016, Celltrion, Inc., Celltrion Healthcare, and TPIG entered into an exclusive
26 partnership to commercialize Herzuma® in the United States. Teva USA will market Herzuma®
27 in the United States. Teva is a leading global pharmaceutical company that delivers high-quality,
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1 patient-centric healthcare solutions used by millions of patients every day. Teva has a portfolio of
2 more than 1,800 molecules and has a world-leading position in innovative treatments. Teva is also
3 a leader in biologic and biosimilar development.

4 **Congress Enacts Legislation Creating a Regulatory Pathway for**
5 **Biosimilar Biological Products**

6 28. With the passage of the BPCIA, Congress created a new pathway for FDA review
7 and approval of “biosimilar” biological products, as well as new mechanisms to resolve patent
8 disputes that may arise with respect to such products.

9 29. “The BPCIA governs a type of drug called a biosimilar, which is a biologic
10 product that is highly similar to a biologic product that has already been approved by the Food and
11 Drug Administration (FDA).” *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

12 30. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars.
13 42 U.S.C. § 262(k). To obtain approval through the BPCIA’s abbreviated process, an applicant
14 must show that its biosimilar product is “highly similar” to the reference product and that there are
15 no “clinically meaningful differences” between the two products in terms of “safety, purity, and
16 potency.” 42 U.S.C. § 262(k)(2). Under the BPCIA, an applicant may not submit an application
17 until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar
18 until 12 years after the reference product is first licensed. 42 U.S.C. § 262(k)(7).

19 31. The reference product sponsor (also known as an “RPS”) may have patents
20 relating to the biological product, as well as therapeutic uses for and/or processes used to
21 manufacture the biological product, that it believes may be relevant to the biosimilar product. In
22 recognition that there may be patent disputes between the RPS and the biosimilar applicant, “[t]he
23 BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating,
24 claims of [patent] infringement.” *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(l)).

25 32. The BPCIA describes a process whereby the RPS and the biosimilar applicant
26 may exchange information in advance of an action for patent infringement. *First*, the process
27 begins when the applicant provides “a copy of the application submitted to the Secretary under
28 subsection (k), and such other information that describes the process or processes used to

1 manufacture the biological product that is the subject of such application.” 42 U.S.C. §
2 262(l)(2)(A). In addition, the applicant “may provide to the reference product sponsor additional
3 information requested by or on behalf of the reference product sponsor.” 42 U.S.C. § 262(l)(2)(B).
4 *Second*, the BPCIA states that the RPS shall provide “a list of patents for which the reference
5 product sponsor believes a claim of patent infringement could reasonably be asserted by the
6 reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in
7 the making, using, offering to sell, selling, or importing into the United States of the biological
8 product that is the subject of the subsection (k) application.” 42 U.S.C. § 262(l)(3)(A). *Third*, the
9 BPCIA requires the applicant who chooses to exchange information in advance of an action for
10 patent infringement to provide a “detailed statement that describes, on a claim by claim basis, the
11 factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid,
12 unenforceable, or will not be infringed by the commercial marketing of the biological product that
13 is the subject of the subsection (k) application.” 42 U.S.C. § 262(l)(3)(B)(ii)(I). Alternatively, the
14 applicant can provide “a statement that the subsection (k) applicant does not intend to begin
15 commercial marketing of the biological product before the date that such patent expires.” 42
16 U.S.C. § 262(l)(3)(B)(ii)(II). *Last*, the BPCIA states that the RPS “shall provide to the subsection
17 (k) applicant a detailed statement that describes, with respect to each patent described in
18 subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the
19 reference product sponsor that such patent will be infringed by the commercial marketing of the
20 biological product that is the subject of the subsection (k) application and a response to the
21 statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).” 42
22 U.S.C. § 262(l)(3)(C).

23 33. Following the information exchange, the BPCIA requires the RPS and the
24 applicant to engage in “good faith negotiations to agree on which, if any, patents listed under
25 paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject
26 of an action for patent infringement under paragraph (6) [of the statute].” 42 U.S.C. § 262(l)(4). If
27 the subsection (k) applicant and RPS disagree over which patents should be litigated, the statute
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1 provides for a mechanism of further exchanges to determine which patent(s) will be the subject of
2 a paragraph (6) patent litigation. 42 U.S.C. § 262(l)(4)(B)-(5). While the procedure and timing
3 depend on whether the RPS and the applicant can reach agreement, the process may result in a
4 statutorily defined action for patent infringement. 42 U.S.C. § 262(l)(6).

5 34. Paragraph (l)(8) of the BPCIA states that “[t]he subsection (k) applicant shall
6 provide notice to the reference product sponsor not later than 180 days before the date of the first
7 commercial marketing of the biological product licensed under subsection (k).” 42 U.S.C. §
8 262(l)(8)(A). Once the applicant’s notice of commercial marketing is received by the RPS, any
9 limitation under the BPCIA on bringing an action under section 2201 of title 28 for a declaration of
10 rights concerning patent infringement, validity and/or enforceability is lifted. 42 U.S.C. §
11 262(l)(9). “If a subsection (k) applicant provides the application and information required under
12 paragraph (2)(A), neither the [RPS] nor the subsection (k) applicant may, prior to the date notice is
13 received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration
14 of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of
15 paragraph (8)(B).” 42 U.S.C. § 262(l)(9)(A).

16 35. Any manufacture and use of CT-P6 by any of the Plaintiffs prior to commercial
17 marketing was and is solely for uses reasonably related to the development and submission of
18 information under a Federal law, for example to the FDA under the Public Health Service Act
19 including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
20 infringement. 35 U.S.C. § 271(e)(1).

21 **The Parties’ Exchanges Following the Filing of Celltrion’s**
22 **Subsection (k) Application for Approval of The Biosimilar Product**

23 36. According to the FDA’s “Purple Book,” Genentech’s Herceptin® was first
24 approved on September 25, 1998.

25 37. On May 30, 2017, Celltrion submitted its Biologics License Application (“BLA”)
26 for Herzuma® pursuant to 42 U.S.C. § 262(k). Celltrion Inc.’s aBLA was filed after the expiration
27 of the 4- year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Celltrion received
28 notification from the FDA that its aBLA had been accepted for review on July 28, 2017.

1 38. On August 1, 2017, prior to the deadline under 42 U.S.C. § 262(l)(2)(A) for
2 Celltrion to produce its aBLA, Genentech wrote a letter to Celltrion requesting that Celltrion
3 produce vaguely defined categories of information relating to the processes used in the production
4 of Herzuma® “irrespective of whether it is contained in the aBLA,” but did not list any patents to
5 which the information sought might be relevant.

6 39. On August 11, 2017, Celltrion, Inc. timely sent to Genentech its disclosure
7 pursuant to 42 U.S.C. § 262(l)(2)(A), including the aBLA for Herzuma® and other detailed
8 information regarding the manufacturing processes used to make Herzuma®. Specifically,
9 Celltrion, Inc. produced its aBLA, and upstream and downstream manufacturing reports describing
10 in detail the manufacturing process for Herzuma®. Celltrion Inc.’s production of more than
11 280,000 pages of technical details and batch records described, among other things, (i) the source,
12 history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and
13 every purification process step, and (iv) raw materials used during the manufacture of Herzuma®.

14 40. Celltrion Inc.’s production contained sufficiently detailed information regarding
15 its biosimilar product and manufacturing processes, which complied with the production
16 requirements in 42 U.S.C. § 262(l)(2)(A)-(B) and enabled Genentech to undertake its obligations
17 under 42 U.S.C. § 262(l)(3)(A).

18 41. On October 10, 2017, Genentech provided Celltrion, Inc. with its list of patents
19 pursuant to 42 U.S.C. § 262(l)(3)(A) (“the (3)(A) list”) that Genentech “believe[d] could
20 reasonably be asserted against Celltrion’s proposed CT-P6 product based upon a review of the
21 product’s aBLA filing.” Genentech’s (3)(A) list included a total of 40 patents, including all of the
22 patents-in-suit. 42 U.S.C. § 262(l)(3)(A) requires an RPS to identify the patents for which the RPS
23 “believes a claim of patent infringement could reasonably be asserted by [the RPS] or by a patent
24 owner that has granted an exclusive license to [the RPS] with respect to [the reference product].”
25 42 U.S.C. § 262(l)(3)(A). Therefore, by identifying a patent on its (3)(A) list, Genentech has
26 represented that Genentech has the right to assert the patent as the patent owner, or exclusive
27 licensee.
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1 46. On January 5, 2018, Celltrion Inc. received Genentech’s alleged statement
2 pursuant to § 262(l)(3)(C) (Genentech’s “(3)(C) statement”). Even though the BPCIA required
3 Genentech to provide, among other things, “on a claim by claim basis, the factual and legal basis
4 of the opinion of the reference product sponsor that [each] patent [identified in Celltrion Inc.’s
5 (3)(B) statement] will be infringed by the commercial marketing of the biological product that is
6 the subject of the subsection (k) application,” and a response to Celltrion Inc.’s opinions
7 concerning the validity and enforceability of the listed patents, [REDACTED]

8 [REDACTED]

9 [REDACTED]	[REDACTED]
10 [REDACTED]	[REDACTED]
11 [REDACTED]	[REDACTED]
12 [REDACTED]	[REDACTED]
13 [REDACTED]	[REDACTED]
14 [REDACTED]	[REDACTED]
15 [REDACTED]	[REDACTED]
16 [REDACTED]	[REDACTED]
17 [REDACTED]	[REDACTED]
18 [REDACTED]	[REDACTED]

19
20 47. [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
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1 48. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 49. On January 11, 2018, Celltrion Inc. wrote to Genentech in response to its (3)(C)
5 statement. Celltrion Inc. stated that, pursuant to 42 U.S.C. § 262(l)(4)(A), Celltrion Inc. wished to
6 litigate all of the patents on Genentech’s (3)(A) list.

7 50. [REDACTED], Celltrion Inc. also notified Genentech that, pursuant to 42
8 U.S.C. §262(l)(8)(A), Celltrion Inc. was providing notice that commercial marketing of Herxuma®
9 may begin as early as 180 days from the date of the notice.

10 **THE PATENTS-IN-SUIT**

11 51. U.S. Patent No. 6,331,415 (Exhibit 1), titled “Methods of Producing
12 Immunoglobulins, Vectors and Transformed Host Cells For Use Therein,” issued on December 18,
13 2001. Upon information and belief, the ’415 patent is assigned to Genentech, Inc. and City of
14 Hope.

15 52. U.S. Patent No. 6,339,142 (Exhibit 2), titled “Protein Purification” issued on
16 January 15, 2002. Upon information and belief, the ’142 patent is assigned to Genentech, Inc.

17 53. U.S. Patent No. 6,407,213 (Exhibit 3), titled “Method for Making Humanized
18 Antibodies” issued on June 18, 2002. Upon information and belief, the ’213 patent is assigned to
19 Genentech, Inc.

20 54. U.S. Patent No. 6,417,335 (Exhibit 4), titled “Protein Purification,” issued on July
21 9, 2002. Upon information and belief, the ’335 patent is assigned to Genentech, Inc.

22 55. U.S. Patent No. 6,489,447 (Exhibit 5), titled “Protein Purification,” issued on
23 December 3, 2002. Upon information and belief, the ’447 patent is assigned to Genentech, Inc.

24 56. U.S. Patent No. 6,586,206 (Exhibit 6), titled “Methods for Making Recombinant
25 Proteins Using Apoptosis Inhibitors,” issued on July 1, 2003. Upon information and belief, the
26 ’206 patent is assigned to Genentech, Inc.

1 57. U.S. Patent No. 6,610,516 (Exhibit 7), titled “Cell Culture Process,” issued on
2 August 26, 2003. Upon information and belief, the ’516 patent is assigned to Genentech, Inc.

3 58. U.S. Patent No. 6,620,918 (Exhibit 8), titled “Separation of Polypeptide
4 Monomers,” issued on September 16, 2003. Upon information and belief, the ’918 patent is
5 assigned to Genentech, Inc.

6 59. U.S. Patent No. 6,627,196 (Exhibit 9), titled “Dosages for Treatment with Anti-
7 ErbB2 Antibodies,” issued on September 30, 2003. Upon information and belief, the ’196 patent
8 is assigned to Genentech, Inc.

9 60. U.S. Patent No. 6,716,602 (Exhibit 10), titled “Metabolic Rate Shifts in
10 Fermentations Expressing Recombinant Proteins,” issued on April 6, 2004. Upon information and
11 belief, the ’602 patent is assigned to Genentech, Inc.

12 61. U.S. Patent No. 7,371,379 (Exhibit 11), titled “Dosages for Treatment with Anti-
13 ErbB2 Antibodies,” issued on May 13, 2008. Upon information and belief, the ’379 patent is
14 assigned to Genentech, Inc.

15 62. U.S. Patent No. 7,390,660 (Exhibit 12), titled “Methods for Growing Mammalian
16 Cells In Vitro,” issued on June 24, 2008. Upon information and belief, the ’660 patent is assigned
17 to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to
18 enforce the ’660 patent.

19 63. U.S. Patent No. 7,449,184 (Exhibit 13), titled “Fixed Dosing of HER Antibodies,”
20 issued on November 11, 2008. Upon information and belief, the ’184 patent is assigned to
21 Genentech, Inc.

22 64. U.S. Patent No. 7,485,704 (Exhibit 14), titled “Reducing Protein A Leaching
23 During Protein A Affinity Chromatography,” issued on February 3, 2009. Upon information and
24 belief, the ’704 patent is assigned to Genentech, Inc.

25 65. U.S. Patent No. 7,501,122 (Exhibit 15), titled “Treatment With Anti-ErbB2
26 Antibody Combinations” issued on March 10, 2009. Upon information and belief, the ’122 patent
27 is assigned to Genentech, Inc.
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1 66. U.S. Patent No. 7,807,799 (Exhibit 16), titled “Reducing Protein A Leaching
2 During Protein A Affinity Chromatography,” issued on October 5, 2010. Upon information and
3 belief, the ’799 patent is assigned to Genentech, Inc.

4 67. U.S. Patent No. 7,846,441 (Exhibit 17), titled “Treatment with Anti-ErbB2
5 Antibodies,” issued on December 7, 2010. Upon information and belief, the ’441 patent is
6 assigned to Genentech, Inc.

7 68. U.S. Patent No. 7,892,549 (Exhibit 18), titled “Treatment with Anti-ErbB2
8 Antibodies,” issued on February 22, 2011. Upon information and belief, the ’549 patent is
9 assigned to Genentech, Inc.

10 69. U.S. Patent No. 7,923,221 (Exhibit 19), titled “Methods of Making Antibody
11 Heavy and Light Chains Having Specificity for a Desired Antigen,” issued on April 12, 2011.
12 Upon information and belief, the ’221 patent is assigned to Genentech, Inc. and City of Hope.

13 70. U.S. Patent No. 7,993,834 (Exhibit 20), titled “Detection of ErbB2 Gene
14 Amplification to Increase the Likelihood of the effectiveness of ErbB2 AntiBody Breast Cancer
15 Therapy,” issued on August 9, 2011. Upon information and belief, the ’834 patent is assigned to
16 Genentech, Inc.

17 71. U.S. Patent No. 8,076,066 (Exhibit 21), titled “Gene Detection Assay for
18 Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy,” issued
19 on December 13, 2011. Upon information and belief, the ’066 patent is assigned to Genentech Inc.

20 72. U.S. Patent No. 8,357,301 (Exhibit 22), titled “Chromatography Equipment
21 Characterization,” issued on January 22, 2013. Upon information and belief, the ’301 patent is
22 assigned to Hoffman-La Roche, Inc. Upon information and belief, one or more of the Defendants
23 has the entire right, interest, and title to enforce the ’301 patent.

24 73. U.S. Patent No. 8,425,908 (Exhibit 23), titled “Treatment with Anti-ErbB2
25 Antibodies,” issued on April 23, 2013. Upon information and belief, the ’301 patent is assigned to
26 Genentech, Inc.

1 74. U.S. Patent No. 8,440,402 (Exhibit 24), titled “Gene Detection Assay for
2 Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy,” issued
3 on May 14, 2013. Upon information and belief, the ’402 patent is assigned to Genentech, Inc.

4 75. U.S. Patent No. 8,460,895 (Exhibit 25), titled “Method for Producing
5 Recombinant Proteins with a Constant Content of pCO₂ in the Medium,” issued on June 11, 2013.
6 Upon information and belief, the ’895 patent is assigned to Hoffmann-La Roche, and Genentech is
7 the exclusive licensee with the sole right to enforce the ’895 patent.

8 76. U.S. Patent No. 8,512,983 (Exhibit 26), titled “Production of Proteins in
9 Glutamine-Free Cell Culture Media,” issued on August 20, 2013. Upon information and belief,
10 Genentech is the owner of all right, title and interest in the ’983 patent.

11 77. U.S. Patent No. 8,574,869 (Exhibit 27), titled “Prevention of Disulfide Bond
12 Reduction During Recombinant Production of Polypeptides,” issued on November 5, 2013. Upon
13 information and belief, the ’869 patent is assigned to Genentech, Inc.

14 78. U.S. Patent No. 8,633,302 (Exhibit 28), titled “Variable Tangential Flow
15 Filtration,” issued on January 21, 2014. Upon information and belief, the ’302 patent is assigned
16 to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to
17 enforce the ’302 patent.

18 79. U.S. Patent No. 8,691,232 (Exhibit 29), titled “Extending Time to Disease
19 Progression or Survival in Cancer Patients,” issued on April 8, 2014. Upon information and belief,
20 the ’232 patent is assigned to Genentech, Inc.

21 80. U.S. Patent No. 8,771,988 (Exhibit 30), titled “Protein expression from multiple
22 nucleic acids,” issued on June 24, 2008. Upon information and belief, the ’988 patent is assigned
23 to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to
24 enforce the ’988 patent.

25 81. U.S. Patent No. 8,822,655 (Exhibit 31), titled “Pre-filtration adjustment of buffer
26 solutes,” issued on September 2, 2014. Upon information and belief, the ’655 patent is assigned to
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1 Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to
2 enforce the '655 patent.

3 82. U.S. Patent No. 9,047,438 (Exhibit 32), titled "Chromatography Equipment
4 Characterization," issued on June 2, 2015. Upon information and belief, the '438 patent is
5 assigned to Hoffmann-La Roche.

6 83. U.S. Patent No. 9,080,183 (Exhibit 33), titled "Promoter," issued on July 14,
7 2015. Upon information and belief, the '183 patent is assigned to Hoffmann-La Roche Inc.

8 84. U.S. Patent No. 9,249,218 (Exhibit 34), titled "Protein Purification," issued on
9 February 2, 2016. Upon information and belief, the '218 patent is assigned to Genentech, Inc.

10 85. U.S. Patent No. 9,428,548 (Exhibit 35), titled "Enhanced Protein Purification
11 through a Modified Protein A Elution," issued on August 30, 2016. Upon information and belief,
12 the '548 patent is assigned to Genentech, Inc.

13 86. U.S. Patent No. 9,428,766 (Exhibit 36), titled "Protein expression from multiple
14 nucleic acids," issued on August 30, 2016. Upon information and belief, the '766 patent is
15 assigned to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole
16 right to enforce the '766 patent.

17 87. U.S. Patent No. 9,487,809 (Exhibit 37), titled "Decreasing Lactate Level and
18 Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase
19 and Pyruvate Dehydrogenase Kinase," issued on November 8, 2016. Upon information and belief,
20 the '809 patent is assigned to Genentech, Inc.

21 88. U.S. Patent No. 9,714,293 (Exhibit 38), titled "Production of Proteins in
22 Glutamine-Free Cell Culture Media," issued on July 25, 2017. Upon information and belief, the
23 '293 patent is assigned to Genentech Inc.

24 **COUNT I**

25 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415**

26 89. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-88
27 above as if fully set forth herein.

1 in view of prior art disclosing reasons and methods for separating native trastuzumab from
2 deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical
3 composition to less than about 25%.

4 111. There is a real, substantial, and justiciable controversy between Plaintiffs and
5 Defendants concerning whether one or more claims of the '142 patent are invalid for failure to
6 comply with the requirements of Title 35 of the United States Code, including, without limitation,
7 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

8 112. The controversy between the parties is amenable to specific relief through a
9 decree of conclusive character.

10 113. Plaintiffs are entitled to a judicial declaration that one or more claims of the '142
11 patent are invalid.

12 **COUNT V**

13 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,407,213**

14 114. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-113
15 above as if fully set forth herein.

16 115. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
17 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
18 Inc.'s opinion that one or more claims of the '213 patent will not be infringed by the commercial
19 manufacture, use, importation, sale, or offer for sale of CT-P6.

20 116. Plaintiffs will not infringe one or more valid claims of the '213 patent at least
21 because the CT-P6 product [REDACTED]

22 [REDACTED]
23 [REDACTED]

24 117. There is a real, substantial, and justiciable controversy between Plaintiffs and
25 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '213
26 patent.

1 “93H.” On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting the claims as
2 obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

3 125. On June 12, 1995, Genentech amended the pending claims and deleted references
4 to amino acid position “62L.”

5 126. Following a final rejection and an Examiner interview, the case was transferred to
6 a different Examiner and a new non-final rejection issued on December 23, 1996. The new
7 Examiner maintained all prior rejections and further rejected the pending claims as anticipated by
8 the ’101 patent.

9 127. In response to the non-final rejection, Genentech once again amended the pending
10 claims on June 27, 1997, adding amino acid position “62L” back into the claims.

11 128. On October 7, 1997, in a letter signed by Wendy M. Lee on behalf of Genentech,
12 Genentech argued in remarks to the Patent Office that Queen 1989 and the ’101 patent were
13 distinguishable because they “use sequential numbering for the variable domain residues of the
14 antibodies described in these references, whereas the claims of the instant application use Kabat
15 numbering for the framework region residues.” In another submission by Wendy M. Lee on behalf
16 of Genentech later in the prosecution of the ’213 patent, Genentech repeated the same argument to
17 distinguish Queen 1989 and the ’101 patent with specific reference to residue “93H”:

18 Applicants point out that – as explained earlier in prosecution – the
19 substituted 93 FR residue in the cited references [Queen 1989 and the
20 ’101 patent] is not 93H ‘utilizing the numbering system set forth in
21 Kabat’ (see page 13, line 33 through to line 22 on page 14 of the
22 present application) as required by claims 115-117, 123 and 127 of the
23 present application. In particular, as noted on page 6 of the
24 amendment hand carried to the Office on 10/7/97, residue no. 93 in the
25 heavy chain of the anti-Tac antibody in the cited references, is actually
26 89H utilizing the numbering system set forth in Kabat. The cited
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1 references use a sequential numbering system, rather than the Kabat
2 numbering system claimed herein.

3 *See* Applicant Remarks, dated Apr. 26, 2001, at 7.

4 129. On December 11, 2001, the Examiner indicated during an interview that the
5 pending claims were allowable.

6 130. Contrary to Genentech's representations to the Patent Office—namely, that the
7 '101 patent does not use the Kabat numbering system—the '101 patent states: “Residues are
8 numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of
9 Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987).” '101 patent at
10 8:15–18. In addition, the '101 patent expressly refers to “numbering according to Kabat, op. cit.”
11 with specific reference to position 93 in the heavy chain. *See id.* at 15:17–37. Moreover, Table 5
12 of the '101 patent refers to residue “H93,” with explicit reference to numbering “according to the
13 Kabat system,” as shown below:

Residue No. ¹	Amino Acid	Contacting CDR residues ²
<u>Fd79</u>		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
<u>Fd138-80</u>		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)); the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

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24 131. In order to overcome the § 102 rejection based on the '101 patent, Genentech
25 falsely represented to the Patent Office that the '101 patent used sequential numbering, while
26 arguing that the “claims of the instant application use Kabat numbering for the framework region
27 residues.” Genentech misrepresented the teachings of the '101 patent, despite clear and repeated
28 references in the '101 patent to the Kabat numbering system. Absent Genentech's false and

1 misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the
2 '101 patent. But-for Genentech's misrepresentations, the Patent Office would not have allowed
3 the claims of the '213 patent.

4 132. Genentech also made deliberate and material misrepresentations and omissions
5 regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen
6 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering
7 system. At the Examiner's request, Genentech submitted a comparison of the different numbering
8 systems purportedly utilized in Queen 1989 and the pending claims. *See* Applicant Remarks at 6-
9 10 (Oct. 7, 1997) ("As requested by the Examiner in the interview, alignments of heavy chain
10 variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101
11 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen et al.)
12 with sequential andKabat residue numbering is attached."). The alignments provided by
13 Genentech to the Examiner conspicuously omitted the "62L" residue in both numbering systems.
14 As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen
15 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain
16 (Fig. 2)." *See* Queen 1989 at 10032. Importantly, Queen 1989 discloses residues in the Kabat
17 numbering system and, in particular, residue "62 of the light chain."

18 133. There is a real, substantial, and justiciable controversy between Plaintiffs and
19 Defendants concerning whether the claims of the '213 patent are enforceable.

20 134. The controversy between the parties is amenable to specific relief through a
21 decree of conclusive character.

22 135. Plaintiffs are entitled to a judicial declaration that the '213 patent is
23 unenforceable.

24 **COUNT VII**

25 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335**

26 136. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-135
27 above as if fully set forth herein.

1 Inc.'s opinion that one or more claims of the '206 patent will not be infringed by the commercial
2 manufacture, use, importation, sale, or offer for sale of CT-P6.

3 158. For example, Plaintiffs will not infringe one or more claims of the '206 patent
4 under 35 U.S.C. § 271(a) because [REDACTED]
5 Plaintiffs also will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(g)
6 because [REDACTED]
7 [REDACTED]
8 [REDACTED]

9 159. Additional non-limiting examples of how Plaintiffs will not infringe one or more
10 valid claims of the '206 patent include [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]

17 160. There is a real, substantial, and justiciable controversy between Plaintiffs and
18 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '206
19 patent.

20 161. The controversy between the parties is amenable to specific relief through a
21 decree of conclusive character.

22 162. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
23 infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

24 **COUNT XI**

25 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516**

26 163. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-162
27 above as if fully set forth herein.

1 177. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
2 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
3 Inc.’s opinion that one or more claims of the ’918 patent will not be infringed by the commercial
4 manufacture, use, importation, sale, or offer for sale of CT-P6.

5 178. For example, Plaintiffs will not infringe one or more claims of the ’918 patent
6 under 35 U.S.C. § 271(a) because [REDACTED]
7 Plaintiffs also will not infringe one or more claims of the ’918 patent under 35 U.S.C. § 271(g)
8 because [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 179. Additional non-limiting examples of how Plaintiffs will not infringe one or more
12 valid claims of the ’918 patent include [REDACTED]

13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 180. There is a real, substantial, and justiciable controversy between Plaintiffs and
19 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’918
20 patent.

21 181. The controversy between the parties is amenable to specific relief through a
22 decree of conclusive character.

23 182. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
24 infringe, directly or indirectly, any valid and enforceable claim of the ’918 patent.

25 **COUNT XIV**

26 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,627,196**

1 183. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-182
2 above as if fully set forth herein.

3 184. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
4 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
5 Inc.'s opinion that one or more claims of the '196 patent will not be infringed by the commercial
6 manufacture, use, importation, sale, or offer for sale of CT-P6.

7 185. Non-limiting examples of how Plaintiffs will not infringe one or more claims of
8 the '196 patent include: 1) Plaintiffs will not infringe one or more claims of the '196 patent under
9 35 U.S.C. § 271(a) because Plaintiffs will not treat patients; and (2) Plaintiffs will not infringe one
10 or more claims of the '196 patent under 35 U.S.C. §§ 271(b) or (c) at least because Plaintiffs will
11 not encourage another party to practice the claimed methods because [REDACTED]

12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 186. There is a real, substantial, and justiciable controversy between Plaintiffs and
16 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '196
17 patent.

18 187. The controversy between the parties is amenable to specific relief through a
19 decree of conclusive character.

20 188. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
21 infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

22 **COUNT XV**

23 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,716,602**

24 189. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-188
25 above as if fully set forth herein.

26 190. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
27 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
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1 Inc.'s opinion that one or more claims of the '602 patent will not be infringed by the commercial
2 manufacture, use, importation, sale, or offer for sale of CT-P6.

3 191. For example, Plaintiffs will not infringe one or more claims of the '602 patent
4 under 35 U.S.C. § 271(a) because [REDACTED]

5 Plaintiffs also will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(g)
6 because [REDACTED]

7 [REDACTED]
8 [REDACTED]

9 192. Additional non-limiting examples of how Plaintiffs will not infringe one or more
10 valid claims of the '602 patent include: [REDACTED]

11 [REDACTED]
12 [REDACTED]

13 [REDACTED]
14 [REDACTED]

15 193. There is a real, substantial, and justiciable controversy between Plaintiffs and
16 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '602
17 patent.

18 194. The controversy between the parties is amenable to specific relief through a
19 decree of conclusive character.

20 195. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
21 infringe, directly or indirectly, any valid and enforceable claim of the '602 patent.

22 **COUNT XVI**

23 **Declaratory Judgment of Invalidity of U.S. Patent No. 6,716,602**

24 196. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-195
25 above as if fully set forth herein.

1 Inc.'s opinion that one or more claims of the '379 patent will not be infringed by the commercial
2 manufacture, use, importation, sale, or offer for sale of CT-P6.

3 204. Non-limiting examples of how Plaintiffs will not infringe one or more claims of
4 the '379 patent include: 1) Plaintiffs will not infringe one or more claims of the '379 patent under
5 35 U.S.C. § 271(a) because Plaintiffs will not treat patients; and (2) Plaintiffs also will not infringe
6 one or more claims of the '379 patent under 35 U.S.C. §§ 271(b) or (c) at least because Plaintiffs
7 will not encourage another party to practice the claimed methods because [REDACTED]

8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 205. There is a real, substantial, and justiciable controversy between Plaintiffs and
12 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '379
13 patent.

14 206. The controversy between the parties is amenable to specific relief through a
15 decree of conclusive character.

16 207. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
17 infringe, directly or indirectly, any valid and enforceable claim of the '379 patent.

18 **COUNT XVIII**

19 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,390,660**

20 208. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-207
21 above as if fully set forth herein.

22 209. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
23 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
24 Inc.'s opinion that one or more claims of the '660 patent will not be infringed by the commercial
25 manufacture, use, importation, sale, or offer for sale of CT-P6.

26 210. For example, Plaintiffs will not infringe one or more claims of the '660 patent
27 under 35 U.S.C. § 271(a) because [REDACTED]

1 Plaintiffs also will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(g)
2 because [REDACTED]

3 [REDACTED]
4 [REDACTED]
5 211. Additional non-limiting examples of how Plaintiffs will not infringe any valid
6 claim of the '660 patent include that [REDACTED]

7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 212. There is a real, substantial, and justiciable controversy between Plaintiffs and
11 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '660
12 patent.

13 213. The controversy between the parties is amenable to specific relief through a
14 decree of conclusive character.

15 214. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
16 infringe, directly or indirectly, any valid and enforceable claim of the '660 patent.

17 **COUNT XIX**

18 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,449,184**

19 215. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-214
20 above as if fully set forth herein.

21 216. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
22 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
23 Inc.'s opinion that one or more claims of the '184 patent will not be infringed by the commercial
24 manufacture, use, importation, sale, or offer for sale of CT-P6.

25 217. For example, Plaintiffs will not directly infringe any claim of the '184 patent
26 because all the claims are all directed to methods of treating patients and Plaintiffs will not treat
27 patients. Plaintiffs will also not induce infringement because [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 218. There is a real, substantial, and justiciable controversy between Plaintiffs and
 7 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '184
 8 patent.

9 219. The controversy between the parties is amenable to specific relief through a
 10 decree of conclusive character.

11 220. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
 12 infringe, directly or indirectly, any valid and enforceable claim of the '184 patent.

13 **COUNT XX**

14 **Declaratory Judgment of Invalidity of U.S. Patent No. 7,449,184**

15 221. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-220
 16 above as if fully set forth herein.

17 222. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
 18 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
 19 Inc.'s opinion that one or more claims of the '184 patent are invalid.

20 223. Non-limiting examples of how one or more claims of '184 patent are invalid is
 21 because the claims are invalid under 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious over
 22 the prior art, including at least U.S. App. 10/619,754, Canadian Patent Application 2,376,596,
 23 WO01000245 and prior art that describes a phase 1b study demonstrating the efficacy of the
 24 combination of pertuzumab and capecitabine, the fixed doses of the claims, and disclosing or
 25 suggesting the other elements of the claims.

26 224. There is a real, substantial, and justiciable controversy between Plaintiffs and
 27 Defendants concerning whether one or more claims of the '184 patent are invalid for failure to
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1 comply with the requirements of Title 35 of the United States Code, including, without limitation,
2 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

3 225. The controversy between the parties is amenable to specific relief through a
4 decree of conclusive character.

5 226. Plaintiffs are entitled to a judicial declaration that claims of the '184 patent are
6 invalid.

7 **COUNT XXI**

8 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,704**

9 227. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-226
10 above as if fully set forth herein.

11 228. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed
12 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion
13 Inc.'s opinion that one or more claims of the '704 patent will not be infringed by the commercial
14 manufacture, use, importation, sale, or offer for sale of CT-P6.

15 229. For example, Plaintiffs will not infringe one or more claims of the '704 patent
16 under 35 U.S.C. § 271(a) because [REDACTED]

17 [REDACTED] Plaintiffs also will not infringe one or more claims of the '704 patent under 35 U.S.C. §
18 271(g) because [REDACTED]

19 [REDACTED]
20 [REDACTED]

21 230. An additional, non-limiting example of how Plaintiffs will not infringe one or
22 more valid claims of the '704 patent is that [REDACTED]

23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]

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[REDACTED]

[REDACTED]

231. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '704 patent.

232. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

233. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '704 patent.

COUNT XXII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,501,122

234. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-233 above as if fully set forth herein.

235. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '122 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

236. For example, Plaintiffs will not directly infringe any claim of the '122 patent because all the claims are all directed to methods of treating patients and Plaintiffs will not treat patients. Plaintiffs will also not induce infringement because [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

237. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '122 patent.

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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] In addition, there are substantial noninfringing uses
for CT-P6. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

262. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '441 patent.

263. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

264. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '441 patent.

COUNT XXVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,892,549

265. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-264 above as if fully set forth herein.

266. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '549 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

267. For example, Plaintiffs will not directly infringe any claim of the '549 patent because all the claims are all directed to methods of treating patients and Plaintiffs will not treat patients.

1 274. For example, Plaintiffs will not infringe one or more claims of the '221 patent under
2 35 U.S.C. § 271(a) because [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

3 [REDACTED] Plaintiffs also will not infringe one or more claims of the '221 patent under 35 U.S.C. §
4 271(g) because [REDACTED]

5 [REDACTED]
6 [REDACTED]
7 275. Additional non-limiting examples of how Plaintiffs will not infringe one or more
8 valid claims of the '221 patent include: [REDACTED]

9 [REDACTED]
10 [REDACTED] [REDACTED]
11 [REDACTED]
12 276. There is a real, substantial, and justiciable controversy between Plaintiffs and
13 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '221
14 patent.

15 277. The controversy between the parties is amenable to specific relief through a decree
16 of conclusive character.

17 278. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
18 infringe, directly or indirectly, any valid and enforceable claim of the '221 patent.

19 **COUNT XXIX**

20 **Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221**

21 279. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-278
22 above as if fully set forth herein.

23 280. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
24 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
25 opinion that one or more claims of '221 patent are invalid.

26 281. Non-limiting examples of how one or more claims of the '221 patent are invalid
27 include: (1) lack of enablement of the claimed "process for producing an immunoglobulin
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1 molecule,” to the extent it encompasses both *in vivo* and *in vitro* assembly, because there is no
2 disclosure in the specification of how to produce an antibody *in vivo* in an microorganism or host
3 cell, and undue experimentation would have been required for a POSA to do so; (2) failure of
4 written description to describe any process for the *in vivo* assembly of an antibody or antibody
5 fragment in either amicroorganism or mammalian cell; and (3) obviousness in view of prior art
6 disclosing processes for producing proteins, including antibodies, that can include immunoglobins
7 (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition,
8 one or more claims of the ’221 patent are invalid in light of prior art that published or was
9 otherwise available to the public before the earliest possible priority date of the ’221 patent.

10 282. There is a real, substantial, and justiciable controversy between Plaintiffs and
11 Defendatns concerning whether one or more claims of the ’221 patent are invalid for failure to
12 comply with the requirements of Title 35 of the United States Code, including, without limitation,
13 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

14 283. The controversy between the parties is amenable to specific relief through a decree
15 of conclusive character.

16 284. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’221
17 patent are invalid.

18 **COUNT XXX**

19 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,993,834**

20 285. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-284
21 above as if fully set forth herein.

22 286. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
23 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.’s
24 opinion that one or more claims of the ’834 patent will not be infringed by the commercial
25 manufacture, use, importation, sale, or offer for sale of CT-P6.

26 287. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims
27 of the ’834 patent include: (1) Plaintiffs cannot be liable for direct infringement of the claimed
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1 method because Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not
2 practice any of the claimed methods; [REDACTED]

3 [REDACTED]
4 [REDACTED] (3) in the patent
5 specification and during prosecution of the patent, the patentees expressly disclaimed [REDACTED]

6 [REDACTED]
7 [REDACTED]
8 [REDACTED] and (4) the patent specification itself acknowledges there are substantial non-
9 infringing uses for Celltrion's CT-P6 product, and [REDACTED]

10 [REDACTED]
11 288. There is a real, substantial, and justiciable controversy between Plaintiffs and
12 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '834
13 patent.

14 289. The controversy between the parties is amenable to specific relief through a decree
15 of conclusive character.

16 290. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
17 infringe, directly or indirectly, any valid and enforceable claim of the '834 patent.

18 **COUNT XXXI**

19 **Declaratory Judgment of Invalidity of U.S. Patent No. 7,993,834**

20 291. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-290
21 above as if fully set forth herein.

22 292. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
23 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
24 opinion that one or more claims of the '834 patent are invalid.

25 293. Non-limiting examples of how one or more claims of the '834 patent are invalid
26 include: (1) the claims are indefinite because they fail to identify a baseline likelihood of
27 effectiveness from which the meaning of the claimed method can be ascertained; (2) the claims are
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1 invalid for lack of written description because the patent fails to disclose any data or information to
2 support the claimed correlations between test results and treatment; (3) the claims are directed to
3 patent-ineligible subject matter, as they do no more than recite a natural correlation between
4 known diagnostic tests and responses rates to a known method of treatment; (4) the claims are
5 obvious in view of prior art disclosing methods for treating patients based on her2 gene
6 amplification or HER2 protein expression and known discrepancies and comparative advantages
7 between the various methods; (5) the claims are anticipated by prior art describing the treatment of
8 patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by
9 IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2
10 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested
11 using IHC.

12 294. There is a real, substantial, and justiciable controversy between Plaintiffs and
13 Defendants concerning whether one or more claims of the '834 patent are invalid for failure to
14 comply with the requirements of Title 35 of the United States Code, including, without limitation,
15 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

16 295. The controversy between the parties is amenable to specific relief through a decree
17 of conclusive character.

18 296. Plaintiffs are entitled to a judicial declaration that one or more claims of the '834
19 patent are invalid.

20 **COUNT XXXII**

21 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,076,066**

22 297. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-296
23 above as if fully set forth herein.

24 298. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
25 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
26 opinion that one or more claims of the '066 patent will not be infringed by the commercial
27 manufacture, use, importation, sale, or offer for sale of CT-P6.

1 known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims
2 are invalid for lack of written description because the patent fails to show a direct correlation
3 between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of
4 prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein
5 expression and known discrepancies and comparative advantages between the various methods;
6 and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with
7 trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2
8 gene amplification, wherein some of the patients included for treatment based on her2 gene
9 amplification would have been determined to have IHC scores of 0 or 1+ had they been tested
10 using IHC.

11 306. There is a real, substantial, and justiciable controversy between Plaintiffs and
12 Defendants concerning whether the claims of the '066 patent are invalid for failure to comply with
13 the requirements of Title 35 of the United States Code, including, without limitation, one or more
14 of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

15 307. The controversy between the parties is amenable to specific relief through a decree
16 of conclusive character.

17 308. Plaintiffs are entitled to a judicial declaration that all claims of the '066 patent are
18 invalid.

19 **COUNT XXXIV**

20 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,357,301**

21 309. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-308
22 above as if fully set forth herein.

23 310. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
24 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
25 opinion that one or more claims of the '301 patent will not be infringed by the commercial
26 manufacture, use, importation, sale, or offer for sale of CT-P6.

1 311. For example, Plaintiffs will not infringe one or more claims of the '301 patent under
2 35 U.S.C. § 271(a) because [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

3 [REDACTED] Plaintiffs also will not infringe one or more claims of the '301 patent under 35 U.S.C. §
4 271(g) because [REDACTED]

5 [REDACTED]
6 [REDACTED]
7 312. Additional, non-limiting examples of how Plaintiffs will not infringe one or more
8 valid claims of the '301 patent include because [REDACTED]

9 [REDACTED]
10 [REDACTED] [REDACTED]
11 [REDACTED]
12 [REDACTED]

13 313. There is a real, substantial, and justiciable controversy between Plaintiffs and
14 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '301
15 patent.

16 314. The controversy between the parties is amenable to specific relief through a decree
17 of conclusive character.

18 315. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
19 infringe, directly or indirectly, any valid and enforceable claim of the '301 patent.

20 **COUNT XXXV**

21 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,357,301**

22 316. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-315
23 above as if fully set forth herein.

24 317. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
25 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
26 opinion that one or more claims of the '301 patent are invalid.

1 because [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]

8 325. There is a real, substantial, and justiciable controversy between Plaintiffs and
9 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '908
10 patent.

11 326. The controversy between the parties is amenable to specific relief through a decree
12 of conclusive character.

13 327. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
14 infringe, directly or indirectly, any valid and enforceable claim of the '908 patent.

15 **COUNT XXXVII**

16 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,425,908**

17 328. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-327
18 above as if fully set forth herein.

19 329. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
20 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
21 opinion that one or more claims of the '908 patent are invalid.

22 330. Non-limiting examples of how one or more claims of the '908 patent are invalid
23 include because the claims are invalid as obvious in view of the prior art, including at least Tokuda
24 et al., In Vitro and In Vivo Anti-Tumour Effects of a Humanised Monoclonal Antibody Against c-
25 erbB-2 Product, 73 BRITISH J. CANCER 1362-1365 (1996); A. Hendlisz et al., Diagnosis and
26 Treatment of Gastric Cancer, 49(5) DRUGS 711-720 (1995) and M. Pegram et al., Phase II Study
27 of Intravenous Recombinant Humanized Anti-p185 HER-2 Monoclonal Antibody (rhuMAB HER-
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1 2) Plus Cisplatin in Patients with HER-2/NEU Overexpressing Metastatic Breast Cancer, 14
2 PROC. AM. SOC'Y CLIN. ONCOLOGY 106, abs. 124.

3 331. There is a real, substantial, and justiciable controversy between Plaintiffs and
4 Defendants concerning whether one or more claims of the '908 patent are invalid for failure to
5 comply with the requirements of Title 35 of the United States Code, including, without limitation,
6 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

7 332. The controversy between the parties is amenable to specific relief through a decree
8 of conclusive character.

9 333. Plaintiffs are entitled to a judicial declaration that one or more claims of the '908
10 patent are invalid.

11 **COUNT XXXVIII**

12 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,440,402**

13 334. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-333
14 above as if fully set forth herein.

15 335. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
16 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
17 opinion that one or more claims of the '402 patent will not be infringed by the commercial
18 manufacture, use, importation, sale, or offer for sale of CT-P6.

19 336. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims
20 of the '402 patent include: (1) Plaintiffs will not be liable for direct infringement of the claimed
21 method because Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not
22 practice any of the claimed methods; [REDACTED]

23 [REDACTED]

24 [REDACTED] (3) in the patent
25 specification and during prosecution of the patent, the patentees expressly disclaimed [REDACTED]

26 [REDACTED]

27 [REDACTED]

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1 [REDACTED] and (4) the patent specification itself acknowledges there are substantial non-
2 infringing uses for the CT-P6 product, [REDACTED]

3 [REDACTED]
4 337. There is a real, substantial, and justiciable controversy between Plaintiffs and
5 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '402
6 patent.

7 338. The controversy between the parties is amenable to specific relief through a decree
8 of conclusive character.

9 339. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
10 infringe, directly or indirectly, any valid and enforceable claim of the '402 patent.

11 **COUNT XXXIV**

12 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,402**

13 340. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-339
14 above as if fully set forth herein.

15 341. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
16 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
17 opinion that one or more claims of the '402 patent are invalid.

18 342. Non-limiting examples of how one or more claims of the '402 patent are invalid
19 include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than
20 recite a natural law relating known biomarkers to known disposition to respond to treatment with
21 trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to
22 show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims
23 are obvious in view of prior art disclosing methods for treating patients based on her2 gene
24 amplification or HER2 protein expression and known discrepancies and comparative advantages
25 between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the
26 treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein
27 overexpression by IHC or her2 gene amplification, wherein some of the patients included for
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1 treatment based on her2 gene amplification would have been determined to have IHC scores of 0
2 or 1+ had they been tested using IHC.

3 343. There is a real, substantial, and justiciable controversy between Plaintiffs and
4 Defendants concerning whether one or more claims of the '402 patent are invalid for failure to
5 comply with the requirements of Title 35 of the United States Code, including, without limitation,
6 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

7 344. The controversy between the parties is amenable to specific relief through a decree
8 of conclusive character.

9 345. Plaintiffs are entitled to a judicial declaration that one or more claims of the '402
10 patent are invalid.

11 **COUNT XL**

12 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895**

13 346. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-345
14 above as if fully set forth herein.

15 347. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
16 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
17 opinion that one or more claims of the '895 patent will not be infringed by the commercial
18 manufacture, use, importation, sale, or offer for sale of CT-P6.

19 348. For example, Plaintiffs will not infringe one or more claims of the '895 patent under
20 35 U.S.C. § 271(a) because [REDACTED]

21 [REDACTED] Plaintiffs also will not infringe one or more claims of the '895
22 patent under 35 U.S.C. § 271(g) because [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

26 349. Additional non-limiting examples of how Plaintiffs will not infringe one or more
27 valid claims of the '895 patent include: [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]

5 350. There is a real, substantial, and justiciable controversy between Plaintiffs and
6 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '895
7 patent.

8 351. The controversy between the parties is amenable to specific relief through a decree
9 of conclusive character.

10 352. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
11 infringe, directly or indirectly, any valid and enforceable claim of the '895 patent.

12 **COUNT XLI**

13 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983**

14 353. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-352
15 above as if fully set forth herein.

16 354. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
17 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
18 opinion that one or more claims fo the '983 patent will not be infringed by the commercial
19 manufacture, use, importation, sale, or offer for sale of CT-P6.

20 355. For example, Plaintiffs will not infringe one or more claims of the '983 patent under
21 35 U.S.C. § 271(a) because [REDACTED]

22 Plaintiffs will not infringe the product claim of the '983 patent (claim 25) under 35 U.S.C. § 271(a)
23 because [REDACTED]

24 [REDACTED]

25 [REDACTED] Plaintiffs also will not infringe one or more claims of the '983 patent under 35
26 U.S.C. § 271(g) because [REDACTED]

27 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 356. Additional non-limiting examples of how Plaintiffs will not infringe one or more
4 valid claims of the '983 patent include: [REDACTED]

5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 357. There is a real, substantial, and justiciable controversy between Plaintiffs and
12 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '983
13 patent.

14 358. The controversy between the parties is amenable to specific relief through a decree
15 of conclusive character.

16 359. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
17 infringe, directly or indirectly, any valid and enforceable claim of the '983 patent.

18 **COUNT XLII**

19 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983**

20 360. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-359
21 above as if fully set forth herein.

22 361. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
23 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
24 opinion that one or more claims of the '983 patent are invalid.

25 362. Non-limiting examples of how one or more claims of the '983 patent are invalid
26 include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells
27 cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mM to 15
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1 mM and every other claim limitation; and (2) obviousness over prior art disclosing expression of
2 therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the
3 claimed range of 7.5 mM to 15 mM, and art disclosing the production of therapeutic proteins,
4 including anti-CD20 antibodies, in CHO cells.

5 363. There is a real, substantial, and justiciable controversy between Plaintiffs and
6 Defendants concerning whether one or more claims of the '983 patent are invalid for failure to
7 comply with the requirements of Title 35 of the United States Code, including, without limitation,
8 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

9 364. The controversy between the parties is amenable to specific relief through a decree
10 of conclusive character.

11 365. Plaintiffs are entitled to a judicial declaration that one or more claims of the '983
12 patent are invalid.

13 **COUNT XLIII**

14 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869**

15 366. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-365
16 above as if fully set forth herein.

17 367. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
18 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
19 opinion that one or more claims of the '869 patent will not be infringed by the commercial
20 manufacture, use, importation, sale, or offer for sale of CT-P6.

21 368. For example, Plaintiffs will not infringe one or more claims of the '869 patent under
22 35 U.S.C. § 271(a) because [REDACTED]

23 [REDACTED] Plaintiffs also will not infringe one or more claims of the '869 patent under 35 U.S.C. §
24 271(g) because [REDACTED]

25 [REDACTED]

26 [REDACTED]

27
28

1 369. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims
2 of the '869 patent include: [REDACTED]
3 [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
4 [REDACTED]
5 [REDACTED]

6 370. There is a real, substantial, and justiciable controversy between Plaintiffs and
7 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '869
8 patent.

9 371. The controversy between the parties is amenable to specific relief through a decree
10 of conclusive character.

11 372. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
12 infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

13 **COUNT XLIV**

14 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869**

15 373. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-372
16 above as if fully set forth herein.

17 374. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
18 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
19 opinion that one or more claims of the '869 patent are invalid.

20 375. Non-limiting examples of how one or more claims of the '869 patent are invalid
21 include: (1) lack of written description for the claim term "following fermentation, sparging the
22 pre-harvest or harvested culture fluid" as the patent is silent concerning any air sparging of a pre-
23 harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in
24 view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds
25 via air sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art
26 that published or was otherwise available to the public before the earliest possible priority date of
27 the '869 patent.
28

1 376. There is a real, substantial, and justiciable controversy between Plaintiffs and
2 Defendants concerning whether one or more claims of the '869 patent are invalid for failure to
3 comply with the requirements of Title 35 of the United States Code, including, without limitation,
4 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

5 377. The controversy between the parties is amenable to specific relief through a decree
6 of conclusive character.

7 378. Plaintiffs are entitled to a judicial declaration that one or more claims of the '869
8 patent are invalid.

9 **COUNT XLV**

10 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302**

11 379. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-378
12 above as if fully set forth herein.

13 380. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
14 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
15 opinion that one or more claims of the '302 patent will not be infringed by the commercial
16 manufacture, use, importation, sale, or offer for sale of CT-P6.

17 381. For example, Plaintiffs will not infringe one or more claims of the '302 patent under
18 35 U.S.C. § 271(a) because [REDACTED]

19 [REDACTED] Plaintiffs also will not infringe one or more claims of the '302 patent under 35 U.S.C. §
20 271(g) because [REDACTED]

21 [REDACTED]
22 [REDACTED]
23 382. Additional non-limiting examples of how Plaintiffs will not infringe one or more
24 valid claims of the '302 patent include that [REDACTED]

25 [REDACTED]
26
27
28

1 383. There is a real, substantial, and justiciable controversy between Plaintiffs and
2 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '302
3 patent.

4 384. The controversy between the parties is amenable to specific relief through a decree
5 of conclusive character.

6 385. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
7 infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

8 **COUNT XLVI**

9 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,691,232**

10 386. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-385
11 above as if fully set forth herein.

12 387. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
13 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
14 opinion that one or more claims of '232 patent will not be infringed by the commercial
15 manufacture, use, importation, sale, or offer for sale of CT-P6.

16 388. For example, Plaintiffs will not directly infringe any claim of the '232 patent
17 because all the claims are all directed to methods of treating patients and Plaintiffs will not treat
18 patients. Plaintiffs will also not induce infringement because [REDACTED]

19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

23 389. There is a real, substantial, and justiciable controversy between Plaintiffs and
24 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '232
25 patent.

26 390. The controversy between the parties is amenable to specific relief through a decree
27 of conclusive character.

28

1 391. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
2 infringe, directly or indirectly, any valid and enforceable claim of the '232 patent.

3 **COUNT XLVII**

4 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,691,232**

5 392. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-391
6 above as if fully set forth herein.

7 393. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
8 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
9 opinion that one or more claims of the '232 patent are invalid.

10 394. A non-limiting example of how one or more claims of the '232 patent are invalid is
11 because the claims are invalid under 35 U.S.C. § 102 as anticipated by the prior art, including at
12 least U.S. Application No. 10/619,754.

13 395. There is a real, substantial, and justiciable controversy between Plaintiffs and
14 Defendants concerning whether one or more claims of the '232 patent are invalid for failure to
15 comply with the requirements of Title 35 of the United States Code, including, without limitation,
16 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

17 396. The controversy between the parties is amenable to specific relief through a decree
18 of conclusive character.

19 397. Plaintiffs are entitled to a judicial declaration that one or more claims of the '232
20 patent are invalid.

21 **COUNT XLVIII**

22 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,771,988**

23 398. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-397
24 above as if fully set forth herein.

25 399. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
26 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
27

1 opinion that the '988 patent would not be infringed by the commercial manufacture, use,
2 importation, sale, or offer for sale of CT-P6.

3 400. For example, Plaintiffs will not infringe one or more claims of the '988 patent under
4 35 U.S.C. § 271(a) because [REDACTED]

5 Plaintiffs also will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(g)
6 because [REDACTED]

7 [REDACTED]
8 [REDACTED]
9 401. Additional non-limiting examples of how Plaintiffs will not infringe one or more
10 valid claims of the '988 patent include [REDACTED]

11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 402. There is a real, substantial, and justiciable controversy between Plaintiffs and
15 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '988
16 patent.

17 403. The controversy between the parties is amenable to specific relief through a decree
18 of conclusive character.

19 404. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
20 infringe, directly or indirectly, any valid and enforceable claim of the '988 patent.

21 **COUNT XLIX**

22 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,822,655**

23 405. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-404
24 above as if fully set forth herein.

25 406. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
26 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
27

1 opinion that one or more claims of the '655 patent will not be infringed by the commercial
2 manufacture, use, importation, sale, or offer for sale of CT-P6.

3 407. For example, Plaintiffs will not infringe one or more claims of the '655 patent under
4 35 U.S.C. § 271(a) because [REDACTED]

5 [REDACTED] Plaintiffs also will not infringe one or more claims of the '655 patent under 35 U.S.C. §
6 271(g) because [REDACTED]

7 [REDACTED]
8 [REDACTED]
9 408. Additional non-limiting examples of how Plaintiffs will not infringe one or more
10 valids claim of the '655 patent at least because [REDACTED]

11 [REDACTED]
12 [REDACTED]
13 409. There is a real, substantial, and justiciable controversy between Plaintiffs and
14 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '655
15 patent.

16 410. The controversy between the parties is amenable to specific relief through a decree
17 of conclusive character.

18 411. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
19 infringe, directly or indirectly, any valid and enforceable claim of the '655 patent.

20 **COUNT L**

21 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,822,655**

22 412. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-411
23 above as if fully set forth herein.

24 413. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
25 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
26 opinion that one or more claims of the '655 patent are invalid.

1 414. Non-limiting examples of how the '655 patent is invalid include a failure to claim
2 patentable subject matter as each claim of the '655 patent is directed towards an abstract idea,
3 including the use of two equations to determine how to adjust a "first concentration" of buffer
4 substance to arrive at "a second concentration" in order to allegedly achieve a more consistent
5 preparation of immunoglobulin after concentration by tangential flow filtration.

6 415. There is a real, substantial, and justiciable controversy between Plaintiffs and
7 Defendants concerning whether one or more claims of the '655 patent are invalid for failure to
8 comply with the requirements of Title 35 of the United States Code, including, without limitation,
9 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

10 416. The controversy between the parties is amenable to specific relief through a decree
11 of conclusive character.

12 417. Plaintiffs are entitled to a judicial declaration that one or more claims of the '655
13 patent are invalid.

14 **COUNT LI**

15 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,047,438**

16 418. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-417
17 above as if fully set forth herein.

18 419. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
19 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
20 opinion that one or more claims of the '438 patent will not be infringed by the commercial
21 manufacture, use, importation, sale, or offer for sale of CT-P6.

22 420. For example, Plaintiffs will not infringe any claim of the '438 patent under 35
23 U.S.C. § 271(a) because [REDACTED] Plaintiffs
24 also will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(g) because [REDACTED]

25 [REDACTED]
26 [REDACTED]
27 [REDACTED]

1 428. There is a real, substantial, and justiciable controversy between Plaintiffs and
2 Defendants concerning whether the claims of the '438 patent are invalid for failure to comply with
3 the requirements of Title 35 of the United States Code, including, without limitation, one or more
4 of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

5 429. The controversy between the parties is amenable to specific relief through a decree
6 of conclusive character.

7 430. Plaintiffs are entitled to a judicial declaration that one or more claims of the '438
8 patent are invalid.

9 **COUNT LIII**

10 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,080,183**

11 431. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-430
12 above as if fully set forth herein.

13 432. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
14 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
15 opinion that one or more claims of the '183 patent will not be infringed by the commercial
16 manufacture, use, importation, sale, or offer for sale of CT-P6.

17 433. For example, Plaintiffs will not infringe one or more claims of the '183 patent under
18 35 U.S.C. § 271(a) because [REDACTED]

19 Plaintiffs also will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(g)
20 because [REDACTED]

21 [REDACTED]
22 [REDACTED]
23 434. Additional non-limiting examples of how Plaintiffs will not infringe one or more
24 valid claims of the '183 patent include [REDACTED]

25 [REDACTED]
26 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 435. There is a real, substantial, and justiciable controversy between Plaintiffs and
4 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '183
5 patent.

6 436. The controversy between the parties is amenable to specific relief through a decree
7 of conclusive character.

8 437. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
9 infringe, directly or indirectly, any valid and enforceable claim of the '183 patent.

10 **COUNT LIV**

11 **Declaratory Judgment of Invalidity of U.S. Patent No. 9,080,183**

12 438. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-437
13 above as if fully set forth herein.

14 439. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
15 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
16 opinion that one or more claims of the '183 patent are invalid.

17 440. Non-limiting examples of how one or more claims of the '183 patent are invalid
18 include obviousness in view of prior art disclosing the use of truncated versions of the SV40
19 promotor to drive protein expression and art disclosing the use of weaker promotor sequences to
20 improve protein expression. In addition, one or more claims of the '183 patent are invalid in light
21 of prior art that published or was otherwise available to the public before the earliest possible
22 priority date of the '183 patent.

23 441. There is a real, substantial, and justiciable controversy between Plaintiffs and
24 Defendants concerning whether one or more claims of the '183 patent are invalid for failure to
25 comply with the requirements of Title 35 of the United States Code, including, without limitation,
26 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

1 442. The controversy between the parties is amenable to specific relief through a decree
2 of conclusive character.

3 443. Plaintiffs are entitled to a judicial declaration that one or more claims of the '183
4 patent are invalid.

5 **COUNT LV**

6 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,249,218**

7 444. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-443
8 above as if fully set forth herein.

9 445. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
10 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
11 opinion that one or more claims of the '218 patent will not be infringed by the commercial
12 manufacture, use, importation, sale, or offer for sale of CT-P6.

13 446. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims
14 of the '218 patent include: [REDACTED]

15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 447. There is a real, substantial, and justiciable controversy between Plaintiffs and
20 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '218
21 patent.

22 448. The controversy between the parties is amenable to specific relief through a decree
23 of conclusive character.

24 449. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
25 infringe, directly or indirectly, any valid and enforceable claim of the '218 patent.

26 **COUNT LVI**

27 **Declaratory Judgment of Invalidity of U.S. Patent No. 9,249,218**

1 450. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-449
2 above as if fully set forth herein.

3 451. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
4 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
5 opinion that one or more claims of the '218 patent are invalid.

6 452. Non-limiting examples of how one or more claims of the '218 patent are invalid
7 include: (1) anticipation by prior art which expressly disclosed a therapeutic lyophilized
8 composition comprising trastuzumab and at most about 18% acidic variants thereof and a
9 pharmaceutically acceptable carrier, and inherently disclosed any valid remaining limitations; (2)
10 obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab
11 from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical
12 composition to low levels, including levels of 13%, for pharmaceutical compositions.

13 453. There is a real, substantial, and justiciable controversy between Plaintiffs and
14 Defendants concerning whether one or more claims of the '218 patent are invalid for failure to
15 comply with the requirements of Title 35 of the United States Code, including, without limitation,
16 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

17 454. The controversy between the parties is amenable to specific relief through a decree
18 of conclusive character.

19 455. Plaintiffs are entitled to a judicial declaration that one or more claims of the '218
20 patent are invalid.

21 **COUNT LVII**

22 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,548**

23 456. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-455
24 above as if fully set forth herein.

25 457. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
26 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s
27
28

1 opinion that one or more claims of the '548 patent will not be infringed by the commercial
2 manufacture, use, importation, sale, or offer for sale of CT-P6.

3 458. For example, Plaintiffs will not infringe one or more claims of the '548 patent under
4 35 U.S.C. § 271(a) because [REDACTED]

5 [REDACTED] Plaintiffs also will not infringe one or more claims of the '548 patent under 35
6 U.S.C. § 271(g) because [REDACTED]

7 [REDACTED]
8 [REDACTED]
9 [REDACTED]

10 459. An additional non-limiting example of how Plaintiffs will not infringe one or more
11 valid claims of the '548 patent include that Plaintiffs [REDACTED]

12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 460. There is a real, substantial, and justiciable controversy between Plaintiffs and
19 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '548
20 patent.

21 461. The controversy between the parties is amenable to specific relief through a decree
22 of conclusive character.

23 462. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
24 infringe, directly or indirectly, any valid and enforceable claim of the '548 patent.

25 **COUNT LVIII**

26 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,766**

1 463. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-462
2 above as if fully set forth herein.

3 464. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
4 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.’s
5 opinion that one or more claims of the ’766 patent will not be infringed by the commercial
6 manufacture, use, importation, sale, or offer for sale of CT-P6.

7 465. For example, Plaintiffs will not infringe the sole claim of the ’766 patent under 35
8 U.S.C. § 271(a) because [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 466. Additional non-limiting examples of how Plaintiffs will not infringe the sole claim
12 of the ’766 patent include [REDACTED]

13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 467. There is a real, substantial, and justiciable controversy between Plaintiffs and
17 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’766
18 patent.

19 468. The controversy between the parties is amenable to specific relief through a decree
20 of conclusive character.

21 469. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
22 infringe, directly or indirectly, any valid and enforceable claim of the ’766 patent.

23 **COUNT LIX**

24 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,487,809**

25 470. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-469
26 above as if fully set forth herein.

1 471. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
2 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.’s
3 opinion that one or more claims of the ’809 patent will not be infringed by the commercial
4 manufacture, use, importation, sale, or offer for sale of CT-P6.

5 472. For example, Plaintiffs will not infringe one or more claims of the ’809 patent under
6 35 U.S.C. § 271(a) because [REDACTED]

7 [REDACTED] Plaintiffs also will not infringe one or more claims of the ’809 patent under 35
8 U.S.C. § 271(g) because [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 473. Additional non-limiting examples of how Plaintiffs will not infringe one or more
13 valid claims of the ’809 patent include that [REDACTED]

14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 474. There is a real, substantial, and justiciable controversy between Plaintiffs and
18 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’809
19 patent.

20 475. The controversy between the parties is amenable to specific relief through a decree
21 of conclusive character.

22 476. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
23 infringe, directly or indirectly, any valid and enforceable claim of the ’809 patent.

24 **COUNT LX**

25 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,714,293**

26 477. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-476
27 above as if fully set forth herein.
28

1 478. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement
2 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.’s
3 opinion that one or more claims of the ’293 patent will not be infringed by the commercial
4 manufacture, use, importation, sale, or offer for sale of CT-P6.

5 479. For example, Plaintiffs will not infringe one or more claims of the ’293 patent under
6 35 U.S.C. § 271(a) because [REDACTED]

7 [REDACTED] Plaintiffs also will not infringe one or more claims of the ’293 patent under 35
8 U.S.C. § 271(g) because [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 480. Additional non-limiting examples of how Plaintiffs will not infringe one or more
13 valid claims of the ’293 patent include: [REDACTED]

14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 481. There is a real, substantial, and justiciable controversy between Plaintiffs and
19 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’293
20 patent.

21 482. The controversy between the parties is amenable to specific relief through a decree
22 of conclusive character.

23 483. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not
24 infringe, directly or indirectly, any valid and enforceable claim of the ’293 patent.

25 **PRAYER FOR RELIEF**

26 WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor
27 against Genentech, Roche, and City of Hope and grant the following relief:
28

1 A. Declare that Plaintiffs have not, do not, and will not infringe any valid and
2 enforceable claim of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,489,447;
3 6,586,206; 6,610,516; 6,620,918; 6,627,196; 6,716,602; 7,371,379; 7,390,660; 7,449,184;
4 7,485,704; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066;
5 8,357,301; 8,425,908; 8,440,402; 8,460,895; 8,512,983; 8,574,869; 8,633,302; 8,691,232;
6 8,771,988; 8,822,655; 9,047,438; 9,080,183; 9,249,218; 9,428,548; 9,428,766; 9,487,809; and
7 9,714,293.

8 B. Declare that one or more claims of U.S. Patent Nos. 6,331,415; 6,339,142; 6,417,335;
9 6,610,516; 6,716,602; 7,449,184; 7,501,122; 7,807,799; 7,923,221; 7,993,834; 8,076,066;
10 8,357,301; 8,425,908; 8,440,402; 8,512,983; 8,574,869; 8,691,232; 8,822,655; 9,047,438;
11 9,080,183; and 9,249,218 are invalid.

12 C. Declare that U.S. Patent No. 6,407,213 is unenforceable.

13 D. Declare that this is an exceptional case in favor of Plaintiffs and award Plaintiffs
14 their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

15 E. Award Plaintiffs costs and expenses.

16 F. Award any and all such other relief as the Court determines to be just and proper,
17 including pursuant to 28 U.S.C. § 2202.

1 Dated: January 11, 2018

GOODWIN PROCTER LLP
NEEL CHATTERJEE (173985)

2
3 /s/ Neel Chatterjee

Neel Chatterjee (173985)
Attorney for all Plaintiffs

4
5
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