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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., CELLTRION  
HEALTHCARE CO., LTD., TEVA  
PHARMACEUTICALS USA, INC., AND  
TEVA PHARMACEUTICALS  
INTERNATIONAL GmbH,

Plaintiffs,

v.

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

Defendants.

Case No. \_\_\_\_\_

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

**REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED**

**[CONFIDENTIAL PORTIONS REDACTED]**

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 and/or invalidity against Defendants Genentech, Inc. (“Genentech”), Biogen Inc.  
6 (“Biogen”), 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.

**NATURE OF THE CASE**

17  
18 1. This is an action for declaratory judgment of non-infringement and/or invalidity  
19 relating to the following patents:

- 20 (i) U.S. Patent No. 6,331,415 (“the ’415 patent”);
- 21 (ii) U.S. Patent No. 6,417,335 (“the ’335 patent”);
- 22 (iii) U.S. Patent No. 6,455,043 (“the ’043 patent”);
- 23 (iv) U.S. Patent No. 6,489,447 (“the ’447 patent”);
- 24 (v) U.S. Patent No. 6,586,206 (“the ’206 patent”);
- 25 (vi) U.S. Patent No. 6,610,516 (“the ’516 patent”);
- 26 (vii) U.S. Patent No. 6,620,918 (“the ’918 patent”);
- 27 (viii) U.S. Patent No. 6,716,602 (“the ’602 patent”);

- 1 (ix) U.S. Patent No. 7,390,660 (“the ’660 patent”);
- 2 (x) U.S. Patent No. 7,485,704 (“the ’704 patent”);
- 3 (xi) U.S. Patent No. 7,682,612 (“the ’612 patent”);
- 4 (xii) U.S. Patent No. 7,807,799 (“the ’799 patent”);
- 5 (xiii) U.S. Patent No. 7,820,161 (“the ’161 patent”);
- 6 (xiv) U.S. Patent No. 7,923,221 (“the ’221 patent”);
- 7 (xv) U.S. Patent No. 7,976,838 (“the ’838 patent”);
- 8 (xvi) U.S. Patent No. 8,044,017 (“the ’017 patent”);
- 9 (xvii) U.S. Patent No. 8,206,711 (“the ’711 patent”);
- 10 (xviii) U.S. Patent No. 8,329,172 (“the ’172 patent”);
- 11 (xix) U.S. Patent No. 8,357,301 (“the ’301 patent”);
- 12 (xx) U.S. Patent No. 8,460,895 (“the ’895 patent”);
- 13 (xxi) U.S. Patent No. 8,512,983 (“the ’983 patent”);
- 14 (xxii) U.S. Patent No. 8,545,843 (“the ’843 patent”);
- 15 (xxiii) U.S. Patent No. 8,557,244 (“the ’244 patent”);
- 16 (xxiv) U.S. Patent No. 8,574,869 (“the ’869 patent”);
- 17 (xxv) U.S. Patent No. 8,633,302 (“the ’302 patent”);
- 18 (xxvi) U.S. Patent No. 8,710,196 (“the ’196 patent”);
- 19 (xxvii) U.S. Patent No. 8,771,988 (“the ’988 patent”);
- 20 (xxviii) U.S. Patent No. 8,821,873 (“the ’873 patent”);
- 21 (xxix) U.S. Patent No. 8,822,655 (“the ’655 patent”);
- 22 (xxx) U.S. Patent No. 9,047,438 (“the ’438 patent”);
- 23 (xxxi) U.S. Patent No. 9,080,183 (“the ’183 patent”);
- 24 (xxxii) U.S. Patent No. 9,296,821 (“the ’821 patent”);
- 25 (xxxiii) U.S. Patent No. 9,428,548 (“the ’548 patent”);
- 26 (xxxiv) U.S. Patent No. 9,428,766 (“the ’766 patent”);
- 27 (xxxv) U.S. Patent No. 9,487,809 (“the ’809 patent”);

28

1 (xxxvi) U.S. Patent No. 9,504,744 (“the ’744 patent”); and

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

3 2. According to Genentech, the patents-in-suit relate to an antibody product called  
4 rituximab, which Genentech markets under the brand name Rituxan®. Rituxan® has been approved  
5 by the FDA for the treatment of several types of cancer, rheumatoid arthritis, and granulomatosis  
6 with polyangiitis and microscopic polyangiitis.

7 3. On information and belief, Genentech and Biogen<sup>1</sup> collaborated in the development  
8 of the technology underlying the patents-in-suit and collaborated on the development of Rituxan®.  
9 See [https://www.biogen.com/en\\_us/therapies.html#partnered-therapies](https://www.biogen.com/en_us/therapies.html#partnered-therapies); [https://www.roche.com/](https://www.roche.com/investors/updates/inv-update-2010-10-21b.htm)  
10 [investors/updates/inv-update-2010-10-21b.htm](https://www.roche.com/investors/updates/inv-update-2010-10-21b.htm). Rituxan® is jointly marketed in the United States  
11 by Genentech and Biogen.

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

14 5. On information and belief, each patent-in-suit is owned by at least one of Genentech,  
15 Biogen, Roche, or City of Hope.

16 6. A substantial controversy exists between Plaintiffs, on the one hand, and Genentech,  
17 Biogen, Roche, and City of Hope, on the other hand, in which the parties have adverse legal interests  
18 of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Celltrion  
19 Healthcare, Celltrion Inc., and TPIG entered into a business collaboration agreement to  
20 commercialize CT-P10, a biosimilar to Rituxan®. Celltrion Inc. submitted an Abbreviated  
21 Biologics License Application (“aBLA”) to the FDA under 42 U.S.C. § 262(k) of the Biologics Price  
22 Competition and Innovation Act of 2009 (the “BPCIA”) for licensure of a rituximab biological  
23 product (hereinafter, “biosimilar product,” “CT-P10,” or “Truxima®”) that is highly similar to  
24 Rituxan®. Teva USA will sell and distribute the CT-P10 product in the United States. The FDA  
25 accepted Celltrion Inc.’s biosimilar application on June 27, 2017. Celltrion Inc. provided Genentech  
26 with a copy of its aBLA and other detailed information regarding the manufacturing processes used  
27

28 <sup>1</sup> Biogen Inc. was previously known as Biogen Idec and IDEC Pharmaceuticals.

1 to make Truxima®, and in response, Genentech identified the patents-in-suit which Genentech  
2 alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for  
3 sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion  
4 Inc. then provided Genentech with a detailed statement regarding the invalidity and/or non-  
5 infringement of the patents that Genentech identified, along with citations to the aBLA and other  
6 manufacturing information that Celltrion Inc. produced to Genentech to support such defenses. In  
7 response, Genentech provided Celltrion Inc. with a statement purporting to contain the factual and  
8 legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the  
9 commercial marketing of the biosimilar product.

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

13 **PARTIES**

14 8. Celltrion Inc. is a corporation organized and existing under the laws of the Republic  
15 of Korea, with a principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South  
16 Korea.

17 9. Celltrion Healthcare, Co. Ltd. is a corporation organized under the laws of the  
18 Republic of Korea, having its principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon,  
19 406-840, South Korea.

20 10. Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a principal place of  
21 business at 1090 Horsham Road, North Wales, PA 19454-1090.

22 11. TPIG is a limited liability company organized and existing under the laws of  
23 Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona  
24 (SG) 8645, Switzerland.

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



1 information and belief, Genentech’s South San Francisco campus is its headquarters for its  
2 pharmaceutical operations in the United States. Genentech also maintains multiple other facilities in  
3 California, including a biotech manufacturing and clinical operations complex in Oceanside,  
4 California, and a biotechnology manufacturing plant in Vacaville, California.

5 20. Upon information and belief, Genentech markets, distributes and sells pharmaceutical  
6 products, including Rituxan®, in California, including in this District. Genentech’s continuous and  
7 systematic corporate operations within California are so substantial and of such a nature to justify  
8 suit against it on causes of action arising from dealings entirely distinct from those activities.

9 21. The Court also has personal jurisdiction over Genentech because, among other  
10 reasons, Genentech’s activities in California gave rise to this action. For example, Genentech, which  
11 is located in this District, directed its counsel in Los Angeles, California, to send Plaintiffs’ counsel  
12 in this District (i) correspondence related to the BPCIA exchanges described above, (ii) a list of  
13 patents that it purports could reasonably be asserted against Plaintiffs, and (iii) a statement that  
14 purports to describe, among other things, the factual and legal basis of Genentech’s opinion that  
15 patents that it owns, or for which it is an exclusive licensee, will be infringed by the commercial  
16 marketing of Plaintiffs’ biosimilar product.

17 22. The Court has personal jurisdiction over Biogen because Biogen markets, distributes  
18 and sells pharmaceutical products, including Rituxan®, in California, including in this District. On  
19 information and belief, Biogen has collaborated with San-Francisco-based Genentech to develop the  
20 technology in the patents-in-suit and to develop and market Rituxan®. Biogen continues to jointly  
21 market Rituxan® with Genentech today. Rituxan® is a registered trademark of Biogen. Biogen also  
22 conducts, and recruits patients for enrollment in, clinical trials in this District. Biogen’s continuous  
23 and systematic corporate operations within California are so substantial and of such a nature to  
24 justify suit against it on causes of action arising from dealings entirely distinct from those activities.

25 23. This Court also has personal jurisdiction over Biogen because Biogen has  
26 purposefully directed various activities at this District which gave rise to this action. For example,  
27 on information and belief, Biogen collaborated with South San Francisco-based Genentech regarding  
28

1 the subject matter of certain patents-in-suit and/or entered into contractual agreements with  
2 Genentech regarding certain patents-in-suit. In addition, on information and belief, Biogen has  
3 knowingly consented to and/or collaborated with South San Francisco-based Genentech's  
4 enforcement actions regarding the patents-in-suit.

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

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

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

25 27. This Court also has personal jurisdiction over Roche because Roche has purposefully  
26 directed various activities at this District which gave rise to this action. For example, on information  
27 and belief, Roche collaborated with South San Francisco-based Genentech to research and/or  
28

1 develop the subject matter of certain patents-in-suit and/or entered into contractual agreements with  
2 South San Francisco-based Genentech regarding certain patents-in-suit. In addition, on information  
3 and belief, Roche has knowingly consented to and/or collaborated with Genentech's enforcement  
4 actions regarding one or more of the patents-in-suit.

5 28. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, among other  
6 reasons, Genentech, Biogen, City of Hope, and Roche all reside and are subject to personal  
7 jurisdiction in this District for purposes of this action as set forth above. In addition, venue is proper  
8 in this district because a substantial part of the events that gave rise to this action occurred in this  
9 District. For example, on information and belief, one or more of Genentech, Biogen, City of Hope,  
10 and Roche collaborated in this District regarding the research and/or development of the subject  
11 matter of certain patents-in-suit and/or entered into contractual agreements with South San  
12 Francisco-based Genentech regarding certain patents-in-suit. In addition, on information and belief,  
13 one or more of Biogen, City of Hope, and Roche have knowingly consented to and/or collaborated  
14 with Genentech's enforcement actions regarding one or more of the patents-in-suit. Moreover,  
15 Genentech, which is located in this District, has directed certain activities at Plaintiffs' counsel in  
16 this District relating to the enforcement of the patents-in-suit, including the transmission of (i)  
17 correspondence related to the BPCIA exchanges described above, (ii) a list identifying the patents-  
18 in-suit among those patents that Genentech believes could reasonably be asserted against Plaintiffs  
19 following the submission of their subsection (k) application, and (iii) a statement that purports to  
20 describe Genentech's opinions regarding the infringement, validity, and enforceability of the  
21 patents-in-suit. Furthermore, Genentech, Biogen, Roche, and/or City of Hope have litigated in this  
22 District at least 19 separate actions relating to patents-in-suit, including those having civil action  
23 numbers 5-15-cv-01238; 3-13-cv-02045; 4-13-cv-00919; 3-13-cv-02904; 4-11-cv-02410; 3-11-cv-  
24 01925; 5-10-cv-04255; 5-10-cv-02037; 3-10-cv-00675; 3-09-cv-04919; 5-08-cv-05590; 3-08-cv-  
25 04909; 4-04-cv-05429; 3-04-cv-01910; 3-03-cv-01603; 3-01-cv-03560; 3:01-cv-00415; 5-01-cv-  
26 20434; 3-98-cv-03926.

**FACTUAL BACKGROUND**

29. Celltrion was founded in 2002 with the mission of developing and supplying medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases. Such patients previously had limited access to advanced therapeutics such as biologic drugs due to their high cost and relative shortage of availability. Celltrion develops, manufactures, and distributes biosimilars and novel biologics to introduce competition in the pharmaceutical market for antibody biologics, to offer alternative solutions for previously limited, high-cost therapies. Because of their complexity, biologic drugs require substantially more effort, monetary resources and technical expertise to develop than traditional drugs that are synthesized chemically.

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

31. In 2013, Celltrion began development of Truxima®, a biosimilar version of Genentech’s Rituxan®. Celltrion has devoted significant time, effort, and substantial monetary resources to the development of Truxima®. With its deep experience in biologics development and manufacturing, Celltrion designed the manufacturing process and process controls that have been and will be used to make Truxima®, including, among other things, developing the cell culture, harvest, and numerous purification steps to manufacture and purify the Truxima® antibody. Celltrion also conducted numerous clinical studies in which it successfully tested Truxima® in humans. In the end, Celltrion generated comprehensive analytical, pharmacokinetic,

1 pharmacodynamics, and clinical data that was submitted to the FDA as part of the FDA-approval  
2 process.

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

9 **Congress Enacts Legislation Creating a Regulatory Pathway for**  
10 **Biosimilar Biological Products**

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

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

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

24 36. The reference product sponsor (also known as an “RPS”) may have patents relating to  
25 the biological product, as well as therapeutic uses for and/or processes used to manufacture the  
26 biological product, that it believes may be relevant to the biosimilar product. In recognition that  
27 there may be patent disputes between the RPS and the biosimilar applicant, “[t]he BPCIA sets forth  
28

1 a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent]  
2 infringement.” *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(l)).

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

1           38. Following the information exchange, the BPCIA requires the reference product  
2 sponsor and the applicant to engage in “good faith negotiations to agree on which, if any, patents  
3 listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be  
4 the subject of an action for patent infringement under paragraph (6) [of the statute].” 42 U.S.C. §  
5 262(l)(4). If the subsection (k) application and RPS disagree over which patents should be litigated,  
6 the statute provides for a mechanism of further exchanges to determine which patent(s) will be the  
7 subject of a paragraph (6) patent litigation. 42 U.S.C. § 262(l)(4)(B)-(5).

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

19           40. Any manufacture and use of CT-P10 by any of Plaintiffs prior to commercial  
20 marketing was and is solely for uses reasonably related to the development and submission of  
21 information under a Federal law, for example to the FDA under the Public Health Service Act  
22 including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of  
23 infringement. 35 U.S.C. § 271(e)(1).

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

26           41. According to the FDA’s “Purple Book,” Genentech’s Rituxan® was first approved on  
27 November 26, 1997.

1           42. On April 28, 2017, Celltrion Inc. submitted its Abbreviated Biologics License  
2 Application (“aBLA”) for Truxima® pursuant to 42 U.S.C. § 262(k). Celltrion Inc.’s aBLA was  
3 filed after the expiration of the 4-year and 12-year statutory periods provided by 42 U.S.C. §  
4 262(k)(7). Celltrion Inc. received notification from the FDA that its aBLA had been accepted for  
5 review on June 27, 2017.

6           43. On June 30, 2017, prior to the deadline under 42 U.S.C. § 262(l)(2)(A) for Celltrion  
7 Inc. to produce its aBLA, Genentech wrote a letter to Celltrion Inc. requesting that Celltrion Inc.  
8 produce vaguely defined information relating to the processes used in the production of Truxima®  
9 regardless of whether such information was included in Celltrion Inc.’s aBLA.

10           44. On July 17, 2017, Celltrion Inc. timely sent to Genentech its disclosure pursuant to 42  
11 U.S.C. § 262(l)(2)(A), including the aBLA for Truxima® and other detailed information regarding  
12 the manufacturing processes used to make Truxima®. Specifically, Celltrion Inc. produced its  
13 aBLA and upstream and downstream manufacturing reports describing in detail the manufacturing  
14 process for Truxima®. Celltrion Inc.’s production of more than 440,000 pages of technical details  
15 and batch records described, among other things, (i) the source, history, and generation of the cell  
16 substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and  
17 (iv) raw materials used during the manufacture of Truxima®.

18           45. Celltrion Inc.’s production contained sufficiently detailed information regarding its  
19 biosimilar product and manufacturing processes, which complied with the production requirements  
20 in 42 U.S.C. § 262(l)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C.  
21 § 262(l)(3)(A).

22           46. On September 14, 2017, Genentech provided Celltrion Inc. with its list of patents  
23 “pursuant to 42 U.S.C. § 262(l)(3)(A)” (“the (3)(A) list”) that Genentech “believe[d] could  
24 reasonably be asserted against Celltrion’s proposed CT-P10 product based upon a review of the  
25 product’s aBLA filing.” Genentech’s (3)(A) list included a total of 40 patents, including all of the  
26 patents-in-suit. 42 U.S.C. § 262(l)(3)(A) requires a reference product sponsor or RPS to identify the  
27 patents for which the RPS “believes a claim of patent infringement could reasonably be asserted by  
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1 [the RPS] or by a patent owner that has granted an exclusive license to [the RPS] with respect to [the  
2 reference product].” 42 U.S.C. § 262(l)(3)(A). Therefore, by identifying a patent on its (3)(A) list,  
3 Genentech has represented that it has the right to assert the patent as the patent owner, or exclusive  
4 licensee. Genentech never stated that there were any patents for which it lacked sufficient  
5 information and therefore was unable to conduct an analysis for its (3)(A) list.

6 47. On November 7, 2017, Celltrion Inc. timely responded to Genentech’s (3)(A) list by  
7 providing Genentech with a statement pursuant to 42 U.S.C. § 262(l)(3)(B)(ii)(II), and further  
8 providing Genentech, pursuant to 42 U.S.C. § 262(l)(3)(B)(ii)(I), with a 466-page detailed statement  
9 that describes on a claim-by-claim basis the factual and legal bases for Celltrion Inc.’s opinion that  
10 patents included on Genentech’s (3)(A) list are not infringed and/or are invalid (Celltrion’s “(3)(B)  
11 statement”). Celltrion Inc. annotated its non-infringement contentions with detailed citations to its  
12 aBLA and the other documents that Celltrion Inc. had produced to Genentech.

13 48. Despite being under no obligation to do so, throughout the summer and fall of 2017,  
14 Celltrion Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the  
15 documents of [REDACTED] that were potentially relevant to Celltrion Inc.’s  
16 CT-P10 manufacturing process. Celltrion Inc. produced these documents, along with recent FDA  
17 correspondence related to Celltrion Inc.’s aBLA, with Celltrion’s (3)(B) statement. Celltrion Inc.’s  
18 extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these  
19 documents.

20 49. Thus, Celltrion’s (3)(B) statement identifying the bases for Celltrion Inc.’s non-  
21 infringement of Genentech’s (3)(A) patents cited extensively to documents that Celltrion Inc. had  
22 produced to Genentech. Therefore, contrary to any allegation by Genentech that Celltrion Inc.’s  
23 document productions pursuant to 42 U.S.C. § 262(l)(2)(A) and 42 U.S.C. § 262(l)(3)(B) were  
24 deficient, Celltrion Inc. produced substantially more documentation than was required by the statute,  
25 and Genentech had in its possession all the information it needed to determine whether Celltrion  
26 Inc.’s Truxima® product would infringe Genentech’s (3)(A) patents.

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50. In Celltrion’s (3)(B) statement, it also stated in accordance with [REDACTED]

[REDACTED]

[REDACTED] Therefore, Celltrion’s (3)(B) statement provided detailed statements regarding non-infringement and/or invalidity for 37 of the 40 patents on Genentech’s (3)(A) list.

51. On January 5, 2018, Celltrion Inc. received Genentech’s alleged statement pursuant to § 262(l)(3)(C) (Genentech’s “(3)(C) statement”). Even though the BPCIA required Genentech to provide, among other things, “on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Celltrion’s (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application,” and a response to Celltrion’s opinions concerning the validity of the listed patents,

[REDACTED]

[REDACTED]

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52. Genentech failed to provide a response as to these patents as required by the BPCIA.

[REDACTED]

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

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

**THE PATENTS-IN-SUIT**

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

56. U.S. Patent No. 6,417,335 (Exhibit 2), titled “Protein Purification,” issued on July 9, 2002. Upon information and belief the ’335 patent is assigned to Genentech.

57. U.S. Patent No. 6,455,043 (Exhibit 3), titled “Combination therapies for B-cell lymphomas comprising administration of anti-CD20 antibody,” issued on September 24, 2002. Upon information and belief, the ’043 patent is assigned to IDEC Pharmaceuticals Corporation.

58. U.S. Patent No. 6,489,447 (Exhibit 4), titled “Protein Purification,” issued on December 3, 2002. Upon information and belief, the ’447 patent is assigned to Genentech.

1           59. U.S. Patent No. 6,586,206 (Exhibit 5), titled “Methods for Making Recombinant  
2 Proteins Using Apoptosis Inhibitors,” issued on July 1, 2003. Upon information and belief, the ’206  
3 patent is assigned to Genentech.

4           60. U.S. Patent No. 6,610,516 (Exhibit 6), titled “Cell Culture Process,” issued on August  
5 26, 2003. Upon information and belief, the ’516 patent is assigned to Genentech.

6           61. U.S. Patent No. 6,620,918 (Exhibit 7), titled “Separation of Polypeptide Monomers,”  
7 issued on September 16, 2003. Upon information and belief, the ’918 patent is assigned to  
8 Genentech.

9           62. U.S. Patent No. 6,716,602 (Exhibit 8), titled “Metabolic Rate Shifts in Fermentations  
10 Expressing Recombinant Proteins,” issued on April 6, 2004. Upon information and belief, the ’602  
11 patent is assigned to Genentech.

12           63. U.S. Patent No. 7,390,660 (Exhibit 9), titled “Methods for Growing Mammalian Cells  
13 In Vitro,” issued on June 24, 2008. Upon information and belief, the ’660 patent is assigned to  
14 Roche, and Genentech is the exclusive licensee with the sole right to enforce the ’660 patent.

15           64. U.S. Patent No. 7,485,704 (Exhibit 10), titled “Reducing Protein A Leaching During  
16 Protein A Affinity Chromatography,” issued on February 3, 2009. Upon information and belief, the  
17 ’704 patent is assigned to Genentech.

18           65. U.S. Patent No. 7,682,612 (Exhibit 11), titled “Treatment of hematologic  
19 malignancies associated with circulating tumor cells using chimeric anti-CD20 antibody” issued on  
20 March 23, 2010. Upon information and belief, the ’612 patent is assigned to Biogen and Genentech.

21           66. U.S. Patent No. 7,807,799 (Exhibit 12), titled “Reducing Protein A Leaching During  
22 Protein A Affinity Chromatography,” issued on October 5, 2010. Upon information and belief, the  
23 ’799 patent is assigned to Genentech.

24           67. U.S. Patent No. 7,820,161 (Exhibit 13), titled “Treatment of Autoimmune Diseases,”  
25 issued on October 26, 2010. Upon information and belief, the ’161 patent is assigned to Biogen and  
26 Genentech.

1           68.     U.S. Patent No. 7,923,221 (Exhibit 14), titled “Methods of Making Antibody Heavy  
2 and Light Chains Having Specificity for a Desired Antigen,” issued on April 12, 2011. Upon  
3 information and belief, the ’221 patent is assigned to Genentech and City of Hope.

4           69.     U.S. Patent No. 7,976,838 (Exhibit 15), titled “Therapy of Autoimmune Disease in a  
5 Patient with an Inadequate Response to a TNF-alpha Inhibitor,” issued on July 12, 2011. Upon  
6 information and belief, the ’838 patent is assigned to Genentech.

7           70.     U.S. Patent No. 8,044,017 (Exhibit 16), titled “Protein Purification,” issued on  
8 October 25, 2011. Upon information and belief, the ’017 patent is assigned to Genentech.

9           71.     U.S. Patent No. 8,206,711 (Exhibit 17), titled “Treatment of chronic lymphocytic  
10 leukemia using anti-CD20 antibodies,” issued on June 26, 2012. Upon information and belief, the  
11 ’711 patent is assigned to Biogen and Genentech.

12           72.     U.S. Patent No. 8,329,172 (Exhibit 18), titled “Combination therapies for B-cell  
13 lymphomas comprising administration of anti-CD20 antibody,” issued on December 11, 2012.  
14 Upon information and belief, the ’172 patent is assigned to Biogen.

15           73.     U.S. Patent No. 8,357,301 (Exhibit 19), titled “Chromatography Equipment  
16 Characterization,” issued on January 22, 2013. Upon information and belief, the ’301 patent is  
17 assigned to Roche. Upon information and belief, one or more of the Defendants has the entire right,  
18 interest, and title to enforce the ’301 patent.

19           74.     U.S. Patent No. 8,460,895 (Exhibit 20), titled “Method for Producing Recombinant  
20 Proteins with a Constant Content of pCO<sub>2</sub> in the Medium,” issued on June 11, 2013. Upon  
21 information and belief, the ’895 patent is assigned to Roche, and Genentech is the exclusive licensee  
22 with the sole right to enforce the ’895 patent.

23           75.     U.S. Patent No. 8,512,983 (Exhibit 21), titled “Production of Proteins in Glutamine-  
24 Free Cell Culture Media,” issued on August 20, 2013. Upon information and belief, Genentech is  
25 the owner of all right, title and interest in the ’983 patent.

26           76.     U.S. Patent No. 8,545,843 (Exhibit 22), titled “Treatment of Vasculitis,” issued on  
27 October 1, 2013. Upon information and belief, the ’843 patent is assigned to Genentech and Biogen.  
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1           77. U.S. Patent No. 8,557,244 (Exhibit 23), titled “Treatment of aggressive non-Hodgkins  
2 lymphoma with anti-CD20 antibody,” issued on October 15, 2013. Upon information and belief, the  
3 ’244 patent is assigned to Biogen.

4           78. U.S. Patent No. 8,574,869 (Exhibit 24), titled “Prevention of Disulfide Bond  
5 Reduction During Recombinant Production of Polypeptides,” issued on November 5, 2013. Upon  
6 information and belief, the ’869 patent is assigned to Genentech.

7           79. U.S. Patent No. 8,633,302 (Exhibit 25), titled “Variable Tangential Flow Filtration,”  
8 issued on January 21, 2014. Upon information and belief, the ’302 patent is assigned to Hoffmann-  
9 La Roche, and Genentech is the exclusive licensee with the sole right to enforce the ’302 patent.

10           80. U.S. Patent No. 8,710,196 (Exhibit 26), titled “Protein Purification,” issued on April  
11 29, 2014. Upon information and belief, the ’196 patent is assigned to Genentech.

12           81. U.S. Patent No. 8,771,988 (Exhibit 27), titled “Protein expression from multiple  
13 nucleic acids,” issued on June 24, 2008. Upon information and belief, the ’988 patent is assigned to  
14 Hoffmann-La Roche, and Genentech is the exclusive licensee with the sole right to enforce the ’988  
15 patent.

16           82. U.S. Patent No. 8,821,873 (Exhibit 28), titled “Treatment of diffuse large-cell  
17 lymphoma with anti-CD20 antibody,” issued on September 2, 2014. Upon information and belief,  
18 the ’873 patent is assigned to Biogen.

19           83. U.S. Patent No. 8,822,655 (Exhibit 29), titled “Pre-filtration adjustment of buffer  
20 solutes,” issued on September 2, 2014. Upon information and belief, the ’655 patent is assigned to  
21 Hoffmann-La Roche, and Genentech is the exclusive licensee with the sole right to enforce the ’655  
22 patent.

23           84. U.S. Patent No. 9,047,438 (Exhibit 30), titled “Chromatography Equipment  
24 Characterization,” issued on June 2, 2015. Upon information and belief, the ’438 patent is assigned  
25 to Hoffmann-La Roche.

26           85. U.S. Patent No. 9,080,183 (Exhibit 31), titled “Promoter,” issued on July 14, 2015.  
27 Upon information and belief, the ’183 patent is assigned to Hoffmann-La Roche.  
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1 86. U.S. Patent No. 9,296,821 (Exhibit 32), titled “Combination therapies for B-cell  
2 lymphomas comprising administration of anti-CD20 antibodies,” issued on March 29, 2016. Upon  
3 information and belief, the ’821 patent is assigned to Biogen.

4 87. U.S. Patent No. 9,428,548 (Exhibit 33), titled “Enhanced Protein Purification through  
5 a Modified Protein A Elution,” issued on August 30, 2016. Upon information and belief, the ’548  
6 patent is assigned to Genentech.

7 88. U.S. Patent No. 9,428,766 (Exhibit 34), titled “Protein expression from multiple  
8 nucleic acids,” issued on August 30, 2016. Upon information and belief, the ’766 patent is assigned  
9 to Hoffmann-La Roche Inc., and Genentech is the exclusive licensee with the sole right to enforce  
10 the ’766 patent.

11 89. U.S. Patent No. 9,487,809 (Exhibit 35), titled “Decreasing Lactate Level and  
12 Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and  
13 Pyruvate Dehydrogenase Kinase,” issued on November 8, 2016. Upon information and belief, the  
14 ’809 patent is assigned to Genentech.

15 90. U.S. Patent No. 9,504,744 (Exhibit 36), titled “Treatment of diffuse large-cell  
16 lymphoma with anti-CD20 antibody,” issued on November 29, 2016. Upon information and belief,  
17 the ’744 patent is assigned to Biogen.

18 91. U.S. Patent No. 9,714,293 (Exhibit 37), titled “Production of Proteins in Glutamine-  
19 Free Cell Culture Media,” issued on July 25, 2017. Upon information and belief, the ’293 patent is  
20 assigned to Genentech.

21 **COUNT I**

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

23 92. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-91  
24 above as if fully set forth herein.

25 93. On November 7, 2017, Celltrion 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’s opinion  
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1 that one or more claims of the '415 patent will not be infringed by the commercial manufacture, use,  
2 importation, sale, or offer for sale of CT-P10.

3 94. For example, Plaintiffs will not infringe one or more claims of the '415 patent under  
4 35 U.S.C. § 271(a) because [REDACTED]. Plaintiffs  
5 also will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(g) because [REDACTED]  
6 [REDACTED]. However, to the extent that § 271(g) applies,  
7 Plaintiffs will not infringe one or more claims under § 271(g) because [REDACTED]  
8 [REDACTED]

9 95. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
10 valid claims of the '415 patent include: [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED] required by certain claims of the '415 patent.

15 96. 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 '415  
17 patent.

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

20 98. 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 '415 patent.

22 **COUNT II**

23 **Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415**

24 99. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-98  
25 above as if fully set forth herein.



1 106. On November 7, 2017, Celltrion 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’s opinion  
3 that one or more claims of the ’335 patent will not be infringed by the commercial manufacture, use,  
4 importation, sale, or offer for sale of CT-P10.

5 107. For example, Plaintiffs will not infringe one or more claims of the ’335 patent under  
6 35 U.S.C. § 271(a) because [REDACTED]  
7 [REDACTED] Plaintiffs also will not infringe one or more claims of the ’335 patent under 35  
8 U.S.C. § 271(g) because [REDACTED]. However, to the  
9 extent that § 271(g) applies, Plaintiffs will not infringe one or more claims under 271(g) because

10 [REDACTED]  
11 [REDACTED]  
12 108. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
13 valid claims of the ’335 patent include: [REDACTED]

14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 109. 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 ’335  
20 patent.

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

23 111. 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 ’335 patent.

25 **COUNT IV**

26 **Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335**

1 112. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-111  
2 above as if fully set forth herein.

3 113. On November 7, 2017, Celltrion 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’s opinion  
5 that one or more claims of the ’335 patent are invalid.

6 114. One or more claims of the ’335 patent are invalid in light of prior art that published or  
7 was otherwise available to the public before the earliest possible priority date of the ’335 patent.  
8 Additional non-limiting examples of how one or more claims of the ’335 patent are invalid include:  
9 (1) anticipation in view of the prior art disclosing each and every limitation of claim 1 of the ’335  
10 patent regarding “purifying” of “an antibody from a composition comprising the antibody and a  
11 contaminant” by “loading the composition onto a cation exchange resin” and “eluting the  
12 contaminant from the cation exchange resin”; and (2) obviousness in view of prior art disclosing the  
13 processes of claims 1 and 3-9 of the ’335 patent regarding the purification of an antibody by loading  
14 that antibody onto a cation exchange resin.

15 115. There is a real, substantial, and justiciable controversy between Plaintiffs and  
16 Defendants concerning whether one or more claims of the ’335 patent are invalid for failure to  
17 comply with the requirements of Title 35 of the United States Code, including, without limitation,  
18 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

21 117. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’335  
22 patent are invalid.

23 **COUNT V**

24 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,455,043**

25 118. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-117  
26 above as if fully set forth herein.

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1 119. On November 7, 2017, Celltrion 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's opinion  
3 that one or more claims of the '043 patent will not be infringed by the commercial manufacture, use,  
4 importation, sale, or offer for sale of CT-P10.

5 120. Plaintiffs will neither directly infringe the '043 patent nor induce others to infringe  
6 nor contribute to infringement by others. Additional non-limiting example of how Plaintiffs will not  
7 infringe one or more claims of the '043 patent is because [REDACTED]  
8 [REDACTED]

9 121. There is a real, substantial, and justiciable controversy between Plaintiffs and  
10 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '043  
11 patent.

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

14 123. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not  
15 infringe, directly or indirectly, any valid and enforceable claim of the '043 patent.

16 **COUNT VI**

17 **Declaratory Judgment of Invalidity of U.S. Patent No. 6,455,043**

18 124. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-123  
19 above as if fully set forth herein.

20 125. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
21 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion  
22 that one or more claims of the '043 patent are invalid.

23 126. Additional non-limiting examples of how one or more claims of the '043 patent are  
24 invalid include: (1) anticipation by prior art disclosing methods of reducing residual CD20+ tumor  
25 cells in bone marrow or stem cell tissue after myeloablative therapy by administering an  
26 amount of a non-radiolabeled anti-CD20 antibody; and (2) obviousness in view of prior art  
27 disclosing methods of reducing residual CD20+ tumor cells in bone marrow or stem cell tissue  
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1 after myeloablative therapy by administering an amount of a non-radiolabeled anti-CD20  
2 antibody. In addition, one or more claims of the '043 patent are invalid in light of prior art that  
3 published or was otherwise available to the public before the earliest possible priority date of the  
4 '043 patent.

5 127. There is a real, substantial, and justiciable controversy between Plaintiffs and  
6 Defendants concerning whether one or more claims of the '043 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.

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

11 129. Plaintiffs are entitled to a judicial declaration that one or more claims of the '043  
12 patent are invalid.

13 **COUNT VII**

14 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,489,447**

15 130. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-129  
16 above as if fully set forth herein.

17 131. On November 7, 2017, Celltrion 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's opinion  
19 that one or more claims of the '447 patent will not be infringed by the commercial manufacture, use,  
20 importation, sale, or offer for sale of CT-P10.

21 132. For example, Plaintiffs will not infringe one or more claims of the '447 patent under  
22 35 U.S.C. § 271(a) because [REDACTED]

23 [REDACTED] Plaintiffs also will not infringe one or more claims of the '447 patent under 35  
24 U.S.C. § 271(g) because [REDACTED]

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

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133. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '447 patent include that [REDACTED]

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

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

136. 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 '447 patent.

**COUNT VIII**

**Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206**

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

138. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '206 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

139. For example, Plaintiffs will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(a) because [REDACTED].

140. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '206 patent include [REDACTED]

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

6 141. 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 '206  
8 patent.

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

11 143. 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 '206 patent.

13 **COUNT IX**

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

15 144. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-143  
16 above as if fully set forth herein.

17 145. On November 7, 2017, Celltrion 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's opinion  
19 that one or more claims of the '516 patent will not be infringed by the commercial manufacture, use,  
20 importation, sale, or offer for sale of CT-P10.

21 146. For example, Plaintiffs will not infringe one or more claims of the '516 patent under  
22 35 U.S.C. § 271(a) because [REDACTED]

23 [REDACTED] Plaintiffs also will not infringe one or more claims of the '516 patent under 35  
24 U.S.C. § 271(g) because [REDACTED]

25 [REDACTED]  
26 [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 147. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
4 valid claims of the '516 patent include that [REDACTED]

5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 148. 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 '516  
10 patent.

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

13 150. 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 '516 patent.

15 **COUNT X**

16 **Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516**

17 151. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-150  
18 above as if fully set forth herein.

19 152. On November 7, 2017, Celltrion 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's opinion  
21 that one or more claims of the '516 patent are invalid.

22 153. Additional non-limiting examples of how one or more claims of the '516 patent are  
23 invalid include: (1) anticipation by prior art disclosing processes for increasing the percentage of a  
24 human glycoprotein having one glycoform by producing the glycoproteins in CHO cells in the  
25 presence of about 0 to 2 mM of a butyrate salts at a temperature of about 30° C to 35° C, and  
26 inherently and/or expressly disclosing all limitations of the claim of the '516 patent; (2) obviousness  
27 in view of prior art disclosing producing human glycoproteins with increased abundance of  
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1 particular glycoforms by including butyrate salts in the media and/or controlling the temperature of  
2 the culture in the range of 30° C. to 35° C; and (3) to the extent not obvious, lack of enablement of  
3 the claimed “process for producing a human glycoprotein having multiple glycoforms” with “an  
4 increased percentage of glycoprotein molecules having one glycoform” because there is no  
5 disclosure in the specification of how to perform the claimed process to produce glycoproteins other  
6 than t-PA, and undue experimentation would have been required for a POSA to do so. In addition,  
7 one or more claims of the ’516 patent are invalid in light of prior art that published or was otherwise  
8 available to the public before the earliest possible priority date of the ’516 patent.

9 154. There is a real, substantial, and justiciable controversy between Plaintiffs and  
10 Defendants concerning whether one or more claims of the ’516 patent are invalid for failure to  
11 comply with the requirements of Title 35 of the United States Code, including, without limitation,  
12 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

15 156. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’516  
16 patent are invalid.

## 17 **COUNT XI**

### 18 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918**

19 157. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-156  
20 above as if fully set forth herein.

21 158. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
22 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion  
23 that one or more claims of the ’918 patent will not be infringed by the commercial manufacture, use,  
24 importation, sale, or offer for sale of CT-P10.

25 159. For example, Plaintiffs will not infringe one or more claims of the ’918 patent under  
26 35 U.S.C. § 271(a) because [REDACTED]

27 [REDACTED] Plaintiffs also will not infringe one or more claims of the ’918 patent under 35  
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1 U.S.C. § 271(g) because [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]

5 160. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
6 valid claims of the '918 patent include [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED] [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]

16 161. 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 '918  
18 patent.

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

21 163. 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 '918 patent.

23 **COUNT XII**

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

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

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165. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’602 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

166. For example, Plaintiffs will not infringe one or more claims of the ’602 patent under 35 U.S.C. § 271(a) because [REDACTED] Plaintiffs also will not infringe one or more claims of the ’602 patent under 35 U.S.C. § 271(g) because [REDACTED]

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

168. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’602 patent.

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

170. 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 ’602 patent.

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**COUNT XIII**

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

171. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-170 above as if fully set forth herein.

172. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’602 patent are invalid.

173. Additional non-limiting examples of how one or more claims of the ’602 patent are invalid include: (1) lack of enablement of the claimed “method for increasing product yield of a properly folded polypeptide,” to the extent it encompasses production of protein in host cells other than prokaryotic and simple eukaryotic systems, because there is no disclosure in the specification of how to practice the invention in any complex eukaryotic system such as a CHO cell; and (2) lack of written description because the specification does not describe increasing the yield of a properly folded polypeptide in any expression system other than prokaryotic and simple eukaryotic systems. In addition, one or more claims of the ’602 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ’602 patent.

174. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the ’602 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

176. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’602 patent are invalid.

**COUNT XIV**

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

1 177. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-176  
2 above as if fully set forth herein.

3 178. On November 7, 2017, Celltrion 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’s opinion  
5 that one or more claims of the ’660 patent will not be infringed by the commercial manufacture, use,  
6 importation, sale, or offer for sale of CT-P10.

7 179. For example, Plaintiffs will not infringe one or more claims of the ’660 patent under  
8 35 U.S.C. § 271(a) because [REDACTED]

9 [REDACTED] Plaintiffs also will not infringe one or more claims of the ’660 patent under 35 U.S.C.  
10 § 271(g) because [REDACTED]

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

17 180. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
18 valid claims of the ’660 patent include that [REDACTED]

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

22 181. There is a real, substantial, and justiciable controversy between Plaintiffs and  
23 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’660  
24 patent.

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

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183. 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 '660 patent.

**COUNT XV**

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

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

185. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '704 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

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

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

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

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

1 188. 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 '704  
3 patent.

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

6 190. 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 '704 patent.

8 **COUNT XVI**

9 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,682,612**

10 191. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-190  
11 above as if fully set forth herein.

12 192. On November 7, 2017, Celltrion 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's opinion  
14 that one or more claims of the '612 patent will not be infringed by the commercial manufacture, use,  
15 importation, sale, or offer for sale of CT-P10.

16 193. Plaintiffs will neither directly infringe the '612 patent nor induce others to infringe  
17 nor contribute to infringement by others. Non-limiting examples of how Plaintiffs will not infringe  
18 one or more valid claims of the '612 patent include: [REDACTED]

19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]

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1 [REDACTED]

2 [REDACTED].

3 194. 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 '612  
5 patent.

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

8 196. 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 '612 patent.

10 **COUNT XVII**

11 **Declaratory Judgment of Invalidity of U.S. Patent No. 7,682,612**

12 197. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-196  
13 above as if fully set forth herein.

14 198. On November 7, 2017, Celltrion 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's opinion  
16 that one or more claims of the '612 patent are invalid.

17 199. Non-limiting examples of how one or more claims of the '612 patent are invalid  
18 include: (1) anticipation by prior art disclosing methods of treating chronic lymphocytic leukemia  
19 patients with anti-CD20 antibody at a dosage of about 500 to about 1500 mg/m<sup>2</sup>; and (2)  
20 obviousness in view of prior art disclosing methods of treating chronic lymphocytic leukemia with  
21 anti-CD20 antibody given repeatedly, either alone or in combination with chemotherapy. In  
22 addition, one or more claims of the '612 patent are invalid in light of prior art that published or was  
23 otherwise available to the public before the earliest possible priority date of the '612 patent.

24 200. There is a real, substantial, and justiciable controversy between Plaintiffs and  
25 Defendants concerning whether one or more claims of the '612 patent are invalid for failure to  
26 comply with the requirements of Title 35 of the United States Code, including, without limitation,  
27 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

3 202. Plaintiffs are entitled to a judicial declaration that one or more claims of the '612  
4 patent are invalid.

5 **COUNT XVIII**

6 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799**

7 203. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-202  
8 above as if fully set forth herein.

9 204. On November 7, 2017, Celltrion 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's opinion  
11 that one or more claims of the '799 patent will not be infringed by the commercial manufacture, use,  
12 importation, sale, or offer for sale of CT-P10.

13 205. For example, Plaintiffs will not infringe one or more claims of the '799 patent under  
14 35 U.S.C. § 271(a) because [REDACTED]

15 [REDACTED] Plaintiffs also will not infringe one or more claims of the '799 patent under 35  
16 U.S.C. § 271(g) because [REDACTED]

17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]

20 206. An additional, non-limiting example of how Plaintiffs will not infringe one or more  
21 valid claims of the '799 patent is that [REDACTED]

22 [REDACTED]  
23 [REDACTED]

24 207. 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 '799  
26 patent.

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1 217. On November 7, 2017, Celltrion 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’s opinion  
3 that one or more of claims of the ’161 patent will not be infringed by the commercial manufacture,  
4 use, importation, sale, or offer for sale of CT-P10.

5 218. Non-limiting examples of how Plaintiffs will not infringe one or more claims of the  
6 ’161 patent includes: [REDACTED]

7 [REDACTED]  
8 [REDACTED]  
9 219. There is a real, substantial, and justiciable controversy between Plaintiffs and  
10 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’161  
11 patent.

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

14 221. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not  
15 infringe, directly or indirectly, any valid and enforceable claim of the ’161 patent.

16 **COUNT XXI**

17 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221**

18 222. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-221  
19 above as if fully set forth herein.

20 223. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
21 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion  
22 that one or more claims of the ’221 patent will not be infringed by the commercial manufacture, use,  
23 importation, sale, or offer for sale of CT-P10.

24 224. For example, Plaintiffs will not infringe one or more claims of the ’221 patent under  
25 35 U.S.C. § 271(a) because [REDACTED] Plaintiffs  
26 also will not infringe one or more claims of the ’221 patent under 35 U.S.C. § 271(g) because [REDACTED]

27 [REDACTED]

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[REDACTED]

[REDACTED]

225. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '221 patent include:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

226. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '221 patent.

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

228. 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 '221 patent.

**COUNT XXII**

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

229. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-228 above as if fully set forth herein.

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

231. One or more claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '221 patent. Non-limiting examples of how one or more claims of the '221 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both *in vivo* and *in vitro* assembly, because there is no disclosure in the specification of how to produce an antibody *in vivo* in a microorganism or host cell, and undue experimentation

1 would have been required for a POSA to do so; (2) failure of written description to describe any  
2 process for the *in vivo* assembly of an antibody or antibody fragment in either a microorganism or  
3 mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing  
4 proteins, including antibodies, that can include immunoglobins (with heavy and light chains) in a  
5 single host cell using a plasmid containing genes. In addition, one or more claims of the '221 patent  
6 are invalid in light of prior art that published or was otherwise available to the public before the  
7 earliest possible priority date of the '221 patent.

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

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

14 234. Plaintiffs are entitled to a judicial declaration that one or more claims of the '221  
15 patent are invalid.

### 16 **COUNT XXIII**

#### 17 **Declaratory Judgment of Invalidity of U.S. Patent No. 7,976,838**

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

20 236. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
21 pursuant to 42 U.S.C. § 262(1)(3)(B) describing the factual and legal bases for Celltrion's opinion  
22 that one or more claims of the '838 patent are invalid.

23 237. One or more claims of the '838 patent are invalid in light of prior art that published or  
24 was otherwise available to the public before the earliest possible priority date of the '838 patent.  
25 Non-limiting examples of how one or more claims of the '838 patent are invalid include: (1)  
26 anticipation over prior art regarding the use of rituximab at the claimed dosage to treat rheumatoid  
27 arthritis "who experience [ ] an inadequate response to a TNF $\alpha$ -inhibitor"; (2) obviousness in view  
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1 of prior art disclosing the use of rituximab to treat rheumatoid arthritis patients who have rheumatoid  
2 arthritis “who experience [ ] an inadequate response to a TNF $\alpha$ -inhibitor” and prior art disclosing the  
3 use of rituximab at various doses to treat patients who have rheumatoid arthritis.

4 238. There is a real, substantial, and justiciable controversy between Plaintiffs and  
5 Defendants concerning whether one or more claims of the '838 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.

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

10 240. Plaintiffs are entitled to a judicial declaration that one or more claims of the '838  
11 patent are invalid.

12 **COUNT XXIV**

13 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,044,017**

14 241. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-240  
15 above as if fully set forth herein.

16 242. On November 7, 2017, Celltrion 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’s opinion  
18 that one or more claims of the '017 patent will not be infringed by the commercial manufacture, use,  
19 importation, sale, or offer for sale of CT-P10.

20 243. For example, Plaintiffs will not infringe one or more claims of the '017 patent under  
21 35 U.S.C. § 271(a) because [REDACTED]

22 [REDACTED] Plaintiffs also will not infringe one or more claims of the '017 patent under 35  
23 U.S.C. § 271(g) because [REDACTED]

24 [REDACTED]

25 [REDACTED]

26 [REDACTED]

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244. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '017 patent include that [REDACTED]

245. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '017 patent.

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

247. 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 '017 patent.

**COUNT XXV**

**Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,206,711**

248. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-247 above as if fully set forth herein.

249. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '711 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

250. Plaintiffs will neither directly infringe the '711 patent nor induce others to infringe nor contribute to infringement by others. Non-limiting examples of how Plaintiffs will not infringe one or more claims of the '711 patent include: [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 251. 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 '711  
5 patent.

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

8 253. 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 '711 patent.

10 **COUNT XXVI**

11 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,206,711**

12 254. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-253  
13 above as if fully set forth herein.

14 255. On November 7, 2017, Celltrion 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's opinion  
16 that one or more claims of the '711 patent are invalid.

17 256. Non-limiting examples of how one or more claims of the '711 patent are invalid  
18 include: (1) anticipation by prior art disclosing methods of treating chronic lymphocytic leukemia  
19 patients with anti-CD20 antibody at a dosage of 500 mg/m<sup>2</sup>, either alone or in combination with  
20 chemotherapeutic regimen; and (2) obviousness in view of prior art disclosing methods of treating  
21 chronic lymphocytic leukemia with anti-CD20 antibody at a dosage of 500 mg/m<sup>2</sup> given weekly, bi-  
22 weekly or monthly, either alone or in combination with chemotherapeutic regimen. In addition, one  
23 or more claims of the '711 patent are invalid in light of prior art that published or was otherwise  
24 available to the public before the earliest possible priority date of the '711 patent.

25 257. There is a real, substantial, and justiciable controversy between Plaintiffs and  
26 Defendants concerning whether one or more claims of the '711 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.

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

5 259. Plaintiffs are entitled to a judicial declaration that one or more claims of the '711  
6 patent are invalid.

7 **COUNT XXVII**

8 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,329,172**

9 260. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-259  
10 above as if fully set forth herein.

11 261. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
12 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion  
13 that one or more claims of the '172 patent will not be infringed by the commercial manufacture, use,  
14 importation, sale, or offer for sale of CT-P10.

15 262. Plaintiffs will neither directly infringe the '172 patent nor induce others to infringe  
16 nor contribute to infringement by others. A non-limiting example of how Plaintiffs will not infringe  
17 one or more claims of the '172 patent includes: [REDACTED]

18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]

21 263. There is a real, substantial, and justiciable controversy between Plaintiffs and  
22 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '172  
23 patent.

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

26 265. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not  
27 infringe, directly or indirectly, any valid and enforceable claim of the '172 patent.

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**COUNT XXVIII**

**Declaratory Judgment of Invalidity of U.S. Patent No. 8,329,172**

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

267. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’172 patent are invalid.

268. Non-limiting examples of how one or more claims of the ’172 patent are invalid include: (1) anticipation by prior art disclosing a method of treating low-grade B-cell non-Hodgkin’s lymphoma in a patient who has responded to CVP therapy by administering rituximab maintenance therapy, comprised of four weekly 375mg/m<sup>2</sup> rituximab doses given every 6 months for 2 years; and (2) obviousness in view of prior art disclosing a method of treating low-grade B-cell non-Hodgkin’s lymphoma in a patient who has responded to CVP (cyclophosphamide, vincristine and prednisone) therapy by administering rituximab maintenance therapy, comprised of four weekly 375mg/m<sup>2</sup> rituximab doses given every 6 months for 2 years. In addition, one or more claims of the ’172 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ’172 patent.

269. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the ’172 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

271. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’172 patent are invalid.

**COUNT XXIV**

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

1 272. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-271  
2 above as if fully set forth herein.

3 273. On November 7, 2017, Celltrion 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’s opinion  
5 that one or more claims of the ’301 patent will not be infringed by the commercial manufacture, use,  
6 importation, sale, or offer for sale of CT-P10.

7 274. For example, Plaintiffs will not infringe one or more claims of the ’301 patent under  
8 35 U.S.C. § 271(a) because [REDACTED]

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

11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 275. Additional, non-limiting examples of how Plaintiffs will not infringe one or more  
15 valid claims of the ’301 patent include because [REDACTED]

16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED].  
19 276. 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 ’301  
21 patent.

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

24 278. 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 ’301 patent.

26 **COUNT XXX**

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

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

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

281. Non-limiting examples of how one or more claims of the ’301 patent are invalid include because the claims of the ’301 patent are directed essentially to a method of calculating using a mathematical formula, which are invalid as unpatentable subject matter under 35 U.S.C. § 101.

282. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the ’301 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

284. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’301 patent are invalid.

**COUNT XXXI**

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

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

286. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’895 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

1 287. For example, Plaintiffs will not infringe one or more claims of the '895 patent under  
2 35 U.S.C. § 271(a) because [REDACTED]

3 [REDACTED]

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

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 289. 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 '895  
12 patent.

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

15 291. 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 '895 patent.

17 **COUNT XXXII**

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

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

21 293. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
22 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion  
23 that one or more claims of the '983 patent will not be infringed by the commercial manufacture, use,  
24 importation, sale, or offer for sale of CT-P10.

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

27 [REDACTED] Plaintiffs will not infringe the product claim of the '983 patent (claim 25) under  
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1 35 U.S.C. § 271(a) because [REDACTED]

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

5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 295. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
10 valid claims of the '983 patent include: [REDACTED]

11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 296. 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 '983  
18 patent.

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

21 298. 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 '983 patent.

23 **COUNT XXXIII**

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

25 299. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-298  
26 above as if fully set forth herein.

1 300. On November 7, 2017, Celltrion 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’s opinion  
3 that one or more claims of the ’983 patent are invalid.

4 301. Non-limiting examples of how one or more claims of the ’983 patent are invalid  
5 include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells  
6 cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mM to 15 mM  
7 and every other claim limitation; and (2) obviousness over prior art disclosing expression of  
8 therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the  
9 claimed range of 7.5 mM to 15 mM, and art disclosing the production of therapeutic proteins,  
10 including anti-CD20 antibodies, in CHO cells. In addition, the claims of the ’983 patent are invalid  
11 in light of prior art that published or was otherwise available to the public before the earliest possible  
12 priority date of the ’983 patent.

13 302. There is a real, substantial, and justiciable controversy between Plaintiffs and  
14 Defendants concerning whether one or more claims of the ’983 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.

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

19 304. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’983  
20 patent are invalid.

21 **COUNT XXXIV**

22 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,545,843**

23 305. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-304  
24 above as if fully set forth herein.

25 306. On November 7, 2017, Celltrion 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’s opinion  
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1 that one or more claims of the '843 patent will not be infringed by the commercial manufacture, use,  
2 importation, sale, or offer for sale of CT-P10.

3 307. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of  
4 the '843 patent include that Plaintiffs will not treat patients and therefore will not infringe the claims  
5 directed to methods of treatment.

6 308. 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 '843  
8 patent.

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

11 310. 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 '843 patent.

13 **COUNT XXXV**

14 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,545,843**

15 311. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-310  
16 above as if fully set forth herein.

17 312. On November 7, 2017, Celltrion 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's opinion  
19 that one or more claims of the '843 patent are invalid.

20 313. Non-limiting examples of how one or more claims of the '843 patent are invalid  
21 include: (1) obviousness in view of prior art teachings that depletion of B-cells would be an effective  
22 mechanism for treating a type of vasculitis, that rituximab causes depletion of B-cells in humans,  
23 and that types of vasculitis were typically treated with combination therapy that included steroids,  
24 including glucocorticosteroids; (2) obviousness in view of prior art teachings that autoimmune or  
25 inflammatory diseases, including vasculitides and Wegener's granulomatosis, can be treated with  
26 administration of TNF antagonists in combination with anti-B cell antibodies, and that rituximab was  
27 an anti-B cell antibody that was used in humans; (3) obviousness in view of prior art teachings that  
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1 vasculitis was known to occur in systemic lupus erythematosus, that B cells were an ideal target for  
2 lupus therapy, and that rituximab was known to cause B-cell depletion in humans; and (4) invalidity  
3 under 35 U.S.C. § 112 for lack of written description because the '843 patent does not provide any  
4 description of the use of rituximab to treat vasculitis that would convey to a POSA that the inventors  
5 had possession of the claimed methods.

6 314. There is a real, substantial, and justiciable controversy between Plaintiffs and  
7 Defendants concerning whether one or more claims of the '843 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.

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

12 316. Plaintiffs are entitled to a judicial declaration that one or more claims of the '843  
13 patent are invalid.

14 **COUNT XXXVI**

15 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,557,244**

16 317. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-316  
17 above as if fully set forth herein.

18 318. On November 7, 2017, Celltrion 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's opinion  
20 that one or more claims of the '244 patent will not be infringed by the commercial manufacture, use,  
21 importation, sale, or offer for sale of CT-P10.

22 319. Plaintiffs will neither directly infringe the '244 patent nor induce others to infringe  
23 nor contribute to infringement by others. A non-limiting example of how Plaintiffs will not infringe  
24 one or more valid claims of the '244 patent includes: [REDACTED]

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

1 320. 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 '244  
3 patent.

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

6 322. 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 '244 patent.

8 **COUNT XXXVII**

9 **Declaratory Judgment of Invalidity of U.S. Patent No. 8,557,244**

10 323. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-322  
11 above as if fully set forth herein.

12 324. On November 7, 2017, Celltrion 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's opinion  
14 that one or more claims of the '244 patent are invalid.

15 325. A non-limiting example of how one or more claims of the '244 patent are invalid  
16 includes: obviousness in view of prior art disclosing methods of treating diffuse large cell lymphoma  
17 patients who are over the age of 60 and have bulky disease with unlabeled anti-CD20 antibody and  
18 CHOP chemotherapy. In addition, one or more of the claims of the '244 patent are invalid in light of  
19 prior art that published or was otherwise available to the public before the earliest possible priority  
20 date of the '244 patent.

21 326. There is a real, substantial, and justiciable controversy between Plaintiffs and  
22 Defendants concerning whether one or more claims of the '244 patent are invalid for failure to  
23 comply with the requirements of Title 35 of the United States Code, including, without limitation,  
24 one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

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

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1 328. Plaintiffs are entitled to a judicial declaration that one or more claims of the '244  
2 patent are invalid.

3 **COUNT XXXVIII**

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

5 329. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-328  
6 above as if fully set forth herein.

7 330. On November 7, 2017, Celltrion 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's opinion  
9 that one or more claims of the '869 patent will not be infringed by the commercial manufacture, use,  
10 importation, sale, or offer for sale of CT-P10.

11 331. For example, Plaintiffs will not infringe one or more claims of the '869 patent under  
12 35 U.S.C. § 271(a) because [REDACTED]

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

15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 332. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of  
19 the '869 patent include: [REDACTED]

20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 333. There is a real, substantial, and justiciable controversy between Plaintiffs and  
26 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '869  
27 patent.  
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1 334. The controversy between the parties is amenable to specific relief through a decree of  
2 conclusive character.

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

5 **COUNT XXXIX**

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

7 336. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-335  
8 above as if fully set forth herein.

9 337. On November 7, 2017, Celltrion 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's opinion  
11 that one or more claims of the '869 patent is invalid.

12 338. Non-limiting examples of how one or more claims of the '869 patent are invalid  
13 include: (1) lack of written description for the claim term "following fermentation, sparging the pre-  
14 harvest or harvested culture fluid" as the patent is silent concerning any air sparging of a pre-harvest  
15 cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in view of  
16 prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air  
17 sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art that  
18 published or was otherwise available to the public before the earliest possible priority date of the  
19 '869 patent.

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

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

26 341. Plaintiffs are entitled to a judicial declaration that one or more claims of the '869  
27 patent are invalid.

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**COUNT XL**

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

342. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-341 above as if fully set forth herein.

343. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’302 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

344. For example, Plaintiffs will not infringe one or more claims of the ’302 patent under 35 U.S.C. § 271(a) because [REDACTED] Plaintiffs also will not infringe one or more claims of the ’302 patent under 35 U.S.C. § 271(g) because [REDACTED]

345. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the ’302 patent include that [REDACTED]

346. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’302 patent.

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

348. 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 ’302 patent.

**COUNT XLI**

**Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,710,196**

1 349. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-348  
2 above as if fully set forth herein.

3 350. On November 7, 2017, Celltrion 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’s opinion  
5 that one or more claims of the ’196 patent will not be infringed by the commercial manufacture, use,  
6 importation, sale, or offer for sale of CT-P10.

7 351. Plaintiffs will not infringe one or more claims of the ’196 patent under 35 U.S.C. §  
8 271(a) because [REDACTED]

9 [REDACTED] Plaintiffs also will not infringe one or more claims of the ’196 patent under 35 U.S.C. §  
10 271(g) because [REDACTED]

11 [REDACTED]  
12 [REDACTED]

13 352. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
14 valid claims of the ’196 patent include: [REDACTED]

15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]

21 353. There is a real, substantial, and justiciable controversy between Plaintiffs and  
22 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’196  
23 patent.

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

26 355. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not  
27 infringe, directly or indirectly, any valid and enforceable claim of the ’196 patent.

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**COUNT XLII**

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

356. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-355 above as if fully set forth herein.

357. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’988 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

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

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

[REDACTED]  
[REDACTED]  
[REDACTED]

359. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the ’988 patent include [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

360. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’988 patent.

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

362. 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 ’988 patent.

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**COUNT XLIII**

**Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,821,873**

363. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-362 above as if fully set forth herein.

364. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion’s opinion that one or more claims of the ’873 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

365. Plaintiffs will neither directly infringe the ’873 patent nor induce others to infringe nor contribute to infringement by others. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the ’873 patent include:

[REDACTED]

366. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’873 patent.

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

368. 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 ’873 patent.

**COUNT XLIV**

**Declaratory Judgment of Invalidity of U.S. Patent No. 8,821,873**

369. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-368 above as if fully set forth herein.

1 370. On November 7, 2017, Celltrion 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's opinion  
3 that one or more claims of the '873 patent are invalid.

4 371. An additional non-limiting example of how one or more claims of the '873 patent are  
5 invalid includes: obviousness in view of prior art disclosing methods of treating diffuse large cell  
6 lymphoma patients over the age of 60 with anti-CD20 antibody in combination with CHOP  
7 chemotherapy and/or stem cell transplantation regimen. In addition, one or more claims of the '873  
8 patent are invalid in light of prior art that published or was otherwise available to the public before  
9 the earliest possible priority date of the '873 patent.

10 372. There is a real, substantial, and justiciable controversy between Plaintiffs and  
11 Defendants concerning whether one or more claims of the '873 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.

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

16 374. Plaintiffs are entitled to a judicial declaration that one or more claims of the '873  
17 patent are invalid.

18 **COUNT XLV**

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

20 375. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-374  
21 above as if fully set forth herein.

22 376. On November 7, 2017, Celltrion 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's opinion  
24 that one or more claims of the '655 patent will not be infringed by the commercial manufacture, use,  
25 importation, sale, or offer for sale of CT-P10.

26 377. For example, Plaintiffs will not infringe one or more claims of the '655 patent under  
27 35 U.S.C. § 271(a) because [REDACTED]

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

6 378. An additional non-limiting examples of how Plaintiffs will not infringe one or more  
7 valid claims of the '655 patent include that [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]

11 379. 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 '655  
13 patent.

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

16 381. 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 '655 patent.

18 **COUNT XLVI**

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

20 382. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-381  
21 above as if fully set forth herein.

22 383. On November 7, 2017, Celltrion 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's opinion  
24 that one or more claims of the '655 patent are invalid.

25 384. Additional non-limiting examples of how one or more claims of the '655 patent are  
26 invalid include a failure to claim patentable subject matter as each claim of the '655 patent is  
27 directed towards an abstract idea, including the use of two equations to determine how to adjust a  
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1 “first concentration” of buffer substance to arrive at “a second concentration” in order to allegedly  
2 achieve a more consistent preparation of immunoglobulin after concentration by tangential flow  
3 filtration.

4 385. There is a real, substantial, and justiciable controversy between Plaintiffs and  
5 Defendants concerning whether one or more claims of the ’655 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.

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

10 387. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’655  
11 patent are invalid.

12 **COUNT XLVII**

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

14 388. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-387  
15 above as if fully set forth herein.

16 389. On November 7, 2017, Celltrion 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’s opinion  
18 that one or more claims of the ’438 patent will not be infringed by the commercial manufacture, use,  
19 importation, sale, or offer for sale of CT-P10.

20 390. For example, Plaintiffs will not infringe one or more claims of the ’438 patent under  
21 35 U.S.C. § 271(a) because [REDACTED] Plaintiffs  
22 also will not infringe one or more claims of the ’438 patent under 35 U.S.C. § 271(g) because [REDACTED]

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

26 391. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
27 valid claims of the ’438 patent include [REDACTED]  
28

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

4 392. 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 '438  
6 patent.

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

9 394. 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 '438 patent.

11 **COUNT XLVIII**

12 **Declaratory Judgment of Invalidity of U.S. Patent No. 9,047,438**

13 395. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-394  
14 above as if fully set forth herein.

15 396. On November 7, 2017, Celltrion 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's opinion  
17 that one or more claims of the '438 patent are invalid.

18 397. Additional non-limiting examples of how one or more claims of the '438 patent are  
19 invalid include because the claims of the '438 patent are directed essentially to a method of  
20 calculating using a mathematical formula, which are invalid as unpatentable subject matter under 35  
21 U.S.C. § 101.

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

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

1 400. Plaintiffs are entitled to a judicial declaration that one or more claims of the '438  
2 patent are invalid.

3 **COUNT XLIX**

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

5 401. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-400  
6 above as if fully set forth herein.

7 402. On November 7, 2017, Celltrion 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's opinion  
9 that one or more claims of the '183 patent will not be infringed by the commercial manufacture, use,  
10 importation, sale, or offer for sale of CT-P10.

11 403. A non-limiting example of how Plaintiffs will not infringe one or more valid claims  
12 of the '183 patent includes: [REDACTED]

13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]

17 404. 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 '183  
19 patent.

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

22 406. 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 '183 patent.

24 **COUNT L**

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

26 407. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-406  
27 above as if fully set forth herein.

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1 414. On November 7, 2017, Celltrion 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’s opinion  
3 that one or more claims of the ’821 patent will not be infringed by the commercial manufacture, use,  
4 importation, sale, or offer for sale of CT-P10.

5 415. Plaintiffs will neither directly infringe the ’821 patent nor induce others to infringe  
6 nor contribute to infringement by others. Additional non-limiting examples of how Plaintiffs will  
7 not infringe one or more valid claims of the ’821 patent include: [REDACTED]

8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED].

11 416. 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 ’821  
13 patent.

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

16 418. 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 ’821 patent.

18 **COUNT LII**

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

20 419. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-418  
21 above as if fully set forth herein.

22 420. On November 7, 2017, Celltrion 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’s opinion  
24 that one or more claims of the ’548 patent will not be infringed by the commercial manufacture, use,  
25 importation, sale, or offer for sale of CT-P10.

26 421. For example, Plaintiffs will not infringe one or more claims of the ’548 patent under  
27 35 U.S.C. § 271(a) because [REDACTED]

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

6 422. An additional non-limiting example of how Plaintiffs will not infringe one or more  
7 valid claims of the '548 patent include that [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14 423. 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 '548  
16 patent.

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

19 425. 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 '548 patent.

21 **COUNT LIII**

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

23 426. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-425  
24 above as if fully set forth herein.

25 427. On November 7, 2017, Celltrion 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's opinion  
27  
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1 that one or more claims of the '766 patent will not be infringed by the commercial manufacture, use,  
2 importation, sale, or offer for sale of CT-P10.

3 428. For example, Plaintiffs will not infringe one or more claims of the '766 patent under  
4 35 U.S.C. § 271(a) because [REDACTED]

5 [REDACTED]  
6 [REDACTED]  
7 429. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
8 valid claims of the '766 patent include [REDACTED]

9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 430. 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 '766  
14 patent.

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

17 432. 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 '766 patent.

19 **COUNT LIV**

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

21 433. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-432  
22 above as if fully set forth herein.

23 434. On November 7, 2017, Celltrion 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's opinion  
25 that one or more claims of the '809 patent will not be infringed by the commercial manufacture, use,  
26 importation, sale, or offer for sale of CT-P10.

1 435. For example, Plaintiffs will not infringe one or more claims of the '809 patent under  
2 35 U.S.C. § 271(a) because [REDACTED]

3 [REDACTED] Plaintiffs also will not infringe one or more claims of the '809 patent under 35 U.S.C.  
4 § 271(g) because [REDACTED]

5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 436. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
11 valid claims of the '809 patent include that [REDACTED]

12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 437. 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 '809  
17 patent.

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

20 439. 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 '809 patent.

22 **COUNT LV**

23 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,504,744**

24 440. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-439  
25 above as if fully set forth herein.

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

1 that one or more claims of the '744 patent will not be infringed by the commercial manufacture, use,  
2 importation, sale, or offer for sale of CT-P10.

3 442. Plaintiffs will neither directly infringe the '744 patent nor induce others to infringe  
4 nor contribute to infringement by others. Additional non-limiting examples of how Plaintiffs will  
5 not infringe one or more valid claims of the '744 patent include: [REDACTED]

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

10 443. 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 '744  
12 patent.

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

15 445. 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 '744 patent.

17 **COUNT LVI**

18 **Declaratory Judgment of Invalidity of U.S. Patent No. 9,504,744**

19 446. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-445  
20 above as if fully set forth herein.

21 447. On November 7, 2017, Celltrion provided Genentech with a detailed statement  
22 pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion  
23 that one or more claims of the '744 patent are invalid.

24 448. Additional non-limiting examples of how one or more claims of the '744 patent are  
25 invalid include: (1) obviousness in view of prior art disclosing methods of treating diffuse large cell  
26 lymphoma patients over the age of 60 with anti-CD20 antibody and CHOP chemotherapy, wherein  
27 anti-CD0 antibody is administered in combination with transplantation regimen; and (2) obviousness  
28

1 in view of prior art disclosing methods of treating diffuse large cell lymphoma patients over the age  
2 of 60 with anti-CD20 antibody and CHOP chemotherapy, wherein both are administered either  
3 concurrently or on day 1 of each chemotherapy cycle. In addition, one or more claims of the '744  
4 patent are invalid in light of prior art that published or was otherwise available to the public before  
5 the earliest possible priority date of the '744 patent.

6 449. There is a real, substantial, and justiciable controversy between Plaintiffs and  
7 Defendants concerning whether one or more claims of the '744 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.

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

12 451. Plaintiffs are entitled to a judicial declaration that one or more claims of the '744  
13 patent are invalid.

14 **COUNT LVII**

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

16 452. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-451  
17 above as if fully set forth herein.

18 453. On November 7, 2017, Celltrion 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's opinion  
20 that one or more claims of the '293 patent will not be infringed by the commercial manufacture, use,  
21 importation, sale, or offer for sale of CT-P10.

22 454. For example, Plaintiffs will not infringe one or more claims of the '293 patent under  
23 35 U.S.C. § 271(a) because [REDACTED]

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

26 [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 455. Additional non-limiting examples of how Plaintiffs will not infringe one or more  
4 valid claims of the '293 patent include: [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 456. There is a real, substantial, and justiciable controversy between Plaintiffs and  
10 Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '293  
11 patent.

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

14 458. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not  
15 infringe, directly or indirectly, any valid and enforceable claim of the '293 patent.

16 **PRAYER FOR RELIEF**

17 WHEREFORE, Celltrion and Teva respectfully request that this Court enter judgment in  
18 their favor against Genentech, Biogen, Roche, and City of Hope and grant the following relief:

19 A. Declare that Plaintiffs have not, do not, and will not infringe any valid claim of U.S.  
20 Patent Nos. 6,331,415; 6,417,335; 6,455,043; 6,489,447; 6,586,206; 6,610,516; 6,620,918;  
21 6,716,602; 7,390,660; 7,485,704; 7,682,612; 7,807,799; 7,820,161; 7,923,221; 8,044,017;  
22 8,206,711; 8,329,172; 8,357,301; 8,460,895; 8,512,983; 8,545,843; 8,557,244; 8,574,869;  
23 8,633,302; 8,710,196; 8,771,988; 8,821,873; 8,822,655; 9,047,438; 9,080,183; 9,296,821;  
24 9,428,548; 9,428,766; 9,487,809; 9,504,744; and 9,714,293.

25 B. Declare that all claims of U.S. Patent Nos. 6,331,415; 6,417,335; 6,455,043;  
26 6,610,516; 6,716,602; 7,682,612; 7,807,799; 7,923,221; 7,976,838; 8,206,711; 8,329,172;

27  
28

1 8,357,301; 8,512,983; 8,545,843; 8,557,244; 8,574,869; 8,821,873; 8,822,655; 9,047,438;  
2 9,080,183; and 9,504,744 are invalid.

3 C. Declare that this is an exceptional case in favor of Celltrion and Teva and award  
4 Celltrion and Teva their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

5 D. Award Celltrion and Teva costs and expenses.

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

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1 Dated: January 11, 2018

COOLEY LLP  
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3  
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