IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech"), City of Hope, and Hoffmann-La Roche Inc. ("HLR"; collectively, "Plaintiffs") bring this Complaint for declaratory and injunctive relief against Defendants Celltrion, Inc. and Celltrion Healthcare Co., Ltd. (collectively, "Celltrion") and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals International GmbH (collectively, "Teva") to address Defendants' infringement of 40 patents relating to Genentech's groundbreaking breast cancer drug Herceptin®.

NATURE OF THE CASE

1. Breast cancer is a serious disease affecting over 2.8 million women in the United States. Approximately 20-25% of those women suffer from "HER2-positive" breast cancer. This is a particularly aggressive form of the disease characterized by overexpression of human epidermal growth factor receptor 2 (i.e., "HER2") proteins due to excessive HER2 gene amplification.

2. In the early 1990s, a diagnosis of HER2-positive breast cancer was effectively a death sentence: patients had an average life expectancy of only 18 months. The quality of life

for those patients was markedly poor—the disease rapidly metastasized (i.e., spread to other parts of the body). The only available treatments were invasive and disfiguring surgery and chemotherapeutic drugs with harsh side effects, and those treatments added little to the patient's life span.

3. The treatment of HER2-positive breast cancer, and the lives of millions of women suffering from the disease, changed dramatically with Genentech's development of Herceptin®. Herceptin® was the first drug of its kind—an antibody called trastuzumab that specifically targeted the biological mechanism that makes HER2-positive breast cancer such an aggressive form of the disease.

4. Although the scientific community was initially skeptical that such an antibody-based therapy could work, Genentech's specific methods of using Herceptin® proved remarkably effective. Indeed, after Genentech revealed the results of its clinical studies, the scientific community hailed Herceptin® as "the beginning of a whole new wave of biological drugs that modulate the causes of cancer"[1] and a sign that "the whole field of cancer research has turned a corner."[2]

5. Since FDA approval of Herceptin® in 1998, Genentech has worked diligently to develop new methods of using Herceptin®—including improved dosing schedules and broader indications—to expand access to therapy and improve the quality of life for millions of patients worldwide. This research has greatly expanded the number of patients who are able to benefit from Herceptin®. To further expand access to this life-saving drug, Genentech also provides Herceptin® free of charge to patients who are uninsured or cannot afford treatment and assists

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[1] Gina Kolata and Lawrence M. Fisher, *Drugs to Fight Breast Cancer Near Approval*, NEW YORK TIMES (FRONT PAGE) (Sept. 3, 1998).

[2] Robert Langreth, *Breast-Cancer Drug Is Backed by FDA Panel*, WALL STREET J. (Sept. 3, 1998).

with out-of-pocket prescription-related expenses. All told, Genentech has spent over two decades, and billions of dollars, developing Herceptin® into the life-saving drug it is today.

6. Genentech's groundbreaking work developing Herceptin® was the result of years of research from a group of talented scientists. The U.S. Patent and Trademark Office recognized that innovative work by granting Genentech numerous patents claiming Herceptin®, its manufacture, and its use. And as one of the pioneers in the biotechnology field, Genentech collaborated with scientists at research institutions like City of Hope to make foundational inventions, such as efficient techniques for making antibodies that can be used as drugs.

7. Seeking to profit from the success of Plaintiffs' innovations, Celltrion submitted Abbreviated Biologics License Application ("aBLA") No. 761091 to the FDA seeking approval to market a biosimilar version of Herceptin® called CT-P6. CT-P6 is a copycat product for which Celltrion is seeking the same label indications and usage as Herceptin®. In fact, Celltrion is relying upon Genentech's own studies demonstrating the safety and efficacy of Herceptin® to obtain approval of its biosimilar product. Upon information and belief, Teva will be engaged in the marketing and distribution of Celltrion's CT-P6 product in the United States upon FDA approval.

8. In 2010, Congress provided a pathway for resolving patent disputes relating to biosimilar products through the Biologics Price Competition and Innovation Act ("BPCIA"). That process is commonly called the "patent dance." Celltrion initially purported to follow the patent dance, which requires biosimilar applicants and innovator companies to exchange certain information concerning the biosimilar product and the patents that may be infringed by the manufacture and sale of the biosimilar product. *See* 42 U.S.C. § 262(*l*). However, before completing the patent dance, Celltrion ended it and, with Teva, filed suit against Plaintiffs in the

U.S. District Court for the Northern District of California seeking a declaratory judgment that 38 of Plaintiffs' patents were invalid or would not be infringed by Defendants' activities related to CT-P6. *See Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal. filed Jan. 11, 2018) ("Defendants' California Action").

9. When Defendants filed their California Action, Celltrion and Genentech were engaged in a statutorily mandated fifteen-day negotiation period under the BPCIA. *See* 42 U.S.C. § 262(*l*)(4)(B). That negotiation period ended no later than January 26, 2018. Had Celltrion continued with the patent dance instead of abandoning it, Celltrion would have been required to notify Genentech of the number of patents that it would propose for inclusion in a first-phase patent infringement case no later than that date (its "5A Number"). *See id.* at § 262(*l*)(5)(A). Then, no later than five days after providing its 5A Number (i.e., no later than January 31, 2018), Celltrion and Genentech would have been required to exchange lists of patents to be included in the first-phase infringement case, with the number of listed patents on each list capped at the 5A Number. *See id.* at § 262(*l*)(5)(B).

10. Defendants' California Action was dismissed on May 9, 2018 because all of Defendants' claims were statutorily barred by the BPCIA—specifically, by 42 U.S.C. § 262(*l*)(9)(B). The California court found that "Celltrion did not provide Genentech with the 5(A) Number or engage in simultaneous exchange of 5(B) Lists with Genentech." *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW, 2018 WL 2448254, at *3 (N.D. Cal. May 9, 2018). "In these circumstances," the California court explained, "the BPCIA is clear: Celltrion may not bring a declaratory judgment action with respect to any patent" that had been at issue in the parties' then-abandoned patent dance. *Id.* at *5.

11. The day after Defendants filed their California Action, Plaintiffs filed an action in this Court asserting that Defendants infringed 40 of Plaintiffs' patents by filing an application seeking regulatory approval to sell CT-P6 within the United States. *See Genentech, Inc. v. Celltrion, Inc.*, C.A. No. 18-0095-GMS (D. Del. filed Jan. 12, 2018) (the "January Action"). Plaintiffs also sought a declaratory judgment that the manufacture, use, offer to sell, sale, or importation into the United States of CT-P6 would infringe those 40 patents. The January Action is currently pending before this Court.

12. On June 6, 2018—after Defendants' California Action was dismissed based on Celltrion's failure to finish the patent dance—Celltrion informed Genentech that it wished to resurrect the patent dance that it had abandoned in January. On June 6, 2018, Celltrion sent Genentech a letter purporting to contain its 5A Number.

13. Five days later, Celltrion wrote to Genentech again, this time purporting to send its 5B List. Celltrion's purported 5B List included the same 40 patents that Plaintiffs asserted in the January Action.

14. Genentech objected to Celltrion's belated attempt to resurrect the patent dance and recapture statutory benefits that it had long ago forfeited by failing to meet the BPCIA's deadlines; but, out of an abundance of caution, Genentech also provided its own list, also listing the same 40 patents that Plaintiffs asserted in the January Action.

15. If the parties' patent dance had progressed as contemplated by the BPCIA—which it did not, because Celltrion missed its deadline to provide its 5A Number by over four months—the BPCIA would have required the reference product sponsor (Genentech) to bring an action for patent infringement for each patent included on the parties' 5B Lists. *See* 42 U.S.C. § 262(*l*)(6)(B). If the parties had reached that stage of the patent dance and Genentech had failed

to bring such an action, another provision of the BPCIA would have limited Genentech's relief for infringement of any patents that it did not assert to a reasonable royalty. *See* 35 U.S.C. §§ 271(e)(6)(A)-(B).

16. Because Celltrion abandoned the patent dance in January, its June 6, 2018 and June 11, 2018 letters had no legal effect and did not trigger an obligation for Genentech to bring an action for patent infringement of the patents listed in the parties' June 11, 2018 letters. Moreover, because Celltrion failed to provide its 5A Number in the time provided by the BPCIA and because Celltrion and Genentech never properly exchanged 5B Lists under the BPCIA, the BPCIA's reasonable royalty provision cannot limit Plaintiffs' remedies for any claim related to CT-P6. However, out of an abundance of caution, Plaintiffs bring this action within 30 days of the parties' June 11, 2018 exchange of letters (i.e., the exchange Celltrion alleges was a 5B List exchange) to avoid the burdens associated with resolving any arguments Defendants may attempt to make suggesting that the BPCIA's reasonable royalty provision limits Plaintiffs' rights.

17. The infringement allegations in this Complaint are essentially identical to the infringement allegations in Plaintiffs' January Action. As in the January Action, Plaintiffs bring this action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Celltrion's submission of its aBLA for CT-P6. To the extent that Celltrion could resurrect the patent dance six months after abandoning it, Plaintiffs also bring this action pursuant to 42 U.S.C. § 262(*l*)(6)(B). Plaintiffs also seek a declaratory judgment pursuant to 42 U.S.C. § 262(*l*)(9) and 28 U.S.C. § 2201 that the manufacture, use, offer to sell, sale, or importation into the United States of Celltrion's biosimilar product would infringe the 40 patents described below. Pursuant to 42 U.S.C. § 262(*l*)(8)(B), Plaintiffs also seek a preliminary and/or permanent injunction barring Defendants' manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to

the expiration of those patents. In the event that Defendants import or launch their biosimilar product and/or otherwise practice the patented inventions in the United States prior to the expiration of those patents, Plaintiffs also seek monetary damages, including lost profits, and any further relief as this Court may deem just and proper. Given the overlap between the two cases, Plaintiffs will seek to consolidate to consolidate this case with the previously filed January Action.

PARTIES

18. Plaintiff Genentech is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080.

19. Genentech was founded in 1976 and for four decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists, and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers. Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range of serious or life-threatening medical conditions, including various forms of cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases.

20. Plaintiff City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

21. Founded in 1913, City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

22. Plaintiff Hoffmann La-Roche Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

23. Upon information and belief, Defendant Celltrion, Inc. is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 19, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, Korea.

24. Celltrion, Inc. is, among other things, engaged in the development of biologic drugs, including a proposed biosimilar version of Genentech's Herceptin® product, CT-P6 ("Celltrion's aBLA product"). Upon information and belief, Celltrion's aBLA product will be distributed and sold in the State of Delaware and throughout the United States.

25. Upon information and belief, Defendant Celltrion Healthcare Co., Ltd. is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 19, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, Korea.

26. Celltrion Healthcare Co., Ltd. is, among other things, engaged in the marketing and distribution of Celltrion's biologic products in the United States, including Celltrion's aBLA product.

27. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

28. Upon information and belief, Defendant Teva Pharmaceuticals International GmbH is a company organized and existing under the laws of Switzerland with its principal place of business located at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

29. Upon information and belief, Celltrion, Inc., Celltrion Healthcare Co., Ltd., and Teva Pharmaceuticals International GmbH have entered into an exclusive partnership to commercialize Celltrion's aBLA product in the United States. Upon information and belief,

Teva Pharmaceuticals USA, Inc. will market and distribute Celltrion's aBLA product in the United States upon FDA approval.

JURISDICTION AND VENUE

30. This action arises under the BPCIA, 42 U.S.C. § 262(*l*), the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338.

31. Venue is proper with respect to Celltrion, Inc., a Korean company, pursuant to 28 U.S.C. § 1391(c)(3).

32. Venue is proper with respect to Celltrion Healthcare Co., Ltd., a Korean company, pursuant to 28 U.S.C. § 1391(c)(3).

33. Venue is proper with respect to Teva Pharmaceuticals USA, Inc. in this Court pursuant to 28 U.S.C. § 1400(b) and/or § 1391 because Teva Pharmaceuticals USA, Inc. is incorporated in Delaware.

34. Venue is proper with respect to Teva Pharmaceuticals International GmbH, a Swiss company, pursuant to 28 U.S.C. § 1391(c)(3).

35. This Court has personal jurisdiction over the Celltrion Defendants because they have aBLA No. 761091 with the FDA seeking approval to market CT-P6, which reliably indicates that they, together with the Teva Defendants, will market their proposed biosimilar product in Delaware if approved. Alternatively, this Court has personal jurisdiction over the Celltrion Defendants pursuant to Federal Rule of Civil Procedure 4(k)(2).

36. This Court has personal jurisdiction over Teva Pharmaceuticals USA, Inc. because it is a Delaware corporation and because, upon information and belief, it will be involved in the marketing and distribution of Celltrion's aBLA product upon FDA approval.

37. This Court has personal jurisdiction over Teva Pharmaceuticals International GmbH because, upon information and belief, it has entered into an exclusive partnership with the Celltrion Defendants to commercialize the Celltrion aBLA product in the United States, which reliably indicates that it will market the Celltrion aBLA product in Delaware if approved. Alternatively, this Court has personal jurisdiction over Teva Pharmaceutical International GmbH pursuant to Federal Rule of Civil Procedure 4(k)(2).

THE PARTIES' EXCHANGES UNDER THE BPCIA

38. On July 31, 2017, Celltrion announced that the FDA had accepted its aBLA for review.

39. On August 1, 2017, Genentech sent a letter to Celltrion's outside counsel requesting that they provide a copy of the aBLA and certain information concerning the manufacture of CT-P6 pursuant to 42 U.S.C. § 262(*l*)(2).

40. Celltrion responded on August 9, 2017 without providing any manufacturing information. Genentech responded on September 19, 2017 to reiterate its request for specific information concerning the manufacture of Celltrion's biosimilar product, and explained why the missing information was necessary to evaluate whether Celltrion's proposed product infringes specific Genentech patents. Celltrion provided some manufacturing information on September 25, 2017, but did not satisfy its disclosure obligations. On October 9, 2017, Celltrion refused to provide the sought-after manufacturing information, in contravention of 42 U.S.C. § 262(*l*)(2). Despite Celltrion's non-compliance (and without waiving Genentech's objection to such non-compliance), Genentech provided its operative list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) on October 10, 2017 ("Genentech's 3A List").

41. On November 7, 2017, Celltrion purported to provide its detailed statement concerning non-infringement and invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(B) for 38 of the 40

patents on Genentech's 3A List ("Celltrion's 3B Statement"). Celltrion's 3B Statement was deficient in numerous ways. For example, it—like Celltrion's document production—failed to fully describe Celltrion's manufacturing process, such that Genentech was unable to evaluate many of Celltrion's non-infringement arguments.

42. Nonetheless, and subject to its objections, Genentech provided its response to Celltrion's 3B Statement on January 5, 2018, pursuant to 42 U.S.C. § 262(*l*)(3)(B) ("Genentech's 3C Statement"). Genentech included responses to Celltrion's non-infringement and invalidity statements for 18 of the 38 patents addressed in Celltrion's 3B Statement. With its 3C Statement, Genentech proposed that Celltrion agree that all patents addressed in Genentech's 3C Statement be included in an infringement action under 42 U.S.C. § 262(*l*)(6).

43. Celltrion wrote to Genentech on January 11, 2018, indicating that it wished to litigate all of the patents on Genentech's 3A list. But, rather than "engage in good faith negotiations" on which patents to litigate as required by 42 U.S.C. § 262(*l*)(4), the Defendants then immediately filed their California Action seeking a declaratory judgment of non-infringement, invalidity, and/or unenforceability for all 38 patents addressed in its 3B Statement on January 11, 2018. Celltrion also purported to provide Genentech with a notice of commercial marketing for its proposed trastuzumab biosimilar pursuant to 42 U.S.C. § 262(*l*)(8)(A).[3] *See id.* ¶ 16.

44. As explained above, *see supra* ¶ 11, Plaintiffs filed the January Action in this Court the day after the Defendants filed their California Action. The January Action alleges that the Defendants have infringed or will infringe all 40 patents on Genentech's 3A List.

[3] Celltrion has taken the position that the exact date of its notice of commercial marketing is confidential.

45. Celltrion did not provide Genentech with a 5A Number by January 26, 2018, which was the last possible day that it could have done so pursuant to 42 U.S.C. § 262(*l*)(4)(B). The patent dance between Celltrion and Genentech related to CT-P6 therefore ended, without reaching completion, no later than January 26, 2018.

46. As explained above, *see supra* ¶ 10, the Defendants' California Action was dismissed on May 9, 2018, because Celltrion's abandonment of the patent dance (and specifically Celltrion's failure to notify Genentech of its 5A Number by the statutory deadline) rendered their declaratory-judgment claims statutorily barred by 42 U.S.C. § 262(*l*)(9)(B). On June 8, 2018, Celltrion informed the court in the California Action that it would not file an amended complaint in that case. The court entered a final judgment dismissing the California Action on June 11, 2018.

47. As explained above, *see supra* ¶ 12, Celltrion attempted to resurrect the patent dance on June 6, 2018, by purporting to notify Genentech with its 5A Number (i.e., 40 patents). This notification had no legal effect because Celltrion made it more than four months after Celltrion was required to do so by 42 U.S.C. § 262(*l*)(4)(B).

48. As explained above, *see supra* ¶ 13, Celltrion purported to provide Genentech with its 5B List on June 11, 2018, and Genentech provided Celltrion with a similar disclosure out of an abundance of caution. The parties' June 11, 2018 lists both included only the 40 patents listed on Genentech's 3A List and asserted in Plaintiffs' January Action. These lists had no legal effect because Celltrion did not provide its 5A Number within the time required by 42 U.S.C. § 262(*l*)(4)(B).

CELLTRION'S aBLA PRODUCT

49. Celltrion's public statements demonstrate that its aBLA product is biosimilar to Herceptin®. For example, Celltrion has issued press releases claiming that CT-P6 is "a

biosimilar to Herceptin (trastuzumab),"[4] "the Herceptin biosimilar,"[5] and that "[i]ts original product is Herceptin."[6]

50. Given Celltrion's claim of biosimilarity, Celltrion's aBLA product must "utilize the same mechanism or mechanisms of action [as Herceptin®] for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling." 42 U.S.C. § 262(k)(2)(A)(i)(II).

51. Under 35 U.S.C. § 271(e)(2)(C), Celltrion has committed a statutory act of patent infringement with respect to patents identified by Genentech under 42 U.S.C. § 262(*l*)(3), through the submission of its aBLA application for CT-P6.

GENENTECH'S ASSERTED PATENTS

52. Genentech has spent over two decades and significant resources developing Herceptin®, and the USPTO has awarded to Genentech numerous patents on innovations resulting from this massive undertaking. These patents cover the antibody trastuzumab, along with its manufacture and use.

53. Upon information and belief, Celltrion's aBLA product will infringe at least the following patents, for which Genentech provided claim-by-claim infringement contentions in its 3C Statement and which Genentech has asserted in this lawsuit: U.S. Patent No. 6,331,415; U.S. Patent No. 7,923,221; U.S. Patent No. 6,407,213; U.S. Patent No. 7,846,441; U.S. Patent No. 7,892,549; U.S. Patent No. 6,627,196; U.S. Patent No. 7,371,379; U.S. Patent No. 6,339,142; U.S. Patent No. 6,417,335; U.S. Patent No. 9,249,218; U.S. Patent No. 8,574,869; U.S. Patent No. 6,620,918; U.S. Patent No. 7,485,704; U.S. Patent No. 7,807,799; U.S. Patent No.

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4 *See* https://www.celltrion.com/en/pr/reportDetail.do?seq=436.

5 *See* https://www.celltrion.com/en/pr/reportDetail.do?seq=403.

6 *See* https://www.celltrion.com/en/pr/reportDetail.do?seq=422.

7,993,834; U.S. Patent No. 8,076,066; U.S. Patent No. 8,425,908; and U.S. Patent No. 8,440,402.

54. Further, upon information and belief, Celltrion's aBLA product has infringed at least the following patents, which Genentech included on its 3A List and which Genentech has asserted in this lawsuit: U.S. Patent No. 6,242,177 and U.S. Patent No. 6,121,428. Celltrion's 3B Statement did not dispute that the manufacturing process for its aBLA product practices the method claims in these patents.

55. Based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is also an active controversy about whether Celltrion's aBLA product will infringe the following patents, which Genentech included on its 3A List and which Genentech has asserted in this lawsuit: U.S. Patent No. 6,489,447; U.S. Patent No. 6,586,206; U.S. Patent No. 6,610,516; U.S. Patent No. 6,716,602; U.S. Patent No. 7,390,660; U.S. Patent No. 7,449,184; U.S. Patent No. 7,501,122; U.S. Patent No. 8,357,301; U.S. Patent No. 8,460,895; U.S. Patent No. 8,512,983; U.S. Patent No. 8,633,302; U.S. Patent No. 8,691,232; U.S. Patent No. 8,771,988; U.S. Patent No. 8,822,655; U.S. Patent No. 9,047,438; U.S. Patent No. 9,080,183; U.S. Patent No. 9,428,548; U.S. Patent No. 9,428,766; U.S. Patent No. 9,487,809; and U.S. Patent No. 9,714,293.

The Cabilly Patents

56. U.S. Patent Nos. 6,331,415 and 7,923,221 (collectively, the "Cabilly Patents") describe and claim a process for producing monoclonal antibodies, such as Herceptin®, from recombinant DNA. This effective and efficient process applies a novel co-expression technique to produce antibody heavy and light chains in a single host cell, and has given rise to an entire industry of therapeutic monoclonal antibodies.

57. U.S. Patent No. 6,331,415 ("the '415 patent"), titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," was duly and legally issued by the Patent Office on December 18, 2001. A true and correct copy of the '415 patent is attached as Exhibit A. Genentech and City of Hope are the owners by assignment of the '415 patent.

58. U.S. Patent No. 7,923,221 ("the '221 patent"), titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," was duly and legally issued by the Patent Office on April 12, 2011. A true and correct copy of the '221 patent is attached as Exhibit B. Genentech and City of Hope are the owners by assignment of the '221 patent.

The '213 Patent

59. U.S. Patent No. 6,407,213 ("the '213 patent") claims the Herceptin® antibody itself, along with other humanized monoclonal antibodies. The inventors of the '213 patent discovered that by grafting the key parts of a mouse antibody onto a human antibody consensus sequence, they could create antibodies that were both tolerated by the immune system and effective to treat diseases like HER2-positive breast cancer. The techniques described in the '213 patent allowed scientists to efficiently design antibodies for specific disease targets by modifying mouse antibodies produced in the laboratory in specific ways so that they are compatible with a human immune system.

60. The '213 patent, titled "Method for Making Humanized Antibodies," was duly and legally issued by the Patent Office on June 18, 2002. A true and correct copy of the '213 patent is attached as Exhibit C. Genentech is the owner by assignment of the '213 patent.

The Combination Chemotherapy Patents

61. U.S. Patent No. 7,846,441 ("the '441 patent"), claims the administration of Herceptin® in combination with a chemotherapy agent known as a taxoid, in the absence of an anthracycline derivative (another chemotherapy agent) in an amount effective to extend time to disease progression without overall increase in severe adverse events. This specific method of treatment unexpectedly resulted in a significant improvement in patient outcomes. It nearly doubled the time until disease progression compared to treatment using a taxoid alone, and it also avoided the serious cardiotoxicity associated with Herceptin® in combination with anthracycline derivatives that unexpectedly presented during the Herceptin® clinical trials.

62. The '441 patent, titled "Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on December 7, 2010. A true and correct copy of the '441 patent is attached as Exhibit D. Genentech is the owner by assignment of the '441 patent.

63. U.S. Patent No. 7,892,549 ("the '549 patent") is a continuation to the '441 patent that claims a method of treating a patient with HER2-positive breast cancer by administering Herceptin® in combination with a taxoid and a further growth inhibitory agent or further therapeutic agent.

64. The '549 patent, titled "Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on February 22, 2011. A true and correct copy of the '549 patent is attached as Exhibit E. Genentech is the owner by assignment of the '549 patent.

65. U.S. Patent No. 8,425,908 ("the '908 patent"), claims priority to the same provisional application as the '441 and '549 patents. The '908 patent claims a method of treating a patient with HER2-positive gastric cancer by administering Herceptin® in combination with chemotherapy and in the absence of an anthracycline derivative.

66. The ’908 patent, titled “Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on April 23, 2013. A true and correct copy of the ’908 patent is attached as Exhibit F. Genentech is the owner by assignment of the ’908 patent.

The Method of Administration Patents

67. U.S. Patent Nos. 6,627,196 and 7,371,379 (collectively, the “Method of Administration Patents”) generally cover the most common administration method for Herceptin®: an initial dose of 8 mg/kg, followed by 6 mg/kg doses once every three weeks. Herceptin® was initially approved for administration on a weekly regimen, but Genentech discovered that the drug could be dosed only once every three weeks without reducing safety or effectiveness. The discovery of three-weekly dosing has had a marked impact on patients’ quality of life by providing the same life-saving effects of Herceptin® while allowing patients to receive treatment less frequently.

68. U.S. Patent No. 6,627,196 (“the ’196 patent”), titled “Dosages for Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on September 30, 2003. A true and correct copy of the ’196 patent is attached as Exhibit G. Genentech is the owner by assignment of the ’196 patent.

69. U.S. Patent No. 7,371,379 (“the ’379 patent”), titled “Dosages for Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on May 13, 2008. A true and correct copy of the ’379 patent is attached as Exhibit H. Genentech is the owner by assignment of the ’379 patent.

The Acidic Variants Patents

70. U.S. Patent Nos. 6,339,142, 6,417,335, 6,489,447, and 9,249,218 (collectively, the “Acidic Variants Patents”) cover compositions with reduced amounts of more acidic structural variants of trastuzumab (“acidic variants”) and chromatographic processes for

removing these acidic variants during purification. Some trastuzumab acidic variants have lower potency than trastuzumab itself. The Acidic Variants Patents describe and claim chromatographic processes and compositions that ensure the Herceptin® drug product is uniformly pure and effective.

71. U.S. Patent No. 6,339,142 ("the '142 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on January 15, 2002. A true and correct copy of the '142 patent is attached as Exhibit I. Genentech is the owner by assignment of the '142 patent.

72. U.S. Patent No. 6,417,335 ("the '335 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on July 9, 2002. A true and correct copy of the '335 patent is attached as Exhibit J. Genentech is the owner by assignment of the '335 patent.

73. U.S. Patent No. 6,489,447 ("the '447 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on December 3, 2002. A true and correct copy of the '447 patent is attached as Exhibit K. Genentech is the owner by assignment of the '447 patent.

74. U.S. Patent No. 9,249,218 ("the '218 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on February 2, 2016. A true and correct copy of the '218 patent is attached as Exhibit L. Genentech is the owner by assignment of the '218 patent.

Combination Therapy with Perjeta

75. U.S. Patent Nos. 7,501,122, 7,449,184, and 8,691,232 claim novel therapies combining trastuzumab with another anti-HER2 antibody developed by Genentech called pertuzumab. That combination therapy is a common method of treatment for HER2-positive breast cancer patients involving Herceptin®.

76. U.S. Patent No. 7,501,122 ("the '122 patent"), titled "Treatment with Anti-ErbB2 Antibody Combinations," was duly and legally issued by the Patent Office on March 10, 2009.

A true and correct copy of the ’122 patent is attached as Exhibit M. Genentech is the owner by assignment of the ’122 patent.

77. U.S. Patent No. 7,449,184 (“the ’184 patent”), titled “Fixed Dosing of HER Antibodies,” was duly and legally issued by the Patent Office on November 11, 2008. A true and correct copy of the ’184 patent is attached as Exhibit N. Genentech is the owner by assignment of the ’184 patent.

78. U.S. Patent No. 8,691,232 (“the ’232 patent”), titled “Extending Time to Disease Progression or Survival in Cancer Patients,” was duly and legally issued by the Patent Office on April 8, 2014. A true and correct copy of the ’232 patent is attached as Exhibit O. Genentech is the owner by assignment of the ’232 patent.

HER2 Diagnostic Patents

79. U.S. Patent Nos. 7,993,834, 8,076,066, and 8,440,402 claim novel techniques for identifying patients who might benefit from trastuzumab therapy using gene amplification techniques even where immunohistochemistry techniques suggest that the patient may not overexpress HER2.

80. U.S. Patent No. 7,993,834 (“the ’834 patent”), titled “Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy,” was duly and legally issued by the Patent Office on August 9, 2011. A true and correct copy of the ’834 patent is attached as Exhibit P. Genentech is the owner by assignment of the ’834 patent.

81. U.S. Patent No. 8,076,066 (“the ’066 patent”), titled “Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy,” was duly and legally issued by the Patent Office on December 13, 2011. A true and correct copy of

the ’066 patent is attached as Exhibit Q. Genentech is the owner by assignment of the ’066 patent.

82. U.S. Patent No. 8,440,402 (“the ’402 patent”), titled “Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy,” was duly and legally issued by the Patent Office on May 14, 2013. A true and correct copy of the ’402 patent is attached as Exhibit R. Genentech is the owner by assignment of the ’402 patent.

Cell Culture, Purification, and Antibody Manufacturing Patents

83. U.S. Patent Nos. 6,586,206, 6,610,516, 6,716,602, 7,390,660, 8,460,895, 8,512,983, 8,574,869, 8,771,988, 9,080,183, 9,428,766, 9,487,809, 9,714,293, 6,417,335, 6,489,447, 6,620,918, 7,485,704, 7,807,799, 8,357,301, 8,633,302, 8,822,655, 9,047,438, and 9,428,548 claim novel techniques developed by Genentech relating to various aspects of cell culture, purification, and antibody purification.

84. U.S. Patent No. 6,620,918 (“the ’918 patent”), titled “Separation of Polypeptide Monomers,” was duly and legally issued by the Patent Office on September 16, 2003. A true and correct copy of the ’918 patent is attached as Exhibit S. Genentech is the owner by assignment of the ’918 patent.

85. U.S. Patent No. 7,485,704 (“the ’704 patent”), titled “Reducing Protein A Leaching During Protein A Affinity Chromatography,” was duly and legally issued by the Patent Office on February 3, 2009. A true and correct copy of the ’704 patent is attached as Exhibit T. Genentech is the owner by assignment of the ’704 patent.

86. U.S. Patent No. 7,807,799 (“the ’799 patent”), titled “Reducing Protein A Leaching During Protein A Affinity Chromatography,” was duly and legally issued by the Patent Office on October 5, 2010. A true and correct copy of the ’799 patent is attached as Exhibit U. Genentech is the owner by assignment of the ’799 patent.

87. U.S. Patent No. 9,428,548 ("the '548 patent"), titled "Enhanced Protein Purification Through a Modified Protein A Elution," was duly and legally issued by the Patent Office on August 30, 2016. A true and correct copy of the '548 patent is attached as Exhibit V. Genentech is the owner by assignment of the '548 patent.

88. U.S. Patent No. 6,586,206 ("the '206 patent"), titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," was duly and legally issued by the Patent Office on July 1, 2003. A true and correct copy of the '206 patent is attached as Exhibit W. Genentech is the owner by assignment of the '206 patent.

89. U.S. Patent No. 6,610,516 ("the '516 patent"), titled "Cell Culture Process," was duly and legally issued by the Patent Office on August 26, 2003. A true and correct copy of the '516 patent is attached as Exhibit X. Genentech is the owner by assignment of the '516 patent.

90. U.S. Patent No. 6,716,602 ("the '602 patent"), titled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," was duly and legally issued by the Patent Office on April 6, 2004. A true and correct copy of the '602 patent is attached as Exhibit Y. Genentech is the owner by assignment of the '602 patent.

91. U.S. Patent No. 7,390,660 ("the '660 patent"), titled "Methods for Growing Mammalian Cells In Vitro," was duly and legally issued by the Patent Office on June 24, 2008. A true and correct copy of the '660 patent is attached as Exhibit Z. The '660 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '660 patent.

92. U.S. Patent No. 8,460,895 ("the '895 patent"), titled "Method for Producing Recombinant Proteins with a Constant Content of pCO.sub.2 in the Medium," was duly and legally issued by the Patent Office on June 11, 2013. A true and correct copy of the '895 patent

is attached as Exhibit AA. The ’895 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’895 patent.

93. U.S. Patent No. 8,512,983 (“the ’983 patent”), titled “Production of Proteins in Glutamine-Free Cell Culture Media,” was duly and legally issued by the Patent Office on August 20, 2013. A true and correct copy of the ’983 patent is attached as Exhibit BB. Genentech is the owner by assignment of the ’983 patent.

94. U.S. Patent No. 8,574,869 (“the ’869 patent”), titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” was duly and legally issued by the Patent Office on November 5, 2013. A true and correct copy of the ’869 patent is attached as Exhibit CC. Genentech is the owner by assignment of the ’869 patent.

95. U.S. Patent No. 8,771,988 (“the ’988 patent”), titled “Protein Expression From Multiple Nucleic Acids,” was duly and legally issued by the Patent Office on July 8, 2014. A true and correct copy of the ’988 patent is attached as Exhibit DD. The ’988 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’988 patent.

96. U.S. Patent No. 9,080,183 (“the ’183 patent”), titled “Promoter,” was duly and legally issued by the Patent Office on July 14, 2015. A true and correct copy of the ’183 patent is attached as Exhibit EE. The ’183 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’183 patent.

97. U.S. Patent No. 9,428,766 (“the ’766 patent”), titled “Protein Expression From Multiple Nucleic Acids,” was duly and legally issued by the Patent Office on August 30, 2016. A true and correct copy of the ’766 patent is attached as Exhibit FF. The ’766 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’766 patent.

98. U.S. Patent No. 9,487,809 ("the '809 patent"), titled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," was duly and legally issued by the Patent Office on November 8, 2016. A true and correct copy of the '809 patent is attached as Exhibit GG. Genentech is the owner by assignment of the '809 patent.

99. U.S. Patent No. 9,714,293 ("the '293 patent"), titled "Production of Proteins in Glutamine-Free Cell Culture Media," was duly and legally issued by the Patent Office on July 25, 2017. A true and correct copy of the '293 patent is attached as Exhibit HH. Genentech is the owner by assignment of the '293 patent.

100. U.S. Patent No. 8,357,301 ("the '301 patent"), titled "Chromatography Equipment Characterization," was duly and legally issued by the Patent Office on January 22, 2013. A true and correct copy of the '301 patent is attached as Exhibit II. The '301 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '301 patent.

101. U.S. Patent No. 8,633,302 ("the '302 patent"), titled "Variable Tangential Flow Filtration," was duly and legally issued by the Patent Office on January 21, 2014. A true and correct copy of the '302 patent is attached as Exhibit JJ. The '302 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '302 patent.

102. U.S. Patent No. 8,822,655 ("the '655 patent"), titled "Pre-filtration Adjustment of Buffer Solutes," was duly and legally issued by the Patent Office on September 2, 2014. A true and correct copy of the '655 patent is attached as Exhibit KK. The '655 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '655 patent.

103. U.S. Patent No. 9,047,438 ("the '438 patent"), titled "Chromatography Equipment Characterization," was duly and legally issued by the Patent Office on June 2, 2015. A true and

correct copy of the ’438 patent is attached as Exhibit LL. The ’438 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’438 patent.

104. U.S. Patent No. 6,242,177 (“the ’177 patent”), titled “Methods and Compositions for Secretion of Heterologous Polypeptides,” was duly and legally issued by the Patent Office on June 5, 2001. A true and correct copy of the ’177 patent is attached as Exhibit MM. Genentech is the owner by assignment of the ’177 patent.

105. U.S. Patent No. 6,121,428 (“the ’428 patent”), titled “Protein Recovery,” was duly and legally issued by the Patent Office on September 19, 2000. A true and correct copy of the ’428 patent is attached as Exhibit NN. Genentech is the owner by assignment of the ’428 patent.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,331,415

106. Plaintiffs incorporate by reference paragraphs 1-105 as if fully set forth herein.

107. Genentech included the ’415 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’415 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

108. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’415 patent is a technical act of infringement of one or more claims of the ’415 patent under 35 U.S.C. § 271(e)(2)(C)(i), either

literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

109. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’415 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’415 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

110. Defendants have knowledge of and are aware of the ’415 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’415 patent is willful.

111. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’415 patent. Plaintiffs have no adequate remedy at law.

112. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 7,923,221

113. Plaintiffs incorporate by reference paragraphs 1-112 as if fully set forth herein.

114. Genentech included the ’221 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’221 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

115. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’221 patent is a technical act of infringement of one or more claims of the ’221 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

116. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’221 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’

proposed CT-P6 drug product will infringe the ’221 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

117. Defendants have knowledge of and are aware of the ’221 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’221 patent is willful.

118. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’221 patent. Plaintiffs have no adequate remedy at law.

119. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 6,407,213

120. Plaintiffs incorporate by reference paragraphs 1-119 as if fully set forth herein.

121. Genentech included the ’213 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’213 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

122. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’213 patent is a technical act of

infringement of one or more claims of the ’213 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

123. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’213 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’213 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

124. Defendants have knowledge of and are aware of the ’213 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’213 patent is willful.

125. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’213 patent. Plaintiffs have no adequate remedy at law.

126. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 7,846,441

127. Plaintiffs incorporate by reference paragraphs 1-126 as if fully set forth herein.

128. Genentech included the ’441 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’441 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

129. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’441 patent is a technical act of infringement of one or more claims of the ’441 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

130. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’441 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’441 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

131. Defendants have knowledge of and are aware of the ’441 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’441 patent is willful.

132. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Celltrion aBLA product, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the ’441 patent, either literally or under the doctrine of equivalents.

133. Upon information and belief, Defendants are aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Celltrion aBLA product according to Celltrion’s proposed package insert and, therefore, will directly infringe at least one claim of the ’441 patent, either literally or under the doctrine of equivalents.

134. Upon information and belief, Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’441 patent, either literally or under the doctrine of equivalents, by at least Celltrion’s proposed package insert for the Celltrion aBLA product.

135. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’441 patent. Plaintiffs have no adequate remedy at law.

136. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing

Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 7,892,549

137. Plaintiffs incorporate by reference paragraphs 1-136 as if fully set forth herein.

138. Genentech included the ’549 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’549 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

139. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’549 patent is a technical act of infringement of one or more claims of the ’549 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

140. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’549 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and

promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '549 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

141. Defendants have knowledge of and are aware of the '549 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '549 patent is willful.

142. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Celltrion aBLA product, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '549 patent, either literally or under the doctrine of equivalents.

143. Upon information and belief, Defendants are aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Celltrion aBLA product according to Celltrion's proposed package insert and, therefore, will directly infringe at least one claim of the '549 patent, either literally or under the doctrine of equivalents.

144. Upon information and belief, Defendants know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '549 patent, either literally or under the doctrine of equivalents, by at least Celltrion's proposed package insert for the Celltrion aBLA product.

145. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '549 patent. Plaintiffs have no adequate remedy at law.

146. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 6,627,196

147. Plaintiffs incorporate by reference paragraphs 1-146 as if fully set forth herein.

148. Genentech included the ’196 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’196 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

149. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’196 patent is a technical act of infringement of one or more claims of the ’196 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

150. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’196 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C

Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '196 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

151. Defendants have knowledge of and are aware of the '196 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '196 patent is willful.

152. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Celltrion aBLA product, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '196 patent, either literally or under the doctrine of equivalents.

153. Upon information and belief, Defendants are aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Celltrion aBLA product according to Celltrion's proposed package insert and, therefore, will directly infringe at least one claim of the '196 patent, either literally or under the doctrine of equivalents.

154. Upon information and belief, Defendants know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '196 patent, either literally or under the doctrine of equivalents, by at least Celltrion's proposed package insert for the Celltrion aBLA product.

155. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’196 patent. Plaintiffs have no adequate remedy at law.

156. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 7,371,379

157. Plaintiffs incorporate by reference paragraphs 1-156 as if fully set forth herein.

158. Genentech included the ’379 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’379 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

159. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’379 patent is a technical act of infringement of one or more claims of the ’379 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

160. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will

infringe the ’379 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’379 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

161. Defendants have knowledge of and are aware of the ’379 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’379 patent is willful.

162. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Celltrion aBLA product, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the ’379 patent, either literally or under the doctrine of equivalents.

163. Upon information and belief, Defendants are aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Celltrion aBLA product according to Celltrion’s proposed package insert and, therefore, will directly infringe at least one claim of the ’379 patent, either literally or under the doctrine of equivalents.

164. Upon information and belief, Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’379 patent, either

literally or under the doctrine of equivalents, by at least Celltrion's proposed package insert for the Celltrion aBLA product.

165. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '379 patent. Plaintiffs have no adequate remedy at law.

166. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 6,339,142

167. Plaintiffs incorporate by reference paragraphs 1-166 as if fully set forth herein.

168. Genentech included the '142 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '142 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

169. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '142 patent is a technical act of infringement of one or more claims of the '142 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

170. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’142 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’142 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

171. Defendants have knowledge of and are aware of the ’142 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’142 patent is willful.

172. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’142 patent. Plaintiffs have no adequate remedy at law.

173. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 6,417,335

174. Plaintiffs incorporate by reference paragraphs 1-173 as if fully set forth herein.

175. Genentech included the ’335 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’335 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

176. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’335 patent is a technical act of infringement of one or more claims of the ’335 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

177. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’335 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’335 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

178. Defendants have knowledge of and are aware of the ’335 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’335 patent is willful.

179. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’335 patent. Plaintiffs have no adequate remedy at law.

180. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 6,489,447

181. Plaintiffs incorporate by reference paragraphs 1-180 as if fully set forth herein.

182. Genentech included the ’447 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’447 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

183. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’447 patent is a technical act of infringement of one or more claims of the ’447 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

184. Likewise, based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the '447 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '447 patent pursuant to 35 U.S.C. § 271.

185. Defendants have knowledge of and are aware of the '447 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '447 patent is willful.

186. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '447 patent. Plaintiffs have no adequate remedy at law.

187. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 9,249,218

188. Plaintiffs incorporate by reference paragraphs 1-187 as if fully set forth herein.

189. Genentech included the '218 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the

parties included the ’218 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

190. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’218 patent is a technical act of infringement of one or more claims of the ’218 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

191. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’218 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’218 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

192. Defendants have knowledge of and are aware of the ’218 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’218 patent is willful.

193. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’218 patent. Plaintiffs have no adequate remedy at law.

194. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 8,574,869

195. Plaintiffs incorporate by reference paragraphs 1-194 as if fully set forth herein.

196. Genentech included the ’869 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’869 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

197. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’869 patent is a technical act of infringement of one or more claims of the ’869 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

198. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will

infringe the ’869 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’869 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

199. Defendants have knowledge of and are aware of the ’869 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’869 patent is willful.

200. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’869 patent. Plaintiffs have no adequate remedy at law.

201. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 6,620,918

202. Plaintiffs incorporate by reference paragraphs 1-201 as if fully set forth herein.

203. Genentech included the ’918 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’918 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48.

As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

204. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '918 patent is a technical act of infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

205. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the '918 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '918 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

206. Defendants have knowledge of and are aware of the '918 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '918 patent is willful.

207. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’918 patent. Plaintiffs have no adequate remedy at law.

208. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XIV
INFRINGEMENT OF U.S. PATENT NO. 7,485,704

209. Plaintiffs incorporate by reference paragraphs 1-208 as if fully set forth herein.

210. Genentech included the ’704 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’704 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

211. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’704 patent is a technical act of infringement of one or more claims of the ’704 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

212. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will

infringe the ’704 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’704 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

213. Defendants have knowledge of and are aware of the ’704 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’704 patent is willful.

214. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’704 patent. Plaintiffs have no adequate remedy at law.

215. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XV
INFRINGEMENT OF U.S. PATENT NO. 7,807,799

216. Plaintiffs incorporate by reference paragraphs 1-215 as if fully set forth herein.

217. Genentech included the ’799 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’799 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48.

As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

218. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '799 patent is a technical act of infringement of one or more claims of the '799 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

219. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the '799 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '799 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

220. Defendants have knowledge of and are aware of the '799 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '799 patent is willful.

221. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’799 patent. Plaintiffs have no adequate remedy at law.

222. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XVI
INFRINGEMENT OF U.S. PATENT NO. 9,428,548

223. Plaintiffs incorporate by reference paragraphs 1-222 as if fully set forth herein.

224. Genentech included the ’548 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’548 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

225. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), and Celltrion’s June 11, 2018 letter to Genentech, Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’548 patent is a technical act of infringement of one or more claims of the ’548 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

226. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’548 patent

as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '548 patent pursuant to 35 U.S.C. § 271.

227. Defendants have knowledge of and are aware of the '548 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '548 patent is willful.

228. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '548 patent. Plaintiffs have no adequate remedy at law.

229. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XVII
INFRINGEMENT OF U.S. PATENT NO. 8,633,302

230. Plaintiffs incorporate by reference paragraphs 1-229 as if fully set forth herein.

231. Genentech included the '302 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '302 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

232. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '302 patent is a technical act of infringement of one or more claims of the '302 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

233. Likewise, based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the '302 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '302 patent pursuant to 35 U.S.C. § 271.

234. Defendants have knowledge of and are aware of the '302 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '302 patent is willful.

235. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '302 patent. Plaintiffs have no adequate remedy at law.

236. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the

commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XVIII
INFRINGEMENT OF U.S. PATENT NO. 8,691,232

237. Plaintiffs incorporate by reference paragraphs 1-236 as if fully set forth herein.

238. Genentech included the ’232 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’232 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

239. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’232 patent is a technical act of infringement of one or more claims of the ’232 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

240. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’232 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of

the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '232 patent pursuant to 35 U.S.C. § 271.

241. Defendants have knowledge of and are aware of the '232 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '232 patent is willful.

242. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '232 patent. Plaintiffs have no adequate remedy at law.

243. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XIX
INFRINGEMENT OF U.S. PATENT NO. 8,771,988

244. Plaintiffs incorporate by reference paragraphs 1-243 as if fully set forth herein.

245. Genentech included the '988 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '988 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

246. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '988 patent is a technical act of

infringement of one or more claims of the ’988 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

247. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’988 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’988 patent pursuant to 35 U.S.C. § 271.

248. Defendants have knowledge of and are aware of the ’988 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’988 patent is willful.

249. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’988 patent. Plaintiffs have no adequate remedy at law.

250. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XX
INFRINGEMENT OF U.S. PATENT NO. 8,822,655

251. Plaintiffs incorporate by reference paragraphs 1-250 as if fully set forth herein.

252. Genentech included the ’655 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’655 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

253. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’655 patent is a technical act of infringement of one or more claims of the ’655 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

254. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’655 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’655 patent pursuant to 35 U.S.C. § 271.

255. Defendants have knowledge of and are aware of the ’655 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’655 patent is willful.

256. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’655 patent. Plaintiffs have no adequate remedy at law.

257. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXI
INFRINGEMENT OF U.S. PATENT NO. 9,047,438

258. Plaintiffs incorporate by reference paragraphs 1-257 as if fully set forth herein.

259. Genentech included the ’438 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’438 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

260. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’438 patent is a technical act of infringement of one or more claims of the ’438 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

261. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’438 patent

as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '438 patent pursuant to 35 U.S.C. § 271.

262. Defendants have knowledge of and are aware of the '438 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '438 patent is willful.

263. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '438 patent. Plaintiffs have no adequate remedy at law.

264. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXII
INFRINGEMENT OF U.S. PATENT NO. 9,080,183

265. Plaintiffs incorporate by reference paragraphs 1-264 as if fully set forth herein.

266. Genentech included the '183 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '183 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

267. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '183 patent is a technical act of infringement of one or more claims of the '183 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

268. Likewise, based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the '183 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '183 patent pursuant to 35 U.S.C. § 271.

269. Defendants have knowledge of and are aware of the '183 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '183 patent is willful.

270. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '183 patent. Plaintiffs have no adequate remedy at law.

271. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the

commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXIII
INFRINGEMENT OF U.S. PATENT NO. 9,428,766

272. Plaintiffs incorporate by reference paragraphs 1-271 as if fully set forth herein.

273. Genentech included the ’766 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’766 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

274. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’766 patent is a technical act of infringement of one or more claims of the ’766 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

275. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’766 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of

the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '766 patent pursuant to 35 U.S.C. § 271.

276. Defendants have knowledge of and are aware of the '766 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '766 patent is willful.

277. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '766 patent. Plaintiffs have no adequate remedy at law.

278. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXIV
INFRINGEMENT OF U.S. PATENT NO. 9,487,809

279. Plaintiffs incorporate by reference paragraphs 1-278 as if fully set forth herein.

280. Genentech included the '809 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '809 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

281. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '809 patent is a technical act of

infringement of one or more claims of the ’809 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

282. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’809 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’809 patent pursuant to 35 U.S.C. § 271.

283. Defendants have knowledge of and are aware of the ’809 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’809 patent is willful.

284. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’809 patent. Plaintiffs have no adequate remedy at law.

285. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXV
INFRINGEMENT OF U.S. PATENT NO. 9,714,293

286. Plaintiffs incorporate by reference paragraphs 1-285 as if fully set forth herein.

287. Genentech included the ’293 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’293 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

288. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’293 patent is a technical act of infringement of one or more claims of the ’293 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

289. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’293 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’293 patent pursuant to 35 U.S.C. § 271.

290. Defendants have knowledge of and are aware of the ’293 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’293 patent is willful.

291. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’293 patent. Plaintiffs have no adequate remedy at law.

292. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXVI
INFRINGEMENT OF U.S. PATENT NO. 7,449,184

293. Plaintiffs incorporate by reference paragraphs 1-292 as if fully set forth herein.

294. Genentech included the ’184 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’184 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

295. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’184 patent is a technical act of infringement of one or more claims of the ’184 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

296. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’184 patent

as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '184 patent pursuant to 35 U.S.C. § 271.

297. Defendants have knowledge of and are aware of the '184 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '184 patent is willful.

298. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '184 patent. Plaintiffs have no adequate remedy at law.

299. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXVII
INFRINGEMENT OF U.S. PATENT NO. 7,501,122

300. Plaintiffs incorporate by reference paragraphs 1-299 as if fully set forth herein.

301. Genentech included the '122 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '122 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

302. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '122 patent is a technical act of infringement of one or more claims of the '122 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

303. Likewise, based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the '122 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '122 patent pursuant to 35 U.S.C. § 271.

304. Defendants have knowledge of and are aware of the '122 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '122 patent is willful.

305. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '122 patent. Plaintiffs have no adequate remedy at law.

306. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the

commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXVIII
INFRINGEMENT OF U.S. PATENT NO. 7,993,834

307. Plaintiffs incorporate by reference paragraphs 1-306 as if fully set forth herein.

308. Genentech included the ’834 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’834 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

309. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’834 patent is a technical act of infringement of one or more claims of the ’834 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

310. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’834 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and

promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '834 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

311. Defendants have knowledge of and are aware of the '834 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '834 patent is willful.

312. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '834 patent. Plaintiffs have no adequate remedy at law.

313. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXIX
INFRINGEMENT OF U.S. PATENT NO. 8,076,066

314. Plaintiffs incorporate by reference paragraphs 1-313 as if fully set forth herein.

315. Genentech included the '066 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '066 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

316. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '066 patent is a technical act of

infringement of one or more claims of the ’066 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

317. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’066 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’066 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

318. Defendants have knowledge of and are aware of the ’066 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’066 patent is willful.

319. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’066 patent. Plaintiffs have no adequate remedy at law.

320. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXX
INFRINGEMENT OF U.S. PATENT NO. 8,357,301

321. Plaintiffs incorporate by reference paragraphs 1-320 as if fully set forth herein.

322. Genentech included the ’301 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’301 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

323. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’301 patent is a technical act of infringement of one or more claims of the ’301 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

324. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’301 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’301 patent pursuant to 35 U.S.C. § 271.

325. Defendants have knowledge of and are aware of the ’301 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’301 patent is willful.

326. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’301 patent. Plaintiffs have no adequate remedy at law.

327. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXI
INFRINGEMENT OF U.S. PATENT NO. 8,425,908

328. Plaintiffs incorporate by reference paragraphs 1-327 as if fully set forth herein.

329. Genentech included the ’908 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’908 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

330. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’908 patent is a technical act of infringement of one or more claims of the ’908 patent under 35 U.S.C. § 271(e)(2)(C)(i), either

literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

331. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’908 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’908 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

332. Defendants have knowledge of and are aware of the ’908 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’908 patent is willful.

333. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’908 patent. Plaintiffs have no adequate remedy at law.

334. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXII
INFRINGEMENT OF U.S. PATENT NO. 8,440,402

335. Plaintiffs incorporate by reference paragraphs 1-334 as if fully set forth herein.

336. Genentech included the ’402 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’402 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

337. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’402 patent is a technical act of infringement of one or more claims of the ’402 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

338. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants will infringe the ’402 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’402 patent pursuant to 35 U.S.C. §§ 271(b) and/or (c).

339. Defendants have knowledge of and are aware of the ’402 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’402 patent is willful.

340. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’402 patent. Plaintiffs have no adequate remedy at law.

341. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXIII
INFRINGEMENT OF U.S. PATENT NO. 8,460,895

342. Plaintiffs incorporate by reference paragraphs 1-341 as if fully set forth herein.

343. Genentech included the ’895 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’895 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

344. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’895 patent is a technical act of infringement of one or more claims of the ’895 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

345. Likewise, based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the '895 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '895 patent pursuant to 35 U.S.C. § 271.

346. Defendants have knowledge of and are aware of the '895 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '895 patent is willful.

347. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '895 patent. Plaintiffs have no adequate remedy at law.

348. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXIV
INFRINGEMENT OF U.S. PATENT NO. 8,512,983

349. Plaintiffs incorporate by reference paragraphs 1-348 as if fully set forth herein.

350. Genentech included the '983 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the

parties included the ’983 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

351. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’983 patent is a technical act of infringement of one or more claims of the ’983 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

352. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’983 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’983 patent pursuant to 35 U.S.C. § 271.

353. Defendants have knowledge of and are aware of the ’983 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’983 patent is willful.

354. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’983 patent. Plaintiffs have no adequate remedy at law.

355. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXV
INFRINGEMENT OF U.S. PATENT NO. 6,586,206

356. Plaintiffs incorporate by reference paragraphs 1-355 as if fully set forth herein.

357. Genentech included the ’206 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’206 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

358. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’206 patent is a technical act of infringement of one or more claims of the ’206 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

359. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’206 patent

as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '206 patent pursuant to 35 U.S.C. § 271.

360. Defendants have knowledge of and are aware of the '206 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '206 patent is willful.

361. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '206 patent. Plaintiffs have no adequate remedy at law.

362. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXVI
INFRINGEMENT OF U.S. PATENT NO. 6,610,516

363. Plaintiffs incorporate by reference paragraphs 1-362 as if fully set forth herein.

364. Genentech included the '516 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '516 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

365. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '516 patent is a technical act of infringement of one or more claims of the '516 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

366. Likewise, based on Defendants' complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion's June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the '516 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '516 patent pursuant to 35 U.S.C. § 271.

367. Defendants have knowledge of and are aware of the '516 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '516 patent is willful.

368. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '516 patent. Plaintiffs have no adequate remedy at law.

369. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the

commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXVII
INFRINGEMENT OF U.S. PATENT NO. 6,716,602

370. Plaintiffs incorporate by reference paragraphs 1-369 as if fully set forth herein.

371. Genentech included the ’602 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’602 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

372. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’602 patent is a technical act of infringement of one or more claims of the ’602 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

373. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’602 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of

the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product will infringe the '602 patent pursuant to 35 U.S.C. § 271.

374. Defendants have knowledge of and are aware of the '602 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants' infringement of the '602 patent is willful.

375. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the '602 patent. Plaintiffs have no adequate remedy at law.

376. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXVIII
INFRINGEMENT OF U.S. PATENT NO. 7,390,660

377. Plaintiffs incorporate by reference paragraphs 1-376 as if fully set forth herein.

378. Genentech included the '660 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the '660 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

379. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the '660 patent is a technical act of

infringement of one or more claims of the ’660 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

380. Likewise, based on Defendants’ complaint in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274-JSW (N.D. Cal. filed Jan. 11, 2018), and Celltrion’s June 11, 2018 letter to Genentech, there is an active controversy about whether Defendants will infringe the ’660 patent as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product will infringe the ’660 patent pursuant to 35 U.S.C. § 271.

381. Defendants have knowledge of and are aware of the ’660 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), the filing of the January Action, and the filing of this Complaint. Defendants’ infringement of the ’660 patent is willful.

382. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Defendants are enjoined from infringing the claims of the ’660 patent. Plaintiffs have no adequate remedy at law.

383. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), and/or 35 U.S.C. § 271 preventing Defendants from the commercial manufacture, use, offer to sell, or sale within the United States of the Celltrion aBLA product.

COUNT XXXIX
INFRINGEMENT OF U.S. PATENT NO. 6,242,177

384. Plaintiffs incorporate by reference paragraphs 1-383 as if fully set forth herein.

385. Genentech included the ’177 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’177 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

386. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’177 patent was a technical act of infringement of one or more claims of the ’177 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

387. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants have infringed the ’177 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Defendants’ manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants’ proposed CT-P6 drug product have infringed the ’177 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

388. Defendants have had knowledge of and were aware of the ’177 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of the January Action. Defendants’ infringement of the ’177 patent was willful.

COUNT XL
INFRINGEMENT OF U.S. PATENT NO. 6,121,428

389. Plaintiffs incorporate by reference paragraphs 1-**Error! Reference source not found.** as if fully set forth herein.

390. Genentech included the ’428 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). When Celltrion purported to resume the patent dance in June 2018, the parties included the ’428 patent in the lists exchanged on June 11, 2018. *See supra* ¶¶ 13, 48. As explained above, Celltrion also has purported to serve Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See supra* ¶ 43.

391. Based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Celltrion’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Celltrion aBLA product prior to the expiration of the ’428 patent was a technical act of infringement of one or more claims of the ’428 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

392. Likewise, based on publicly available information and/or information provided by Celltrion pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Defendants have infringed the ’428 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and its proposed CT-P6 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201,

Plaintiffs are entitled to a declaratory judgment that Defendants' manufacture, importation, sale, offer for sale, use, and promotion of the use of the CT-P6 drug substance and Defendants' proposed CT-P6 drug product has infringed the '428 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

393. Defendants have had knowledge of and were aware of the '428 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of the January Action. Defendants' infringement of the '428 patent was willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor against the Defendants and grant the following relief:

a. a judgment that Celltrion has infringed or induced infringement of one or more claims of the asserted patents under 35 U.S.C. § 271(e)(2)(C);

b. a judgment that the Defendants have infringed or will infringe, or have induced or will induce infringement, of one or more claims of the asserted patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Celltrion aBLA product before the expirations of the asserted patents;

c. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins the Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with the Defendants and/or their successors or assigns from infringing the asserted patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or

importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes the asserted patents;

d. monetary damages in the event that the Defendants import or launch their biosimilar product and/or otherwise practice the patented inventions in the United States prior to the expiration of the asserted patents, including lost profits and/or a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement;

e. a judgment that the Defendants' infringement was willful and enhancement of any monetary damages pursuant to 35 U.S.C. § 284;

f. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

g. such other relief as this Court may deem just and proper.

MORRIS NICHOLS ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Genentech, Inc., City of Hope, and Hoffmann-La Roche Inc.

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Kevin Prussia
Andrew J. Danford
WILMER CUTLER PICKERING

HALE AND DORR LLP
60 State Street
Boston, MA 02109
(627) 526-6000
Robert J. Gunther Jr.
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Robert Galvin
WILMER CUTLER PICKERING
HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304
(650) 858-6000

Daralyn J. Durie
Adam R. Brausa
DURIE TANGRI LLP
217 Leidesdorff St.
San Francisco, CA 94111
(415) 362-6666

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