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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC., a Delaware corporation, BIOGEN, INC., a Delaware corporation, HOFFMANN-LA ROCHE INC., a New Jersey corporation, and CITY OF HOPE, a California not-for-profit organization, Plaintiffs, v. CELLTRION, INC., a Korean corporation, CELLTRION HEALTHCARE CO., LTD., a Korean corporation, TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICALS INTERNATIONAL GmbH, a Swiss corporation, Defendants.	Case No. **COMPLAINT FOR: PATENT INFRINGEMENT; DECLARATORY RELIEF** **DEMAND FOR JURY TRIAL**

Pursuant to Local Civil Rule 10.1, the address of Plaintiff Genentech, Inc. ("Genentech") is 1 DNA Way, South San Francisco, California, 94080. The address of Plaintiff Biogen, Inc. ("Biogen") is 225 Binney Street, Cambridge, Massachusetts, 02142. The address of Plaintiff City of Hope is 1500 East Duarte Road, Duarte, California, 91010. The address of Plaintiff Hoffmann-La Roche Inc. ("Roche") is 150 Clove Road, Little Falls, New Jersey, 07424. The address of

Defendant Celltrion, Inc. ("Celltrion") is 23, Academy-ro, Yeonsu-gu, Incheon, Korea. The address of Defendant Celltrion Healthcare, Co. Ltd. ("Celltrion Healthcare") is 23, Academy-ro, Yeonsu-gu, Incheon, Korea. The address of Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is 1090 Horsham Road, North Wales, PA 19454-1090. The address of Defendant Teva Pharmaceuticals International GmbH ("TPIG") is Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

Plaintiffs Genentech, Biogen, Roche, and City of Hope (individually or collectively, "Plaintiffs") by their undersigned attorneys, for their Complaint against Celltrion, Celltrion Healthcare, Teva, and TPIG (individually or collectively, "Defendants") allege as follows:

NATURE OF THIS ACTION

1. Plaintiffs file this new lawsuit for patent infringement under the Biologics Price Competition and Innovation Act ("BPCIA") (codified at 42 U.S.C. § 262) because Celltrion is taking the position that it has complied with the requirements of the BPCIA's so-called "patent dance" set forth at § 262(l)(2)-(l)(6). Plaintiffs' claims mirror those asserted in *Genentech, Inc. et al. v. Celltrion, Inc. et al.*, No. 18-cv-00574-RMB-KMW (D.N.J.), currently pending before this Court ("574 Celltrion Action" or "the related action").

2. On June 6, 2018, months after Celltrion repudiated the requirements of the BPCIA, and one month after Celltrion's declaratory judgment action in the Northern District of California was dismissed by Judge Jeffrey White on the ground that Celltrion had failed to comply with its statutory obligations under the BPCIA, *see Celltrion, Inc. v. Genentech, Inc.*, 2018 WL 2448254 (N.D. Cal. May 9, 2018), Celltrion improperly attempted to resurrect the patent dance. In particular, Celltrion notified Genentech of the number of patents it believed should be the subject of a patent infringement action under § 262(l)(5)(A) on June 6, 2018 and demanded that the parties exchange lists "of the patents each believes should be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6)." Out of an abundance of caution, while reserving all rights and waiving none, Genentech objected and sent a responsive letter on June 11, 2018.

3. Celltrion asserts that the parties exchanged patent lists under § 262(l)(5)(B) on June 11, 2018. If Celltrion is correct that it was permitted to resurrect the patent dance and that the June 11, 2018 exchange completes and satisfies the BPCIA requirements under § 262(l)(5), then the next step in the patent dance would require Genentech to have brought an action for infringement not later than 30 days after such exchange, which is today, July 11, 2018. *See* 42 U.S.C. § 262(l)(6).

4. Wary of filing a new lawsuit, particularly given the harsh penalties (*e.g.*, loss of right to lost profits or injunctive relief) that could apply to a patent owner under 35 U.S.C. § 271(e)(6) if an action for infringement of certain patents is dismissed without prejudice or not prosecuted to judgment in good faith, Genentech met and conferred with Celltrion and asked for clarification on whether Celltrion's position was that the BPCIA required Genentech to file a new lawsuit even though Genentech has already asserted its patents against Celltrion in the related action. Celltrion refused to engage. Rather, Celltrion responded that it was leaving it to Genentech to figure out whether any further action under the BPCIA was required. Genentech raised this issue with this Court in a June 22, 2018 letter filed in the related action.

5. Solely out of an abundance of caution, Genentech now files this new lawsuit for patent infringement against Celltrion. Genentech has designated this new lawsuit as related to the 574 Celltrion Action and will promptly file a motion to consolidate this new lawsuit with the 574 Celltrion Action in the event Celltrion declines to stipulate to such consolidation. This new action for patent infringement arises under 28 U.S.C. § 1331 and the United States Patent Act, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, seeking a declaratory judgment of patent infringement.

6. The claims for patent infringement brought in this action are necessitated by Defendants' stated intent to import, market, and sell in New Jersey and throughout the United States a copy of Genentech and Biogen's groundbreaking medicinal product, Rituxan®, which aids millions of patients in their fight against debilitating and life-threatening diseases, including blood cancers such as Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia, as well as Rheumatoid Arthritis and Vasculitis, which are chronic and painful autoimmune diseases. First

approved in 1997, Rituxan® is proven to improve both the length and quality of life for patients with these and other diseases and has been recognized internationally for its pioneering effect on patients' lives and medicine in general.

7. Such benefits and success did not come quickly or easily. Genentech and Biogen invested many years of work and many hundreds of millions of dollars into developing and testing Rituxan® and ensuring that the product is both safe and effective. Those investments include, *inter alia*, years of laborious and expensive clinical trials that were required before medical professionals could use Rituxan® to help their patients—clinical trials on which the U.S. Food and Drug Administration ("FDA") relied in making Rituxan® the first monoclonal antibody approved for therapeutic use in fighting cancer in the United States.

8. In contrast, Defendants have piggybacked on Plaintiffs' investments and success and seek to profit from a copied version of Rituxan®. Claiming that their copycat product is "biosimilar" to Rituxan®, Defendants have not borne the expense of conducting their own clinical trials—instead relying on Genentech and Biogen's costly and time-consuming proprietary clinical trials—and have applied to the FDA for approval to market and sell that product.

9. Irrespective of whether they are able to secure FDA approval for its copy of Rituxan®, however, Defendants do not have the right to infringe Plaintiffs' patents. Defendants' intended activities would unquestionably infringe many of those patents, *none* of which Plaintiffs have licensed to Defendants and *all* of which are valid and enforceable. Plaintiffs bring this action to stop that infringement.

PARTIES

10. Plaintiff Genentech, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, California, 94080.

11. Plaintiff Biogen, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 225 Binney Street, Cambridge, Massachusetts, 02142.

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

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

14. Genentech and Biogen, two pioneers of the biotechnology industry, have been discovering, developing, manufacturing, and commercializing innovative therapies to address significant unmet medical needs for more than 40 years. Collectively, they manufacture and commercialize products for a variety of medical conditions, including numerous types of cancer, Rheumatoid Arthritis, Multiple Sclerosis, and many other serious conditions. Genentech and Biogen developed and jointly market Rituxan®, the revolutionary antibody-based medicine at issue in this case.[1]

15. 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.

16. Plaintiffs regularly seek patents on inventions originating from their research and development activities, and each has been issued numerous patents relating to its proprietary

[1] Genentech initially collaborated with IDEC Pharmaceuticals, which subsequently merged with Biogen (forming Biogen-Idec) and later adopted the name Biogen. We use "Biogen" herein for simplicity.

technology. Among those patents are several that claim, *inter alia*, the manufacture and use of Rituxan®.

17. Plaintiffs are informed and believe, and on that basis allege, that Defendant Celltrion, Inc. is a corporation organized and existing under the laws of the Republic of Korea, having its principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South Korea. Plaintiffs are further informed and believe, and on that basis allege, that Celltrion is a pharmaceutical company that develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

18. Plaintiffs are informed and believe, and on that basis allege, that Defendant Celltrion Healthcare, Co. Ltd. is a corporation organized and existing under the laws of the Republic of Korea, having its principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South Korea. Plaintiffs are further informed and believe, and on that basis allege, that Celltrion Healthcare is a pharmaceutical company that develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

19. Plaintiffs are informed and believe, and on that basis allege, that Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Plaintiffs are further informed and believe, and on that basis allege, that Teva Pharmaceuticals USA, Inc. is a pharmaceutical company that, *inter alia*, develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

20. Plaintiffs are informed and believe, and on that basis allege, that Defendant Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland. Plaintiffs are further informed and believe, and on that basis allege, that Teva

Pharmaceuticals International GmbH is a pharmaceutical company that develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

JURISDICTION AND VENUE

21. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. § 1331, § 1338(a), 2201(a), and 2202 because this is a civil action arising under the Patent Act.

22. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), including because Defendants are subject to this Court's personal jurisdiction, Defendants have and/or will commit acts of infringement in this district, Celltrion, Inc., Celltrion Healthcare, Co. Ltd., and Teva Pharmaceuticals International GmbH do not reside in the United States, and Teva Pharmaceuticals USA, Inc. has regular and established places of business located in New Jersey.

A. Celltrion, Inc.

23. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion because Celltrion has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. In particular, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has taken the costly, significant step of filing an Abbreviated Biologic License Application ("aBLA") with the United States Food and Drug Administration ("FDA") seeking FDA approval of the proposed biosimilar product "Truxima" (also known under the development code "CT-P10") for the express purposes of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States.

24. Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

25. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

26. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion pursuant to Federal Rule of Civil Procedure 4(k)(2) because Celltrion has extensive contacts with the United States, including but not limited to the above-described contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Celltrion is consistent with the laws of the United States and the United States Constitution.

27. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has purposefully established commercial relationships and business dealings with several pharmaceutical companies in the United States, including Teva, Teva subsidiaries, Hospira, Inc., and Pfizer Inc. ("Pfizer"). In addition to Celltrion's aforementioned contractual relationship with Teva to market, distribute, and sell Truxima/CT-P10, Celltrion and Pfizer are, on information and belief, currently marketing the biosimilar Inflectra® in New Jersey and throughout the United States.

28. In addition, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has availed itself of the benefits of United States law by applying for and obtaining registrations for at least one trademark with the United States Patent and Trademark Office ("PTO") for the word "Truxima," which trademark Celltrion has declared its intent to use in commerce in the United States.

29. Celltrion has further availed itself of the benefits of United States law by filing with the PTO at least ten (10) *inter partes* review petitions challenging Plaintiffs' patents relating to the pioneering biological drug at issue in this case, Rituxan®.

B. Celltrion Healthcare, Co. Ltd.

30. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion Healthcare because Celltrion Healthcare has purposefully

directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. In particular, Plaintiffs are informed and believe, and on that basis allege, that Celltrion Healthcare has assisted Celltrion to aid Celltrion in filing an aBLA with the FDA seeking FDA approval of the proposed biosimilar product Truxima for the express purposes of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States. Celltrion Healthcare and Celltrion share the same principal place of business and, on information and belief, Celltrion Healthcare markets, sells, and distributes products developed by Celltrion.

31. Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

32. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

33. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion Healthcare pursuant to Federal Rule of Civil Procedure 4(k)(2) because Celltrion Healthcare has extensive contacts with the United States, including but not limited to the above-described contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Celltrion Healthcare is consistent with the laws of the United States and the United States Constitution.

C. Teva Pharmaceuticals USA, Inc.

34. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Teva because Teva has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. For example, Plaintiffs are informed and believe, and on that basis allege, that (1) Teva is registered to do business in New Jersey under Entity Identification Number 0100250184 and has appointed a registered agent in New Jersey, Corporate Creations Network Inc., 811 Church Road #105, Cherry Hill, NJ 08002;

(2) Teva is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Numbers 5000583 and 5003436; (3) Teva manufactures and distributes brand and generic drugs for sale and use throughout the United States, including in New Jersey; (4) Teva has regular and established places of business in New Jersey, where it has employees and from which it services customers in New Jersey, located at least at 8 Gloria Lane, Fairfield, New Jersey 07004; 400 Chestnut Ridge Rd, Woodcliff Lake, NJ 07677; 208 Passaic Avenue, Fairfield, New Jersey 07004; and 200 Elmora Avenue, Elizabeth, New Jersey 07202; and (5) Teva has additional facilities in New Jersey at least in Elizabeth, Newark, Ewing, Parsippany, and Woodcliff Lake, from which it engages in sales.

35. Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

36. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

37. Plaintiffs are informed and believe, and on that basis allege, that Teva has been sued and has litigated in the District of New Jersey, in connection with which it has repeatedly submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by asserting claims or counterclaims involving pharmaceutical drug patent disputes in this Judicial District in at least the following cases in the past year alone: *Teva Pharms. USA, Inc., et al. v. Sandoz Inc., et al.*, Civil Action No. 17-275; *Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 17-517; *BTG Int'l Ltd., et al. v. Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-6435; *Adapt Pharma Operations Ltd., et al. v. Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-5100; *Celgene Corp. v. Par Pharm., Inc., et al.*, Civil Action No. 17-3159; *Adapt Pharma Operations Ltd., et al.* v. *Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-2877; *Adapt Pharma Operations Ltd., et al.* v. *Teva Pharms. USA, Inc., et al.*, Civil Action

No. 17-864; *Mitsubishi Tanabe Pharma Corp., et al.* v. *MSN Labs. Private Ltd., et al.*, Civil Action No. 17-5302; *Astrazeneca Pharms. LP, et al.* v. *Teva Pharms. USA, Inc.*, Civil Action No. 17-2448.

D. Teva Pharmaceuticals International GmbH

38. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over TPIG because TPIG has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities.

39. In particular, Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

40. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

41. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over TPIG pursuant to Federal Rule of Civil Procedure 4(k)(2) because TPIG has extensive contacts with the United States, including but not limited to the above-described commercial contract, is not subject to jurisdiction in any particular state, and exercising jurisdiction over TPIG is consistent with the laws of the United States and the United States Constitution.

BACKGROUND FACTS

42. This case relates to the pioneering product Rituxan® and the duly-issued United States patents that cover the manufacture and use of that product. Rituxan® was the first monoclonal antibody approved by the FDA for therapeutic use in fighting cancer and is one of the most successful medicinal products in the world.

43. Plaintiffs are informed and believe, and on that basis allege, that (i) Defendants are engaged in the development of a proposed biosimilar copy of Rituxan®, Truxima/CT-P10, (ii) the

aBLA filed by Celltrion seeking FDA approval for Truxima/CT-P10 has named Rituxan® as the reference product that Truxima/CT-P10 is intended to copy, and (iii) the FDA has accepted Celltrion's aBLA for review.

44. Plaintiffs are informed and believe, and on that basis allege, that upon FDA approval Defendants intend to market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States as an alleged biosimilar substitute for Rituxan®.

45. As alleged herein, the manufacture, importation, use, offer for sale, and/or sale of Truxima/CT-P10 infringes one or more patents owned by Plaintiffs, who therefore bring this patent action to address Defendants' infringement and to protect the intellectual property into which they have invested innumerable resources, investments which have redounded to the benefit of the public and medicine in general.

GENENTECH AND BIOGEN'S RITUXAN® PRODUCT

46. Antibodies are produced by cells of the immune system and are an important component in the immune system's fight against foreign invaders, such as bacteria, viruses, and other microbes and pathogens. In particular, antibodies can bind (attach) to a specific molecular structure that can be present on such foreign invaders or can be present on the body's own cells. A structure to which an antibody binds is called an "antigen." By binding to specific antigens, antibodies help the immune system identify and attack the foreign invaders.

47. Although the human body creates antibodies for various antigens naturally, for several decades scientists have successfully engineered in laboratories antibodies capable of binding to a predetermined antigen, such that the antibodies can be used to develop therapeutic products that target specific medical conditions in humans.

48. In the early 1990s, after many years of research, IDEC Pharmaceuticals (which subsequently merged with Biogen) first created the antibody rituximab (then known as IDEC-C2B8). Researchers at IDEC Pharmaceuticals created rituximab in the laboratory to bind to the human CD20 antigen, a protein expressed on the surface of immune cells called B-cells. By

binding to the CD20 antigen, rituximab helps to fight diseases caused or exacerbated by B-cells, including several forms of B-cell cancer.

49. Rituximab is a "chimeric" antibody, meaning that part of its structure is derived from human genetic sequence and part is derived from mouse genetic sequence. Creating this hybrid antibody and studying it in the laboratory, however, was only the beginning of the years-long process required to create an effective yet safe human therapeutic.

50. Following the creation of rituximab, IDEC Pharmaceuticals, Genentech, and F. Hoffmann-La Roche AG, in a tri-company collaboration, spent many years and many hundreds of millions of dollars on scientific studies and clinical trials to develop that therapeutic, which is marketed under the trade name Rituxan® in the United States and MabThera® abroad. They also dedicated enormous time and resources to establish the safety and efficacy of Rituxan®, to investigate numerous ways to use Rituxan® to treat different diseases, and to determine how to manufacture Rituxan® in sufficient quantity and purity for administration to humans. For example, Rituxan® aids millions of patients in their fight against debilitating and life-threatening diseases, including Non-Hodgkin's Lymphomas (NHLs) and Chronic Lymphocytic Leukemia (CLL), both of which are blood cancers, as well as Rheumatoid Arthritis (RA) and Vasculitis, both chronic and painful autoimmune diseases. Genentech and Biogen continue to dedicate significant time and resources to their ongoing efforts to maximize the effectiveness and use of Rituxan® to benefit patients across the world.

51. Because of its effectiveness against several diseases, including several forms of cancer, Rituxan®/MabThera® has been an enormous commercial success, generating over $7 billion in worldwide revenue in 2016 alone.

52. The innovative work dedicated to creating and developing Rituxan® has been recognized repeatedly by the medical and scientific communities. For example, Rituxan® is on the World Health Organization's List of Essential Medicines (a well-recognized publication that identifies essential medicines for priority diseases) and Plaintiffs have been honored with the Trailblazers Award from the Cure for Lymphoma Foundation and with the Peter McCuen Cancer

Research Award for their groundbreaking research and development of Rituxan®.

THE BPCIA PATHWAY FOR BIOSIMILAR APPROVAL

53. In 1984, Congress created an abbreviated regulatory pathway for the approval of generic small-molecule drugs through the passage of the Hatch-Waxman Act. Small molecule drugs are made from chemicals synthesized in a laboratory and contain both a relatively small number of atoms and a specific, known chemical structure. For example, the active ingredient in aspirin, acetylsalicylic acid, has only 21 atoms. Its chemical makeup and structure is easy to identify and characterize, and it is relatively simple to copy, develop, and manufacture.

54. Biologic agents, like the rituximab antibody in Rituxan®, are much larger and more complex molecules, and are not produced by chemical synthesis in a laboratory. Rather, they are produced in, and purified from, specially modified living cells, making them extremely difficult to develop and manufacture. Whereas the small-molecule acetylsalicylic acid has only 21 atoms, a complex antibody biologic like rituximab contains about 20,000 atoms. Accordingly, the efforts and investment needed to develop a therapeutic antibody like Rituxan® are significantly greater than for a small-molecule drug like aspirin.

55. In contrast to the abbreviated regulatory pathway for generic small-molecule medicines provided in the Hatch-Waxman Act, no abbreviated pathway for approval of follow-on biologic products existed until the enactment in 2010 of the Biologics Price Competition and Innovation Act ("BPCIA") (codified at 42 U.S.C. § 262) as part of the Patient Protection and Affordable Care Act. As a result, before the enactment of the BPCIA, the only way to obtain FDA approval of a biologic product was through an original Biologic License Application ("BLA") supported by a full complement of pre-clinical and clinical study data. Genentech and Biogen underwent that long, laborious, and expensive process to obtain FDA approval for Rituxan®.

56. The BPCIA's abbreviated pathway for biologic products requires a determination that the proposed product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" as a biological product that is (1) "highly similar to

the reference product notwithstanding minor differences in clinically inactive components" and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A), (B).

57. The BPCIA defines a "reference product" to be a "single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4). Here, Rituxan® is the reference product and Truxima/CT-P10 is the proposed biosimilar.

58. Under the BPCIA, biosimilar applicants are permitted to make use of the reference product sponsor's proprietary safety and efficacy data and the FDA's prior determinations as to the safety, purity, and potency of the already-approved reference product. A biosimilar applicant must identify a single reference product that has already been approved by the FDA and submit to the FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

59. Consequently, the abbreviated regulatory pathway created by the BPCIA allows a biosimilar applicant like Celltrion to avoid the time, expense, and risks of original research and development—as well as the need to conduct a full complement of pre-clinical and clinical testing—required for the submission of an original BLA. The abbreviated pathway thus permits a biosimilar applicant like Celltrion to gain approval to commercialize its biological product much more quickly than if it had undertaken the significant activities required for submission of an original BLA.

CELLTRION'S PROPOSED BIOSIMILAR PRODUCT TRUXIMA/CT-P10

60. Plaintiffs are informed and believe, and on that basis allege, that on a date prior to June 29, 2017, Celltrion submitted to the FDA an aBLA for Truxima/CT-P10. On or about June 29, 2017, Celltrion and Teva issued a joint press release announcing that the FDA had accepted that aBLA for review. https://www.celltrion.com/en/pr/reportDetail.do?seq=436. More specifically, that press release stated that the FDA had "accepted for review the Biologics License Application

(BLA) for CT-P10, a proposed Monoclonal Antibody (mAb) biosimilar to Rituxan® (rituximab), which is used to treat patients with non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis and microscopic polyangiitis." *Id*.

61. Those listed diseases, for which Rituxan® is approved, are the same diseases for which Celltrion sought and received approval in Europe to market CT-P10. *Id*. Plaintiffs are informed and believe, and on that basis allege, that Celltrion is seeking FDA approval to treat those same diseases, i.e., those same "indications," in the United States, thereby seeking FDA approval for a proposed biosimilar copying Plaintiffs' Rituxan® while intending to market that proposed biosimilar as a substitute treatment for the same medicinal purposes.

THE BPCIA'S DISPUTE RESOLUTION PROCEDURES

62. Although the BPCIA provides for an abbreviated regulatory pathway, it does not give biosimilar applicants like Celltrion the right to infringe validly issued patents through, *inter alia*, the manufacture, use, offer for sale, sale, or importation of a biologic product—even if approved by the FDA.

63. Recognizing that valid patents might preclude such activities, the BPCIA established a set of procedures for addressing patent disputes relating to prospective biosimilar products. These procedures are set forth in 42 U.S.C. § 262(l) and 35 U.S.C. § 271 and are intended to ensure that the innovator company whose product serves as the reference product has the opportunity to enforce its patent rights before a biosimilar product enters the market. The procedures are also intended to ensure that disputes over patent rights will take place in an orderly fashion, with the least possible uncertainty, brinksmanship, and burden on the parties and the courts.

64. The BPCIA dispute resolution procedure commences when a biosimilar application is accepted for review by the FDA. Within twenty days thereafter, the biosimilar applicant "shall provide" the reference sponsor with confidential access to "a copy of the [aBLA] submitted" to

the FDA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A).

65. After the applicant provides a copy of the aBLA and the required manufacturing information, the BPCIA contemplates a series of pre-litigation exchanges—including of a "list of patents for which the reference sponsor believes a claim of patent infringement could reasonably be asserted by the reference sponsor" regarding the proposed biosimilar, *id*. at § 262(l)(3)(A)(i), and contentions regarding the alleged infringement, non-infringement, invalidity, and unenforceability of those patents, *id*. at § 262(l)(3)(B)—so that the parties may engage in good-faith negotiations over which patents should be litigated regarding the proposed biosimilar. *See id*. at § 262(l)(2)-(l)(6). These exchanges are colloquially referred to as the "patent dance."

THE PARTIES' EXCHANGES UNDER THE BPCIA

66. On June 30, 2017, after Celltrion's announcement of the FDA's acceptance for review of the aBLA for Truxima/CT-P10, Plaintiffs requested that Celltrion confirm its intention to provide a copy of that aBLA and the required manufacturing information pursuant to 42 U.S.C. § 262(l)(2)(A) so that Plaintiffs could evaluate whether Truxima/CT-P10 infringes Plaintiffs' patents. Concurrently, Plaintiffs provided Celltrion with a list of exemplary categories of information concerning processes used to manufacture a biological product such as rituximab, information Plaintiffs expected Celltrion to provide so that Plaintiffs could understand the process or processes used to manufacture Celltrion's proposed rituximab biosimilar and determine whether those processes infringe Plaintiffs' patents. In addition, Plaintiffs provided citations to exemplary patents, the content of which clarified the nature of the information Plaintiffs sought for purposes of evaluating possible infringement. A copy of Plaintiffs' letter to Celltrion is attached as Exhibit 19.

67. On or about July 17, 2017, Celltrion provided Plaintiffs with its aBLA for Truxima/CT-P10, but did not meet its obligation to provide "other information that describes the

process or processes used to manufacture" Truxima/CT-P10 as required by 42 U.S.C. § 262(l)(2)(A).

68. On August 25, 2017, after Celltrion's deadline for production under 42 U.S.C. § 262(l)(2) but prior to what would have been Plaintiffs' § 262(l)(3)(A) deadline to provide a "list of patents for which the reference sponsor believes a claim of patent infringement could reasonably be asserted by the reference sponsor" if Celltrion had complied with its obligations under 42 U.S.C. § 262(l)(2)(A), Plaintiffs again asked Celltrion to provide the required manufacturing information. Plaintiffs identified a list of missing information and, again, a list of exemplary patents. Plaintiffs informed Celltrion that—if the requested information was not received—they would assume that the cited patents, and other patents, related to the missing information could reasonably be asserted if Celltrion engaged in making, using, offering to sell, selling, or importing into the United States Truxima/CT-P10.

69. On September 6, 2017, Celltrion declined to provide any additional information.

70. On September 14, 2017, following a meet and confer, Plaintiffs again informed Celltrion that it had not complied with 42 U.S.C. § 262(l)(2)(A) and reserved all of their rights regarding Celltrion's failure to do so. Subject to and without waiver of those reservations, Plaintiffs provided Celltrion with a list of the patents Plaintiffs believed could reasonably be asserted against Truxima/CT-P10 in light of the information provided by Celltrion and given Celltrion's refusal to provide the additional, required information, including those patents that Plaintiffs believed could reasonably be asserted after a reasonable investigation or discovery ("Plaintiffs' Patent List").

71. Two months later, long after the deadline set forth by 42 U.S.C. § 262(l)(2), Celltrion finally produced more than 50,000 pages of new information that Plaintiffs had requested before the deadline. In particular, Celltrion produced such information on or about November 9, 2017, in a production accompanying its purported contentions under 42 U.S.C. § 262(l)(3)(B), alleging that patents on Plaintiffs' Patent List are invalid, unenforceable, or will not be infringed by the commercial marketing of Truxima/CT-P10. In those contentions, Celltrion cites and relies upon this late-produced information in support of non-infringement arguments, thereby

demonstrating that such information was, in fact, necessary for evaluating patent infringement and should have been provided earlier pursuant to 42 U.S.C. § 262(l)(2).

72. On January 5, 2018, Plaintiffs again informed Celltrion that it had not complied with 42 U.S.C. § 262(l)(2)(A) and reserved all of their rights regarding Celltrion's failure to do so. Subject to and without waiver of those reservations, Plaintiffs provided to Celltrion a response and detailed statement that describes, with respect to certain patents described in Celltrion's purported 42 U.S.C. § 262(l)(3)(B) list, on a claim by claim basis, the factual and legal basis of Plaintiffs' opinion that such patent will be infringed by the commercial marketing of Truxima/CT-P10 and a response to Celltrion's statement concerning validity and enforceability. In reliance on representations made by Celltrion in its contentions under 42 U.S.C. § 262(l)(3)(B), Plaintiffs omitted certain patents from its detailed statement but reserved the right to bring suit on such patents if Celltrion refused to produce evidence supporting Celltrion's factual assertions regarding non-infringement.

73. The next step in the patent dance would have been for the parties to engage in good faith negotiations to agree on which, if any, patents shall be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6). But instead of engaging in such negotiations, Celltrion repudiated them. Accordingly, even if Celltrion had complied with its obligations under 42 U.S.C. § 262(l)(2), it failed to comply with its obligations under 42 U.S.C. § 262(l)(4)-(5).

74. Celltrion provided a Notice of Commercial Marketing (the "Notice"), starting a 180-day clock before the first possible date on which Celltrion or its partners could market and/or sell its proposed biosimilar Truxima/CT-P10.

75. Celltrion's failure to provide Plaintiffs with "information that describes the process or processes used to manufacture" Truxima/CT-P10, as required by 42 U.S.C. § 262(l)(2)(A), is particularly prejudicial in light of the Notice of Commercial Marketing, i.e., in light of stated intent to begin marketing its proposed biosimilar of Rituxan® in as few as 180 days.

76. On January 11, 2018, Celltrion repudiated its obligations under the BPCIA and filed a preemptory lawsuit in the District Court of Northern California (the "California lawsuit"), docketed as *Celltrion Inc., et al.,* v. *Genentech, Inc., et al.*, Case No. 18-cv-00276-JSW.

77. With Celltrion having abandoned all pretext of participating in the patent dance, on January 12, 2018, Plaintiffs exercised their right to bring suit pursuant to 42 U.S.C. § 262(l)(9). In the alternative, and/or in addition, Plaintiffs brought suit under 35 U.S.C. § 271(e)(2). Given 42 U.S.C. § 262, Plaintiffs brought suit on all forty patents on the September 14, 2017 Patent List, out of an abundance of caution, to preserve all rights. Plaintiffs' lawsuit, the aforementioned 574 Celltrion Action, was docketed as *Genentech, Inc., et al.* v. *Celltrion, Inc., et al.*, 1:18-cv-00574-RMB-KMW. On July 5, 2018, Plaintiffs filed an amended complaint in the 574 Celltrion Action.

CELLTRION'S ATTEMPT TO RESURRECT THE BPCIA PATENT DANCE

78. On May 9, 2018, Plaintiffs successfully dismissed the California lawsuit filed by Celltrion. In granting Plaintiffs' motion to dismiss, Judge White concluded that Celltrion had not complied with its obligations under the BPCIA and was therefore barred under the BPCIA from filing its claims for declaratory judgment. *Celltrion*, 2018 WL 2448254, at *5. Judge White entered a final judgment in the California lawsuit on June 11, 2018.

79. On June 6, 2018, months after repudiating the patent dance, and nearly one month after Judge White dismissed the California lawsuit, Celltrion sent Genentech a letter purporting to "address[] expressly the patent dance steps set forth in 42 U.S.C. § 262(l)(5)(A) and 5(B)." Celltrion demanded that the parties exchange lists "of the patents each believes should be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6)."

80. While reserving all rights and waiving none, Genentech sent a responsive letter on June 11, 2018, identifying all forty patents that Plaintiffs had asserted against Defendants on January 12, 2018 in the 574 Celltrion Action. Celltrion takes the position that, pursuant to the foregoing correspondence of June 6 and June 11, the parties have now properly exchanged patent lists under 42 U.S.C. § 262(l)(5).

THIS ACTION

81. For parties that comply with the patent dance, 42 U.S.C. § 262(l)(6) requires a reference product sponsor to have brought an action for patent infringement "not later than 30 days after" the parties either agree on, or exchange competing lists of, the patents to be litigated.

82. If Celltrion successfully resurrected the patent dance and is now in compliance with the BPCIA, then § 262(l)(6) arguably requires Genentech to have brought an action for patent infringement not later than today, July 11, 2018.

83. Prior to the filing of this lawsuit, Genentech met and conferred with Celltrion and asked for clarification on whether Celltrion's position was that the BPCIA required Genentech to file a new lawsuit (as the 574 Celltrion Action had already been filed). Celltrion refused to engage. Rather, Celltrion responded that it was leaving it to Genentech to figure out whether any further action under the BPCIA was required. Genentech raised this issue with the Court in a June 22, 2018 letter in the 574 Celltrion Action.

84. Solely out of an abundance of caution, Genentech now files this new lawsuit for patent infringement against Celltrion. Genentech has designated this new lawsuit as related to the 574 Celltrion Action and will promptly file a motion to consolidate this new lawsuit with the 574 Celltrion Action in the event Celltrion declines to stipulate to such consolidation.

THE ASSERTED PATENTS

85. Plaintiffs have applied for and obtained dozens of issued patents related to Rituxan®, including regarding its therapeutic uses, its administration, its formulation, and the processes by which it is manufactured.

86. Plaintiffs' ability to evaluate Defendants' infringement of their patent estate has been hampered by Celltrion's refusal to provide, *inter alia*, manufacturing information as required by 42 U.S.C. § 262(l)(2)(A). Plaintiffs requested that information multiple times and informed Celltrion that failure to provide it would necessitate legal action. Celltrion continued to evade its statutory obligations.

87. In light of the foregoing, and reserving all rights, Plaintiffs are informed and believe to the best of their present ability, and on that basis allege, that making, using, offering to sell, selling, or importing into the United States Truxima/CT-P10 will infringe, or reasonably could infringe, the following patents (collectively, the "Asserted Patents"), each of which is owned by one or more Plaintiffs and each of which was identified on Plaintiffs' Patent List and in Genentech's responsive letter dated June 11, 2018:

- **U.S. Patent No. 6,331,415**

88. U.S. Patent No. 6,331,415 ("the '415 patent") is entitled "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, and has not expired.

89. One or more Plaintiffs have maintained the entire right, title, and interest in the '415 patent throughout the period of Defendants' infringement. A copy of the '415 patent is attached as Exhibit 1.

- **U.S. Patent No. 6,489,447**

90. U.S. Patent No. 6,489,447 ("the '447 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on December 3, 2002, and has not expired.

91. One or more Plaintiffs have maintained the entire right, title, and interest in the '447 patent throughout the period of Defendants' infringement. A copy of the '447 patent is attached as Exhibit 2.

- **U.S. Patent No. 6,610,516**

92. U.S. Patent No. 6,610,516 ("the '516 patent") is entitled "Cell Culture Process," was duly and legally issued by the Patent Office on August 26, 2003, and has not expired.

93. One or more Plaintiffs have maintained the entire right, title, and interest in the '516 patent throughout the period of Defendants' infringement. A copy of the '516 patent is attached as Exhibit 3.

- **U.S. Patent No. 6,620,918**

94. U.S. Patent No. 6,620,918 ("the '918 patent") is entitled "Separation of Polypeptide Monomers," was duly and legally issued by the Patent Office on September 16, 2003, and has not expired.

95. One or more Plaintiffs have maintained the entire right, title, and interest in the '918 patent throughout the period of Defendants' infringement. A copy of the '918 patent is attached as Exhibit 4.

- **U.S. Patent No. 7,381,560**

96. U.S. Patent No. 7,381,560 ("the '560 patent") is entitled "Expression and Use of Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on June 3, 2008, and has not expired.

97. One or more Plaintiffs have maintained the entire right, title, and interest in the '560 patent throughout the period of Defendants' infringement. A copy of the '560 patent is attached as Exhibit 5.

- **U.S. Patent No. 7,485,704**

98. U.S. Patent No. 7,485,704 ("the '704 patent") is entitled "Reducing Protein A Leaching during Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on February 3, 2009, and has not expired.

99. One or more Plaintiffs have maintained the entire right, title, and interest in the '704 patent throughout the period of Defendants' infringement. A copy of the '704 patent is attached as Exhibit 6.

- **U.S. Patent No. 7,807,799**

100. U.S. Patent No. 7,807,799 ("the '799 patent") is entitled "Reducing Protein A Leaching during Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on October 5, 2010, and has not expired.

101. One or more Plaintiffs have maintained the entire right, title, and interest in the ’799 patent throughout the period of Defendants’ infringement. A copy of the ’799 patent is attached as Exhibit 7.

- **U.S. Patent No. 7,820,161**

102. U.S. Patent No. 7,820,161 (“the ’161 patent”) is entitled “Treatment of Autoimmune Diseases,” was duly and legally issued by the Patent Office on October 26, 2010, and has not expired.

103. One or more Plaintiffs have maintained the entire right, title, and interest in the ’161 patent throughout the period of Defendants’ infringement. A copy of the ’161 patent is attached as Exhibit 8.

- **U.S. Patent No. 7,923,221**

104. U.S. Patent No. 7,923,221 (“the ’221 patent”) is entitled “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, and has not expired.

105. One or more Plaintiffs have maintained the entire right, title, and interest in the ’221 patent throughout the period of Defendants’ infringement. A copy of the ’221 patent is attached as Exhibit 9.

- **U.S. Patent No. 7,976,838**

106. U.S. Patent No. 7,976,838 (“the ’838 patent”) is entitled “Therapy of Autoimmune Disease in a Patient with an Inadequate Response to a TNF-α inhibitor,” was duly and legally issued by the Patent Office on July 12, 2011, and has not expired.

107. One or more Plaintiffs have maintained the entire right, title, and interest in the ’838 patent throughout the period of Defendants’ infringement. A copy of the ’838 patent is attached as Exhibit 10.

- **U.S. Patent No. 8,206,711**

108. U.S. Patent No. 8,206,711 ("the '711 patent") is entitled "Treatment of Chronic Lymphocytic Leukemia using Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on June 26, 2012, and has not expired.

109. One or more Plaintiffs have maintained the entire right, title, and interest in the '711 patent throughout the period of Defendants' infringement. A copy of the '711 patent is attached as Exhibit 11.

- **U.S. Patent No. 8,329,172**

110. U.S. Patent No. 8,329,172 ("the '172 patent") is entitled "Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibody," was duly and legally issued by the Patent Office on December 11, 2012, and has not expired.

111. One or more Plaintiffs have maintained the entire right, title, and interest in the '172 patent throughout the period of Defendants' infringement. A copy of the '172 patent is attached as Exhibit 12.

- **U.S. Patent No. 8,545,843**

112. U.S. Patent No. 8,545,843 ("the '843 patent") is entitled "Treatment of Vasculitis," was duly and legally issued by the Patent Office on October 1, 2013, and has not expired.

113. One or more Plaintiffs have maintained the entire right, title, and interest in the '843 patent throughout the period of Defendants' infringement. A copy of the '843 patent is attached as Exhibit 13.

- **U.S. Patent No. 8,557,244**

114. U.S. Patent No. 8,557,244 ("the '244 patent") is entitled "Treatment of Aggressive Non-Hodgkins Lymphoma with Anti-CD20 Antibody," was duly and legally issued by the Patent Office on October 15, 2013, and has not expired.

115. One or more Plaintiffs have maintained the entire right, title, and interest in the '244 patent throughout the period of Defendants' infringement. A copy of the '244 patent is attached as Exhibit 14.

- **U.S. Patent No. 8,574,869**

116. U.S. Patent No. 8,574,869 ("the '869 patent") is entitled "Prevention of Disulfide Bond Reduction during Recombinant Production of Polypeptides," was duly and legally issued by the Patent Office on November 5, 2013, and has not expired.

117. One or more Plaintiffs have maintained the entire right, title, and interest in the '869 patent throughout the period of Defendants' infringement. A copy of the '869 patent is attached as Exhibit 15.

- **U.S. Patent No. 8,821,873**

118. U.S. Patent No. 8,821,873 ("the '873 patent") is entitled "Treatment of Diffuse Large-cell Lymphoma with Anti-CD20 Antibody," was duly and legally issued by the Patent Office on September 2, 2014, and has not expired.

119. One or more Plaintiffs have maintained the entire right, title, and interest in the '873 patent throughout the period of Defendants' infringement. A copy of the '873 patent is attached as Exhibit 16.

- **U.S. Patent No. 9,296,821**

120. U.S. Patent No. 9,296,821 ("the '821 patent") is entitled "Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on March 29, 2016, and has not expired.

121. One or more Plaintiffs have maintained the entire right, title, and interest in the '821 patent throughout the period of Defendants' infringement. A copy of the '821 patent is attached as Exhibit 17.

- **U.S. Patent No. 9,504,744**

122. U.S. Patent No. 9,504,744 ("the '744 patent") is entitled "Treatment of Diffuse Large-cell Lymphoma with Anti-CD20 Antibody," was duly and legally issued by the Patent Office on November 29, 2016, and has not expired.

123. One or more Plaintiffs have maintained the entire right, title, and interest in the ’744 patent throughout the period of Defendants’ infringement. A copy of the ’744 patent is attached as Exhibit 18.

COUNT 1

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,331,415)

124. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 123 as if fully set forth herein.

125. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

126. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

127. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’415 patent.

128. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

129. The ’415 patent claims compositions used in and methods of making a therapeutic antibody product such as Truxima/CT-P10.

130. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’415 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

131. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

132. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '415 patent.

COUNT 2

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,489,447)

133. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 132 as if fully set forth herein.

134. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

135. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

136. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '447 patent.

137. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

138. The '447 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

139. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '447 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

140. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

141. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '447 patent.

COUNT 3

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,610,516)

142. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 141 as if fully set forth herein.

143. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

144. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

145. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '516 patent.

146. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

147. The '516 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

148. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’516 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

149. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

150. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’516 patent.

COUNT 4

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,620,918)

151. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 150 as if fully set forth herein.

152. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

153. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

154. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’918 patent.

155. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

156. The ’918 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

157. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’918 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

158. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

159. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’918 patent.

COUNT 5

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,381,560)

160. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 159 as if fully set forth herein.

161. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

162. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

163. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’560 patent.

164. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

165. The '560 patent claims compositions used in and methods of making a therapeutic antibody product such as Truxima/CT-P10.

166. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '560 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

167. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

168. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '560 patent.

COUNT 6

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,485,704)

169. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 168 as if fully set forth herein.

170. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

171. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

172. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’704 patent.

173. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

174. The ’704 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

175. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’704 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

176. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

177. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’704 patent.

COUNT 7

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,807,799)

178. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 177 as if fully set forth herein.

179. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

180. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and

when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

181. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’799 patent.

182. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

183. The ’799 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

184. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’799 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

185. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

186. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’799 patent.

COUNT 8

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,820,161)

187. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 186 as if fully set forth herein.

188. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

189. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

190. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '161 patent.

191. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

192. The '161 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

193. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '161 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

194. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

195. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '161 patent.

COUNT 9

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,923,221)

196. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 195 as if fully set forth herein.

197. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

198. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

199. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '221 patent.

200. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

201. The '221 patent claims compositions used in and methods of making a therapeutic antibody product such as Truxima/CT-P10.

202. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '221 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

203. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

204. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '221 patent.

COUNT 10

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,976,838)

205. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 204 as if fully set forth herein.

206. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

207. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

208. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '838 patent.

209. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

210. The '838 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

211. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '838 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

212. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

213. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless

Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’838 patent.

COUNT 11

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,206,711)

214. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 213 as if fully set forth herein.

215. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

216. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

217. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’711 patent.

218. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

219. The ’711 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

220. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’711 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

221. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

222. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '711 patent.

COUNT 12

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,172)

223. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 222 as if fully set forth herein.

224. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

225. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

226. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '172 patent.

227. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

228. The '172 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

229. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '172 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

230. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

231. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '172 patent.

COUNT 13

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,545,843)

232. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 231 as if fully set forth herein.

233. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

234. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

235. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '843 patent.

236. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

237. The '843 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

238. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’843 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

239. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

240. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’843 patent.

COUNT 14

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,557,244)

241. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 240 as if fully set forth herein.

242. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

243. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

244. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’244 patent.

245. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

246. The ’244 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

247. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’244 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

248. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

249. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’244 patent.

COUNT 15

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,574,869)

250. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 249 as if fully set forth herein.

251. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

252. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

253. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’869 patent.

254. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

255. The '869 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

256. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '869 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

257. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

258. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '869 patent.

COUNT 16

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,821,873)

259. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 258 as if fully set forth herein.

260. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

261. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

262. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '873 patent.

263. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

264. The '873 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

265. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '873 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

266. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

267. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '873 patent.

COUNT 17

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,296,821)

268. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 267 as if fully set forth herein.

269. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

270. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and

when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

271. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '821 patent.

272. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

273. The '821 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

274. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '821 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

275. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

276. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '821 patent.

COUNT 18

(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,504,744)

277. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 276 as if fully set forth herein.

278. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

279. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

280. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '744 patent.

281. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

282. The '744 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

283. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '744 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

284. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

285. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '744 patent.

COUNT 19

(INFRINGEMENT OF U.S. PATENT NO. 6,331,415 UNDER 35 U.S.C. § 271(E)(2))

286. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 285 as if fully set forth herein.

287. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

288. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

289. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

290. In the alternative and/or in addition to the declaratory judgment of infringement in Count 1, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '415 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

291. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '415 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

292. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '415 patent, with knowledge that the resulting conduct would infringe one or more claims of the '415 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '415 patent.

293. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’415 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

294. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’415 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’415 patent.

295. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’415 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’415 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’415 patent.

296. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

297. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’415 patent. *See* 35 U.S.C. § 271(e)(4)(B).

298. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’415 patent and its infringement thereof, Defendants willfully,

wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

299. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '415 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 20

(INFRINGEMENT OF U.S. PATENT NO. 6,489,447 UNDER 35 U.S.C. § 271(E)(2))

300. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 299 as if fully set forth herein.

301. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

302. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

303. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

304. In the alternative and/or in addition to the declaratory judgment of infringement in Count 2, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '447 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

305. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the ’447 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

306. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’447 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’447patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’447 patent.

307. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’447 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

308. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’447 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’447 patent.

309. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’447 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’447 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’447 patent.

310. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

311. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '447 patent. *See* 35 U.S.C. § 271(e)(4)(B).

312. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '447 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

313. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '447 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 21

(INFRINGEMENT OF U.S. PATENT NO. 6,610,516 UNDER 35 U.S.C. § 271(E)(2))

314. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 313 as if fully set forth herein.

315. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

316. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

317. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and

when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

318. In the alternative and/or in addition to the declaratory judgment of infringement in Count 3, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '516 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

319. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '516 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

320. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '516 patent, with knowledge that the resulting conduct would infringe one or more claims of the '516 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '516 patent.

321. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '516 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

322. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '516 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or

under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '516 patent.

323. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '516 patent, with knowledge that the resulting conduct would infringe one or more claims of the '516 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '516 patent.

324. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

325. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '516 patent. *See* 35 U.S.C. § 271(e)(4)(B).

326. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '516 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

327. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '516 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 22

(INFRINGEMENT OF U.S. PATENT NO. 6,620,918 UNDER 35 U.S.C. § 271(E)(2))

328. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 327 as if fully set forth herein.

329. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

330. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

331. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

332. In the alternative and/or in addition to the declaratory judgment of infringement in Count 4, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

333. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '918 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

334. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’918 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’918 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’918 patent.

335. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’918 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

336. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’918 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’918 patent.

337. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’918 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’918 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’918 patent.

338. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

339. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or

participation with them, are enjoined from any and all activities that would infringe the claims of the ’918 patent. *See* 35 U.S.C. § 271(e)(4)(B).

340. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’918 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

341. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’918 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 23

(INFRINGEMENT OF U.S. PATENT NO. 7,381,560 UNDER 35 U.S.C. § 271(E)(2))

342. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 341 as if fully set forth herein.

343. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

344. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion’s aBLA for review on or about June 27, 2017.

345. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

346. In the alternative and/or in addition to the declaratory judgment of infringement in Count 5, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the ’560 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for

Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

347. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '560 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

348. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '560 patent, with knowledge that the resulting conduct would infringe one or more claims of the '560 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '560 patent.

349. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '560 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

350. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '560 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '560 patent.

351. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '560 patent, with knowledge that the resulting conduct would infringe one or more claims of the

’560 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’560 patent.

352. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

353. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’560 patent. *See* 35 U.S.C. § 271(e)(4)(B).

354. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’560 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

355. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’560 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 24

(INFRINGEMENT OF U.S. PATENT NO. 7,485,704 UNDER 35 U.S.C. § 271(E)(2))

356. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 355 as if fully set forth herein.

357. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

358. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

359. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

360. In the alternative and/or in addition to the declaratory judgment of infringement in Count 6, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '704 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

361. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '704 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

362. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '704 patent, with knowledge that the resulting conduct would infringe one or more claims of the '704 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '704 patent.

363. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '704 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by

numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

364. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '704 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '704 patent.

365. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '704 patent, with knowledge that the resulting conduct would infringe one or more claims of the '704 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '704 patent.

366. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

367. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '704 patent. *See* 35 U.S.C. § 271(e)(4)(B).

368. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '704 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

369. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '704 patent justifies an injunction and an award

to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 25

(INFRINGEMENT OF U.S. PATENT NO. 7,807,799 UNDER 35 U.S.C. § 271(E)(2))

370. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 369 as if fully set forth herein.

371. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

372. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

373. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

374. In the alternative and/or in addition to the declaratory judgment of infringement in Count 7, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '799 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

375. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '799 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

376. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’799 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’799 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’799 patent.

377. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’799 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

378. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’799 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’799 patent.

379. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’799 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’799 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’799 patent.

380. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

381. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless

Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’799 patent. *See* 35 U.S.C. § 271(e)(4)(B).

382. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’799 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

383. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’799 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 26

(INFRINGEMENT OF U.S. PATENT NO. 7,820,161 UNDER 35 U.S.C. § 271(E)(2))

384. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 383 as if fully set forth herein.

385. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

386. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion’s aBLA for review on or about June 27, 2017.

387. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

388. In the alternative and/or in addition to the declaratory judgment of infringement in Count 8, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed

one or more claims of the ’161 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

389. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the ’161 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

390. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’161 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’161 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’161 patent.

391. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’161 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

392. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’161 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’161 patent.

393. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the

’161 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’161 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’161 patent.

394. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

395. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’161 patent. *See* 35 U.S.C. § 271(e)(4)(B).

396. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’161 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

397. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’161 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 27

(INFRINGEMENT OF U.S. PATENT NO. 7,923,221 UNDER 35 U.S.C. § 271(E)(2))

398. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 397 as if fully set forth herein.

399. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial

manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

400. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

401. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

402. In the alternative and/or in addition to the declaratory judgment of infringement in Count 9, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '221 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

403. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '221 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

404. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '221 patent, with knowledge that the resulting conduct would infringe one or more claims of the '221 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '221 patent.

405. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '221 patent, including because Celltrion has

extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

406. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '221 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '221 patent.

407. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '221 patent, with knowledge that the resulting conduct would infringe one or more claims of the '221 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '221 patent.

408. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

409. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '221 patent. *See* 35 U.S.C. § 271(e)(4)(B).

410. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '221 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

411. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '221 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 28

(INFRINGEMENT OF U.S. PATENT NO. 7,976,838 UNDER 35 U.S.C. § 271(E)(2))

412. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 411 as if fully set forth herein.

413. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

414. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

415. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

416. In the alternative and/or in addition to the declaratory judgment of infringement in Count 10, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '838 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

417. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '838 patent by actively inducing infringement of one

or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

418. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’838 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’838 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’838 patent.

419. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’838 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

420. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’838 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’838 patent.

421. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’838 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’838 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’838 patent.

422. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

423. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '838 patent. *See* 35 U.S.C. § 271(e)(4)(B).

424. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '838 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

425. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '838 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 29

(INFRINGEMENT OF U.S. PATENT NO. 8,206,711 UNDER 35 U.S.C. § 271(E)(2))

426. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 425 as if fully set forth herein.

427. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

428. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

429. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

430. In the alternative and/or in addition to the declaratory judgment of infringement in Count 11, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '711 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

431. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '711 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

432. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '711 patent, with knowledge that the resulting conduct would infringe one or more claims of the '711 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '711 patent.

433. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '711 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

434. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '711 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '711 patent.

435. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’711 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’711 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’711 patent.

436. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

437. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’711 patent. *See* 35 U.S.C. § 271(e)(4)(B).

438. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’711 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

439. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’711 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 30

(INFRINGEMENT OF U.S. PATENT NO. 8,329,172 UNDER 35 U.S.C. § 271(E)(2))

440. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 439 as if fully set forth herein.

441. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

442. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

443. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

444. In the alternative and/or in addition to the declaratory judgment of infringement in Count 12, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '172 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

445. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '172 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

446. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '172 patent, with knowledge that the resulting conduct would infringe one or more claims of the '172 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '172 patent.

447. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’172 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

448. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’172 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’172 patent.

449. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’172 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’172 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’172 patent.

450. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

451. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’172 patent. *See* 35 U.S.C. § 271(e)(4)(B).

452. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’172 patent and its infringement thereof, Defendants willfully,

wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

453. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '172 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 31

(INFRINGEMENT OF U.S. PATENT NO. 8,545,843 UNDER 35 U.S.C. § 271(E)(2))

454. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 453 as if fully set forth herein.

455. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

456. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

457. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

458. In the alternative and/or in addition to the declaratory judgment of infringement in Count 13, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '843 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

459. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '843 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

460. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '843 patent, with knowledge that the resulting conduct would infringe one or more claims of the '843 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '843 patent.

461. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '843 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

462. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '843 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '843 patent.

463. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '843 patent, with knowledge that the resulting conduct would infringe one or more claims of the '843 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '843 patent.

464. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants'

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

465. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '843 patent. *See* 35 U.S.C. § 271(e)(4)(B).

466. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '843 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

467. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '843 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 32

(INFRINGEMENT OF U.S. PATENT NO. 8,557,244 UNDER 35 U.S.C. § 271(E)(2))

468. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 467 as if fully set forth herein.

469. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

470. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

471. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and

when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

472. In the alternative and/or in addition to the declaratory judgment of infringement in Count 14, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '244 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

473. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '244 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

474. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '244 patent, with knowledge that the resulting conduct would infringe one or more claims of the '244 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '244 patent.

475. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '244 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

476. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '244 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or

under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '244 patent.

477. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '244 patent, with knowledge that the resulting conduct would infringe one or more claims of the '244 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '244 patent.

478. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

479. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '244 patent. *See* 35 U.S.C. § 271(e)(4)(B).

480. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '244 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

481. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '244 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 33

(INFRINGEMENT OF U.S. PATENT NO. 8,574,869 UNDER 35 U.S.C. § 271(E)(2))

482. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 481 as if fully set forth herein.

483. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

484. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

485. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

486. In the alternative and/or in addition to the declaratory judgment of infringement in Count 15, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

487. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '869 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

488. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’869 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’869 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’869 patent.

489. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’869 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

490. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’869 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’869 patent.

491. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’869 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’869 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’869 patent.

492. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

493. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or

participation with them, are enjoined from any and all activities that would infringe the claims of the ’869 patent. *See* 35 U.S.C. § 271(e)(4)(B).

494. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’869 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

495. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’869 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 34

(INFRINGEMENT OF U.S. PATENT NO. 8,821,873 UNDER 35 U.S.C. § 271(E)(2))

496. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 495 as if fully set forth herein.

497. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

498. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion’s aBLA for review on or about June 27, 2017.

499. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

500. In the alternative and/or in addition to the declaratory judgment of infringement in Count 16, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the ’873 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for

Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

501. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '873 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

502. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '873 patent, with knowledge that the resulting conduct would infringe one or more claims of the '873 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '873 patent.

503. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '873 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

504. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '873 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '873 patent.

505. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '873 patent, with knowledge that the resulting conduct would infringe one or more claims of the

’873 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’873 patent.

506. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

507. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’873 patent. *See* 35 U.S.C. § 271(e)(4)(B).

508. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’873 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

509. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’873 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

COUNT 35

(INFRINGEMENT OF U.S. PATENT NO. 9,296,821 UNDER 35 U.S.C. § 271(E)(2))

510. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 509 as if fully set forth herein.

511. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

512. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

513. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

514. In the alternative and/or in addition to the declaratory judgment of infringement in Count 17, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '821 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

515. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '821 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

516. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '821 patent, with knowledge that the resulting conduct would infringe one or more claims of the '821 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '821 patent.

517. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '821 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by

numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

518. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '821 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '821 patent.

519. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '821 patent, with knowledge that the resulting conduct would infringe one or more claims of the '821 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '821 patent.

520. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

521. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '821 patent. *See* 35 U.S.C. § 271(e)(4)(B).

522. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '821 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

523. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '821 patent justifies an injunction and an award

to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

COUNT 36

(INFRINGEMENT OF U.S. PATENT NO. 9,504,744 UNDER 35 U.S.C. § 271(E)(2))

524. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 523 as if fully set forth herein.

525. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

526. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

527. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

528. In the alternative and/or in addition to the declaratory judgment of infringement in Count 18, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '744 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

529. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '744 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

530. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the ’744 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’744 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’744 patent.

531. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the ’744 patent, including because Celltrion has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs’ Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

532. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the ’744 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion’s infringement of the ’744 patent.

533. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the ’744 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’744 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’744 patent.

534. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

535. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless

Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the ’744 patent. *See* 35 U.S.C. § 271(e)(4)(B).

536. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’744 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

537. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’744 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. A declaration that the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the Asserted Patents;

B. A declaration that the Asserted Patents are valid and enforceable;

C. An award of damages pursuant to 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

D. A declaration that Defendants’ infringement was willful and deliberate, an injunction, and a three-fold increase in the award of any damages in accordance with 35 U.S.C. § 284;

E. An award for an accounting of damages from Defendants’ infringement;

F. Preliminary and/or permanent injunctive relief, including pursuant to 35 U.S.C. § 271(e)(4)(B), including an order that Defendants and any of their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, and other persons in active concert or participation with any of them directly and/or indirectly, be preliminarily and permanently enjoined from infringing, inducing others to infringe, or contributing to the infringement of the Asserted Patents;

G. An award to Plaintiffs of their costs and reasonable expenses to the fullest extent permitted by law;

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

I. An award of such other and further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand trial by jury of all issues so triable by a jury in this action.

Dated: July 11, 2018 *Of Counsel:* David I. Gindler Gary N. Frischling Keith A. Orso IRELL & MANELLA LLP 1800 Avenue of the Stars, Suite 900 Los Angeles, CA 90067 Telephone: (310) 277-1010	By: */s/ Keith J. Miller* Keith J. Miller, Esq. ROBINSON MILLER LLC One Newark Center, 19th Floor Newark, NJ 07102 Telephone: (973) 690-5400 kmiller@rwmlegal.com *Attorneys for Plaintiffs Genentech, Inc., Biogen, Inc., Hoffmann-La Roche Inc., and City of Hope*