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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC., HOFFMANN-LA ROCHE INC., and BIOGEN INC. Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES SA, DR. REDDY'S LABORATORIES LTD., FRESENIUS KABI USA, LLC, FRESENIUS KABI SWISSBIOSIM GmbH, and FRESENIUS KABI DEUTSCHLAND GmbH, Defendants.	C.A. No. _____ **JURY TRIAL REQUESTED**

COMPLAINT FOR PATENT INFRINGEMENT

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 Hoffmann-La Roche Inc. ("HLR") is 150 Clove Road, Little Falls, New Jersey, 07424. The address of Plaintiff Biogen Inc. ("Biogen") is 225 Binney Street, Cambridge, Massachusetts, 02142. The address of Defendant Dr. Reddy's Laboratories SA ("DRL SA") is Elisabethenanlage 11, CH-4051 Basel, Switzerland. The address of Defendant Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is 107 College Road East, Princeton, NJ 08540. USA. The address of Defendant Dr. Reddy's Laboratories, Ltd.

("DRL Ltd.") is 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. The Dr. Reddy's Laboratories entities are individually and collectively referred to as "DRL." The address of Defendant Fresenius Kabi USA, LLC ("Fresenius USA") is Three Corporate Drive, Lake Zurich, Illinois 60047. The address of Defendant Fresenius Kabi Swissbiosim GmbH ("Fresenius Switzerland") is Terre Bonne Business Park, Route de Crassier 23 – Bâtiment A3, 1262 Eysins, Switzerland. The address of Defendant Fresenius Kabi Deutschland GmbH ("Fresenius Germany") is Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany. The Fresenius entities are individually and collectively referred to as "Fresenius."

Plaintiffs Genentech, HLR, and Biogen (collectively, "Plaintiffs") by their undersigned attorneys, for their Complaint against Defendants allege as follows:

OVERVIEW OF THE ACTION

1. This is an action for patent infringement arising 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.

2. 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 Plaintiffs' 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 serious diseases and has been recognized internationally for its pioneering effect on patients' lives and medicine in general.

3. Such benefits and success did not come quickly or easily. Plaintiffs invested many years of work and 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.

4. 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 research and are attempting to profit off of Plaintiffs' hard-earned success and intellectual property.

5. Defendants do not have the right to infringe Plaintiffs' patents relating to the manufacture and use of Rituxan®. Defendants' intended activities would unquestionably infringe many of those patents, none of which has been licensed to Defendants and all of which are valid and enforceable. Plaintiffs bring this action to stop that infringement.

PARTIES

6. Genentech is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080.

7. HLR is a corporation organized under the laws of the state of New Jersey, with its principal place of business at 150 Clove Road, Little Falls, New Jersey, 07424.

8. Biogen is a corporation organized under the laws of the state of Delaware with its principal place of business at 225 Binney Street, Cambridge, Massachusetts 02142.

9. Plaintiffs are 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. Plaintiffs jointly developed and market Rituxan®, the revolutionary antibody-based medicine at issue in this case.

10. Plaintiffs are informed and believe that Defendant DRL Inc. is a corporation organized and existing under the laws of the state of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. Plaintiffs are informed and believe that DRL Inc. is a wholly owned subsidiary of DRL Ltd.

11. Plaintiffs are informed and believe that Defendant DRL SA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Elisabethenanlage 11, CH-4051 Basel, Switzerland. Plaintiffs are informed and believe that DRL SA is a wholly owned subsidiary of DRL Ltd.

12. Plaintiffs are informed and believe that Defendant DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

13. Plaintiffs are informed and believe that Defendant Fresenius USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

14. Plaintiffs are informed and believe that Defendant Fresenius Switzerland is a corporation organized and existing under the laws of Switzerland, having a principal place of

business at Terre Bonne Business Park, Route de Crassier 23 – Bâtiment A3, 1262 Eysins, Switzerland.

15. Plaintiffs are informed and believe that Defendant Fresenius Germany is a corporation organized and existing under the laws of Germany, having a principal place of business at Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany.

JURISDICTION AND VENUE

16. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

A. DRL SA

17. DRL SA is subject to personal jurisdiction in New Jersey because, *inter alia*, Plaintiffs are informed and believe, and on that basis allege that DRL SA has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court. In particular, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has taken the costly, significant step of filing an Abbreviated Biologic License Application ("aBLA") with the FDA seeking FDA approval of the proposed biosimilar of Rituxan® called DRL_RI for the express purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States.

18. Plaintiffs are informed and believe, and on that basis allege, that DRL has entered into a commercial, contractual relationship with Fresenius for the purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States. For example, Plaintiffs are informed and believe, and on that basis allege, that DRL has purposefully established commercial relationships and business dealings with several pharmaceutical companies in the

United States, including Fresenius. *See* Fresenius March 2022 Company Presentation (Exhibit 16) at 40 ("Kabi entered into an exclusive license agreement with Dr. Reddy's to commercialize Rituximab in the US.").

19. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves DRL SA's aBLA for DRL_RI, Defendants will market, distribute, and sell DRL_RI in New Jersey and throughout the United States.

20. DRL SA has also consented to or did not contest personal jurisdiction and has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in this District, for example, in *Bausch & Lomb Inc. et al v. Slayback Pharma LLC et al.*, Civil Action No. 3:23-cv-2454 (D.N.J. June 30, 2023).

21. Additionally, and in the alternative, this Court has personal jurisdiction over DRL SA under Federal Rule of Civil Procedure 4(k)(2) because Plaintiffs' claim arises under federal law, DRL SA is a foreign defendant that is not subject to general personal jurisdiction in any state, and DRL SA has sufficient contacts with the United States as a whole, including but not limited to the above-described contacts such that this Court's exercise of jurisdiction over DRL SA satisfies due process.

22. Venue is proper in this Court with respect to DRL SA because it is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

B. DRL Ltd.

23. DRL Ltd. is subject to personal jurisdiction in New Jersey because, *inter alia*, Plaintiffs are informed and believe, and on that basis allege that DRL Ltd. itself, and through DRL Inc., purposely availed itself of the benefits and protections of New Jersey laws such that it should

reasonably anticipate being sued in this Court. Plaintiffs are informed and believe, and on that basis allege that DRL Ltd. was and is actively involved with planning the development, manufacture and launch of DRL_RI. In particular, Plaintiffs are informed and believe, and on that basis allege, that DRL Ltd. has assisted DRL SA in filing an aBLA with the FDA seeking FDA approval of the proposed biosimilar product DRL_RI for the express purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States.

24. Plaintiffs are informed and believe that DRL Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in at least the following actions: *Eisai Management Co., Ltd., et al. v. Dr. Reddy's Laboratories Inc., et al.*, Civil Action No. 2:22-cv-5950 (D.N.J. Jan. 6, 2023); *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 2:21-cv-2111 (D.N.J. Apr. 23, 2021); *Horizon Medicines LLC, et al. v. Dr. Reddy's Laboratories Inc., et al.*, Civil Action No. 2:15-cv-3324 (D.N.J. July 29, 2020); *Merck Sharp & Dohme B.V., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 2:20-cv-2909 (D.N.J. June 8, 2020).

25. Additionally, and in the alternative, this Court has personal jurisdiction over DRL Ltd. under Federal Rule of Civil Procedure 4(k)(2) because Plaintiffs' claims arise under federal law, DRL Ltd. is a foreign defendant that is not subject to general personal jurisdiction in any state, and DRL Ltd. has sufficient contacts with the United States as a whole, including but not limited to, collaborating with other Defendants in concert to manufacture, offer to sell, and sell DRL_RI through its U.S. affiliates and agents that are distributed throughout the United States, such that this Court's exercise of jurisdiction over DRL Ltd. satisfies due process.

26. Venue is proper in this Court with respect to DRL Ltd. because it is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

C. DRL Inc.

27. This Court has personal jurisdiction over DRL Inc. because, *inter alia*, DRL Inc.'s principal place of business is in New Jersey and its contacts with the state are so continuous and systematic as to render it essentially at home in New Jersey. DRL Inc. has availed itself of the legal protections of New Jersey by, among other things, maintaining its principal place of business in New Jersey, registering to do business in New Jersey, and conducting operations related to the manufacturing, marketing, and/or selling of pharmaceutical biosimilar products in New Jersey.

28. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over DRL Inc. because DRL Inc. has assisted DRL SA in filing an aBLA with the FDA seeking approval of the proposed biosimilar product DRL_RI for the express purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States.

29. DRL Inc. has consented to or did not contest personal jurisdiction and has availed itself of the rights, benefits, and privileges of this Court by previously initiating litigation in this District, for example, in *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products LP et al.*, Civil Action No. 2:14-cv-03230 (D.N.J. May 20, 2014).

30. Venue is proper in this Court with respect to DRL Inc. pursuant to 28 U.S.C. § 1400(b) because, Plaintiffs are informed and believe that DRL Inc. has a regular and established place of business, in this judicial district at 107 College Road East, Princeton, New Jersey 08540.

D. Fresenius USA

31. Fresenius USA is subject to personal jurisdiction in New Jersey because, *inter alia*, Plaintiffs are informed and believe, Fresenius USA has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court. Plaintiffs are informed and believe, and on that basis allege that Fresenius USA develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

32. In particular, Plaintiffs are informed and believe, and on that basis allege, that Fresenius USA in concert with DRL SA, has taken the costly, significant step of filing an aBLA with the FDA seeking FDA approval of the proposed biosimilar product DRL_RI for the express purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States.

33. Plaintiffs are informed and believe, and on that basis allege that Fresenius USA has consented to jurisdiction and venue in New Jersey in one or more prior cases and/or has filed counterclaims in such cases. *See, e.g., Pacira Pharmaceuticals, Inc. et al., v. Evenus Pharmaceuticals Laboratories, Inc. et al.*, Civil Action No. 2:23-cv-02367 (D.N.J. July 24, 2023); *Merck Sharp & Dohme BV, et al. v. Fresenius Kabi USA, LLC et al.*, Civil Action No. 2:20-cv-02892(D.N.J. June 8, 2020); *Boehringer Ingelheim Pharm., Inc. et al. v. Fresenius Kabi USA, LLC et al.*, Civil Action No. 3:18-cv-03244 (D.N.J. Mar. 28, 2018).

E. Fresenius Switzerland

34. Fresenius Switzerland is subject to personal jurisdiction in New Jersey because, *inter alia*, Plaintiffs are informed and believe that Fresenius Switzerland purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

35. Plaintiffs are informed and believe, and on that basis allege that Fresenius Switzerland was and is actively involved with planning the development, manufacture and launch of DRL_RI. In particular, Plaintiffs are informed and believe, and on that basis allege, that Fresenius Switzerland has assisted DRL SA in filing an aBLA with the FDA seeking FDA approval of the proposed biosimilar product DRL_RI for the express purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States.

36. Plaintiffs are informed and believe, and on that basis allege that Fresenius Switzerland has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in at least the following action: *La Jolla Pharmaceutical Company et al. v. Gland Pharma Limited et al.*, Civil Action No. 2:22-cv-01754 (D.N.J. April 14, 2023).

37. Additionally, and in the alternative, this Court has personal jurisdiction over Fresenius Switzerland under Federal Rule of Civil Procedure 4(k)(2) because Plaintiffs' claim arises under federal law, Fresenius Switzerland is a foreign defendant that is not subject to general personal jurisdiction in any state, and Fresenius Switzerland has sufficient contacts with the United States as a whole, including but not limited to, collaborating with other Defendants in concert to manufacture, offer to sell, and sell DRL_RI through its U.S. affiliates and agents that are

distributed throughout the United States, such that this Court's exercise of jurisdiction over Fresenius Switzerland satisfies due process.

38. Venue is proper in this Court with respect to Fresenius Switzerland because it is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

F. Fresenius Germany

39. Fresenius Germany is subject to personal jurisdiction in New Jersey because, *inter alia*, Plaintiffs are informed and believe that Fresenius Germany purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

40. Plaintiffs are informed and believe, and on that basis allege that Fresenius Germany was and is actively involved with planning the development, manufacture and launch of DRL_RI. In particular, Plaintiffs are informed and believe, and on that basis allege, that Fresenius Germany has assisted DRL SA in filing an aBLA with the FDA seeking FDA approval of the proposed biosimilar product DRL_RI for the express purposes of marketing, distributing, and selling DRL_RI in New Jersey and throughout the United States.

41. Plaintiffs are informed and believe, and on that basis allege that Fresenius Germany has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by initiating litigation in at least the following actions: *Fresenius Kabi USA, LLC et al. v. Gland Pharma Limited*, Civil Action No. 3:20-cv-12347 (D.N.J. Sept. 4, 2020); *Fresenius Kabi USA, LLC et al. v. Wockhardt USA, LLC et al.*, Civil Action No. 2:19-cv-20383 (D.N.J. Nov. 15, 2019).

42. Additionally, and in the alternative, this Court has personal jurisdiction over Fresenius Germany under Federal Rule of Civil Procedure 4(k)(2) because Plaintiffs' claim arises under federal law, Fresenius Germany is a foreign defendant that is not subject to general personal jurisdiction in any state, and Fresenius Germany has sufficient contacts with the United States as a whole, including but not limited to, collaborating with other Defendants in concert to manufacture, offer to sell, and sell DRL_RI through its U.S. affiliates and agents that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Fresenius Germany satisfies due process.

43. Venue is proper in this Court with respect to Fresenius Germany because it is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

BACKGROUND FACTS

44. 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.

45. 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®, DRL_RI, (ii) the aBLA filed by DRL SA seeking FDA approval for DR_RI names Rituxan® as the reference product that DRL_RI is intended to copy, and (iii) the FDA has accepted DRL SA's aBLA for review.

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

47. As alleged herein, the manufacture, importation, use, offer for sale, and/or sale of DRL_RI 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.

PLAINTIFFS' RITUXAN® PRODUCT

48. 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.

49. 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.

50. 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.

51. Rituximab is a "chimeric" antibody, meaning that part of its structure is derived from a human genetic sequence and part is derived from a 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.

52. Following the creation of rituximab, IDEC Pharmaceuticals, Genentech, and HLR, 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 lymphoma and chronic lymphocytic leukemia, both of which are blood cancers, as well as rheumatoid arthritis and vasculitis, both chronic and painful autoimmune diseases. Plaintiffs 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.

53. Because of its effectiveness against several diseases, including several forms of cancer, Rituxan® has been an enormous commercial success, generating over $2 billion in worldwide revenue in 2022 alone.

54. 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

55. 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.

56. 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.

57. 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. Plaintiffs underwent that long, laborious, and expensive process to obtain FDA approval for Rituxan®.

58. 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).

59. 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 DRL_RI is the proposed biosimilar.

60. 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).

61. Consequently, the abbreviated regulatory pathway created by the BPCIA allows a biosimilar applicant like DRL SA 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 DRL SA 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.

DRL SA'S PROPOSED BIOSIMILAR PRODUCT DRL_RI

62. Plaintiffs are informed and believe, and on that basis allege, that on a date prior to April 21, 2023, DRL SA submitted to the FDA an aBLA for DRL_RI. On or about July 12, 2023, DRL Ltd. issued a press release announcing that DRL SA's proposed biosimilar rituximab candidate DRL_RI has been accepted for a substantive review by the FDA.

63. The press release further stated that DRL_RI is being developed as a biosimilar of Rituxan®, and that Rituxan® is approved for various indications including for the treatment of adult patients with rheumatoid arthritis, non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis and microscopic polyangiitis.

64. Plaintiffs are informed and believe that DRL SA 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

65. Although the BPCIA provides for an abbreviated regulatory pathway, it does not give biosimilar applicants like DRL SA 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.

66. 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.

67. 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).

68. 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

69. On or about July 3, 2023, DRL SA provided Plaintiffs with its aBLA for DRL_RI pursuant to 42 U.S.C. § 262(l)(2), but did not meet its obligation to provide "other information that describes the process or processes used to manufacture" DRL_RI as required by 42 U.S.C. § 262(l)(2)(A).

70. On August 1, 2023, Plaintiffs requested DRL SA to provide the required manufacturing information under 42 U.S.C. § 262(l)(2)(A). In its request, Plaintiffs identified a list of missing information, and a list of exemplary patents to help clarify the nature of the information needed. Plaintiffs informed DRL that—if the requested information was not received, the cited patents, and other patents, related to the missing information could reasonably be asserted if DRL SA engaged in making, using, offering to sell, selling, or importing into the United States DRL_RI.

71. On September 1, 2023, Plaintiffs again informed DRL SA that it had not complied with 42 U.S.C. § 262(l)(2)(A) and reserved all of their rights regarding DRL SA's failure to do so. Subject to and without waiver of those reservations, Plaintiffs provided Defendants an operative list of patents pursuant to 42 U.S.C. § 262(l)(3)(A) that could reasonably be asserted against DRL SA's DRL_RI product based on upon the deficient materials received to date ("Plaintiffs' Patent List"). Despite DRL SA's refusal to provide the required manufacturing information, Plaintiffs' Patent List nonetheless includes patents that Plaintiffs believed could be asserted after a reasonable investigation based on the information provided to date.

72. On November 16, 2023, DRL SA provided a Notice of Commercial Marketing starting a 180-day clock before the first possible date on which DRL SA or its partners could market and/or sell its proposed biosimilar DRL_RI.

73. DRL SA's failure to provide Plaintiffs with "other information that describes the process or processes used to manufacture" DRL_RI, 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 Defendants' stated intent to begin marketing its proposed biosimilar of Rituxan® in as few as 180 days. This

reduces the amount of time and materials Plaintiffs have to analyze all the relevant documents in Defendants' possession.

74. With DRL SA having served a Notice of Commercial Marketing and having failed to comply with 42 U.S.C. § 262(l)(2)(A), Plaintiffs exercise the right to bring suit pursuant to 42 U.S.C. § 262(l)(8) and 42 U.S.C. § 262(l)(9). In the alternative, and/or in addition, Plaintiffs bring suit under 35 U.S.C. § 271(e)(2). Plaintiffs bring suit on all fifteen patents on Plaintiffs' Patent List, out of an abundance of caution, to preserve all rights.

THE ASSERTED PATENTS

75. 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.

76. Plaintiffs' ability to evaluate Defendants' infringement of their patent estate has been hampered by DRL SA'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 DRL SA that failure to provide it would necessitate legal action. DRL SA continued to evade its statutory obligations.

77. 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 DRL_RI 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:

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

78. 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.

79. One or more Plaintiffs have maintained all substantial rights in the '704 patent throughout the period of Defendants' infringement. A copy of the '704 patent is attached as Exhibit 1.

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

80. 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.

81. One or more Plaintiffs have maintained all substantial rights in the '838 patent throughout the period of Defendants' infringement. A copy of the '838 patent is attached as Exhibit 2.

- **U.S. Patent No. 8,460,895**

82. U.S. Patent No. 8,460,895 (the "'895 patent") is entitled "Method for Producing Recombinant Proteins with a Constant Content of pCO_2 in the Medium," was duly and legally issued by the Patent Office on June 11, 2013, and has not expired.

83. One or more Plaintiffs have maintained all substantial rights in the '895 patent throughout the period of Defendants' infringement. A copy of the '895 patent is attached as Exhibit 3.

- **U.S. Patent No. 8,512,983**

84. U.S. Patent No. 8,512,983 (the "'2983 patent") is entitled "Production of Proteins in Glutamine-free Cell Culture Media," was duly and legally issued by the Patent Office on August 20, 2013, and has not expired.

85. One or more Plaintiffs have maintained all substantial rights in the '2983 patent throughout the period of Defendants' infringement. A copy of the '2983 patent is attached as Exhibit 4.

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

86. 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.

87. One or more Plaintiffs have maintained all substantial rights in the '869 patent throughout the period of Defendants' infringement. A copy of the '869 patent is attached as Exhibit 5.

- **U.S. Patent No. 9,714,293**

88. U.S. Patent No. 9,714,293 (the "'293 patent") is entitled "Production of Proteins in Glutamine-free Cell Culture Media," was duly and legally issued by the Patent Office on July 25, 2017, and has not expired.

89. One or more Plaintiffs have maintained all substantial rights in the '293 patent throughout the period of Defendants' infringement. A copy of the '293 patent is attached as Exhibit 6.

- **U.S. Patent No. 10,017,732**

90. U.S. Patent No. 10,017,732 (the "'7732 patent") is entitled "Cell Culture Compositions with Antioxidants and Methods for Polypeptide Production," was duly and legally issued by the Patent Office on July 10, 2018, and has not expired.

91. One or more Plaintiffs have maintained all substantial rights in the '7732 patent throughout the period of Defendants' infringement. A copy of the '7732 patent is attached as Exhibit 7.

- **U.S. Patent No. 10,336,983**

92. U.S. Patent No. 10,336,983 (the "'6983 patent") is entitled "Method for Increasing the Specific Production Rate of Eukaryotic Cells," was duly and legally issued by the Patent Office on July 2, 2019, and has not expired.

93. One or more Plaintiffs have maintained all substantial rights in the '6983 patent throughout the period of Defendants' infringement. A copy of the '6983 patent is attached as Exhibit 8.

- **U.S. Patent No. 10,450,379**

94. U.S. Patent No. 10,450,379 (the "'379 patent") is entitled "Method for Treating Joint Damage," was duly and legally issued by the Patent Office on October 22, 2019, and has not expired.

95. One or more Plaintiffs have maintained all substantial rights in the '379 patent throughout the period of Defendants' infringement. A copy of the '379 patent is attached as Exhibit 9.

- **U.S. Patent No. 10,654,940**

96. U.S. Patent No. 10,654,940 (the "'940 patent") is entitled "Method for Treating Joint Damage," was duly and legally issued by the Patent Office on May 19, 2020, and has not expired.

97. One or more Plaintiffs have maintained all substantial rights in the '940 patent throughout the period of Defendants' infringement. A copy of the '940 patent is attached as Exhibit 10.

- **U.S. Patent No. 10,662,237**

98. U.S. Patent No. 10,662,237 (the "'237 patent") is entitled "Method to Improve Virus Filtration Capacity," was duly and legally issued by the Patent Office on May 26, 2020, and has not expired.

99. One or more Plaintiffs have maintained all substantial rights in the '237 patent throughout the period of Defendants' infringement. A copy of the '237 patent is attached as Exhibit 11.

- **U.S. Patent No. 10,676,710**

100. U.S. Patent No. 10,676,710 (the "'710 patent") is entitled "Cell Culture Compositions with Antioxidants and Methods for Polypeptide Production," was duly and legally issued by the Patent Office on June 9, 2020, and has not expired.

101. One or more Plaintiffs have maintained all substantial rights in the '710 patent throughout the period of Defendants' infringement. A copy of the '710 patent is attached as Exhibit 12.

- **U.S. Patent No. 10,759,866**

102. U.S. Patent No. 10,759,866 (the "'866 patent") is entitled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued by the Patent Office on September 1, 2020, and has not expired.

103. One or more Plaintiffs have maintained all substantial rights in the '866 patent throughout the period of Defendants' infringement. A copy of the '866 patent is attached as Exhibit 13.

- **U.S. Patent No. 10,829,732**

104. U.S. Patent No. 10,829,732 (the "'9732 patent") is entitled "Cell Culture Compositions with Antioxidants and Methods for Polypeptide Production," was duly and legally issued by the Patent Office on November 10, 2020, and has not expired.

105. One or more Plaintiffs have maintained all substantial rights in the '9732 patent throughout the period of Defendants' infringement. A copy of the '9732 patent is attached as Exhibit 14.

- **U.S. Patent No. 10,982,003**

106. U.S. Patent No. 10,982,003 (the "'003 patent") is entitled "Production of Proteins in Glutamine-free Cell Culture Media," was duly and legally issued by the Patent Office on April 20, 2021, and has not expired.

107. One or more Plaintiffs have maintained all substantial rights in the '003 patent throughout the period of Defendants' infringement. A copy of the '003 patent is attached as Exhibit 15.

COUNT I

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

108. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 107 as if fully set forth herein.

109. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

110. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

111. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

112. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

113. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

114. The '704 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

115. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '704 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

116. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI without license or authority from Plaintiffs.

117. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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.

118. For example, DRL SA has knowledge of the '704 patent as it was included on Plaintiffs' Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the '704 patent, because DRL SA has extensively monitored Plaintiffs' Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs' Rituxan® patent rights in the United States and worldwide.

119. Plaintiffs are informed and believe, and on that basis allege, that Defendants 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 DRL SA's infringement of the '704 patent.

120. Plaintiffs are informed and believe, and on that basis allege, that Defendants 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.

121. 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.

122. 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).

123. 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.

124. 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 II

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

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

126. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

127. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

128. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

129. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

130. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

131. The '838 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

132. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '838 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

133. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI without license or authority from Plaintiffs.

134. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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.

135. For example, DRL SA has knowledge of the ’838 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’838 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

136. Plaintiffs are informed and believe, and on that basis allege, that Defendants 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 DRL SA’s infringement of the ’838 patent.

137. Plaintiffs are informed and believe, and on that basis allege, that Defendants 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.

138. 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.

139. 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).

140. 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.

141. 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 III

(INFRINGEMENT OF U.S. PATENT NO. 8,460,895 UNDER 35 U.S.C. § 271(e)(2))

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

143. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

144. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

145. On November 16, 2023, Plaintiffs received DRL SA’s Notice of Commercial Marketing for DRL_RI.

146. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of

DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

147. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

148. The ’895 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

149. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’895 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

150. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’895 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 DRL_RI without license or authority from Plaintiffs.

151. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’895 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’895 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’895 patent.

152. For example, DRL SA has knowledge of the ’895 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that

DRL SA has knowledge of and is aware of the ’895 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

153. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’895 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 DRL SA’s infringement of the ’895 patent.

154. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’895 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’895 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’895 patent.

155. 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.

156. 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 ’895 patent. *See* 35 U.S.C. § 271(e)(4)(B).

157. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’895 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.

158. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '895 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 IV

(INFRINGEMENT OF U.S. PATENT NO. 8,512,983 UNDER 35 U.S.C. § 271(e)(2))

159. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 158 as if fully set forth herein.

160. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

161. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

162. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

163. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

164. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

165. The ’2983 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

166. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’2983 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

167. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’2983 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 DRL_RI without license or authority from Plaintiffs.

168. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’2983 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’2983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’2983 patent.

169. For example, DRL SA has knowledge of the ’2983 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’2983 patent because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

170. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’2983 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 DRL SA’s infringement of the ’2983 patent.

171. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’2983 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’2983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’2983 patent.

172. 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.

173. 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 ’2983 patent. *See* 35 U.S.C. § 271(e)(4)(B).

174. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’2983 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.

175. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’2983 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 V

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

176. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 175 as if fully set forth herein.

177. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

178. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

179. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

180. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

181. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

182. The '869 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

183. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing

DRL_RI 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.

184. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI without license or authority from Plaintiffs.

185. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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.

186. For example, DRL SA has knowledge of the '869 patent as it was included on Plaintiffs' Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the '869 patent, because DRL SA has extensively monitored Plaintiffs' Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs' Rituxan® patent rights in the United States and worldwide.

187. Plaintiffs are informed and believe, and on that basis allege, that Defendants 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 DRL SA's infringement of the '869 patent.

188. Plaintiffs are informed and believe, and on that basis allege, that Defendants 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.

189. 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.

190. 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).

191. 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.

192. 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 VI

(INFRINGEMENT OF U.S. PATENT NO. 9,714,293 UNDER 35 U.S.C. § 271(e)(2))

193. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 192 as if fully set forth herein.

194. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

195. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

196. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

197. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

198. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

199. The '293 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

200. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '293 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

201. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the '293 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 DRL_RI without license or authority from Plaintiffs.

202. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’293 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’293 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’293 patent.

203. For example, DRL SA has knowledge of the ’293 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’293 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

204. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’293 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 DRL SA’s infringement of the ’293 patent.

205. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’293 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’293 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’293 patent.

206. 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.

207. 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 '293 patent. *See* 35 U.S.C. § 271(e)(4)(B).

208. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '293 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.

209. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '293 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 VII

(INFRINGEMENT OF U.S. PATENT NO. 10,017,732 UNDER 35 U.S.C. § 271(e)(2))

210. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 209 as if fully set forth herein.

211. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

212. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

213. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

214. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

215. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

216. The '7732 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

217. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '7732 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

218. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the '7732 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 DRL_RI without license or authority from Plaintiffs.

219. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the '7732 patent, with knowledge

that the resulting conduct would infringe one or more claims of the '7732 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '7732 patent.

220. For example, DRL SA has knowledge of the '7732 patent as it was included on Plaintiffs' Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the '7732 patent, because DRL SA has extensively monitored Plaintiffs' Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs' Rituxan® patent rights in the United States and worldwide.

221. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the '7732 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 DRL SA's infringement of the '7732 patent.

222. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the '7732 patent, with knowledge that the resulting conduct would infringe one or more claims of the '7732 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '7732 patent.

223. 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.

224. 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 ’7732 patent. *See* 35 U.S.C. § 271(e)(4)(B).

225. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’7732 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.

226. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’7732 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 VIII

(INFRINGEMENT OF U.S. PATENT NO. 10,336,983 UNDER 35 U.S.C. § 271(e)(2))

227. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 226 as if fully set forth herein.

228. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

229. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

230. On November 16, 2023, Plaintiffs received DRL SA’s Notice of Commercial Marketing for DRL_RI.

231. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of

DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

232. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

233. The ’6983 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

234. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’6983 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

235. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’6983 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 DRL_RI without license or authority from Plaintiffs.

236. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’6983 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’6983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’6983 patent.

237. For example, DRL SA has knowledge of the ’6983 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that

DRL SA has knowledge of and is aware of the ’6983 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

238. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’6983 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 DRL SA’s infringement of the ’6983 patent.

239. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’6983 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’6983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’6983 patent.

240. 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.

241. 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 ’6983 patent. *See* 35 U.S.C. § 271(e)(4)(B).

242. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’6983 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.

243. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '6983 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 IX

(INFRINGEMENT OF U.S. PATENT NO. 10,450,379 UNDER 35 U.S.C. § 271(e)(2))

244. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 243 as if fully set forth herein.

245. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

246. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

247. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

248. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

249. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

250. The ’379 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

251. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’379 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

252. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’379 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 DRL_RI without license or authority from Plaintiffs.

253. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’379 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’379 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’379 patent.

254. For example, DRL SA has knowledge of the ’379 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’379 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

255. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’379 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 DRL SA’s infringement of the ’379 patent.

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

257. 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.

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 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 ’379 patent. *See* 35 U.S.C. § 271(e)(4)(B).

259. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’379 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.

260. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '379 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 X

(INFRINGEMENT OF U.S. PATENT NO. 10,654,940 UNDER 35 U.S.C. § 271(e)(2))

261. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 260 as if fully set forth herein.

262. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

263. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

264. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

265. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

266. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

267. The '940 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

268. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’940 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

269. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’940 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 DRL_RI without license or authority from Plaintiffs.

270. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’940 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’940 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’940 patent.

271. For example, DRL SA has knowledge of the ’940 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’940 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

272. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’940 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 DRL SA's infringement of the '940 patent.

273. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the '940 patent, with knowledge that the resulting conduct would infringe one or more claims of the '940 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '940 patent.

274. 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.

275. 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 '940 patent. *See* 35 U.S.C. § 271(e)(4)(B).

276. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '940 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.

277. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '940 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 XI

(INFRINGEMENT OF U.S. PATENT NO. 10,662,237 UNDER 35 U.S.C. § 271(e)(2))

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

279. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

280. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

281. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

282. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

283. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

284. The '237 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

285. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '237 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

286. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’237 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 DRL_RI without license or authority from Plaintiffs.

287. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’237 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’237 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’237 patent.

288. For example, DRL SA, has knowledge of the ’237 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’237 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

289. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’237 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 DRL SA’s infringement of the ’237 patent.

290. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’237 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’237 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’237 patent.

291. 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.

292. 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 '237 patent. *See* 35 U.S.C. § 271(e)(4)(B).

293. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '237 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.

294. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '237 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 XII

(INFRINGEMENT OF U.S. PATENT NO. 10,676,710 UNDER 35 U.S.C. § 271(e)(2))

295. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 294 as if fully set forth herein.

296. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

297. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

298. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

299. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

300. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

301. The '710 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

302. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '710 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

303. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the '710 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 DRL_RI without license or authority from Plaintiffs.

304. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’710 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’710 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’710 patent.

305. For example, DRL SA has knowledge of the ’710 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’710 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

306. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’710 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 DRL SA’s infringement of the ’710 patent.

307. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’710 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’710 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’710 patent.

308. 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.

309. 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 ’710 patent. *See* 35 U.S.C. § 271(e)(4)(B).

310. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’710 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.

311. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’710 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 XIII

(INFRINGEMENT OF U.S. PATENT NO. 10,759,866 UNDER 35 U.S.C. § 271(e)(2))

312. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 311 as if fully set forth herein.

313. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

314. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

315. On November 16, 2023, Plaintiffs received DRL SA’s Notice of Commercial Marketing for DRL_RI.

316. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of

DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

317. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

318. The ’866 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

319. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’866 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

320. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’866 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 DRL_RI without license or authority from Plaintiffs.

321. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’866 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’866 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’866 patent.

322. For example, DRL SA has knowledge of the ’866 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that

DRL SA has knowledge of and is aware of the '866 patent, because DRL SA has extensively monitored Plaintiffs' Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs' Rituxan® patent rights in the United States and worldwide.

323. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the '866 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 DRL SA's infringement of the '866 patent.

324. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the '866 patent, with knowledge that the resulting conduct would infringe one or more claims of the '866 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '866 patent.

325. 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.

326. 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 '866 patent. *See* 35 U.S.C. § 271(e)(4)(B).

327. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '866 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.

328. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '866 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 XIV

(INFRINGEMENT OF U.S. PATENT NO. 10,829,732 UNDER 35 U.S.C. § 271(e)(2))

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

330. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

331. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

332. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

333. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

334. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

335. The ’9732 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

336. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the ’9732 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing DRL_RI 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.

337. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’9732 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 DRL_RI without license or authority from Plaintiffs.

338. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’9732 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’9732 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’9732 patent.

339. For example, DRL SA has knowledge of the ’9732 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’9732 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

340. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’9732 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 DRL SA’s infringement of the ’9732 patent.

341. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’9732 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’9732 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’9732 patent.

342. 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.

343. 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 ’9732 patent. *See* 35 U.S.C. § 271(e)(4)(B).

344. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’9732 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.

345. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’9732 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 XV

(INFRINGEMENT OF U.S. PATENT NO. 10,982,003 UNDER 35 U.S.C. § 271(e)(2))

346. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 345 as if fully set forth herein.

347. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

348. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

349. On November 16, 2023, Plaintiffs received DRL SA's Notice of Commercial Marketing for DRL_RI.

350. Plaintiffs are informed and believe, and on that basis allege, that DRL SA and Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of DRL_RI if and when DRL SA receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes.

351. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

352. The '003 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

353. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has infringed one or more claims of the '003 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for DRL_RI for the express purpose of making, using, offering for sale, selling, and/or importing

DRL_RI 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.

354. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has further infringed, or will further infringe, the ’003 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 DRL_RI without license or authority from Plaintiffs.

355. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has engaged and continues to engage in these acts with knowledge of the ’003 patent, with knowledge that the resulting conduct would infringe one or more claims of the ’003 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’003 patent.

356. For example, DRL SA has knowledge of the ’003 patent as it was included on Plaintiffs’ Patent List. Further, Plaintiffs are informed and believe, and on that basis allege, that DRL SA has knowledge of and is aware of the ’003 patent, because DRL SA has extensively monitored Plaintiffs’ Rituxan® patent estate for several years, including the numerous legal proceedings relating to Plaintiffs’ Rituxan® patent rights in the United States and worldwide.

357. Plaintiffs are informed and believe, and on that basis allege, that Defendants have infringed, or will further infringe, the ’003 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 DRL SA’s infringement of the ’003 patent.

358. Plaintiffs are informed and believe, and on that basis allege, that Defendants have engaged and continue to engage in these acts with knowledge of the ’003 patent, with knowledge

that the resulting conduct would infringe one or more claims of the ’003 patent, and with the specific intent that the resulting conduct infringe one or more claims of the ’003 patent.

359. 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.

360. 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 ’003 patent. *See* 35 U.S.C. § 271(e)(4)(B).

361. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants’ knowledge of the ’003 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.

362. Plaintiffs are informed and believe, and on that basis allege, that Defendants’ willful, wanton, and deliberate infringement of the ’003 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 XVI

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

363. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 362 as if fully set forth herein.

364. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

365. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

367. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

369. 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 DRL_RI has or will infringe one or more claims of the '704 patent.

370. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

371. The '704 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

372. The ’704 patent claims methods of making a therapeutic antibody product such as DRL_RI.

373. 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).

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

375. 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, is enjoined from any and all activities that would infringe the claims of the ’704 patent.

COUNT XVII

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

376. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 375 as if fully set forth herein.

377. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

378. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

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

380. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

382. 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 DRL_RI has or will infringe one or more claims of the '838 patent.

383. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

384. The '838 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

385. The '838 patent claims methods of using a therapeutic antibody product such as DRL_RI.

386. 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).

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

388. 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, is enjoined from any and all activities that would infringe the claims of the '838 patent.

COUNT XVIII

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,460,895)

389. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 388 as if fully set forth herein.

390. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

391. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

393. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

395. 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 DRL_RI has or will infringe one or more claims of the ’895 patent.

396. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA’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.

397. The ’895 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

398. The ’895 patent claims methods of making a therapeutic antibody product such as DRL_RI.

399. 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 ’895 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

401. 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, is enjoined from any and all activities that would infringe the claims of the ’895 patent.

COUNT XIX

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,512,983)

402. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 401 as if fully set forth herein.

403. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

404. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

406. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

408. 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 DRL_RI has or will infringe one or more claims of the '2983 patent.

409. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

410. The ’2983 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

411. The ’2983 patent claims methods of making a therapeutic antibody product such as DRL_RI.

412. 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 ’2983 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

414. 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, is enjoined from any and all activities that would infringe the claims of the ’2983 patent.

COUNT XX

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

415. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 414 as if fully set forth herein.

416. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

417. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

419. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

421. 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 DRL_RI has or will infringe one or more claims of the '869 patent.

422. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

423. The '869 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

424. The '869 patent claims methods of making a therapeutic antibody product such as DRL_RI.

425. 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).

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

427. 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, is enjoined from any and all activities that would infringe the claims of the ’869 patent.

COUNT XXI

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,714,293)

428. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 427 as if fully set forth herein.

429. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

430. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

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

432. On November 16, 2023, Plaintiffs received DRL’s Notice of Commercial Marketing for DRL_RI.

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

434. 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 DRL_RI has or will infringe one or more claims of the ’293 patent.

435. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA’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.

436. The ’293 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

437. The ’293 patent claims methods of making a therapeutic antibody product such as DRL_RI.

438. 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 ’293 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

440. 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, is enjoined from any and all activities that would infringe the claims of the ’293 patent.

COUNT XXII

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,017,732)

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

442. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

443. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

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

445. On November 16, 2023, Plaintiffs received DRL’s Notice of Commercial Marketing for DRL_RI.

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

447. 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 DRL_RI has or will infringe one or more claims of the ’7732 patent.

448. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

449. The '7732 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

450. The '7732 patent claims methods of making a therapeutic antibody product such as DRL_RI.

451. 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 '7732 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

453. 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, is enjoined from any and all activities that would infringe the claims of the '7732 patent.

COUNT XXIII

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,336,983)

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 DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

456. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

458. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

460. 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 DRL_RI has or will infringe one or more claims of the '6983 patent.

461. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

462. The '6983 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

463. The ’6983 patent claims methods of making a therapeutic antibody product such as DRL_RI.

464. 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 ’6983 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

466. 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, is enjoined from any and all activities that would infringe the claims of the ’6983 patent.

COUNT XXIV

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,450,379)

467. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 466 as if fully set forth herein.

468. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

469. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

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

471. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

473. 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 DRL_RI has or will infringe one or more claims of the '379 patent.

474. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

475. The '379 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

476. The '379 patent claims methods of using a therapeutic antibody product such as DRL_RI.

477. 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 '379 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

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, *inter alia,* all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '379 patent.

COUNT XXV

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,654,940)

480. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 479 as if fully set forth herein.

481. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

482. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

484. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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/or sale of DRL_RI if and when it receives FDA approval to do so, as well as to import DRL_RI into the United States for those purposes; and induce and/or contribute to these activities.

486. 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 DRL_RI has or will infringe one or more claims of the ’940 patent.

487. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA’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.

488. The ’940 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

489. The ’940 patent claims methods of using a therapeutic antibody product such as DRL_RI.

490. 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 ’940 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

492. 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, is enjoined from any and all activities that would infringe the claims of the ’940 patent.

COUNT XXVI

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,662,237)

493. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 492 as if fully set forth herein.

494. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

495. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

497. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

499. 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 DRL_RI has or will infringe one or more claims of the '237 patent.

500. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

501. The ’237 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

502. The ’237 patent claims methods of making a therapeutic antibody product such as DRL_RI.

503. 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 ’237 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

505. 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, is enjoined from any and all activities that would infringe the claims of the ’237 patent.

COUNT XXVII

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,676,710)

506. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 505 as if fully set forth herein.

507. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

508. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

510. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

512. 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 DRL_RI has or will infringe one or more claims of the '710 patent.

513. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

514. The '710 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

515. The '710 patent claims methods of making a therapeutic antibody product such as DRL_RI.

516. 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 ’710 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

518. 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, is enjoined from any and all activities that would infringe the claims of the ’710 patent.

COUNT XXVIII

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,759,866)

519. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 518 as if fully set forth herein.

520. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

521. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

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

523. On November 16, 2023, Plaintiffs received DRL’s Notice of Commercial Marketing for DRL_RI.

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

525. 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 DRL_RI has or will infringe one or more claims of the ’866 patent.

526. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA’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.

527. The ’866 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

528. The ’866 patent claims methods of making a therapeutic antibody product such as DRL_RI.

529. 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 ’866 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

531. 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, is enjoined from any and all activities that would infringe the claims of the ’866 patent.

COUNT XXIX

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,829,732)

532. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 531 as if fully set forth herein.

533. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

534. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA’s aBLA for review prior to July 3, 2023.

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

536. On November 16, 2023, Plaintiffs received DRL’s Notice of Commercial Marketing for DRL_RI.

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

538. 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 DRL_RI has or will infringe one or more claims of the ’9732 patent.

539. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

540. The '9732 patent has been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

541. The '9732 patent claims methods of making a therapeutic antibody product such as DRL_RI.

542. 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 '9732 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

544. 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, is enjoined from any and all activities that would infringe the claims of the '9732 patent.

COUNT XXX

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,982,003)

545. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 544 as if fully set forth herein.

546. Plaintiffs are informed and believe, and on that basis allege, that DRL SA 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 DRL_RI, a proposed biosimilar version of Rituxan®.

547. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted DRL SA's aBLA for review prior to July 3, 2023.

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

549. On November 16, 2023, Plaintiffs received DRL's Notice of Commercial Marketing for DRL_RI.

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

551. 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 DRL_RI has or will infringe one or more claims of the '003 patent.

552. Plaintiffs are informed and believe, and on that basis allege, that DRL SA has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A). On account of DRL SA'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.

553. The ’003 patent has been identified pursuant to the BPCIA’s dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

554. The ’003 patent claims methods of making a therapeutic antibody product such as DRL_RI.

555. 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 ’003 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

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

557. 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, is enjoined from any and all activities that would infringe the claims of the ’003 patent.

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 DRL_RI 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 Federal Rule of Civil Procedure 38(b), Plaintiffs respectfully demand a jury trial as to all issues so triable.

Dated: November 17, 2023

/s/ Cynthia S. Betz

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned attorney of record for Plaintiff, hereby certifies that to the best of my knowledge and based upon information available to be, the matter in controversy is not the subject of any other action pending or any court or of any pending arbitration or administrative proceeding.

Dated: November 17, 2023

/s/ Cynthia S. Betz

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