IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and GENENTECH, INC.,	)	
	)	
	)	
	)	
Plaintiffs,	)	C.A. No. _____
	)	
	)	
v.	)	
	)	
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AbbVie Inc. ("AbbVie") and Genentech, Inc. ("Genentech") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Dr. Reddy's Laboratories, Inc. ("DRLI") and Dr. Reddy's Laboratories, Ltd. ("DRLL") (collectively, "Defendants" or "DRL"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*., arises from DRL's submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") No. 214733 ("DRL's ANDA") seeking approval to market a generic version of Plaintiffs' highly successful pharmaceutical product VENCLEXTA®, prior to the expiration of the patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for VENCLEXTA®. The Orange Book-listed patents are U.S. Patent Nos. 8,546,399 ("the '399 Patent"), 9,174,982 ("the '982 Patent"), 8,722,657 ("the

'657 Patent"), and 9,539,251 ("the '251 Patent"). The '399 Patent, the '982 Patent, and the '657 Patent are collectively referred to as "the Patents-in-suit."

VENCLEXTA®

2. VENCLEXTA® (venetoclax) is a ground-breaking drug which has gained widespread acceptance in the medical community. It has been used to treat over 31,000 patients in the United States and around the world who suffer from chronic lymphocytic leukemia ("CLL"), small lymphocytic lymphoma ("SLL"), and, as part of a combination therapy, acute myeloid leukemia ("AML").

3. VENCLEXTA® selectively targets and inhibits the B-cell CLL/lymphoma 2 ("BCL-2") protein and is the first FDA-approved BCL-2 inhibitor. BCL-2 prevents apoptosis, or programmed cell death, which is the process for removal of aged or damaged cells.

4. VENCLEXTA® was first approved by the FDA on April 11, 2016 pursuant to New Drug Application ("NDA") No. 208573. It is available as an oral tablet containing 10 mg, 50 mg, or 100 mg of venetoclax as the active pharmaceutical ingredient.

5. VENCLEXTA® is currently approved for use and indicated as follows: (1) for the treatment of adult patients with CLL or SLL; (2) in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly-diagnosed AML in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

6. AbbVie and Genentech co-market and sell VENCLEXTA® in the United States and other parts of the world. They have invested hundreds of millions of dollars to discover venetoclax and develop VENCLEXTA®, including investing significant resources investigating whether VENCLEXTA® alone and in combination with other drugs can treat other types of cancer.

7. The FDA has recognized the innovative nature of VENCLEXTA® in granting it five breakthrough therapy designations: (1) treatment of patients with relapsed or refractory CLL who harbor the 17p deletion mutation; (2) treatment of patients with relapsed or refractory CLL in combination with the anti-CD20 antibody rituximab (Rituxan®); (3) venetoclax in combination with hypomethylating agents for the treatment of patients with untreated (treatment-naïve) AML who are ineligible to receive standard induction therapy (high-dose chemotherapy); (4) combination of venetoclax and low-dose cytarabine for treatment-naïve patients with AML, who are ineligible for intensive chemotherapy; and (5) venetoclax in combination with obinutuzumab for the treatment of adult patients with CLL. A breakthrough designation is reserved for a drug intended to treat a serious condition where preliminary clinical results indicate that the drug may demonstrate substantial improvement over available therapies.

8. VENCLEXTA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with approximately 195 ongoing clinical trials (including 15 Phase 3 trials).

9. In addition to being well-received by the FDA and the medical community, VENCLEXTA® received the biomedical industry's highest accolade in 2017 when it was awarded the Prix Galien Award for Best Pharmaceutical Product.

THE PARTIES

10. Plaintiff AbbVie is a corporation organized and existing under the laws of the state of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach

to innovation to markedly improve treatments across therapeutic areas, including in oncology. AbbVie holds NDA No. 208573 for VENCLEXTA® and is an assignee of all Patents-in-suit.

11. Plaintiff Genentech is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080. Genentech is a biotechnology company dedicated to pursuing ground-breaking science to discover and develop medicines for people with serious and life-threatening diseases. Genentech is an assignee of the '399 and '982 Patents and an exclusive licensee of the '657 Patent.

12. On information and belief, Defendant DRLL is a company organized and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, India.

13. On information and belief, Defendant DRLI is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

14. On information and belief, Defendants are agents of one another and/or operate in concert as integrated parts of the same business group.

15. On information and belief, DRLI is a wholly owned subsidiary of DRLL and acts as its authorized agent in the United States.

16. On information and belief, DRLL, itself and through its wholly owned subsidiary DRLI, develops, manufactures, markets, sells, and/or imports generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District.

17. On information and belief, DRLI, itself and through DRLL, is in the business of developing, manufacturing, and/or distributing generic drugs for marketing, sale, and/or use throughout the United States, including in this Judicial District.

18. On information and belief, DRLL is the holder of Drug Master File 33669 for venetoclax.

19. On information and belief, and as described in Defendants' written notification of DRL's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification received June 8, 2020 ("DRL's Notice Letter"), Defendants caused DRL's ANDA to be submitted to the FDA and seek FDA approval of DRL's ANDA prior to the expiration of the patents listed in the Orange Book for VENCLEXTA®.

20. On information and belief, DRL intends to commercially manufacture, market, offer for sale, and sell the proposed generic venetoclax tablets described in DRL's ANDA ("DRL's Generic Version") throughout the United States, including in the State of Delaware, in the event the FDA approves DRL's ANDA.

JURISDICTION & VENUE

21. This civil action for patent infringement arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code.

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

23. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, on information and belief, Defendants having availed themselves of the rights and benefits of the laws of the State of Delaware by engaging in substantial, continuous, and systematic contacts with the State of Delaware and because Defendants intend to indirectly or directly market, sell, and/or distribute generic drugs to residents of this State, including DRL's Generic Version. Accordingly, Defendants should reasonably anticipate being hauled into court in this Judicial District.

24. On information and belief, Defendants acting in concert and/or as agents of one another filed DRL's ANDA.

25. On information and belief, Defendants acting in concert and/or as agents of one another will market, distribute, and/or sell DRL's Generic Version in the United States, including in Delaware, upon approval of DRL's ANDA, and will derive substantial revenue from the sale of DRL's Generic Version.

26. On information and belief, DRL's Generic Version will be used within and throughout the United States, including in Delaware.

27. On information and belief, DRL's Generic Version will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware.

28. This Court also has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, with both Plaintiffs being organized under the laws of the State of Delaware.

29. This Court also has personal jurisdiction over DRLI because, *inter alia*, DRLI, on information and belief, is registered as a pharmacy wholesaler under license No. A-4-0002524 and as a controlled substances distributor/manufacturer under license No. DM-0013148 with the Delaware Division of Professional Regulation.

30. This Court also has personal jurisdiction over DRLL and DRLI because they have previously been sued, individually or together, in this Judicial District and have not challenged personal jurisdiction or venue, and have purposefully availed themselves of the rights

and benefits of the jurisdiction of this Court by filing claims and counterclaims in this Judicial District. *See, e.g.*, *Novartis Pharm. Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-2053-LPS (D. Del. Feb. 6, 2020), D.I. 34; *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-2045-CFC (D. Del. Nov. 20, 2019), D.I. 8; *Boehringer Ingelheim Pharm. Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-1495-CFC (D. Del. Sep. 4, 2019), D.I. 9; *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 18-1839-CFC (D. Del. Jan. 16, 2019), D.I. 13; *Pfizer Inc. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-750-CFC (D. Del. Jul. 15, 2019), D.I. 12; *Onyx Therapeutics, Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 17-1811-LPS (D. Del. Jan. 23, 2018), D.I. 11; *Viiv Healthcare Co. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 17-1678-MSG (D. Del. Feb. 12, 2018), D.I. 13; *Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd. v. GlaxoSmithKline LLC et al.*, C.A. No. 18-cv-0548-LPS (D. Del. Apr. 12, 2018), D.I. 1; *Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd. v. Fresenius Kabi USA, LLC*, C.A. No. 15-cv-0714-RGA (D. Del. Aug. 18, 2015), D.I. 1.

31. Moreover, this Court has jurisdiction over DRLL pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) DRLL is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) DRLL has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over DRLL satisfies due process.

32. Venue is proper in this Judicial District for DRL pursuant to 28 U.S.C. §§ 1391 and/or 1400 because, on information and belief, *inter alia*, DRLL is a company organized and existing under the laws of India, and may be sued in any judicial district pursuant to 28 U.S.C.

§ 1391(c) and DRL's Generic Version will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute an act of infringement of the Patents-in-suit if DRL's Generic Version is approved before the Patents-in-suit expire.

33. Venue is further proper against DRLI as it is the agent or alter ego of DRLL (which is also subject to venue in this Judicial District) in connection with the submission of DRL's ANDA. Moreover, DRLI has litigated other Hatch-Waxman patent infringement disputes in this Judicial District.

34. In addition, venue is also proper in this Court because DRLI and DRLL have not objected to Plaintiffs' July 7, 2020 request that they consent to venue in this Judicial District for the purposes of this action.

THE ASSERTED PATENTS

35. The '399 patent, titled "Apoptosis Inducing Agents for the Treatment of Cancer and Immune and Autoimmune Diseases," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 1, 2013. A true and correct copy of the '399 patent is attached as Exhibit A.

36. The '399 patent is assigned to AbbVie, Genentech, and the Walter and Eliza Hall Institute of Medical Research.

37. The '982 patent, titled "Apoptosis-Inducing Agents for the Treatment of Cancer and Immune and Autoimmune Diseases," was duly and legally issued by the USPTO on November 3, 2015. A true and correct copy of the '982 patent is attached as Exhibit B.

38. The '982 patent is assigned to AbbVie, Genentech, and the Walter and Eliza Hall Institute of Medical Research.

39. The '657 patent, titled "Salts and Crystalline Forms of an Apoptosis-Inducing Agent," was duly and legally issued by the USPTO on May 13, 2014. A true and correct copy of the '657 patent is attached as Exhibit C.

40. The '657 patent is assigned to AbbVie and exclusively licensed to Genentech.

DRL'S ANDA

41. On information and belief, DRL's Notice Letter represents that DRL submitted and continues to maintain DRL's ANDA to the FDA under 21 U.S.C. § 355(j).

42. On information and belief, and based on DRL's Notice Letter, DRL has submitted DRL's ANDA to the FDA in order to obtain approval to engage in the commercial manufacture, use, or sale of venetoclax tablets as a purported generic version of VENCLEXTA® prior to the expiration of the Patents-in-suit and the '251 Patent.

43. On information and belief, the FDA has not approved DRL's ANDA.

44. DRL's Notice Letter states that "DRL seeks to obtain approval to engage in the commercial manufacture, use, or sale of" "venetoclax tablets, 10 mg, 50 mg, 100 mg." DRL's Notice Letter also states that "[t]he active ingredient present in [DRL's Generic Version] is 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-*N*-({3-nitro-4-[(tetrahydro-*2H*-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1*H*-pyrrolo[2,3-*b*]pyridin-5-yloxy)benzamide), commonly known as venetoclax."

45. VENCLEXTA®'s Prescribing Information ("VENCLEXTA® PI") states that "VENCLEXTA® tablets for oral administration . . . contain 10, 50, or 100 mg venetoclax as the active ingredient" and "[v]enetoclax is described chemically as 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-*N*-({3-nitro-4-[(tetrahydro-*2H*-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1*H*-pyrrolo[2,3-*b*]pyridin-5-yloxy)benzamide)."

46. On information and belief, and as supported by DRL's Notice Letter, by filing DRL's ANDA, DRL has certified to the FDA that DRL's Generic Version has the same active pharmaceutical ingredient as VENCLEXTA® and either the same or similar proposed labeling as VENCLEXTA®.

47. DRL's Notice Letter represents that DRL certified in DRL's ANDA that the claims of the Patents-in-suit are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of DRL's Generic Version.

48. According to applicable regulations, Notice Letters such as DRL's Notice Letter must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

49. For at least one claim of each of the '399 and '982 Patents, DRL's Notice Letter failed to allege that DRL's Generic Version or the proposed administration of DRL's Generic Version would not meet the limitations of that claim.

50. DRL's Notice Letter also fails to address the '251 Patent, which is listed in the Orange Book for VENCLEXTA®.

51. DRL's Notice Letter contained an Offer of Confidential Access ("OCA") to certain confidential information regarding DRL's Generic Version. Plaintiffs and DRL subsequently exchanged proposed revisions to the draft OCA in an attempt to reach agreement on the terms for confidential access, but DRL refused Plaintiffs' reasonable requests, including

requests for samples of DRL's Generic Version and active pharmaceutical ingredient. Thus, as of the filing of this Complaint, the parties have not been able to reach an agreement.

52. To date, DRL has not provided Plaintiffs with any portion of DRL's ANDA nor any information regarding DRL's Generic Version, beyond the information in DRL's Notice Letter.

53. To date, DRL has not provided Plaintiffs with samples of DRL's Generic Version embodied by DRL's ANDA or the active pharmaceutical ingredient.

54. The limited information relating to DRL's Generic Version that was provided in DRL's Notice Letter does not demonstrate that DRL's Generic Version, which DRL has asked the FDA to approve for sale in the U.S., will not fall within the scope of claims of the Patents-in-suit.

55. This action is being brought within 45 days of Plaintiffs' receipt on June 8, 2020 of DRL's Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

CLAIM FOR RELIEF
COUNT 1: INFRINGEMENT OF THE '399 PATENT BY DRL

56. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-55 as if fully set forth herein.

57. On information and belief, DRL submitted or caused the submission of DRL's ANDA to the FDA, and thereby seeks FDA approval of DRL's Generic Version.

58. DRL's Generic Version infringes one or more claims of the '399 Patent.

59. DRL did not contest infringement of any claim of the '399 Patent in DRL's Notice Letter. If DRL had a factual or legal basis to contest infringement of the '399 Patent, it

was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

60. DRL has infringed one or more claims of the '399 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with Paragraph IV certification and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '399 Patent.

61. On information and belief, the importation, manufacture, sale, offer for sale, or use of DRL's Generic Version prior to the expiration of the '399 Patent would infringe one or more claims of the '399 Patent under 35 U.S.C. § 271(a), and/or DRL would induce or contribute to the inducement of the infringement of one or more claims of the '399 Patent under 35 USC § 271(b) and/or (c).

62. DRL had actual and constructive notice of the '399 Patent prior to filing DRL's ANDA, and was aware that the filing of DRL's ANDA with the request for FDA approval prior to the expiration of the '399 Patent would constitute an act of infringement of the '399 Patent.

63. DRL filed its ANDA without adequate justification for asserting that the '399 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of DRL's Generic Version.

64. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '399 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

CLAIM FOR RELIEF
COUNT 2: INFRINGEMENT OF THE '982 PATENT BY DRL

65. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-64 as if fully set forth herein.

66. On information and belief, DRL submitted or caused the submission of DRL's ANDA to the FDA, and thereby seeks FDA approval of DRL's Generic Version.

67. DRL's Generic Version infringes one or more claims of the '982 Patent.

68. DRL did not contest infringement of any claim of the '982 Patent in DRL's Notice Letter. If DRL had a factual or legal basis to contest infringement of the '982 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

69. DRL has infringed one or more claims of the '982 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with Paragraph IV certification and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '982 Patent.

70. On information and belief, the importation, manufacture, sale, offer for sale, or use of DRL's Generic Version prior to the expiration of the '982 Patent would infringe one or more claims of the '982 Patent under 35 U.S.C. § 271(a), and/or DRL would induce or contribute to the inducement of the infringement of one or more claims of the '982 Patent under 35 USC § 271(b) and/or (c).

71. DRL had actual and constructive notice of the '982 Patent prior to filing DRL's ANDA, and was aware that the filing of DRL's ANDA with the request for FDA approval prior to the expiration of the '982 Patent would constitute an act of infringement of the '982 Patent.

72. DRL filed its ANDA without adequate justification for asserting that the '982 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of DRL's Generic Version.

73. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '982 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

CLAIM FOR RELIEF
COUNT 3: INFRINGEMENT OF THE '657 PATENT BY DRL

74. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-73 as if fully set forth herein.

75. On information and belief, DRL submitted or caused the submission of DRL's ANDA to the FDA, and thereby seeks FDA approval of DRL's Generic Version.

76. On information and belief, DRL's Generic Version infringes one or more claims of the '657 Patent.

77. DRL has infringed one or more claims of the '657 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with Paragraph IV certification and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '657 Patent.

78. On information and belief, the importation, manufacture, sale, offer for sale, or use of DRL's Generic Version prior to the expiration of the '657 Patent would infringe one or more claims of the '657 Patent under 35 U.S.C. § 271(a), and/or DRL would induce or contribute to the inducement of the infringement of one or more claims of the '657 Patent under 35 USC § 271(b) and/or (c).

79. DRL had actual and constructive notice of the '657 Patent prior to filing DRL's ANDA, and was aware that the filing of DRL's ANDA with the request for FDA approval prior to the expiration of the '657 Patent would constitute an act of infringement of the '657 Patent.

80. DRL filed its ANDA without adequate justification for asserting that the '657 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of DRL's Generic Version.

81. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '657 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that DRL has infringed each of the Patents-in-suit under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment and Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of DRL's ANDA shall be no be earlier than the last expiration date of any of the Patents-in-suit, or any later expiration of exclusivity for the Patents-in-suit, including any extensions or regulatory exclusivities;

C. A Judgment and Order that DRL, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, are permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distribution, or importing DRL's Generic Version and any other product that infringes or induces or contributes to the infringement of one or more of the Patents-in-suit, prior to the expiration of the Patents-in-suit, including any exclusivities or extensions to which Plaintiffs are or become entitled;

D. A Judgment declaring that making, using, selling, offering to sell, or importing DRL's Generic Version, or inducing or contributing to such conduct, would constitute infringement of one or more of the Patents-in-suit pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A declaration under 28 U.S.C. § 2201 that, if DRL, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of DRL's Generic Version, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if DRL engages in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's Generic Version, or any product that infringes one or more Patents-in-suit, or induces or contributes to such conduct, prior to the expiration of the Patents-in-suit, including any additional exclusivity period applicable to those patents;

G. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other and further relief as this Court deems just and proper.

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July 21, 2020

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