IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC. and INTERCEPT PHARMA EUROPE LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Intercept Pharmaceuticals, Inc. ("Intercept Pharmaceuticals") and Intercept Pharma Europe Limited ("IPEL") (collectively "Intercept" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL" or "Defendants"), 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.*, and in particular under 35 U.S.C. § 271, arises from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 214899 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to market a generic version of the pharmaceutical product OCALIVA® (obeticholic acid, 5 and 10 mg) prior to the expiration of U.S. Patent Nos. RE 48,286 (filed June 21, 2019) ("the RE286 Patent"); 9,238,673 (filed June 17, 2013) ("the '673 Patent"); 10,047,117 (filed Nov. 20, 2015) ("the '117 Patent"); 10,052,337 (filed Apr. 26, 2016) ("the '337 Patent"); 10,174,073 (filed Apr. 25, 2017) ("the '073 Patent"); 10,751,349 (filed Jan. 15, 2019) ("the '349 Patent"); and

10,758,549 (filed Feb. 11, 2020) ("the '549 Patent") (collectively the "patents-in-suit"). Plaintiffs seek injunctive relief prohibiting infringement, attorneys' fees, and any other relief the Court deems just and proper.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271.

THE PARTIES

3. Plaintiff Intercept Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Hudson Yards, 37th Floor, New York, New York 10001.

4. Plaintiff IPEL is a limited corporation organized under the laws of the United Kingdom, having a principal place of business at One Glass Wharf, Bristol, BS2 0ZX United Kingdom.

5. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, Telangana, India.

6. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having an address at 107 College Road East, Princeton, New Jersey 08540.

7. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

8. On information and belief, Dr. Reddy's Laboratories, Ltd. is the holder of FDA Drug Master File No. 31977 for obeticholic acid.

9. On information and belief, Dr. Reddy's Laboratories, Inc. acts at the direction, and for the benefit, of Dr. Reddy's Laboratories, Ltd., and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

10. On further information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

11. On information and belief, Dr. Reddy's Laboratories, Inc. acts as the U.S. agent for Dr. Reddy's Laboratories, Ltd. for purposes of regulatory submissions to the FDA in seeking approval for generic drugs.

12. On information and belief, Defendants prepared and submitted ANDA No. 214899 (the "DRL ANDA") and continue to seek FDA approval of that application.

13. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the products described in the DRL ANDA (the "DRL ANDA Products" or "ANDA Products") throughout the United States, including in the State of Delaware, in the event the FDA approves the DRL ANDA.

JURISDICTION AND VENUE

14. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

15. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with Delaware, regularly

conduct business in Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in Delaware, and intend to sell the DRL ANDA Products in Delaware upon approval of the DRL ANDA.

16. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Defendants manufacture, distribute, market, and/or sell throughout the United States and in this judicial district.

17. On information and belief, Dr. Reddy's Laboratories, Inc. 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.

18. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated November 30, 2020 sent by DRL to Intercept Pharmaceuticals pursuant to 21 U.S.C. § 355(j)(2)(b), Defendants prepared and filed the DRL ANDA with the intention of seeking to market the DRL ANDA Products nationwide, including within this judicial district.

19. On information and belief, Defendants plan to sell the DRL ANDA Products in Delaware, list the DRL ANDA Products on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the DRL ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Defendants know and intend that the DRL ANDA Products will be distributed and sold in Delaware and will thereby displace sales of OCALIVA®, causing injury to Plaintiffs. Defendants intend to take advantage of their established channels of distribution in Delaware for the sale of the DRL ANDA Products.

21. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See, e.g.*, *Abbvie Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 20-968 (LPS) (D. Del. Oct. 19, 2020); *Bial - Portela & CA S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 20-784 (CFC) (D. Del. Aug. 11, 2020); *Takeda Pharmaceuticals U.S.A., Inc. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 20-845 (RGA) (D. Del. July 29, 2020); *Merck Sharp & Dohme Corp. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 20-847 (RGA) (D. Del. July 23, 2020); *Sanofi-Aventis U.S. LLC, et al. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 20-804 (RGA) (D. Del. July 20, 2020); *Genzyme Corp., et al., v. Dr. Reddy's Laboratories, Inc., et al.*, No. 19-2045 (CFC) (D. Del. Nov. 20, 2019).

22. Additionally, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Intercept's claims arise under federal law; (b) Dr. Reddy's Laboratories, Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Dr. Reddy's Laboratories, Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the DRL ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Dr. Reddy's Laboratories, Ltd. satisfies due process.

23. Venue is proper in this district for Dr. Reddy's Laboratories, Ltd. pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district.

24. Venue is further proper against Dr. Reddy's Laboratories, Inc. as it is the agent or alter ego of Dr. Reddy's Laboratories, Ltd. (which is also subject to venue in this Judicial District) in connection with the submission of DRL's ANDA. Moreover, Dr. Reddy's Laboratories, Inc. has litigated other Hatch-Waxman patent infringement disputes in this judicial district. In addition, counsel for DRL has advised counsel for Plaintiffs that DRL would not contest venue in this judicial district for purposes of this action.

INTERCEPT'S APPROVED OCALIVA® DRUG PRODUCT AND PATENTS

25. Intercept makes and sells OCALIVA®, a product used in the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. The active ingredient in OCALIVA® is obeticholic acid. OCALIVA® is available in two strengths, 5 mg and 10 mg. A true and correct copy of the prescribing label for OCALIVA® is attached as Exhibit A.

26. Intercept Pharmaceuticals is the holder of New Drug Application ("NDA") No. 207999 for OCALIVA® and the owner of the patents-in-suit. The FDA approved NDA No. 207999 for OCALIVA® on May 27, 2016, and granted OCALIVA® five years of regulatory exclusivity for a new chemical entity pursuant to 21 C.F.R. § 314.108, which expires on May 27, 2021. The FDA also granted OCALIVA® orphan drug exclusivity pursuant to 21 C.F.R. § 316.31, which expires on May 27, 2023.

27. IPEL is the exclusive licensee of the patents-in-suit, which are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for OCALIVA®.

28. The RE286 Patent entitled, "Steroids as Agonists for FXR," was duly and lawfully issued by the USPTO on October 27, 2020. A true and correct copy of the RE286 Patent is attached as Exhibit B. RE286 is a reissue of U.S. Patent No. 7,138,390 ("the '390 Patent").

29. The '673 Patent entitled, "Preparation and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on January 19, 2016. A true and correct copy of the '673 Patent is attached as Exhibit C.

30. The '117 Patent entitled, "Preparation and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on August 14, 2018. A true and correct copy of the '117 Patent is attached as Exhibit D.

31. The '337 Patent entitled, "Compositions of Obeticholic Acid and Methods of Use," was duly and lawfully issued by the USPTO on August 21, 2018. A true and correct copy of the '337 Patent is attached as Exhibit E.

32. The '073 Patent entitled, "Preparation and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on January 8, 2019. A true and correct copy of the '073 Patent is attached as Exhibit F.

33. The '349 Patent entitled, "Compositions of Obeticholic Acid and Methods of Use," was duly and lawfully issued by the USPTO on August 25, 2020. A true and correct copy of the '349 Patent is attached as Exhibit G.

34. The '549 Patent entitled, "Compositions of Obeticholic Acid and Methods of Use," was duly and lawfully issued by the USPTO on September 1, 2020. A true and correct copy of the '549 Patent is attached as Exhibit H.

DRL'S ANDA

35. On information and belief, DRL has submitted or caused to be submitted the DRL ANDA to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the

commercial manufacture, use, or sale of obeticholic acid tablets, as a purported generic version of OCALIVA®, prior to the expiration of the patents-in-suit.

36. On information and belief, on or about November 30, 2020, DRL mailed a letter to Intercept Pharmaceuticals regarding "Notification Pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95) Concerning ANDA No. 214899 and Ocaliva® (Obeticholic Acid Oral Tablets)" (the "Notice Letter"). The Notice Letter represented that DRL had submitted to the FDA the DRL ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the DRL ANDA before the expiration of patents listed in the Orange Book for OCALIVA®. Hence, DRL's purpose in submitting the DRL ANDA is to manufacture and market the ANDA Products before the expiration of the patents-in-suit.

37. DRL's Notice Letter stated that the Paragraph IV certification in the DRL ANDA alleges that the RE286, '673, '117, '337, '073, '349, and '549 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.[1]

38. DRL's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Detailed Statement").

39. On information and belief, Defendants have participated in the preparation and submission of the DRL ANDA, have provided material support to the preparation and submission of the DRL ANDA, and intend to support the further prosecution of the DRL ANDA.

[1] The Notice Letter also stated that the Paragraph IV certification in the DRL ANDA alleges that the '390 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products. The '390 Patent has been reissued as the RE286 Patent, which is asserted in this action.

40. On information and belief, if the FDA approves the DRL ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products within the United States, including within Delaware, or will import the ANDA Products into the United States, including Delaware.

41. Alternatively, on information and belief, if the FDA approves the DRL ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products.

42. This action was filed within forty-five days of Intercept Pharmaceuticals' receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF THE RE286 PATENT

43. Plaintiffs incorporate by reference paragraphs 1–42 as if fully set forth herein.

44. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

45. Defendants have infringed the RE286 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the RE286 Patent.

46. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the RE286 Patent.

47. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will

induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the RE286 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the RE286 Patent and knowledge that they are encouraging infringement.

48. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the RE286 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent.

49. Defendants had actual knowledge of the RE286 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the RE286 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the RE286 Patent renders this case "exceptional" under 35 U.S.C. § 285.

50. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the RE286 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE RE286 PATENT

51. Plaintiffs incorporate by reference paragraphs 1–50 as if fully set forth herein.

52. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

54. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

55. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the RE286 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

56. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the RE286 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

57. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

58. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '673 PATENT

59. Plaintiffs incorporate by reference paragraphs 1–58 as if fully set forth herein.

60. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

61. Defendants have infringed the '673 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '673 Patent.

62. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '673 Patent.

63. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '673 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '673 Patent and knowledge that they are encouraging infringement.

64. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement

of the ’673 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the ’673 Patent.

65. Defendants had actual knowledge of the ’673 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the ’673 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’673 Patent renders this case “exceptional” under 35 U.S.C. § 285.

66. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the ’673 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’673 PATENT

67. Plaintiffs incorporate by reference paragraphs 1–66 as if fully set forth herein.

68. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

69. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

70. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

71. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '673 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

72. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '673 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

73. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

74. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE '117 PATENT

75. Plaintiffs incorporate by reference paragraphs 1–74 as if fully set forth herein.

76. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

77. Defendants have infringed the '117 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '117 Patent.

78. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '117 Patent.

79. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '117 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '117 Patent and knowledge that they are encouraging infringement.

80. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '117 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent.

81. Defendants had actual knowledge of the '117 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '117 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '117 Patent renders this case "exceptional" under 35 U.S.C. § 285.

82. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '117 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '117 PATENT

83. Plaintiffs incorporate by reference paragraphs 1–82 as if fully set forth herein.

84. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

85. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

86. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

87. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '117 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

88. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '117 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

89. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

90. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE '337 PATENT

91. Plaintiffs incorporate by reference paragraphs 1–90 as if fully set forth herein.

92. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

93. Defendants have infringed the '337 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '337 Patent.

94. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '337 Patent.

95. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '337 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '337 Patent and knowledge that they are encouraging infringement.

96. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '337 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent.

97. Defendants had actual knowledge of the '337 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '337 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or

non-infringement with respect to the '337 Patent renders this case "exceptional" under 35 U.S.C. § 285.

98. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '337 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '337 PATENT

99. Plaintiffs incorporate by reference paragraphs 1–98 as if fully set forth herein.

100. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

101. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

102. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

103. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '337 Patent expires will contribute to the infringement of and/or induce the infringement

of one or more claims of the '337 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

104. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '337 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

105. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

106. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IX
INFRINGEMENT OF THE '073 PATENT

107. Plaintiffs incorporate by reference paragraphs 1–106 as if fully set forth herein.

108. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

109. Defendants have infringed the '073 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '073 Patent.

110. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '073 Patent.

111. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care

professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '073 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '073 Patent and knowledge that it is encouraging infringement.

112. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '073 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent.

113. Defendants had actual knowledge of the '073 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '073 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '073 Patent renders this case "exceptional" under 35 U.S.C. § 285.

114. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '073 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

115. Plaintiffs incorporate by reference paragraphs 1–114 as if fully set forth herein.

116. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

117. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

118. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

119. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '073 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

120. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement

of the ’073 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

121. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

122. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT XI
INFRINGEMENT OF THE ’349 PATENT

123. Plaintiffs incorporate by reference paragraphs 1–122 as if fully set forth herein.

124. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

125. Defendants have infringed the ’349 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the ’349 Patent.

126. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the ’349 Patent.

127. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the

DRL ANDA Products to directly infringe one or more claims of the '349 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '349 Patent and knowledge that it is encouraging infringement.

128. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '349 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '349 Patent.

129. Defendants had actual knowledge of the '349 Patent prior to filing the Paragraph IV certification to the DRL ANDA, and were aware that submitting a Paragraph IV certification requesting FDA approval prior to the expiration of the '349 Patent would constitute an act of infringement of the '349 Patent. Defendants filed the Paragraph IV certification to the DRL ANDA without a reasonable basis for asserting the '349 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '349 Patent renders this case "exceptional" under 35 U.S.C. § 285.

130. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '349 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '349 PATENT

131. Plaintiffs incorporate by reference paragraphs 1–130 as if fully set forth herein.

132. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

133. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

134. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '349 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

135. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '349 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '349 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

136. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '349 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

137. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

138. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XIII
INFRINGEMENT OF THE '549 PATENT

139. Plaintiffs incorporate by reference paragraphs 1–138 as if fully set forth herein.

140. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

141. Defendants have infringed the '549 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '549 Patent.

142. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '549 Patent.

143. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '549 Patent. In addition, on

information and belief, Defendants will encourage acts of direct infringement with knowledge of the '549 Patent and knowledge that it is encouraging infringement.

144. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '549 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the DRL ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent.

145. Defendants had actual knowledge of the '549 Patent prior to filing the Paragraph IV certification to the DRL ANDA, and were aware that submitting a Paragraph IV certification requesting FDA approval prior to the expiration of the '549 Patent would constitute an act of infringement of the '549 Patent. Defendants filed the Paragraph IV certification to the DRL ANDA without a reasonable basis for asserting the '549 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '549 Patent renders this case "exceptional" under 35 U.S.C. § 285.

146. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '549 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XIV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '549 PATENT

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

148. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

149. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

150. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

151. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '549 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

152. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '549 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

153. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

154. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed the RE286, '673, '117, '337, '073, '349, and '549 Patents under 35 U.S.C. § 271(e)(2)(A);

B. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the RE286, '673, '117, '337, '073, '349, and '549 Patents;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, using, offering for sale, or selling or importing any product that infringes the RE286, '673, '117, '337, '073, '349, and '549 Patents, including the ANDA Products described in the DRL ANDA;

D. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the DRL ANDA shall be no earlier than the expiration date of the RE286, '673, '117, '337, '073, '349, and '549 Patents, or any later expiration of exclusivity for the RE286, '673, '117, '337, '073, '349, and '549 Patents, including any extensions or regulatory exclusivities;

E. A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of the product described

in the DRL ANDA, it will constitute an act of direct and/or indirect infringement of the RE286, '673, '117, '337, '073, '349, and '549 Patents;

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, or any product that infringes the RE286, '673, '117, '337, '073, '349, and '549 Patents, or induce or contribute to such conduct, prior to the expiration of the RE286, '673, '117, '337, '073, '349, and '549 Patents, or any later expiration of exclusivity for the RE286, '673, '117, '337, '073, '349, and '549 Patents, including any extensions or regulatory exclusivities;

G. The entry of judgment declaring that Defendants' acts render this case an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

H. An award to Plaintiffs of their costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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