IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAUSCH HEALTH IRELAND LIMITED, SALIX PHARMACEUTICALS, INC., and NORGINE B.V., Plaintiffs, v. LUPIN LTD., LUPIN ATLANTIS HOLDINGS SA, LUPIN INC., and LUPIN PHARMACEUTICALS, INC. Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited, Salix Pharmaceuticals, Inc., and Norgine B.V. (collectively, "Plaintiffs") by way of Complaint against Defendants Lupin Ltd., Lupin Atlantis Holdings SA, Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principle place of business at 400 Somerset Blvd., Bridgewater, NJ 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 209381, which covers Plenvu®.

3. Plaintiff Norgine B.V. ("Norgine") is a corporation organized and existing under the laws of the Netherlands, having a corporate headquarters at Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

4. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a corporate headquarters at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051.

5. Upon information and belief, Defendant Lupin Atlantis Holdings SA ("Lupin Atlantis") is a corporation organized and existing under the laws of Switzerland, having a corporate headquarters at Landis & Gyr-Strasse 1, Zug, Switzerland 6300. Upon information and belief, Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

6. Upon information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Atlantis.

7. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharm.") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharm. is a subsidiary of Lupin Ltd. (3%) and Lupin Inc. (97%).

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 8,999,313 B2 ("the '313 patent"); 9,326,969 B2 ("the '969 patent"); 9,592,252 B2 ("the '252 patent"); 9,707,297 B2 ("the '297 patent"); and 10,016,504 B2 ("the '504 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for

declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Lupin's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic polyethylene glycol 3350 (140 g), sodium ascorbate (48.11 g), sodium sulfate (9 g), ascorbic acid (7.54 g), sodium chloride (5.2 g), and potassium chloride (2.2 g) for oral solution ("Lupin's ANDA Product").

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Upon information and belief, this Court has jurisdiction over Lupin Ltd. Upon information and belief, Lupin Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Lupin Ltd. directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Lupin's ANDA Product. Upon information and belief, Lupin Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Ltd. maintains continuous and systematic contacts with Delaware through its subsidiaries incorporated in Delaware, including Lupin Inc. and Lupin Pharm. Upon information and belief, Lupin Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

11. Upon information and belief, this Court has jurisdiction over Lupin Atlantis. Upon information and belief, Lupin Atlantis directly or indirectly manufactures, markets, and sells

generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Atlantis purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Atlantis maintains continuous and systematic contacts with Delaware through its Delaware subsidiary, Lupin Inc. Upon information and belief, Lupin Atlantis has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Upon information and belief, this Court has jurisdiction over Lupin Inc. Upon information and belief, Lupin Inc. directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Inc. is incorporated in Delaware and has a registered agent for service of process in this judicial district. Upon information and belief, Lupin Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Upon information and belief, this Court has jurisdiction over Lupin Pharm. Upon information and belief, Lupin Pharm. directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Pharm. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Pharm. is incorporated in Delaware and has a registered agent for service of process in this judicial district. Upon information and belief, Lupin Pharm. has

previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Upon information and belief, Lupin Ltd., Lupin Atlantis, Lupin Inc., and Lupin Pharm. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States. Upon information and belief, Lupin employs "vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings." (*See* http://www.lupinpharmaceuticals.com/about.htm, accessed April 1, 2019.)

15. Lupin Ltd., Lupin Atlantis, Lupin Inc., and/or Lupin Pharm. consented to or did not contest jurisdiction of this Court, for example, in at least the following District of Delaware actions: *Unimed Pharm., LLC v. Lupin Atlantis Holdings SA*, Civil Action No. 15-cv-00904-RGA (Lupin Ltd., Lupin Atlantis, and Lupin Pharm.); *Astellas Pharma Inc. v. Lupin Ltd.*, Civil Action No. 16-cv-00908-SLR (Lupin Ltd. and Lupin Pharm.); *Biogen Int'l GmbH v. Lupin Atlantis Holdings SA*, Civil Action No. 17-cv-00853-LPS (Lupin Atlantis and Lupin Inc.); *Mayne Pharma Int'l Pty Ltd. v. Lupin Ltd.*, Civil Action No. 17-cv-01637-VAC-SRF (Lupin Atlantis and Lupin Pharm.).

16. Lupin Ltd., Lupin Atlantis, and/or Lupin Pharm. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims, for example, in at least the following District of Delaware actions: *Unimed Pharm., LLC v. Lupin Atlantis Holdings SA*, Civil Action No. 15-cv-00904-RGA (Lupin Ltd., Lupin Atlantis, and Lupin Pharm.); *Astellas Pharma Inc. v. Lupin Ltd.*, Civil Action No. 16-cv-00908-SLR (Lupin Ltd.); *Biogen Int'l GmbH v. Lupin Atlantis Holdings SA*, Civil Action No. 17-cv-00853-LPS (Lupin Atlantis); *Mayne Pharma Int'l Pty Ltd. v. Lupin Ltd.*, Civil Action No. 17-cv-01637-VAC-SRF (Lupin Atlantis).

17. Lupin is subject to specific jurisdiction in this district based on the filing of its ANDA for its generic polyethylene glycol 3350 (140 g), sodium ascorbate (48.11 g), sodium sulfate (9 g), ascorbic acid (7.54 g), sodium chloride (5.2 g), and potassium chloride (2.2 g) for oral solution product.

18. Lupin has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, this judicial district and elsewhere.

19. Lupin's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.

20. Upon information and belief, Lupin intends to direct sales of its drugs into Delaware, among other places, once it has requested FDA approval to market them.

21. Upon information and belief, Lupin will engage in marketing of Lupin's ANDA Product in Delaware, upon approval of its ANDA.

22. Lupin's ANDA filing regarding the '313, '969, '252, '297, and '504 patents at issue here is suit-related and has a substantial connection with this judicial district because it reliably, non-speculatively predicts activities by Lupin in this judicial district.

23. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

24. Lupin Ltd., Lupin Atlantis, Lupin Inc., and/or Lupin Pharm. did not contest venue in this judicial district in at least the following actions: *Unimed Pharm., LLC v. Lupin Atlantis Holdings SA*, Civil Action No. 15-cv-00904-RGA (Lupin Ltd., Lupin Atlantis, and Lupin Pharm.); *Astellas Pharma Inc. v. Lupin Ltd.*, Civil Action No. 16-cv-00908-SLR (Lupin Ltd. and Lupin Pharm.); *Biogen Int'l GmbH v. Lupin Atlantis Holdings SA*, Civil Action No. 17-cv-00853-LPS

(Lupin Atlantis and Lupin Inc.); *Mayne Pharma Int'l Pty Ltd. v. Lupin Ltd.*, Civil Action No. 17-cv-01637-VAC-SRF (Lupin Atlantis and Lupin Pharm.).

25. Venue is proper against Lupin Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this district.

26. Venue is proper against Lupin Atlantis, a foreign corporation, in any judicial district that has personal jurisdiction, including this district.

27. Venue is proper against Lupin Inc. because, *inter alia*, it is incorporated in Delaware.

28. Venue is proper against Lupin Pharm. because, *inter alia*, it is incorporated in Delaware.

THE PATENTS IN SUIT

29. The U.S. Patent and Trademark Office ("PTO") issued the '313 patent on April 7, 2015. The '313 patent claims, *inter alia*, compositions for admixture with water, compositions, and kits comprising compositions for the preparation of colon cleansing solutions. Plaintiffs hold all substantial rights in the '313 patent and have the right to sue for infringement thereof. Norgine is the assignee of the '313 patent. A copy of the '313 patent is attached hereto as Exhibit A.

30. The PTO issued the '969 patent on May 3, 2016. The '969 patent claims, *inter alia*, methods of cleansing the colon. Plaintiffs hold all substantial rights in the '969 patent and have the right to sue for infringement thereof. Norgine is the assignee of the '969 patent. A copy of the '969 patent is attached hereto as Exhibit B.

31. The PTO issued the '252 patent on March 14, 2017. The '252 patent claims, *inter alia*, colon cleansing solutions, kits comprising colon cleansing solutions, kits comprising compositions for the preparation of colon cleansing solutions, and methods of cleansing the colon.

Plaintiffs hold all substantial rights in the ’252 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’252 patent. A copy of the ’252 patent is attached hereto as Exhibit C.

32. The PTO issued the ’297 patent on July 18, 2017. The ’297 patent claims, *inter alia*, kits comprising compositions for the preparation of colon cleansing solutions and kits comprising colon cleansing solutions. Plaintiffs hold all substantial rights in the ’297 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’297 patent. A copy of the ’297 patent is attached hereto as Exhibit D.

33. The PTO issued the ’504 patent on July 10, 2018. The ’504 patent claims, *inter alia*, solutions in water and methods of preparing solutions. Plaintiffs hold all substantial rights in the ’504 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’504 patent. A copy of the ’504 patent is attached hereto as Exhibit E.

34. Salix is the holder of NDA No. 209381 for Plenvu®, which the FDA approved on May 4, 2018. In conjunction with NDA No. 209381, the ’313, ’969, ’252, ’297, and ’504 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

35. Polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution is sold in the United States under the trademark Plenvu®.

LUPIN’S INFRINGING ANDA SUBMISSION

36. Upon information and belief, Lupin filed or caused to be filed with the FDA ANDA No. 212934, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

37. Upon information and belief, Lupin's ANDA No. 212934 seeks FDA approval to engage in the commercial manufacture, use, and sale in the United States of Lupin's ANDA Product, which Lupin intends to be a generic version of Plenvu®.

38. Plaintiffs received a letter from Lupin Inc. dated February 18, 2019, purporting to be a Notice of Certification for ANDA No. 212934 ("Lupin's Notice Letter") under Section 505(j)(2)(B)(ii)–(iv) of the Act and 21 § C.F.R. 314.95(c). Lupin's Notice Letter was addressed to Salix, Norgine, and Bausch Health Companies Inc.

39. Lupin's Notice Letter alleges that Lupin Inc. has submitted to the FDA ANDA No. 212934 seeking to engage in the manufacture, use, and sale of Lupin's ANDA Product.

40. Lupin's Notice Letter states that Lupin's ANDA No. 212934 "contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver" for Lupin's ANDA Product.

41. Lupin's Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, does not set forth any non-infringement defense related to claims 1–4, 7–9, 11–14, 16–20, 22–23, and 29 of the '313 patent; claims 1–9 of the '252 patent; claims 1–6, 8–18, and 20–24 of the '297 patent; and claims 1–11, 13–14, and 20 of the '504 patent.

42. The '313, '969, '252, '297, and '504 patents are listed in the Orange Book in conjunction with NDA No. 209381 for Plenvu®.

43. Upon information and belief, ANDA No. 212934 seeks approval of Lupin's ANDA Product that is the same, or substantially the same, as Plenvu®.

44. Upon information and belief, Lupin Inc.'s actions related to ANDA No. 212934 complained of herein were done at the direction of, with the authorization of, or with the

cooperation, the participation, the assistance of, or at least in part for the benefit of Lupin Ltd., Lupin Atlantis, and Lupin Pharm.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the ’313 Patent Under § 271(e)(2)

45. Paragraphs 1–44 are incorporated herein as set forth above.

46. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the ’313 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212934 seeking approval for the commercial marketing of Lupin’s ANDA Product before the expiration date of the ’313 patent.

47. Upon information and belief, Lupin’s ANDA Product will, if approved and marketed, infringe at least one claim of the ’313 patent.

48. Upon information and belief, Lupin will, through the manufacture, use, import, offer for sale, and/or sale of Lupin’s ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’313 patent.

49. If Lupin’s marketing and sale of Lupin’s ANDA Product prior to the expiration of the ’313 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’313 Patent

50. Paragraphs 1–49 are incorporated herein as set forth above.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

53. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Lupin's ANDA Product before the expiration date of the '313 patent, including Lupin's filing of ANDA No. 212934.

54. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '313 patent.

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Lupin's ANDA Product will constitute infringement of at least one claim of the '313 patent.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the '969 Patent Under § 271(e)(2)

56. Paragraphs 1–55 are incorporated herein as set forth above.

57. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '969 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212934 seeking approval for the commercial marketing of Lupin's ANDA Product before the expiration date of the '969 patent.

58. Upon information and belief, Lupin's ANDA Product will, if approved and marketed, infringe at least one claim of the '969 patent.

59. Upon information and belief, Lupin will, through the manufacture, use, import, offer for sale, and/or sale of Lupin's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '969 patent.

60. If Lupin's marketing and sale of Lupin's ANDA Product prior to the expiration of the '969 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '969 Patent

61. Paragraphs 1–60 are incorporated herein as set forth above.

62. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

64. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Lupin's ANDA Product before the expiration date of the '969 patent, including Lupin's filing of ANDA No. 212934.

65. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '969 patent.

66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Lupin's ANDA Product will constitute infringement of at least one claim of the '969 patent.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the ’252 Patent Under § 271(e)(2)

67. Paragraphs 1–66 are incorporated herein as set forth above.

68. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the ’252 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212934 seeking approval for the commercial marketing of Lupin’s ANDA Product before the expiration date of the ’252 patent.

69. Upon information and belief, Lupin’s ANDA Product will, if approved and marketed, infringe at least one claim of the ’252 patent.

70. Upon information and belief, Lupin will, through the manufacture, use, import, offer for sale, and/or sale of Lupin’s ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’252 patent.

71. If Lupin’s marketing and sale of Lupin’s ANDA Product prior to the expiration of the ’252 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’252 Patent

72. Paragraphs 1–71 are incorporated herein as set forth above.

73. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

74. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

75. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Lupin's ANDA Product before the expiration date of the '252 patent, including Lupin's filing of ANDA No. 212934.

76. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '252 patent.

77. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Lupin's ANDA Product will constitute infringement of at least one claim of the '252 patent.

COUNT VII FOR PATENT INFRINGEMENT

Infringement of the '297 Patent Under § 271(e)(2)

78. Paragraphs 1–77 are incorporated herein as set forth above.

79. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '297 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212934 seeking approval for the commercial marketing of Lupin's ANDA Product before the expiration date of the '297 patent.

80. Upon information and belief, Lupin's ANDA Product will, if approved and marketed, infringe at least one claim of the '297 patent.

81. Upon information and belief, Lupin will, through the manufacture, use, import, offer for sale, and/or sale of Lupin's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '297 patent.

82. If Lupin's marketing and sale of Lupin's ANDA Product prior to the expiration of the '297 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '297 Patent

83. Paragraphs 1–82 are incorporated herein as set forth above.

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

85. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

86. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Lupin's ANDA Product before the expiration date of the '297 patent, including Lupin's filing of ANDA No. 212934.

87. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '297 patent.

88. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Lupin's ANDA Product will constitute infringement of at least one claim of the '297 patent.

COUNT IX FOR PATENT INFRINGEMENT

Infringement of the '504 Patent Under § 271(e)(2)

89. Paragraphs 1–88 are incorporated herein as set forth above.

90. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the ’504 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212934 seeking approval for the commercial marketing of Lupin’s ANDA Product before the expiration date of the ’504 patent.

91. Upon information and belief, Lupin’s ANDA Product will, if approved and marketed, infringe at least one claim of the ’504 patent.

92. Upon information and belief, Lupin will, through the manufacture, use, import, offer for sale, and/or sale of Lupin’s ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’504 patent.

93. If Lupin’s marketing and sale of Lupin’s ANDA Product prior to the expiration of the ’504 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’504 Patent

94. Paragraphs 1–93 are incorporated herein as set forth above.

95. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

96. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

97. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Lupin’s ANDA Product before the expiration date of the ’504 patent, including Lupin’s filing of ANDA No. 212934.

98. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '504 patent.

99. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Lupin's ANDA Product will constitute infringement of at least one claim of the '504 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Lupin on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '313 patent by submitting or causing to be submitted ANDA No. 212934 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Lupin's ANDA Product before the expiration of the '313 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '969 patent by submitting or causing to be submitted ANDA No. 212934 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Lupin's ANDA Product before the expiration of the '969 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '252 patent by submitting or causing to be submitted ANDA No. 212934 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Lupin's ANDA Product before the expiration of the '252 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the ’297 patent by submitting or causing to be submitted ANDA No. 212934 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Lupin’s ANDA Product before the expiration of the ’297 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the ’504 patent by submitting or causing to be submitted ANDA No. 212934 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Lupin’s ANDA Product before the expiration of the ’504 patent;

6. Order that the effective date of any approval by the FDA of Lupin’s ANDA Product be a date that is not earlier than the expiration of the ’313, ’969, ’252, ’297, and ’504 patents or such later date as the Court may determine;

7. Enjoin Lupin from the commercial manufacture, use, import, offer for sale, and/or sale of Lupin’s ANDA Product until expiration of the ’313, ’969, ’252, ’297, and ’504 patents or such later date as the Court may determine;

8. Enjoin Lupin and all persons acting in concert with Lupin from seeking, obtaining, or maintaining approval of Lupin’s ANDA No. 212934 until expiration of the ’313, ’969, ’252, ’297, and ’504 patents;

9. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney’s fees; and

10. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: April 3, 2019

GIBBONS P.C.

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