IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAYNE PHARMA INTERNATIONAL PTY LTD, Plaintiff, v. LUPIN LIMITED, LUPIN ATLANTIS HOLDINGS SA, LUPIN INC., and LUPIN PHARMACEUTICALS, INC. Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mayne Pharma International Pty Ltd ("Mayne" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendants Lupin Limited, Lupin Atlantis Holdings SA, Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively, "Defendants"), and hereby alleges 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 Defendants' recent submission to the United States Food and Drug Administration ("FDA") of an Amendment to Abbreviated New Drug Application ("ANDA") No. 208741 (hereinafter, the "Amendment"). Through the Amendment, Defendants seek approval to market generic versions of Mayne's pharmaceutical product DORYX® MPC (doxycycline hyclate delayed-release tablets), 60 mg and 120 mg, prior to the expiration of United States Patent No. 9,295,652 ("the '652 Patent"); United States Patent No. 9,446,057 ("the '057 Patent"); and United States Patent No. 9,511,031 ("the '031 Patent"). Plaintiff seeks injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

2. Plaintiff Mayne Pharma International Pty Ltd is a corporation organized and existing under the laws of the Commonwealth of Australia, with a place of business at 1538 Main North Road, Salisbury South, SA 5106, Australia. Mayne is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

4. On information and belief, Defendant Lupin Atlantis Holdings SA is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Landis + Gyr – Strasse 1, 6300 Zug, Switzerland.

5. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

6. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

7. On information and belief, Lupin Atlantis Holdings SA is a wholly owned subsidiary of Lupin Limited.

8. On information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Atlantis Holdings SA.

9. On information and belief, Lupin Inc. owns more than a 10% interest in Lupin Pharmaceuticals, Inc.

10. On information and belief, Lupin Pharmaceuticals, Inc. is an indirect, wholly owned subsidiary of Lupin Limited.

11. On information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products.

12. On information and belief, Defendants collaborated in the preparation and submission of the Amendment and continue to collaborate in seeking FDA approval of that amendment.

13. On information and belief, Defendants intend to collaborate in the commercial manufacture, marketing, offer for sale, and sale of the 60 mg and 120 mg doxycycline hyclate products described in the Amendment (hereinafter, "Defendants' ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves Defendants' ANDA Products.

14. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Defendants' ANDA Products, and enter into agreements with each other that are nearer than arm's length.

15. On information and belief, Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc., participated in, assisted, and cooperated with Lupin Atlantis Holdings SA in the acts complained of herein.

JURISDICTION AND VENUE

16. 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 '652 Patent, the '057 Patent, and the '031 Patent.

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

18. This Court has personal jurisdiction over Lupin Limited because, *inter alia*, on information and belief its fully owned subsidiaries Lupin Inc. and Lupin Pharmaceuticals, Inc. are corporations organized and existing under the laws of the State of Delaware.

19. This Court has personal jurisdiction over Lupin Atlantis Holdings SA because, *inter alia*, on information and belief its fully owned subsidiary Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware.

20. This Court has personal jurisdiction over Lupin Inc. because, *inter alia*, on information and belief it is a corporation organized and existing under the laws of the State of Delaware.

21. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because, *inter alia*, on information and belief it is a corporation organized and existing under the laws of the State of Delaware.

22. This Court also has personal jurisdiction over Defendants because each Defendant has continuous and systematic contacts with the State of Delaware. On information and belief, Defendants regularly conduct business in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. On information and belief, Defendants receive Medicaid reimbursements for drugs sold in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. On information and belief, Defendants do business in the State of Delaware through a

permanent and continuous presence there. On information and belief, Defendants and/or their subsidiaries in the State of Delaware develop, manufacture, and/or market generic and proprietary pharmaceuticals. On information and belief, Defendants and/or their subsidiaries actively seek employment of sales representatives to serve customers in the State of Delaware, continuously employ sales representatives in the State of Delaware, and regularly market their products in the State of Delaware.

23. This Court also has personal jurisdiction over Defendants because each Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures DORYX® MPC for sale and use throughout the United States, including this judicial district. On information and belief and as stated in a letter dated October 6, 2017 sent by Lupin Atlantis Holdings SA to Mayne pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), Defendants prepared and filed the Amendment with the intention of seeking to market Defendants' ANDA Products nationwide, including within this judicial district. On information and belief, Defendants plan to sell Defendants' ANDA Products in the State of Delaware, list Defendants' ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of Defendants' ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. The activities described in paragraph 22 and this paragraph satisfy due process and confer personal jurisdiction over Defendants consistent with the laws of Delaware. *See, e.g., Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016) (holding that minimum-contacts requirement for specific personal jurisdiction is established where the defendant's "ANDA filings and its distribution channels establish that [the defendant] plans to

market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about patent constraints on such in-State marketing").

24. This Court also has personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc. because each of them regularly engages in patent litigation concerning FDA-approved branded drug products in this judicial district, does not contest personal jurisdiction in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Bayer Intellectual Prop. GmbH v. Lupin Ltd.*, 17-cv-01047, D.I. 9 (D. Del. Aug. 22, 2017); *Bristol-Myers Squibb Co. v. Lupin Ltd.*, 17-cv-00378, D.I. 8 (D. Del. May 4, 2017); *ViiV Healthcare Co. v. Lupin Ltd.*, 17-cv-00315, D.I. 8 (D. Del. Apr. 17, 2017); *Astellas Pharma Inc. v. Lupin Ltd.*, 16-cv-00908, D.I. 20 (D. Del. Jan. 17, 2017); *Arena Pharm., Inc. v. Lupin Ltd.*, 16-cv-00887, D.I. 12 (Jan. 11, 2017); *Lupin Atlantis Holdings, S.A. v. InvaGen Pharm., Inc.*, 16-cv-00708, D.I. 1 (D. Del. Aug. 11, 2016); *Sanofi v. Lupin Atlantis Holdings S.A.*, 15-cv-00415, D.I. 31 (D. Del. Nov. 2, 2015).

25. In the alternative, this Court has personal jurisdiction over Lupin Limited and Lupin Atlantis Holdings SA pursuant to Federal Rule of Civil Procedure 4(k)(2). If Lupin Limited's connections with the State of Delaware, including its connections with Lupin Inc. and Lupin Pharmaceuticals, Inc., are found to be insufficient to confer personal jurisdiction, then, on information and belief, Lupin Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Lupin Limited in the State of Delaware is consistent with the United States Constitution and laws. Similarly, if Lupin Atlantis Holdings SA's connections with the State of Delaware, including its connections with Lupin Inc., are found to be insufficient to confer personal jurisdiction, then, on information and belief, Lupin

Atlantis Holdings SA is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Lupin Atlantis Holdings SA in the State of Delaware is consistent with the United States Constitution and laws.

26. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief Lupin Limited is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district in the United States, in which Lupin Limited is subject to the court's personal jurisdiction.

27. Venue is proper in this district for Lupin Atlantis Holdings SA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief Lupin Atlantis Holdings SA is a corporation organized and existing under the laws of Switzerland and may be sued in any judicial district in the United States, in which Lupin Atlantis Holdings SA is subject to the court's personal jurisdiction.

28. Venue is proper in this district for Lupin Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware.

29. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware.

30. In the alternative, venue is proper in this district for Defendants because, on information and belief, each Defendant has committed acts of infringement and has a regular and established place of business in this district. *See, e.g., Bristol-Myers Squibb Co. v. Mylan Pharm.*

Inc., No. 17-CV-379-LPS, 2017 WL 3980155, at *13 (D. Del. Sept. 11, 2017) (holding that "an applicant's submission of an ANDA, in conjunction with other acts the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District, . . . can be sufficient to demonstrate that the ANDA-filing Defendant 'has committed' 'acts of infringement' in this District"). On information and belief, each Defendant is part of a family of companies all of which ultimate corporate parent is Lupin Limited. On information and belief, the family of companies includes at least five U.S. subsidiaries that are incorporated under the laws of the State of Delaware. On information and belief, the family of companies leverages a broad network of local and global access channels in order to get its generic drugs to customers in the State of Delaware. The activities described in paragraphs 22 through 24 and this paragraph amount to a regular and established place of business sufficient to confer venue.

MAYNE'S APPROVED DORYX® MPC DRUG PRODUCT AND PATENTS

31. Mayne is the holder of New Drug Application ("NDA") No. 050795 for DORYX® tablets (50 mg, 75 mg, 80 mg, 100 mg, 150 mg, and 200 mg dosage strengths) and DORYX® MPC tablets (60 mg and 120 mg dosage strengths), each of which contains the active ingredient doxycycline hyclate. FDA first approved NDA No. 050795 for tablets containing 75 mg and 100 mg dosage strengths on May 6, 2005. FDA approved a supplement to NDA No. 050795 for tablets with a modified polymer coat (MPC) and containing 60 mg and 120 mg dosage strengths on May 20, 2016. DORYX® MPC is an oral antibacterial drug prescribed for several indications including, but not limited to, spotted and typhus fevers, anthrax, and severe acne. A true and correct copy of the current FDA-approved Prescribing Information for DORYX® MPC, covering both the 60 mg and 120 mg dosage strengths, is attached hereto as Exhibit A.

32. Mayne owns the ’652 Patent, the ’057 Patent, and the ’031 Patent.

33. The ’652 Patent, the ’057 Patent, and the ’031 Patent are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for DORYX® MPC, 60 mg and 120 mg.

34. The ’652 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the USPTO on March 29, 2016. A true and correct copy of the ’652 Patent is attached hereto as Exhibit B.

35. The ’057 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the USPTO on September 20, 2016. A true and correct copy of the ’057 Patent is attached hereto as Exhibit C.

36. The ’031 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the USPTO on December 6, 2016. A true and correct copy of the ’031 Patent is attached hereto as Exhibit D.

DEFENDANTS’ AMENDMENT TO ANDA NO. 208741

37. On information and belief, Defendants have submitted or caused to be submitted the Amendment to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of Doxycycline Hyclate Delayed-released Tablets, 60 mg and 120 mg, as purported generic versions of DORYX® MPC tablets containing 60 mg and 120 mg dosage strengths, respectively, prior to the expiration of the ’652 Patent, the ’057 Patent, and the ’031 Patent.

38. On information and belief, FDA has not approved the Amendment.

39. On information and belief, on or about October 6, 2017, Lupin Atlantis Holdings SA mailed the Notice Letter. The Notice Letter represented that Lupin Atlantis Holdings SA had submitted to FDA the Amendment and a purported Paragraph IV certification to obtain approval

to engage in the commercial manufacture, use, or sale of Defendants' ANDA Products before the expiration of the patents listed in the Orange Book for DORYX® MPC. Hence, Defendants' purpose in submitting the Amendment is to manufacture and market Defendants' ANDA Products before the expiration of the '652 Patent, the '057 Patent, and the '031 Patent.

40. Lupin Atlantis Holdings SA's Notice Letter stated that the Paragraph IV certification in the Amendment alleges that no valid claim of the '652 Patent, the '057 Patent, and the '031 Patent will be infringed by the manufacture, importation, use, or sale of Defendants' ANDA Products.

41. Lupin Atlantis Holdings SA's Notice Letter contained a "detailed statement" of the factual and legal basis for the Paragraph IV certification in the Amendment (hereinafter, "Detailed Statement").

42. Lupin Atlantis Holdings SA's Detailed Statement identified no theory of non-infringement for the '057 Patent or the '031 Patent.

43. After receiving Lupin Atlantis Holdings SA's Notice Letter and accompanying purported Offer of Confidential Access ("OCA"), Plaintiff wrote to Lupin Atlantis Holdings SA in an effort to negotiate reasonable terms of access to the Amendment. The parties agreed on terms for a revised OCA on October 23, 2017. Plaintiff's outside counsel received the Amendment on October 27, 2017, pursuant to the revised OCA.

44. On information and belief, Defendants have assisted with and participated in the preparation and submission of the Amendment, have provided material support to the preparation and submission of the Amendment, and intend to support the further prosecution of the Amendment.

45. On information and belief, if FDA approves the Amendment, Defendants will manufacture, offer for sale, or sell Defendants' ANDA Products, within the United States, including within the State of Delaware, or will import Defendants' ANDA Products into the United States, including the State of Delaware.

46. On information and belief, if FDA approves the Amendment, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of Defendants' ANDA Products.

47. This action is being brought within forty-five days of Plaintiff's receipt of the Notice Letter. Accordingly, Plaintiff is entitled to a thirty-month stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
INFRINGEMENT OF THE '652 PATENT

48. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–47 as if fully set forth herein.

49. On information and belief, Defendants have submitted or caused the submission of the Amendment to FDA, and are thereby continuing to seek FDA approval of the Amendment.

50. Plaintiff owns all rights, title, and interest in and to the '652 Patent.

51. As demonstrated below, Defendants have infringed at least one claim of the '652 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the '652 Patent.

52. On information and belief, at least one of Defendants' ANDA Products consists of a plurality of modified release doxycycline pellets.

53. On information and belief, at least one of Defendants' ANDA Products includes doxycycline.

54. On information and belief, at least one of Defendants' ANDA Products includes a controlled release polymer composition disposed over doxycycline.

55. On information and belief, at least one of Defendants' ANDA Products includes 60 mg or 120 mg of doxycycline.

56. On information and belief, at least one of Defendants' ANDA Products releases less than 15% of the doxycycline at pH 1.2, and less than 40% of the doxycycline at pH 4.5 after 60 minutes, measured under USP <711> conditions.

57. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 625-1600 ng/ml.

58. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 1250-3200 ng/ml.

59. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 10000-24000 ng·hr/ml.

60. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions

to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 20000-48500 ng·hr/ml.

61. On information and belief, at least one of Defendants' ANDA Products includes a doxycycline-containing core.

62. On information and belief, at least one of Defendants' ANDA Products includes a controlled release polymer composition that is disposed as a layer over a doxycycline-containing core.

63. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA products includes a blend of an enteric polymer and a water-soluble polymer.

64. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA products includes a plasticizer.

65. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products consists of a blend of an enteric polymer, a water-soluble polymer, and a plasticizer.

66. On information and belief, an enteric polymer included in at least one of Defendants' ANDA Products is selected from a group consisting of hydroxypropyl methylcellulose phthalate, poly(methacrylic acid-co-ethyl acrylate), poly(methacrylic acid-co-methyl methacrylate), poly(methyl acrylate-co-methyl methacrylate-co-methacrylic acid), hydroxypropylmethyl cellulose acetate succinate, cellulose acetate succinate, polyvinyl acetate phthalate, shellac, cellulose acetate trimellitate, sodium alginate, and combinations thereof.

67. On information and belief, a water-soluble polymer included in at least one of Defendants' ANDA Products is selected from the group consisting of hydroxypropyl

methylcellulose, methylcellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, polyethylene glycol, polyvinyl alcohol, and combinations thereof.

68. On information and belief, a plasticizer included in at least one of Defendants' ANDA Products is selected from the group consisting of citric acid esters, tartaric acid esters, glycerol, glycerol esters, phthalic acid esters, adipic acid esters, sebacic acid esters, polyethylene glycol esters, sorbitan esters, and combinations thereof.

69. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products consists of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose, and triethyl citrate.

70. On information and belief, for at least one of Defendants' ANDA Products including a controlled release polymer composition that consists of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose, and triethyl citrate, the ratio of hydroxypropyl methylcellulose phthalate to hydroxypropyl methylcellulose ranges from 3.5:1 to 6:1.

71. On information and belief, at least one of Defendants' ANDA Products includes a stabilizing coating disposed between a doxycycline-containing core and a controlled release polymer composition layer.

72. On information and belief, a stabilizing coating included in at least one of Defendants' ANDA Products comprises a water-soluble polymer and talc.

73. On information and belief, at least one of Defendants' ANDA Products is orally administered to treat a skin condition in a patient.

74. On information and belief, at least one of Defendants' ANDA Products is administered to treat a skin condition selected from the group consisting of: a skin infection, rosacea, acne, papules, pustules, open comedo, closed comedo, or a combination thereof.

75. On information and belief, at least one of Defendants' ANDA Products can be administered once per day.

76. On information and belief, a controlled release polymer included in at least one of Defendants' ANDA Products includes a blend of an enteric polymer and a plasticizer.

77. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '652 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Amendment, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within the United States, or will import Defendants' 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 '652 Patent.

78. On information and belief, upon FDA approval of the Amendment, Defendants will market and distribute Defendants' ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants' ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Products with a product label and product insert that will include instructions for using and administering Defendants' ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants' ANDA Products to directly infringe one or more claims of the '652 Patent. In addition, on information

and belief, Defendants will encourage acts of direct infringement with knowledge of the ’652 Patent and knowledge that they are encouraging infringement.

79. Defendants had actual and constructive notice of the ’652 Patent prior to filing the Amendment, and were aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’652 Patent would constitute an act of infringement of the ’652 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA Products will not contribute to the infringement of and/or induce the infringement of the ’652 Patent.

80. In addition, Defendants filed the Amendment without adequate justification for asserting the ’652 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’652 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

81. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’652 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff 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 ’652 PATENT

82. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–81 as if fully set forth herein.

83. Plaintiff’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

84. On information and belief, if the Amendment is approved, Defendants' ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

85. On information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA Products in accordance with the labeling sought by the Amendment and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '652 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

86. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves the Amendment. Any such conduct before the '652 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '652 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

87. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '652 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

88. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

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

COUNT III
INFRINGEMENT OF THE ’057 PATENT

90. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–47 as if fully set forth herein.

91. On information and belief, Defendants have submitted or caused the submission of the Amendment to FDA, and are thereby continuing to seek FDA approval of the Amendment.

92. Plaintiff owns all rights, title, and interest in and to the ’057 Patent.

93. As demonstrated below, Defendants have infringed at least one claim of the ’057 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the ’057 Patent.

94. On information and belief, at least one of Defendants’ ANDA Products consists of a plurality of modified release doxycycline pellets.

95. On information and belief, at least one of Defendants’ ANDA Products includes doxycycline.

96. On information and belief, at least one of Defendants’ ANDA Products includes a controlled release polymer composition disposed over doxycycline.

97. On information and belief, at least one of Defendants’ ANDA Products includes 60 or 120 mg of doxycycline.

98. On information and belief, at least one of Defendants’ ANDA Products maintains doxycycline release levels measured under USP <711> conditions at pH 5 that provide a clinically effective plasma level of doxycycline.

99. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 625-1600 ng/ml.

100. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 1250-3200 ng/ml.

101. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 10000-24000 ng·hr/ml.

102. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 20000-48500 ng·hr/ml.

103. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least one of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

104. On information and belief, at least one of Defendants' ANDA Products maintains release levels measured under USP <711> conditions that are low at pH values up to pH 4.5.

105. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least two of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

106. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least three of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

107. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least four of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

108. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

109. On information and belief, at least one of Defendants' ANDA Products includes a doxycycline-containing core.

110. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products is disposed as a layer over a doxycycline-containing core.

111. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products includes a blend of an enteric polymer and a water-soluble polymer.

112. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products includes a plasticizer.

113. On information and belief, a controlled release polymer composition included in at least on of Defendants' ANDA Products consists of a blend of an enteric polymer, a water-soluble polymer, and a plasticizer.

114. On information and belief, at least one of Defendants' ANDA Products includes a stabilizing coating disposed between a doxycycline-containing core and a controlled release polymer composition layer.

115. On information and belief, at least one of Defendants' ANDA Products is orally administered to treat a skin condition in a patient.

116. On information and belief, at least one of Defendants' ANDA Products is orally administered to treat at least one skin condition selected from the group consisting of: a skin infection, rosacea, acne, papules, pustules, open comedo, closed comedo, or a combination thereof.

117. On information and belief, at least one of Defendants' ANDA Products can be administered once per day.

118. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '057 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Amendment, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products

within the United States, or will import Defendants' 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 '057 Patent.

119. On information and belief, upon FDA approval of the Amendment, Defendants will market and distribute Defendants' ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants' ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Products with a product label and product insert that will include instructions for using and administering Defendants' ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants' ANDA Products to directly infringe one or more claims of the '057 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '057 Patent and knowledge that they are encouraging infringement.

120. Defendants had actual and constructive notice of the '057 Patent prior to filing the Amendment, and were aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '057 Patent would constitute an act of infringement of the '057 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA Products will not contribute to the infringement of and/or induce the infringement of the '057 Patent.

121. Lupin Atlantis Holdings SA's Detailed Statement in the Notice Letter lacks any contention that Defendants' ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '057 Patent.

122. In addition, Defendants filed the Amendment without adequate justification for asserting the ’057 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’057 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

123. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’057 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff 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 ’057 PATENT

124. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–47 and 90–123 as if fully set forth herein.

125. Plaintiff’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

126. On information and belief, if the Amendment is approved, Defendants’ ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

127. On information and belief, Defendants know that health care professionals or patients will use Defendants’ ANDA Products in accordance with the labeling sought by the Amendment and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the ’057 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

128. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves the Amendment. Any such conduct before the '057 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '057 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

129. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '057 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

130. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

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

COUNT V
INFRINGEMENT OF THE '031 PATENT

132. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–47 as if fully set forth herein.

133. On information and belief, Defendants have submitted or caused the submission of the Amendment to FDA, and are thereby continuing to seek FDA approval of the Amendment.

134. Plaintiff owns all rights, title, and interest in and to the '031 Patent.

135. As demonstrated below, Defendants have infringed at least one claim of the '031 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the '031 Patent.

136. On information and belief, at least one of Defendants' ANDA Products consists of doxycycline combined with a controlled release composition.

137. On information and belief, at least one of Defendants' ANDA Products includes 60 or 120 mg of doxycycline.

138. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline measured under USP <711> conditions is at least one of: less than 48% at 15 minutes; less than 64% at 20 minutes; and less than 72% at 25 minutes.

139. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 625-1600 ng/ml.

140. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 1250-3200 ng/ml.

141. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose to a patient in need thereof,

the average area under the curve (from zero to infinity) is 80% to 125% of 10000-24000 ng·hr/ml.

142. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 20000-48500 ng·hr/ml.

143. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline is at least one of: 30% to 48% at 15 minutes; 30% to 64% at 20 minutes; and 45% to 72% at 25 minutes.

144. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline is at least one of: 35% to 48% at 15 minutes; 40% to 64% at 20 minutes; and 50% to 72% at 25 minutes.

145. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 20 minutes ranges from 42% to 64%.

146. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 20 minutes ranges from 47% to 64%.

147. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes ranges from 58% to 72%.

148. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes ranges from 65% to 72%.

149. On information and belief, at least one of Defendants' ANDA Products includes a plurality of pellets.

150. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products is disposed over doxycycline.

151. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes ranges from 60% to 72%.

152. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes is about 65%.

153. On information and belief, at least one of Defendants' ANDA Products can be administered once per day.

154. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline is measured under USP <711> conditions with stirring at 50 RPM.

155. On information and belief, for at least one of Defendants' ANDA Products, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 10-27 ng/ml per mg of doxycycline administered.

156. On information and belief, for at least one of Defendants' ANDA Products, after administration of a single dose to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 167-404 ng·hr/ml per mg of doxycycline administered.

157. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '031 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Amendment, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within the United States, or will import Defendants' 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 ’031 Patent.

158. On information and belief, upon FDA approval of the Amendment, Defendants will market and distribute Defendants’ ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants’ ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants’ ANDA Products with a product label and product insert that will include instructions for using and administering Defendants’ ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants’ ANDA Products to directly infringe one or more claims of the ’031 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the ’031 Patent and knowledge that they are encouraging infringement.

159. Defendants had actual and constructive notice of the ’031 Patent prior to filing the Amendment, and were aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’031 Patent would constitute an act of infringement of the ’031 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA Products will not contribute to the infringement of and/or induce the infringement of the ’031 Patent.

160. Lupin Atlantis Holdings SA’s Detailed Statement in the Notice Letter lacks any contention that Defendants’ ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the ’031 Patent.

161. In addition, Defendants filed the Amendment without adequate justification for asserting the ’031 Patent to be invalid, unenforceable, and/or not infringed by the commercial

manufacture, use, offer for sale, or sale of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '031 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

162. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '031 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff 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 '031 PATENT

163. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–47 and 132–162 as if fully set forth herein.

164. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

165. On information and belief, if the Amendment is approved, Defendants' ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

166. On information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA Products in accordance with the labeling sought by the Amendment and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '031 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

167. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products

complained of herein will begin immediately after FDA approves the Amendment. Any such conduct before the ’031 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’031 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

168. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the ’031 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

169. Plaintiff will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

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

REQUEST FOR RELIEF

WHEREFORE, Mayne respectfully requests the following relief:

(A) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission to FDA of the Amendment to ANDA No. 208741 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants’ ANDA Products before the expiration of the ’652 Patent was an act of infringement of one or more claims of the ’652 Patent;

(B) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants’ submission to FDA of the Amendment to ANDA No. 208741 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of

Defendants' ANDA Products before the expiration of the '057 Patent was an act of infringement of one or more claims of the '057 Patent;

(C) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Amendment to ANDA No. 208741 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products before the expiration of the '031 Patent was an act of infringement of one or more claims of the '031 Patent;

(D) The entry of 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 Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '652 Patent;

(E) The entry of 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 Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '057 Patent;

(F) The entry of 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 Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '031 Patent;

(G) The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), 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 Defendants' ANDA Products within the United States, or importing Defendants' ANDA

Products into the United States, until the expiration of the ’652 Patent, the ’057 Patent, and the ’031 Patent;

(H) 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 Amendment to ANDA No. 208741 shall be no earlier than the last expiration date of any of the ’652 Patent, the ’057 Patent, and the ’031 Patent, or any later expiration of exclusivity for any of the ’652 Patent, the ’057 Patent, and the ’031 Patent, including any extensions or regulatory exclusivities;

(I) 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 Defendants’ ANDA Products, or any product that infringes the ’652 Patent, or induces or contributes to such conduct, prior to the expiration of the ’652 Patent;

(J) 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 Defendants’ ANDA Products, or any product that infringes the ’057 Patent, or induces or contributes to such conduct, prior to the expiration of the ’057 Patent;

(K) 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 Defendants’ ANDA Products, or any product that infringes the ’031 Patent, or induces or contributes to such conduct, prior to the expiration of the ’031 Patent;

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

(M) An award to Plaintiff of its costs and expenses in this action; and

(N) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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