IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAYNE PHARMA INTERNATIONAL PTY LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. and SOLCO HEALTHCARE U.S., LLC,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mayne Pharma International Pty Ltd. ("Mayne" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendant Prinston Pharmaceutical Inc. ("Prinston"), Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai"), and Solco Healthcare U.S., LLC ("Solco Healthcare") (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 a Prior Approval Supplement to Abbreviated New Drug Application ("ANDA") No. 207494 (hereinafter, the "Supplement"). Through the Supplement, Defendants seek approval to market generic versions of Mayne's pharmaceutical product DORYX® MPC (doxycycline hyclate delayed-release tablets), 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 such other relief as 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 Prinston Pharmaceutical Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

4. On information and belief, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of the People's Republic of China, with a principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

5. On information and belief, Defendant Solco Healthcare U.S., LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

6. On information and belief, Prinston is a wholly owned subsidiary of Zhejiang Huahai.

7. On information and belief, Solco Healthcare is a wholly owned subsidiary of Prinston.

8. On information and belief, Prinston and Solco Healthcare act at the direction, and for the benefit, of Zhejiang Huahai and are controlled and/or dominated by Zhejiang Huahai.

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

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

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

12. 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 Product, and enter into agreements with each other that are nearer than arm's length.

13. On information and belief, Zhejiang Huahai and Solco Healthcare participated in, assisted, and cooperated with Prinston in the acts complained of herein.

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

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

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

17. This Court has personal jurisdiction over Zhejiang Huahai because, *inter alia*, on information and belief, its subsidiary Prinston is a corporation organized and existing under the laws of the State of Delaware.

18. This Court has personal jurisdiction over Solco Healthcare because, *inter alia*, on information and belief, it is a limited liability company organized and existing under the laws of the State of Delaware.

19. 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.

20. 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 February 7, 2019 sent by Prinston to Mayne pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), Defendants prepared and filed the Supplement with the intention of seeking to market Defendants' ANDA Product nationwide, including within this judicial district. On information and belief, Defendants plan to sell Defendants' ANDA Product in the State of Delaware, list Defendants' ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of Defendants' ANDA Product 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 19 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).

21. In the alternative, this Court has personal jurisdiction over Zhejiang Huahai pursuant to Federal Rule of Civil Procedure 4(k)(2). If Zhejiang Huahai's connections with the State of Delaware, including its connections with Prinston and Solco Healthcare, are found to be insufficient to confer personal jurisdiction, then, on information and belief, Zhejiang Huahai is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction

over Zhejiang Huahai in the State of Delaware is consistent with the United States Constitution and laws.

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

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

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

MAYNE'S APPROVED DORYX® MPC DRUG PRODUCT AND PATENTS

25. 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.

26. Mayne owns the '652 Patent, the '057 Patent, and the '031 Patent.

27. 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.

28. The ’652 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on March 29, 2016. A true and correct copy of the ’652 Patent is attached hereto as Exhibit A.

29. 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 B.

30. 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 C.

DEFENDANTS’ SUPPLEMENT TO ANDA NO. 207494

31. On information and belief, Defendants have submitted or caused to be submitted the Supplement 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-Release Tablets, 120 mg, as a purported generic version of DORYX® MPC tablets containing a 120 mg dosage strength, prior to the expiration of the ’652 Patent, the ’057 Patent, and the ’031 Patent.

32. On information and belief, FDA has not approved the Supplement.

33. On information and belief, on or about February 7, 2019, Prinston sent the Notice Letter to Plaintiff. The Notice Letter represented that Prinston had submitted to FDA the Supplement and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Defendants’ ANDA Product before the expiration of the patents listed in the Orange Book for DORYX® MPC.

34. Upon information and belief, upon FDA approval, Zhejiang Huahai will manufacture, test, package, and label Defendants' ANDA Product for commercial sale in the United States. Accordingly, Zhejiang Huahai intends to benefit financially in a significant manner from FDA's approval of the Supplement through active involvement in the commercial manufacture, use or sale of Defendants' ANDA Product. Thus, Zhejiang Huahai submitted the Supplement pursuant to 35 U.S.C. § 271(e)(2).

35. Upon information and belief, upon FDA approval, Solco Healthcare will distribute Defendants' ANDA Product for commercial sale in the United States. Accordingly, Solco Healthcare intends to benefit financially in a significant manner from FDA's approval of the Supplement through active involvement in the commercial manufacture, use or sale of Defendants' ANDA Product. Thus, Solco Healthcare submitted the Supplement pursuant to 35 U.S.C. § 271(e)(2).

36. Prinston's Notice Letter stated that the Paragraph IV certification in the Supplement 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 Product. Hence, Defendants' purpose in submitting the Supplement is to manufacture and market Defendants' ANDA Product before the expiration of the '652 Patent, the '057 Patent, and the '031 Patent.

37. Prinston's Notice Letter contained a "detailed statement" of the factual and legal basis for the Paragraph IV certification in the Supplement (hereinafter, "Detailed Statement").

38. Prinston's Detailed Statement did not contest infringement of any claim of the '652 Patent, the '057 Patent, or the '031 Patent.

39. After receiving Prinston's Notice Letter and accompanying purported Offer of Confidential Access ("OCA"), Plaintiff wrote to Prinston in an effort to negotiate reasonable terms of access to the Supplement. The parties agreed on terms for a revised OCA on February 20, 2019. Plaintiff's outside counsel received the Supplement on February 21, 2019, pursuant to the revised OCA.

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

41. On information and belief, if FDA approves the Supplement, Defendants will manufacture, offer for sale, or sell Defendants' ANDA Product, within the United States, including within the State of Delaware, or will import Defendants' ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Product will infringe the '652 Patent, the '057 Patent, and the '031 Patent.

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

43. 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) and U.S.C. § 355(j)(5)(F)(ii).

COUNT I
INFRINGEMENT OF THE ’652 PATENT

44. Plaintiff restates, realleges, and incorporates by reference Paragraphs 1–43 if fully set forth herein.

45. Plaintiff owns all rights, title, and interest in and to the ’652 Patent.

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

47. As demonstrated below, Defendants have infringed at least claim 1 of the ’652 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of a generic version of DORYX® MPC prior to the expiration of the ’652 Patent.

48. On information and belief, Defendants’ ANDA Product consists of a plurality of modified release doxycycline pellets.

49. On information and belief, Defendants’ ANDA Product includes doxycycline.

50. On information and belief, Defendants’ ANDA Product includes a controlled release polymer composition disposed over doxycycline.

51. On information and belief, Defendants’ ANDA Product includes 120 mg of doxycycline.

52. On information and belief, Defendants’ ANDA Product 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.

53. On information and belief, for Defendants’ ANDA Product, 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.

54. On information and belief, for Defendants' ANDA Product, 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.

55. On information and belief, Defendants' ANDA Product includes a doxycycline-containing core.

56. On information and belief, Defendants' ANDA Product includes a controlled release polymer composition that is disposed as a layer over a doxycycline-containing core.

57. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product includes a blend of an enteric polymer and a water-soluble polymer.

58. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product includes a plasticizer.

59. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product consists of a blend of an enteric polymer, a water-soluble polymer, and a plasticizer.

60. On information and belief, an enteric polymer included in Defendants' ANDA Product 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.

61. On information and belief, a water-soluble polymer included in Defendants' ANDA Product is selected from the group consisting of hydroxypropyl methylcellulose,

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

62. On information and belief, a plasticizer included in Defendants' ANDA Product 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.

63. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product consists of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose, and triethyl citrate.

64. On information and belief, Defendants' ANDA Product includes 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.

65. On information and belief, Defendants' ANDA Product includes a stabilizing coating disposed between a doxycycline-containing core and a controlled release polymer composition layer.

66. On information and belief, a stabilizing coating included in Defendants' ANDA Product comprises a water-soluble polymer and talc.

67. On information and belief, Defendants' ANDA Product is orally administered to treat a skin condition in a patient.

68. On information and belief, Defendants' ANDA Product 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.

69. On information and belief, Defendants' ANDA Product can be administered once per day.

70. On information and belief, a controlled release polymer included in Defendants' ANDA Product includes a blend of an enteric polymer and a plasticizer.

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

72. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Defendants' ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Product with a product label and product insert that will include instructions for using and administering Defendants' ANDA Product. Accordingly, Defendants will induce healthcare professionals, resellers, pharmacies, and end users of Defendants' ANDA Product 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.

73. Defendants had actual and constructive notice of the '652 Patent prior to filing the Supplement, and were aware that the filing of the Supplement 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 Product will not contribute to the infringement of and/or induce the infringement of the ’652 Patent.

74. Prinston’s Detailed Statement in the Notice Letter lacks any contention that Defendants’ ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of claims 1–26 of the ’652 Patent. If Defendants had a factual or legal basis to contest infringement of the claims of the ’652 Patent, they were required by applicable regulations to state such a basis in their Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

75. In addition, Defendants filed the Supplement 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 Product. 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.

76. 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

77. Plaintiff restates, realleges, and incorporates by reference Paragraphs 1–76 as if fully set forth herein.

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

79. On information and belief, if the Supplement is approved, Defendants' ANDA Product 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.

80. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Product in accordance with the labeling sought by the Supplement 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).

81. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product complained of herein will begin immediately after FDA approves the Supplement. 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).

82. 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.

83. 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.

84. 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

85. Plaintiff restates, realleges, and incorporates by reference Paragraphs 1–84 as if fully set forth herein.

86. Plaintiff owns all rights, title, and interest in and to the '057 Patent.

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

88. As demonstrated below, Defendants have infringed at least claim 1 of the '057 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of a generic version of DORYX® MPC prior to the expiration of the '057 Patent.

89. On information and belief, Defendants' ANDA Product consists of a plurality of modified release doxycycline pellets.

90. On information and belief, Defendants' ANDA Product includes doxycycline.

91. On information and belief, Defendants' ANDA Product includes a controlled release polymer composition disposed over doxycycline.

92. On information and belief, Defendants' ANDA Product includes 120 mg of doxycycline.

93. On information and belief, Defendants' ANDA Product maintains doxycycline release levels measured under USP <711> conditions at pH 5 that provide a clinically effective plasma level of doxycycline.

94. On information and belief, for Defendants' ANDA Product, 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.

95. On information and belief, for Defendants' ANDA Product, 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.

96. On information and belief, for Defendants' ANDA Product, 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.

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

98. On information and belief, for Defendants' ANDA Product, 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.

99. On information and belief, for Defendants' ANDA Product, 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.

100. On information and belief, for Defendants' ANDA Product, 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.

101. On information and belief, for Defendants' ANDA Product, 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.

102. On information and belief, Defendants' ANDA Product includes a doxycycline-containing core.

103. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product is disposed as a layer over a doxycycline-containing core.

104. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product includes a blend of an enteric polymer and a water-soluble polymer.

105. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product includes a plasticizer.

106. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product consists of a blend of an enteric polymer, a water-soluble polymer, and a plasticizer.

107. On information and belief, Defendants' ANDA Product is orally administered to treat a skin condition in a patient.

108. On information and belief, Defendants' ANDA Product 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.

109. On information and belief, Defendants' ANDA Product can be administered once per day.

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

111. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Defendants' ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Product with a product label and product insert that will include instructions for using and administering Defendants' ANDA Product. Accordingly, Defendants will induce healthcare professionals, resellers, pharmacies, and end users of Defendants' ANDA Product 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.

112. Defendants had actual and constructive notice of the '057 Patent prior to filing the Supplement, and were aware that the filing of the Supplement 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 Product will not contribute to the infringement of and/or induce the infringement of the '057 Patent.

113. Prinston's Detailed Statement in the Notice Letter lacks any contention that Defendants' ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of claims 1–27 of the '057 Patent. If Defendants had a factual or legal basis to contest infringement of the claims of the '057 Patent, they were required by applicable regulations to state such a basis in their Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

114. In addition, Defendants filed the Supplement 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 Product. 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.

115. 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

116. Plaintiff restates, realleges, and incorporates by reference Paragraphs 1–115 as if fully set forth herein.

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

118. On information and belief, if the Supplement is approved, Defendants' ANDA Product 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.

119. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Product in accordance with the labeling sought by the Supplement 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).

120. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product complained of herein will begin immediately after FDA approves the Supplement. 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).

121. 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.

122. 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.

123. 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

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

125. Plaintiff owns all rights, title, and interest in and to the ’031 Patent.

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

127. As demonstrated below, Defendants have infringed at least claim 1 of the ’031 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the ’031 Patent.

128. On information and belief, Defendants’ ANDA Product consists of doxycycline combined with a controlled release composition.

129. On information and belief, Defendants’ ANDA Product includes 120 mg of doxycycline.

130. On information and belief, for Defendants’ ANDA Product, 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.

131. On information and belief, for Defendants’ ANDA Product, 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.

132. On information and belief, for Defendants’ ANDA Product, 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.

133. On information and belief, for Defendants' ANDA Product, 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.

134. On information and belief, for Defendants' ANDA Product, 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.

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

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

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

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

139. On information and belief, Defendants' ANDA Product includes a plurality of pellets.

140. On information and belief, a controlled release polymer composition included in Defendants' ANDA Product is disposed over doxycycline.

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

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

143. On information and belief, Defendants' ANDA Product can be administered once per day.

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

145. On information and belief, for Defendants' ANDA Product, 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.

146. On information and belief, for Defendants' ANDA Product, 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.

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

148. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Defendants' ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Product with a product label and product insert that will include instructions for using and administering Defendants' ANDA Product. Accordingly, Defendants will induce

healthcare professionals, resellers, pharmacies, and end users of Defendants' ANDA Product 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.

149. Defendants had actual and constructive notice of the '031 Patent prior to filing the Supplement, and were aware that the filing of the Supplement 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 Product will not contribute to the infringement of and/or induce the infringement of the '031 Patent.

150. Prinston's Detailed Statement in the Notice Letter lacks any contention that Defendants' ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of claims 1–30 of the '031 Patent. If Defendants had a factual or legal basis to contest infringement of the claims of the '031 Patent, they were required by applicable regulations to state such a basis in their Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

151. In addition, Defendants filed the Supplement 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 Product. 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.

152. 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

153. Plaintiff restates, realleges, and incorporates by reference Paragraphs 1–152 as if fully set forth herein.

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

155. On information and belief, if the Supplement is approved, Defendants' ANDA Product 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.

156. On information and belief, Defendants know that healthcare professionals or patients will use Defendants' ANDA Product in accordance with the labeling sought by the Supplement 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).

157. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product complained of herein will begin immediately after FDA approves the Supplement. 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).

158. 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.

159. 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.

160. 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 Supplement to ANDA No. 207494 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Product 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 Supplement to ANDA No. 207494 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Product 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 Supplement to ANDA No. 207494 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of

Defendants' ANDA Product 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 Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Product, 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 Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Product, 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 Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Product, 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 Product within the United States, or importing Defendants' ANDA Product into the United States, until the expiration of the '652 Patent, the '057 Patent, and the '031 Patent including any extensions or regulatory exclusivities applicable to those patents;

(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 Supplement to ANDA No. 207494 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 Product, 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 Product, 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 Product, 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.

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