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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

VALEANT PHARMACEUTICALS
NORTH AMERICA LLC; VALEANT
PHARMACEUTICALS IRELAND LTD.;
DOW PHARMACEUTICAL SCIENCES, INC.;
and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

MACLEODS PHARMACEUTICALS LTD.
and MACLEODS PHARMA USA, INC.,

Defendants.

Civil Action No. 18-14204

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals North America LLC (“Valeant”), Valeant Pharmaceuticals Ireland Ltd. (“Valeant Ireland”), Dow Pharmaceutical Sciences, Inc. (“Dow”), and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, “Macleods”) allege as follows:

THE PARTIES

1. Plaintiff Valeant is a limited liability company organized and existing under the

laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Valeant Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Dow is a corporation organized and existing under the laws of Delaware having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Macleods Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (east), Mumbai, 400059, India.

6. Upon information and belief, Macleods Pharma USA, Inc. is a Delaware corporation having a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ 08536. Upon information and belief, Macleods Pharma USA, Inc. is a wholly-owned subsidiary of Macleods Pharmaceuticals Ltd.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”) and 9,877,955 (“the ’955 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Macleods Pharmaceuticals Ltd.’s filing of an Abbreviated New Drug Application (“ANDA”)

under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic efinaconazole topical solution, 10% (“Macleods’s generic efinaconazole topical solution”).

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

9. Upon information and belief, this Court has jurisdiction over Macleods Pharmaceuticals Ltd. Upon information and belief, Macleods Pharmaceuticals Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Macleods Pharmaceuticals Ltd. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Macleods’s generic efinaconazole topical solution. Upon information and belief, Macleods Pharmaceuticals Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Macleods Pharmaceuticals Ltd. operates a United States headquarters through its wholly-owned subsidiary Macleods Pharma USA, Inc. at 666 Plainsboro Rd Ste 230, Plainsboro, New Jersey 08536-0009. Upon information and belief, Macleods Pharmaceuticals Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Macleods Pharmaceuticals Ltd. has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the New Jersey and

elsewhere. Macleods Pharmaceuticals Ltd.'s ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Macleods Pharmaceuticals Ltd. intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Macleods Pharmaceuticals Ltd. will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

11. Upon information and belief, this Court has jurisdiction over Macleods Pharma USA, Inc. Upon information and belief, Macleods Pharma USA, Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Macleods Pharma USA, Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Macleods's generic efinaconazole topical solution. Upon information and belief, Macleods Pharma USA, Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Macleods Pharma USA, Inc. is headquartered at 666 Plainsboro Rd Ste 230, Plainsboro, New Jersey 08536-0009. Upon information and belief, Macleods Pharma USA, Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Macleods knows or should know that Jublia[®] is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Jublia[®].

13. Upon information and belief, venue is proper in this judicial district under

28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

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

15. Venue is proper against Macleods Pharma USA, Inc., which has a regular and established place of business in this judicial district.

THE PATENTS IN SUIT

16. The United States Patent and Trademark Office (“PTO”) issued the ’506 patent on May 8, 2007. The ’506 patent claims, generally speaking, *inter alia*, methods for treating onychomycosis by administering efinaconazole. Plaintiffs hold all substantial rights in the ’506 patent and have the right to sue for infringement thereof. The ’506 patent is valid and enforceable. A copy of the ’506 patent is attached hereto as Exhibit A.

17. The PTO issued the ’494 patent on October 18, 2011. The ’494 patent claims, generally speaking, *inter alia*, methods for treatment of a disorder of the nail or nail bed by applying pharmaceutical compositions consisting essentially of a vehicle that is volatile and/or that rapidly penetrates a nail following application onto the surface of the nail, a triazole antifungal active pharmaceutical ingredient (encompassing efinaconazole) and a wetting agent. Plaintiffs hold all substantial rights in the ’494 patent and have the right to sue for infringement thereof. The ’494 patent is valid and enforceable. A copy of the ’494 patent is attached hereto as Exhibit B.

18. The PTO issued the ’978 patent on July 16, 2013. The ’978 patent claims, generally speaking *inter alia*, pharmaceutical compositions consisting essentially of a vehicle that is volatile and/or that rapidly penetrates a nail following application onto the surface of the nail, a triazole antifungal active pharmaceutical ingredient (encompassing efinaconazole) and a

wetting agent. Plaintiffs hold all substantial rights in the '978 patent and have the right to sue for infringement thereof. The '978 patent is valid and enforceable. A copy of the '978 patent is attached hereto as Exhibit C.

19. The PTO issued the '009 patent on April 5, 2016. The '009 patent claims, generally speaking, *inter alia*, pharmaceutical compositions for the topical treatment of a disorder of the nail or nail bed including efinaconazole, ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and antioxidant. Plaintiffs hold all substantial rights in the '009 patent and have the right to sue for infringement thereof. The '009 patent is valid and enforceable. A copy of the '009 patent is attached hereto as Exhibit D.

20. The PTO issued the '272 patent on February 14, 2017. The '272 patent claims, generally speaking, *inter alia*, methods for the treatment of onychomycosis by topically applying pharmaceutical compositions including efinaconazole, ethanol, diisopropyl adipate, C12-15 alkyl lactate and cyclomethicone. Plaintiffs hold all substantial rights in the '272 patent and have the right to sue for infringement thereof. The '272 patent is valid and enforceable. A copy of the '272 patent is attached hereto as Exhibit E.

21. The PTO issued the '394 patent on May 30, 2017. The '394 patent claims, generally speaking, *inter alia*, compositions including efinaconazole, water, C12-15 alkyl lactate, diisopropyl adipate, cyclomethicone, ethanol, BHT, a salt of EDTA, and citric acid, and methods of treating a fungal infection with the same compositions. Plaintiffs hold all substantial rights in the '394 patent and have the right to sue for infringement thereof. The '394 patent is valid and enforceable. A copy of the '394 patent is attached hereto as Exhibit F.

22. The PTO issued the '698 patent on January 9, 2018. The '698 patent claims, generally speaking, *inter alia*, pharmaceutical formulations comprising ethanol, cyclomethicone,

diisopropyl adipate and mixed C12-15 alkyl lactates, and methods for the treatment of a disorder of the nail or nail bed by applying the same compositions. Plaintiffs hold all substantial rights in the '698 patent and have the right to sue for infringement thereof. The '698 patent is valid and enforceable. A copy of the '698 patent is attached hereto as Exhibit G.

23. The PTO issued the '955 patent on January 30, 2018. The '955 patent claims, generally speaking, *inter alia*, methods for the treatment of onychomycosis by applying a pharmaceutical composition including efinaconazole, ethanol, diisopropyl adipate, C12-15 alkyl lactate and cyclomethicone. Plaintiffs hold all substantial rights in the '955 patent and have the right to sue for infringement thereof. The '955 patent is valid and enforceable. A copy of the '955 patent is attached hereto as Exhibit H.

24. Dow is the holder of New Drug Application ("NDA") No. 203567 for Jublia[®], which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

25. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia[®].

MACLEODS'S INFRINGING ANDA SUBMISSION

26. Upon information and belief, Macleods Pharmaceuticals Ltd. filed or caused to be filed with the FDA ANDA No. 212147, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

27. Upon information and belief, Macleods Pharmaceuticals Ltd.'s ANDA No. 212147 seeks FDA approval to sell in the United States Macleods's generic efinaconazole

topical solution, intended to be a generic version of Jublia[®].

28. Dow received a letter dated August 9, 2018 from Macleods Pharmaceuticals Ltd. purporting to be a Notice of Certification for ANDA No. 212147 (“Macleods’s notice letter”) under Section 505(j)(2)(B)(i)-(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

29. Macleods’s notice letter alleges that Macleods Pharmaceuticals Ltd. has submitted to the FDA ANDA No. 212147 seeking FDA approval to sell Macleods’s generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

30. Upon information and belief, ANDA No. 212147 seeks approval of Macleods’s generic efinaconazole topical solution that is the same, or substantially the same, as Jublia[®].

COUNT I AGAINST MACLEODS

Infringement of the ’506 Patent under § 271(e)(2)

31. Paragraphs 1-30 are incorporated herein as set forth above.

32. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the ’506 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods’s generic efinaconazole topical solution before the expiration date of the ’506 patent.

33. Upon information and belief, Macleods’s generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the ’506 patent.

34. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods’s generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’506

patent.

35. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '506 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST MACLEODS

Declaratory Judgment of Infringement of the '506 Patent

36. Paragraphs 1-35 are incorporated herein as set forth above.

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

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

39. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '506 patent, including Macleods's filing of ANDA No. 212147.

40. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '506 patent.

41. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '506 patent.

COUNT III AGAINST MACLEODS

Infringement of the '494 Patent under § 271(e)(2)

42. Paragraphs 1-41 are incorporated herein as set forth above.

43. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '494 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '494 patent.

44. Upon information and belief, Macleods's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '494 patent.

45. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '494 patent.

46. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '494 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV AGAINST MACLEODS

Declaratory Judgment of Infringement of the '494 Patent

47. Paragraphs 1-46 are incorporated herein as set forth above.

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

49. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States

Constitution, and this actual case or controversy requires a declaration of rights by this Court.

50. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '494 patent, including Macleods's filing of ANDA No. 212147.

51. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '494 patent.

52. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '494 patent.

COUNT V AGAINST MACLEODS

Infringement of the '978 Patent under § 271(e)(2)

53. Paragraphs 1-52 are incorporated herein as set forth above.

54. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '978 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '978 patent.

55. Upon information and belief, Macleods's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '978 patent.

56. Upon information and belief, Macleods will, through the manufacture, use,

import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '978 patent.

57. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '978 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI AGAINST MACLEODS

Declaratory Judgment of Infringement of the '978 Patent

58. Paragraphs 1-57 are incorporated herein as set forth above.

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

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

61. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '978 patent, including Macleods's filing of ANDA No. 212147.

62. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '978 patent.

63. Plaintiffs are entitled to a declaratory judgment that future commercial

manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '978 patent.

COUNT VII AGAINST MACLEODS

Infringement of the '009 Patent under § 271(e)(2)

64. Paragraphs 1-63 are incorporated herein as set forth above.

65. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '009 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '009 patent.

66. Upon information and belief, Macleods's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '009 patent.

67. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '009 patent.

68. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '009 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII AGAINST MACLEODS

Declaratory Judgment of Infringement of the '009 Patent

69. Paragraphs 1-68 are incorporated herein as set forth above.

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

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

72. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '009 patent, including Macleods's filing of ANDA No. 212147.

73. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '009 patent.

74. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '009 patent.

COUNT IX AGAINST MACLEODS

Infringement of the '272 Patent under § 271(e)(2)

75. Paragraphs 1-74 are incorporated herein as set forth above.

76. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '272 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '272 patent.

77. Upon information and belief, Macleods's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at

least one claim of the '272 patent.

78. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '272 patent.

79. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '272 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X AGAINST MACLEODS

Declaratory Judgment of Infringement of the '272 Patent

80. Paragraphs 1-79 are incorporated herein as set forth above.

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

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

83. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '272 patent, including Macleods's filing of ANDA No. 212147.

84. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '272

patent.

85. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '272 patent.

COUNT XI AGAINST MACLEODS

Infringement of the '394 Patent under § 271(e)(2)

86. Paragraphs 1-85 are incorporated herein as set forth above.

87. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '394 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '394 patent.

88. Upon information and belief, Macleods's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '394 patent.

89. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '394 patent.

90. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '394 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XII AGAINST MACLEODS

Declaratory Judgment of Infringement of the '394 Patent

91. Paragraphs 1-90 are incorporated herein as set forth above.

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

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

94. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '394 patent, including Macleods's filing of ANDA No. 212147.

95. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '394 patent.

96. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '394 patent.

COUNT XIII AGAINST MACLEODS

Infringement of the '698 Patent under § 271(e)(2)

97. Paragraphs 1-96 are incorporated herein as set forth above.

98. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '698 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '698 patent.

99. Upon information and belief, Macleods's generic efinaconazole topical solution

will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '698 patent.

100. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '698 patent.

101. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '698 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XIV AGAINST MACLEODS

Declaratory Judgment of Infringement of the '698 Patent

102. Paragraphs 1-101 are incorporated herein as set forth above.

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

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

105. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '698 patent, including Macleods's filing of ANDA No. 212147.

106. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly

infringe, contributorily infringe, and/or induce infringement of at least one claim of the '698 patent.

107. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '698 patent.

COUNT XV AGAINST MACLEODS

Infringement of the '955 Patent under § 271(e)(2)

108. Paragraphs 1-107 are incorporated herein as set forth above.

109. Under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '955 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212147 seeking approval for the commercial marketing of Macleods's generic efinaconazole topical solution before the expiration date of the '955 patent.

110. Upon information and belief, Macleods's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '955 patent.

111. Upon information and belief, Macleods will, through the manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '955 patent.

112. If Macleods's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '955 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XVI AGAINST MACLEODS

Declaratory Judgment of Infringement of the '955 Patent

113. Paragraphs 1-112 are incorporated herein as set forth above.

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

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

116. Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Macleods's generic efinaconazole topical solution before the expiration date of the '955 patent, including Macleods's filing of ANDA No. 212147.

117. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '955 patent.

118. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's generic efinaconazole topical solution will constitute infringement of at least one claim of the '955 patent.

PRAYER FOR RELIEF

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

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '506 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '506 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '494 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '494 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '978 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '978 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '009 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '009 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '272 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale

in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '272 patent;

6. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '394 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '394 patent;

7. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '698 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '698 patent;

8. enter judgment that, under 35 U.S.C. § 271(e)(2), Macleods has infringed at least one claim of the '955 patent by submitting or causing to be submitted ANDA No. 212147 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Macleods's generic efinaconazole topical solution before the expiration of the '955 patent;

9. order that that the effective date of any approval by the FDA of Macleods's generic efinaconazole topical solution be a date that is not earlier than the expiration of the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent, or such later date as the Court may determine;

10. enjoin Macleods from the commercial manufacture, use, import, offer for sale, and/or sale of Macleods's generic efinaconazole topical solution until expiration of the '506

patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent, or such later date as the Court may determine;

11. enjoin Macleods and all persons acting in concert with Macleods from seeking, obtaining, or maintaining approval of Macleods's ANDA No. 212147 until expiration of the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent;

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

13. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: September 21, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: September 21, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

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