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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.

ALEOR DERMACEUTICALS LTD.,

Defendant.

Civil Action No.: 18-13954

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 Aleor Dermaceuticals Ltd. (“Aleor”) 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, Aleor is an Indian corporation having a principal place of business at 5th Floor, Administrative Building Alembic Limited, Alembic Road, Vadodara, Vadodara, Gujarat, 390003, India.

NATURE OF THE ACTION

6. 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 Aleor’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% (“Aleor’s generic efinaconazole topical solution”).

JURISDICTION AND VENUE

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

8. Upon information and belief, this Court has jurisdiction over Aleor. Upon information and belief, Aleor is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Aleor 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 Aleor's generic efinaconazole topical solution. Upon information and belief, Aleor has a related corporate entity located in New Jersey. Upon information and belief, Aleor purposefully has conducted and continues to conduct business in this judicial district.

9. Aleor 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. Aleor's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Aleor intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Aleor's notice letter invoked the jurisdiction and venue of this judicial district. Upon information and belief, Aleor will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

10. Aleor 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[®].

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

12. Venue is proper against Aleor, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENT IN SUIT

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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").

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

ALEOR'S INFRINGING ANDA SUBMISSION

23. Upon information and belief, Aleor filed or caused to be filed with the FDA ANDA No. 212027, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

24. Upon information and belief, Aleor's ANDA No. 212027 seeks FDA approval to sell in the United States Aleor's generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

25. Dow received a letter dated August 3, 2018 from Aleor purporting to be a Notice of Certification for ANDA No. 212027 (“Aleor’s notice letter”) under Section 21 U.S.C. § 505(j)(2)(B)(ii) and (iv), 21 U.S.C. § 355(j)(2)(B)(ii) and (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).

26. Aleor’s notice letter alleges that Aleor has submitted to the FDA ANDA No. 212027 seeking FDA approval to sell Aleor’s generic efinaconazole topical solution, intended to be a generic version of Jublia[®]. Aleor’s notice letter further invoked the jurisdiction and venue of the District of New Jersey.

27. Upon information and belief, ANDA No. 212027 seeks approval of Aleor’s generic efinaconazole topical solution that is the same, or substantially the same, as Jublia[®].

COUNT I AGAINST ALEOR

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

28. Paragraphs 1-27 are incorporated herein as set forth above.

29. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the ’506 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor’s generic efinaconazole topical solution before the expiration date of the ’506 patent.

30. Upon information and belief, Aleor’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.

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

32. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '506 Patent

33. Paragraphs 1-32 are incorporated herein as set forth above.

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

35. 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.

36. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '506 patent, including Aleor's filing of ANDA No. 212027.

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

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

COUNT III AGAINST ALEOR

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

39. Paragraphs 1-38 are incorporated herein as set forth above.

40. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '494 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '494 patent.

41. Upon information and belief, Aleor'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.

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

43. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '494 Patent

44. Paragraphs 1-43 are incorporated herein as set forth above.

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

46. 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.

47. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical

solution before the expiration date of the '494 patent, including Aleor's filing of ANDA No. 212027.

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

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

COUNT V AGAINST ALEOR

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

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

51. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '978 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '978 patent.

52. Upon information and belief, Aleor'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.

53. Upon information and belief, Aleor will, through the manufacture, use, import, offer for sale, and/or sale of Aleor's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '978 patent.

54. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '978 Patent

55. Paragraphs 1-54 are incorporated herein as set forth above.

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

57. 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.

58. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '978 patent, including Aleor's filing of ANDA No. 212027.

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

60. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aleor's generic efinaconazole topical solution will constitute infringement of at least one claim of the '978 patent.

COUNT VII AGAINST ALEOR

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

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

62. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '009 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking

approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '009 patent.

63. Upon information and belief, Aleor'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.

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

65. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '009 Patent

66. Paragraphs 1-65 are incorporated herein as set forth above.

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

68. 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.

69. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '009 patent, including Aleor's filing of ANDA No. 212027.

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

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

COUNT IX AGAINST ALEOR

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

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

73. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '272 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '272 patent.

74. Upon information and belief, Aleor'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.

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

76. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '272 Patent

77. Paragraphs 1-76 are incorporated herein as set forth above.

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

79. 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.

80. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '272 patent, including Aleor's filing of ANDA No. 212027.

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

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

COUNT XI AGAINST ALEOR

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

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

84. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '394 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '394 patent.

85. Upon information and belief, Aleor'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.

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

87. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '394 Patent

88. Paragraphs 1-87 are incorporated herein as set forth above.

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

90. 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.

91. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '394 patent, including Aleor's filing of ANDA No. 212027.

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

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

COUNT XIII AGAINST ALEOR

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

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

95. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '698 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '698 patent.

96. Upon information and belief, Aleor'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.

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

98. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '698 Patent

99. Paragraphs 1-98 are incorporated herein as set forth above.

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

101. 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.

102. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '698 patent, including Aleor's filing of ANDA No. 212027.

103. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aleor's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '698 patent.

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

COUNT XV AGAINST ALEOR

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

105. Paragraphs 1-104 are incorporated herein as set forth above.

106. Under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '955 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212027 seeking approval for the commercial marketing of Aleor's generic efinaconazole topical solution before the expiration date of the '955 patent.

107. Upon information and belief, Aleor'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.

108. Upon information and belief, Aleor will, through the manufacture, use, import,

offer for sale, and/or sale of Aleor's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '955 patent.

109. If Aleor'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 ALEOR

Declaratory Judgment of Infringement of the '955 Patent

110. Paragraphs 1-109 are incorporated herein as set forth above.

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

112. 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.

113. Aleor has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Aleor's generic efinaconazole topical solution before the expiration date of the '955 patent, including Aleor's filing of ANDA No. 212027.

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

115. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aleor'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 Aleor 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), Aleor has infringed at least one claim of the '506 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '506 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '494 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '494 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '978 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '978 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '009 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '009

patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '272 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '272 patent;

6. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '394 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '394 patent;

7. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '698 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor's generic efinaconazole topical solution before the expiration of the '698 patent;

8. enter judgment that, under 35 U.S.C. § 271(e)(2), Aleor has infringed at least one claim of the '955 patent by submitting or causing to be submitted ANDA No. 212027 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aleor'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 Aleor'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 Aleor from the commercial manufacture, use, import, offer for sale, and/or sale of Aleor'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 Aleor and all persons acting in concert with Aleor from seeking, obtaining, or maintaining approval of Aleor's ANDA No. 212027 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 17, 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 17, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

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