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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.

ALKEM LABORATORIES LTD.,

Defendant.

Civil Action No.: 18-13905

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 Alkem Laboratories Ltd. (“Alkem”) 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, Alkem is an Indian corporation having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai – 400 013, 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 Alkem’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% (“Alkem’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 Alkem. Upon information and belief, Alkem is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Alkem 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 Alkem's generic efinaconazole topical solution. Upon information and belief, Alkem has a wholly-owned subsidiary located in New Jersey. Upon information and belief, Alkem purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Alkem 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.

9. Alkem 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 State of New Jersey and elsewhere. Alkem's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Alkem 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, Alkem will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

10. Alkem 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 Alkem, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENTS 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[®].

ALKEM'S INFRINGING ANDA SUBMISSION

23. Upon information and belief, Alkem filed or caused to be filed with the FDA ANDA No. 212195, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

24. Upon information and belief, Alkem's ANDA No. 212195 seeks FDA approval to sell in the United States Alkem's generic efinaconazole topical solution, intended to be a

generic version of Jublia[®].

25. Kaken and Dow received a letter dated August 1, 2018 from Alkem purporting to be a Notice of Certification for ANDA No. 212195 (“Alkem’s notice letter”) under Section 505(j)(2)(B)(ii) and (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).

26. Alkem’s notice letter alleges that Alkem has submitted to the FDA ANDA No. 212195 seeking FDA approval to sell Alkem’s generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

27. Upon information and belief, ANDA No. 212195 seeks approval of Alkem’s generic efinaconazole topical solution that is the same, or substantially the same, as Jublia[®].

COUNT I AGAINST ALKEM

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), Alkem has infringed at least one claim of the ’506 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem’s generic efinaconazole topical solution before the expiration date of the ’506 patent.

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

32. If Alkem’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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '506 patent, including Alkem's filing of ANDA No. 212195.

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

COUNT III AGAINST ALKEM

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), Alkem has infringed at least one claim of the '494

patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '494 patent.

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

43. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '494 patent, including Alkem's

filing of ANDA No. 212195.

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

COUNT V AGAINST ALKEM

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), Alkem has infringed at least one claim of the '978 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '978 patent.

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

54. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '978 patent, including Alkem's filing of ANDA No. 212195.

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

COUNT VII AGAINST ALKEM

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), Alkem has infringed at least one claim of the '009 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before

the expiration date of the '009 patent.

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

65. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '009 patent, including Alkem's filing of ANDA No. 212195.

70. Upon information and belief, any commercial manufacture, use, offer for sale,

sale, and/or importation of Alkem'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 Alkem's generic efinaconazole topical solution will constitute infringement of at least one claim of the '009 patent.

COUNT IX AGAINST ALKEM

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), Alkem has infringed at least one claim of the '272 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '272 patent.

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

76. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '272 patent, including Alkem's filing of ANDA No. 212195.

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

COUNT XI AGAINST ALKEM

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), Alkem has infringed at least one claim of the '394 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '394 patent.

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

87. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '394 patent, including Alkem's filing of ANDA No. 212195.

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

COUNT XIII AGAINST ALKEM

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), Alkem has infringed at least one claim of the '698 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '698 patent.

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

98. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '698 patent, including Alkem's filing of ANDA No. 212195.

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

COUNT XV AGAINST ALKEM

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), Alkem has infringed at least one claim of the '955 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '955 patent.

107. Upon information and belief, Alkem'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, Alkem will, through the manufacture, use, import, offer for sale, and/or sale of Alkem's generic efinaconazole topical solution, directly infringe,

contributorily infringe, and/or induce infringement of at least one claim of the '955 patent.

109. If Alkem'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 ALKEM

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. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '955 patent, including Alkem's filing of ANDA No. 212195.

114. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Alkem'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 Alkem'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 Alkem 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), Alkem has infringed at least one claim of the '506 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '506 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '494 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '494 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '978 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '978 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '009 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of

the '009 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '272 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '272 patent;

6. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '394 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '394 patent;

7. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '698 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '698 patent;

8. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '955 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem'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 Alkem'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 Alkem from the commercial manufacture, use, import, offer for sale, and/or sale of Alkem'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 Alkem and all persons acting in concert with Alkem from seeking, obtaining, or maintaining approval of Alkem's ANDA No. 212195 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 14, 2018

Respectfully submitted,

s/William P. Deni, Jr.

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

Dated: September 14, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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