

William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs

**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.

AMNEAL PHARMACEUTICALS LLC and
AMNEAL PHARMACEUTICALS INDIA
PVT. LTD.,

Defendants.

Civil Action No. 18-14468

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 Defendants Amneal Pharmaceuticals LLC (“Amneal LLC”) and Amneal Pharmaceuticals India Pvt. Ltd. (“Amneal Ltd.”) (collectively, “Amneal”) 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, Defendant Amneal LLC is a Delaware limited liability company, having its principal place of business at 400 Crossing Blvd, Third Floor, Bridgewater, New Jersey 08807-2863.

6. Upon information and belief, Defendant Amneal Ltd. is a private limited liability company organized and existing under the laws of India, having its principal place of business at 882/1-871, Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, Ahmedabad-382220, Gujarat, India. Upon information and belief, Amneal Ltd. is a wholly-owned subsidiary of Amneal LLC.

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 Amneal'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% ("Amneal'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 Amneal LLC. Upon information and belief, Amneal LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Amneal LLC 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 Amneal's generic efinaconazole topical solution. Upon information and belief, Amneal LLC purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Amneal LLC is registered to do business in New Jersey under Business ID 0600211542. Upon information and belief, Amneal LLC has its principal place of business at 400 Crossing Blvd, Third Floor, Bridgewater, New Jersey 08807-2863, and Amneal owns a facility named "Transdermal, Topicals & Complex Oral Solids Manufacturing and R&D" having an address of 1 New England Avenue, Piscataway, New Jersey 08854.

10. Amneal LLC has admitted to, consented to, or has not contested the jurisdiction of this Court in prior District of New Jersey actions, including, for example: *Forest*

Laboratories, LLC, et al. v. Amneal Pharmaceuticals LLC, et al., Case No. 2:17-cv-11680; *Sucampo Pharma, LLC, et al. v. Amneal Pharmaceuticals LLC*, Case No. 3:17-cv-02577; *AstraZeneca Pharmaceuticals LP, et al. v. Amneal Pharmaceuticals LLC*, Case No. 1:17-cv-01968; *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals LLC*, Case No. 2:17-cv-01440; and *Senju Pharmaceutical Co., Ltd., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:18-cv-05571.

11. Amneal LLC has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of New Jersey actions, including, for example: *Forest Laboratories, LLC, et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 2:17-cv-11680; *Sucampo Pharma, LLC, et al. v. Amneal Pharmaceuticals LLC*, Case No. 3:17-cv-02577; *AstraZeneca Pharmaceuticals LP, et al. v. Amneal Pharmaceuticals LLC*, Case No. 1:17-cv-01968; *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals LLC*, Case No. 2:17-cv-01440; and *Senju Pharmaceutical Co., Ltd., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:18-cv-05571

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

13. Upon information and belief, this Court has jurisdiction over Amneal Ltd. Upon

information and belief, Amneal Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Amneal 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 Amneal's generic efinaconazole topical solution. Upon information and belief, Amneal Ltd. purposefully has conducted and continues to conduct business in this judicial district.

14. Amneal Ltd. has admitted to, consented to, or has not contested the jurisdiction of this Court in prior District of New Jersey actions, including, for example: *Shire Pharmaceutical Development Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 1:15-cv-02865; *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 1:15-cv-01585; *AstraZeneca Pharmaceuticals LP, et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:12-cv-04841; and *Senju Pharmaceutical Co., Ltd., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:18-cv-05571.

15. Amneal Ltd. has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of New Jersey actions, including, for example: *Shire Pharmaceutical Development Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 1:15-cv-02865; *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 1:15-cv-01585; *AstraZeneca Pharmaceuticals LP, et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:12-cv-04841; and *Senju Pharmaceutical Co., Ltd., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:18-cv-05571.

16. Amneal 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[®].

17. Upon information and belief, Amneal LLC and Amneal Ltd. operate as a single integrated business. The Amneal website states that “[t]he company’s expanding operations in India are an integral part of Amneal’s R&D and manufacturing capabilities and expertise.” See <http://www.amneal.com/international/>.

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

THE PATENTS IN SUIT

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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").

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

AMNEAL'S INFRINGING ANDA SUBMISSION

29. Upon information and belief, Amneal filed or caused to be filed with the FDA ANDA No. 212085, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

30. Upon information and belief, Amneal's ANDA No. 212085 seeks FDA approval

to sell in the United States Amneal's generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

31. Dow and Kaken received a letter dated August 15, 2018, from Amneal LLC purporting to be a Notice of Certification for ANDA No. 212085 ("Amneal's notice letter") under Section 505(j)(2)(B)(ii) and (iv) of the Act, 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).

32. Amneal's notice letter alleges that Amneal LLC has submitted to the FDA ANDA No. 212085 seeking FDA approval to sell Amneal's generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

33. Upon information and belief, ANDA No. 212085 seeks approval of Amneal's generic efinaconazole topical solution that is the same, or substantially the same, as Jublia[®].

COUNT I AGAINST AMNEAL

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

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

35. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '506 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '506 patent.

36. Upon information and belief, Amneal'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.

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

contributorily infringe, and/or induce infringement of at least one claim of the '506 patent.

38. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '506 Patent

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

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

41. 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.

42. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '506 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT III AGAINST AMNEAL

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

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

46. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '494 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '494 patent.

47. Upon information and belief, Amneal'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.

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

49. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '494 Patent

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

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

52. 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.

53. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '494 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT V AGAINST AMNEAL

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

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

57. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '978 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '978 patent.

58. Upon information and belief, Amneal'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.

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

60. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '978 Patent

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

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

63. 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.

64. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '978 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT VII AGAINST AMNEAL

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

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

68. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '009 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '009 patent.

69. Upon information and belief, Amneal'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.

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

71. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '009 Patent

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

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

74. 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.

75. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '009 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT IX AGAINST AMNEAL

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

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

79. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '272 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '272 patent.

80. Upon information and belief, Amneal'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.

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

82. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '272 Patent

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

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

85. 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.

86. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '272 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT XI AGAINST AMNEAL

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

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

90. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '394 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '394 patent.

91. Upon information and belief, Amneal'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.

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

93. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '394 Patent

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

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

96. 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.

97. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '394 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT XIII AGAINST AMNEAL

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

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

101. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '698 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '698 patent.

102. Upon information and belief, Amneal'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.

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

104. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '698 Patent

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

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

107. 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.

108. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic efinaconazole topical solution before the expiration date of the '698 patent, including Amneal's filing of ANDA No. 212085.

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

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

COUNT XV AGAINST AMNEAL

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

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

112. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '955 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212085 seeking approval for the commercial marketing of Amneal's generic efinaconazole topical solution before the expiration date of the '955 patent.

113. Upon information and belief, Amneal'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.

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

115. If Amneal'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 AMNEAL

Declaratory Judgment of Infringement of the '955 Patent

116. Paragraphs 1-115 are incorporated herein as set forth above.

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

118. 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.

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

efinaconazole topical solution before the expiration date of the '955 patent, including Amneal's filing of ANDA No. 212085.

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

121. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Amneal'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 Amneal 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), Amneal has infringed at least one claim of the '506 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of the '506 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '494 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of the '494 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least

one claim of the '978 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of the '978 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '009 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of the '009 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '272 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of the '272 patent;

6. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '394 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of the '394 patent;

7. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '698 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic efinaconazole topical solution before the expiration of

the '698 patent;

8. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '955 patent by submitting or causing to be submitted ANDA No. 212085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal'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 Amneal'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 Amneal from the commercial manufacture, use, import, offer for sale, and/or sale of Amneal'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 Amneal and all persons acting in concert with Amneal from seeking, obtaining, or maintaining approval of Amneal's ANDA No. 212085 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 28, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

Charles H. Chevalier

J. Brugh Lower

GIBBONS P.C.

One Gateway Center

Newark, New Jersey 07102

Tel: (973) 596-4500

Fax: (973) 596-0545

wdeni@gibbonslaw.com

cchevalier@gibbonslaw.com

jlower@gibbonslaw.com

Attorneys for Plaintiffs

Of Counsel:

John D. Livingstone (*pro hac vice* to be submitted)

FINNEGAN, HENDERSON,

FARABOW, GARRETT & DUNNER, LLP

271 17th Street, NW

Suite 1400

Atlanta, GA 30363-6209

(404) 653-6400

Naoki Yoshida (*pro hac vice* to be submitted)

FINNEGAN, HENDERSON,

FARABOW, GARRETT & DUNNER, LLP

33rd Floor, Shiroyama Trust Tower

3-1, Toranomom 4-chome, Minato-ku

Tokyo, 105-6033 Japan

+81-3-3431-6943

Attorneys for Plaintiff

Kaken Pharmaceutical Co., Ltd.

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 28, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

GIBBONS P.C.

One Gateway Center

Newark, New Jersey 07102

Tel: (973) 596-4500

Fax: (973) 596-0545

wdeni@gibbonslaw.com

Attorneys for Plaintiffs