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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC and AMNEAL EU, LIMITED, *Defendants.*	Civil Action No. 25-2642 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited (collectively, "Amneal" or "Defendants") alleges as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Amneal's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219027 ("the ANDA") which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL single-dose vials drug product ("the ANDA Product") prior to the expiration of United States Patent Nos. 11,786,548 (the "'548 patent"), 11,975,022 (the "'022 patent"), 11,998,565 (the "'565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit").

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

3. On information and belief, Amneal Pharmaceuticals of New York, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. On further information and belief, Amneal Pharmaceuticals of New York, LLC is the U.S. Agent for Amneal EU, Limited.

4. On information and belief, Amneal EU, Limited is a corporation organized and existing under the laws of Ireland with its principal place of business at Cahir Road, Cashel, Co. Tipperary, E25 XD51, Ireland.

5. On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited are both subsidiaries of Amneal Pharmaceuticals, Inc.

6. On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited acted in concert to prepare and submit Amneal's ANDA to the FDA.

JURISDICTION AND VENUE

7. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. On information and belief, this Court has personal jurisdiction over Amneal EU, Limited, under the New Jersey state long arm statute and consistent with due process of law because Amneal EU, Limited has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Amneal plans to sell the ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

9. On information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals of New York, LLC., under the New Jersey state long arm statute and consistent with due process of law, because Amneal Pharmaceuticals of New York, LLC maintains its principal place of business in New Jersey.

10. This Court has personal jurisdiction over Amneal EU, Limited because it has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Amneal EU, Limited regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Amneal EU, Limited derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

11. This Court has personal jurisdiction over Amneal Pharmaceuticals of New York, LLC by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Amneal Pharmaceuticals of New York, LLC's principal place of business is in Bridgewater, New Jersey. On information and belief, Amneal Pharmaceuticals of New York, LLC purposefully has conducted and continues to conduct business in this judicial district. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Amneal Pharmaceuticals of New York, LLC.

12. On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

13. On information and belief, Amneal Pharmaceuticals of New York, LLC is the United States agent acting at the direction of, and for the benefit of, Amneal EU, Limited regarding the ANDA.

14. This Court has personal jurisdiction over Amneal because Amneal has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Amneal Pharmaceuticals of New York, LLC is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey under Registration Number 5003663. On information and belief, Amneal regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Amneal derives

substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

15. This Court has personal jurisdiction over Amneal because, on information and belief, Amneal derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

16. This Court has personal jurisdiction over Amneal EU, Limited because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting personal jurisdiction and through the assertion of counterclaims in suits brought in New Jersey, including in at least *Celgene Corp. v. Amneal Pharms. of N.Y., LLC et al*, No. 2:24-cv-00500 (D.N.J. Jan. 26, 2024).

17. This Court has personal jurisdiction over Amneal Pharmaceuticals of New York, LLC because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting personal jurisdiction and through the assertion of counterclaims in suits brought in New Jersey, including in at least *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, No. 2:23-cv-20964 (D.N.J. Oct. 6, 2023); *Celgene Corp. v. Amneal Pharms. of N.Y., LLC*, No. 2:24-cv-00500 (D.N.J. Jan. 26, 2024); *Janssen Prods., L.P. v. Amneal Pharms. LLC*, No. 2:18-cv-17585 (D.N.J. Dec. 26, 2018); *BTG Int'l. Ltd. v. Actavis Labs. FL, Inc.*, No. 2:15-cv-05909 (D.N.J. July 31, 2015); and *THERAPEUTICSMD, Inc. v. Amneal Pharms., Inc.*, No. 3:20-cv-05256 (D.N.J. Apr. 29, 2020).

18. This Court has personal jurisdiction over Amneal because, *inter alia*, Amneal has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will

lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following approval of the ANDA, Amneal will make, use, import, sell, and/or offer for sale the ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit .

19. In the alternative, this Court has personal jurisdiction over Amneal EU, Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (a) ARI's claims arise under federal law; (b) Amneal EU, Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Amneal EU, Limited has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Amneal EU, Limited satisfies due process.

20. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

21. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Amneal Pharmaceuticals of New York, LLC has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. Amneal EU, Limited is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

22. On information and belief, Amneal has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps indicating its intent to market the ANDA Product in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

23. On information and belief, Amneal Pharmaceuticals of New York, LLC has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, Amneal Pharmaceuticals of New York, LLC maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

24. On information and belief, Amneal EU, Limited and Amneal Pharmaceuticals of New York, LLC have taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate their intent to market the ANDA Product. As set forth above, on information and belief, if the ANDA is approved, Amneal intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Product.

BACKGROUND

25. ARI holds New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP), which was approved by the FDA on July 2, 2020 and which ARI manufactures and sells in this judicial district and throughout the United States.

26. Tralement® is the first and only FDA-approved multi-trace element injection for patients weighing at least 10 kg. The FDA has approved both 1 mL and 5 mL forms of Tralement®; ARI markets a 1 mL Tralement® product.

27. Tralement® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

28. Tralement®, as well as the use of Tralement® in accordance with its label, is covered by one or more claims of the Patents-in-Suit.

29. ARI is the owner of the ’548 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on October 17, 2023. A copy of the ’548 patent is attached as Exhibit 1.

30. The ’548 patent has been listed in connection with Tralement® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

31. As indicated in the Orange Book, the patent expiration date for the ’548 patent is July 1, 2041.

32. ARI is the owner of the ’022 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on May 7, 2024. A copy of the ’022 patent is attached as Exhibit 2.

33. The ’022 patent has been listed in connection with Tralement® in the Orange Book.

34. As indicated in the Orange Book, the patent expiration date for the ’022 patent is July 1, 2041.

35. ARI is the owner of the ’565 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on June 4, 2024. A copy of the ’565 patent is attached as Exhibit 3.

36. The ’565 patent has been listed in connection with Tralement® in the Orange Book.

37. As indicated in the Orange Book, the patent expiration date for the ’565 patent is July 1, 2041.

38. ARI is the owner of the ’956 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on November 26, 2024. A copy of the ’956 patent is attached as Exhibit 4.

39. The ’956 patent has been listed in connection with Tralement® in the Orange Book.

40. As indicated in the Orange Book, the patent expiration date for the ’956 patent is July 1, 2041.

41. ARI is the owner of the ’957 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on November 26, 2024. A copy of the ’957 patent is attached as Exhibit 5.

42. The ’957 patent has been listed in connection with Tralement® in the Orange Book.

43. As indicated in the Orange Book, the patent expiration date for the ’957 patent is July 1, 2041.

44. By letter dated March 3, 2025 (“the Notice Letter”), Amneal notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Amneal had submitted to the FDA the ANDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product prior to the expiration of the Patents-in-Suit.

45. On information and belief, Amneal was responsible for preparing the ANDA which contained a Paragraph IV Certification.

46. On information and belief, Amneal submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Product, or alternatively, that the Patents-in-Suit are invalid.

47. On information and belief, the ANDA Product is a generic version of Tralement® (trace elements injection 4*, USP), as it is the reference listed drug in the ANDA, containing the same or equivalent ingredients in the same or equivalent amounts.

48. In the Notice Letter, Amneal disclosed that the ANDA Product is Trace Elements Injection 4* USP, (3 mg Zn/mL, 0.3 mg Cu/mL, 55 mcg Mn/mL and 60 mcg Se/mL) single-dose vials (1 mL Fill).

49. On information and belief, the ANDA Product contains zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement®.

50. On information and belief, the ANDA Product will feature the same or equivalent chemical and therapeutic properties as Tralement®.

COUNT I: INFRINGEMENT OF THE ’548 PATENT

51. ARI realleges paragraphs 1–50 as if fully set forth herein.

52. Amneal’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the Patents-in-Suit, constitutes direct and indirect infringement of the ’548 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

53. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Amneal or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’548 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Amneal’s specific

intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '548 patent.

54. On information and belief, Amneal's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '548 patent, either literally or under the doctrine of equivalents. On information and belief, Amneal intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Amneal knows that the ANDA Product is especially made or adapted for use in infringing the '548 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

55. ARI will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '548 patent, or any later expiration of exclusivity for the '548 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

56. Amneal has had knowledge of the '548 patent since at least the date Amneal submitted the ANDA with a Paragraph IV Certification and was aware that submission of the

ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

57. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '022 PATENT

58. ARI realleges paragraphs 1–57 as if fully set forth herein.

59. Amneal's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '022 patent, constitutes infringement of the '022 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

60. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Amneal or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '022 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Amneal's specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '022 patent.

61. On information and belief, Amneal's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved

by the FDA, would constitute induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the ’022 patent, either literally or under the doctrine of equivalents. On information and belief, Amneal intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Amneal knows that the ANDA Product is especially made or adapted for use in infringing the ’022 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

62. ARI will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the ’022 patent, or any later expiration of exclusivity for the ’022 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

63. Amneal has had knowledge of the ’022 patent since at least the date Amneal submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

64. This case is “exceptional,” and ARI is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE ’565 PATENT

65. ARI realleges paragraphs 1–64 as if fully set forth herein.

66. Amneal’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the ’565 patent,

constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

67. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Amneal or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Amneal's specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

68. On information and belief, Amneal's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Amneal intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Amneal knows that the ANDA Product is especially made or adapted for use in infringing the '565 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

69. ARI will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

70. Amneal has had knowledge of the '565 patent since at least the date Amneal submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

71. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '956 PATENT

72. ARI realleges paragraphs 1–71 as if fully set forth herein.

73. Amneal's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '956 patent, constitutes direct and indirect infringement of the '956 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

74. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Amneal or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert,

which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’956 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Amneal’s specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI’s rights under the ’956 patent.

75. On information and belief, Amneal’s manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the ’956 patent, either literally or under the doctrine of equivalents. On information and belief, Amneal intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Amneal knows that the ANDA Product is especially made or adapted for use in infringing the ’956 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

76. ARI will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the ’956 patent, or any later expiration of exclusivity for the ’956 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

77. Amneal has had knowledge of the ’956 patent since at least the date Amneal submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

78. This case is “exceptional,” and ARI is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE ’957 PATENT

79. ARI realleges paragraphs 1–78 as if fully set forth herein.

80. Amneal’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the ’957 patent, constitutes direct and indirect infringement of the ’957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

81. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Amneal or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Amneal’s specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI’s rights under the ’957 patent.

82. On information and belief, Amneal's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either literally or under the doctrine of equivalents. On information and belief, Amneal intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Amneal knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

83. ARI will be irreparably harmed if Amneal is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

84. Amneal has had knowledge of the '957 patent since at least the date Amneal submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

85. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, ARI prays that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Amneal has infringed at least one claim of the Patents-in-Suit through Amneal's submission of the ANDA with a Paragraph IV Certification to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Product before the expiration of the Patents-in-Suit;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Amneal's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Product before the expiration of the Patents-in-Suit will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Patents-in-Suit;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the ANDA, shall not be earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Amneal, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States the ANDA Product, or any product that infringes any of the Patents-in-Suit, or inducing or contributing to the infringement of any of the Patents-in-Suit until after the expiration date of the Patents-in-Suit, including any extension and/or additional periods of exclusivity to which ARI is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Amneal,

and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Amneal engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding ARI its attorneys' fees incurred in this action; and

(h) Such further relief as this Court deems proper and just.

Dated: April 11, 2025
Newark, New Jersey

By: s/ Charles H. Chevalier

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