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

AMERICAN REGENT, INC., *Plaintiff*, v. SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, ODIN PHARMACEUTICALS, LLC, APOTEX INC, APOTEX CORP., and RK PHARMA, INC., . *Defendants.*	Civil Action Nos. 24 CV 1022 (BRM)(CLW) 24 CV 1030 (BRM)(CLW) 24 CV 1169 (BRM)(CLW) 24 CV 2268 (BRM)(CLW) (Consolidated) (Filed Electronically)

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT TO RK PHARMA

Pursuant to the Court's Pretrial Scheduling Order (ECF No. 38), Plaintiff American Regent, Inc. ("ARI"), by its undersigned attorneys, for their amended Complaint against Defendant RK Pharma, Inc. ("RK Pharma"), 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 RK Pharma's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218537 ("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, or sale of generic versions of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL single-dose vials and 5 mL Pharmacy Bulk Package vials and Multrys® (trace elements injection 4*, USP) drug products ("the ANDA Products") 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, Defendant RK Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principle place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, New York 10965 and a regular and established place of business at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558 through its operations with its affiliate VGYAAN Pharmaceuticals LLC ("VGYAAN"), a regular and established place of business at 49 Napoleon Court, Somerset, New Jersey 08873 through its operations with its affiliate Apicore US LLC ("Apicore"), and a regular and established place of business at 15 Corporate Pl S, Piscataway, New Jersey 08854 through its operations with its affiliate Archis Pharma LLC ("Archis").

JURISDICTION AND VENUE

4. 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.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, on information and belief, RK Pharma submitted the ANDA with a Paragraph IV Certification from its affiliate VGYAAN's Skillman, New Jersey place of business and therefore RK Pharma has committed acts of infringement and has a regular and established place of business in New Jersey for the purposes of venue.

6. Venue is further proper in this Court because RK Pharma has agreed that it will not contest venue for the purposes of this action. *See* ECF. No. 37 ¶ 9.

7. Based on the facts and causes alleged herein, including infringement under 35 U.S.C. § 271(e)(2) by RK Pharma's filing of the ANDA with a Paragraph IV Certification and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over RK Pharma.

8. On information and belief, RK Pharma has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101052900. RK Pharma has thus consented to personal jurisdiction in New Jersey.

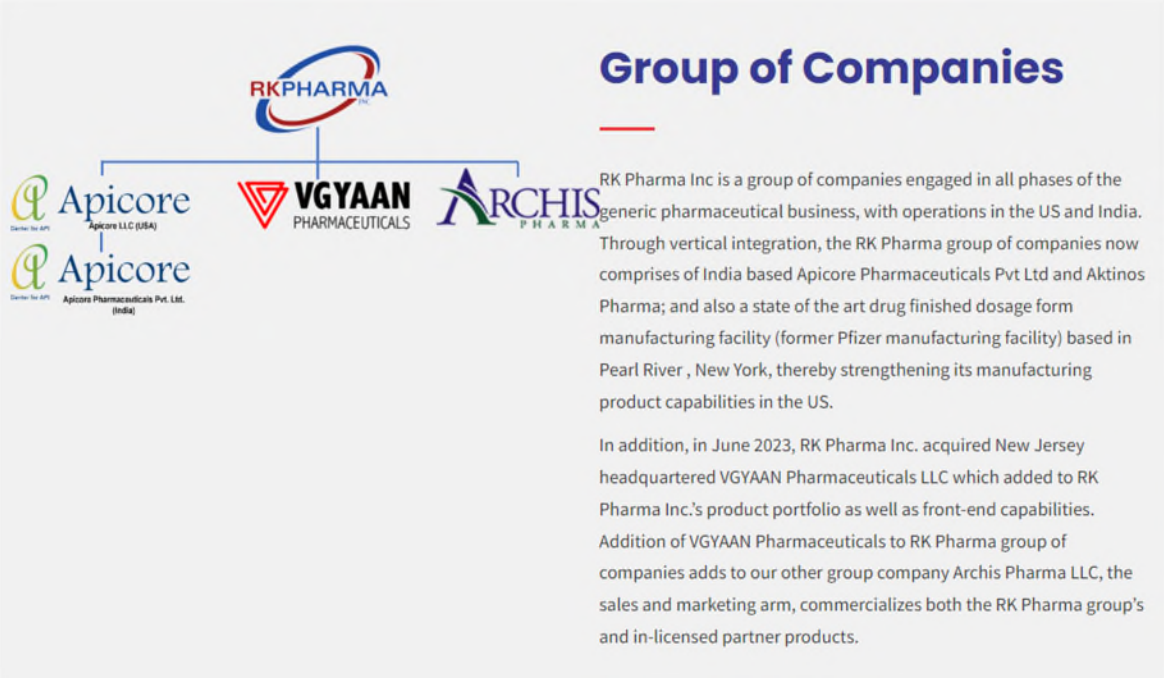
9. This Court additionally has personal jurisdiction of RK Pharma because RK Pharma has agreed that it will not contest personal jurisdiction in New Jersey for the purposes of this action. *See* ECF No. 37 ¶ 11.

10. On information and belief, RK Pharma, Inc., VGYAAN, Apicore, and Archis act, operate, and/or hold themselves out to the public as a "vertically integrated" business such that RK

Pharma has an established and regular place of business in the State of New Jersey at least through activities performed in conjunction with VGYAAN, Apicore, and Archis.

11. On information and belief, RK Pharma, itself and/or through VGYAAN, Apicore, and Archis, is in the business of developing, manufacturing, importing, marketing, and/or selling generic pharmaceutical products throughout the United States, including in this judicial district.

12. On information and belief, and as confirmed by RK Pharma's website, "RK Pharma Inc[.] is a group of companies engaged in all phases of the generic pharmaceutical business" consisting of the "vertical[ly] integrat[ed]" defendants:



[1]

13. On information and belief, VGYAAN is the entity within RK Pharma responsible for "development, filing with the regulatory agencies and commercialization" of "generics and 505(b)(2) drugs."[2]

[1] About Us. https://rkpharmainc.com/about-us.html (last visited on June 20, 2024)

[2] Products, http://vgyaan.com/products/ (last visited on June 20, 2024).

14. On information and belief, RK Pharma filed the ANDA with a Paragraph IV Certification for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products in the United States, including in New Jersey.

15. On information and belief, actions related to the submission of the ANDA with a Paragraph IV Certification occurred in the State of New Jersey, and if RK Pharma receives approval for the ANDA, RK Pharma will market, distribute, offer for sale, and/or sell the ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the ANDA Products in the State of New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

16. On information and belief, if the ANDA with a Paragraph IV Certification is approved, the ANDA Products would, among other things, be manufactured, marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

17. On information and belief, and as confirmed by RK Pharma's website, RK Pharma, VGYAAN, Apicore, and Archis operate through "vertical integration"[3] wherein VGYAAN works to "develop[] and commercializ[e] clinically critical therapies,"[4] Apicore "is a leading process R&D and API manufacturing service provider,"[5] and "Archis [], the sales and marketing arm, commercializes both RK Pharma group's and in-licensed partner products." [6]

[3] About Us. https://rkpharmainc.com/about-us.html (last visited on June 20, 2024)

[4] About Us, http://vgyaan.com/about/ (last visited on June 20, 2024).

[5] About Us, https://rkpharmainc.com/about-us.html (last visited on June 20, 2024)

[6] *Id.*

18. On information and belief, VGYAAN, Apicore, and Archis are wholly-owned subsidiaries of and operate under common management by RK Pharma.[7]

19. On information and belief, following any FDA approval of the ANDA with a Paragraph IV Certification, RK Pharma, VGYAAN, Apicore, and Archis will work in concert with one another to make, use, offer to sell, and/or sell the ANDA Products throughout the United States, and/or import the ANDA Products into the United States, including in this judicial district.

20. On information and belief, RK Pharma derives substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and New Jersey.

BACKGROUND

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

22. 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.

23. 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.

[7] *Id.*

24. Multrys® is the first and only FDA-approved multi-trace element injection for neonatal and pediatric patients weighing less than 10 kg.

25. Multrys® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 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.

26. Tralement® and Multrys®, as well as the use of Tralement® and Multrys® in accordance with their labels, are covered by one or more claims of the Patents-in-Suit.

27. 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.

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

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

30. On information and belief, RK Pharma was responsible for preparing and submitting the ANDA with a Paragraph IV Certification.

31. By letter dated January 23, 2024 (“the Notice Letter”), RK Pharma notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”) that RK Pharma had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the ’548 patent.

32. On information and belief, RK Pharma submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the ’548 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the ’548 patent is invalid.

33. The Notice Letter asserted defenses of non-infringement for certain, but not all, claims of the ’548 patent. The Notice Letter did not set forth positions of non-infringement for Claims 1–2, 4–6, 9–19, 21–43, and 46–56.

34. The Notice Letter contained an offer of confidential access (“OCA”) to the ANDA; however, the proposed OCA contained unreasonable restrictions and RK Pharma refused to negotiate any terms of the OCA with ARI. Consequently, ARI was unable to access the ANDA to assess any claims of non-infringement for the ’548 patent prior to the filing of this Complaint.

35. Since ARI received the Notice Letter and filed its initial Complaint against RK Pharma (ECF No. 1), the ’565 and ’022 patents have been listed in connection with Tralement® and Multrys® in the Orange Book.

36. 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.

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

38. 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.

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

40. 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.

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

42. 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.

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

44. Since ARI received the Notice Letter and filed its first amended Complaint against RK Pharma (ECF No. 43), the ’956 and ’957 patents have been listed in connection with Tralement® and Multrys® in the Orange Book.

45. On information and belief, the ANDA Products are generic versions of Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

46. In the Notice Letter, RK Pharma disclosed that the ANDA Products are (1) a single-dose, 1 mL generic version of Tralement® containing 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of selenium; (2) a 5 mL Pharmacy Bulk Package generic version of Tralement® containing 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of

selenium; and (3) a generic version of Multrys® containing 1000 mcg of zinc, 60 mcg of copper, 3 mcg of manganese, and 6 mcg of selenium.

47. On information and belief, the ANDA Products contain zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement® and Multrys®, respectively.

48. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as Tralement® and Multrys®.

COUNT I: INFRINGEMENT OF THE '548 PATENT

49. ARI realleges paragraphs 1–48 as if fully set forth herein.

50. RK Pharma'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 Products in or into the United States, prior to the expiration of the '548 patent, 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.

51. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by RK Pharma 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 Products will occur with RK Pharma's specific intent and encouragement, and will be conduct that RK Pharma knows or should know will occur. On information and belief, RK Pharma 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.

52. On information and belief, RK Pharma's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, 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 '548 patent, either literally or under the doctrine of equivalents. On information and belief, RK Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, RK Pharma knows that the ANDA Products are especially made or adapted for use in infringing the '548 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

53. ARI will be irreparably harmed if RK Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products 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.

54. RK Pharma has had knowledge of the '548 patent since at least the date RK Pharma 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).

55. 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

56. ARI realleges paragraphs 1–55 as if fully set forth herein.

57. RK Pharma'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 Products 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.

58. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by RK Pharma 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 Products will occur with RK Pharma's specific intent and encouragement, and will be conduct that RK Pharma knows or should know will occur. On information and belief, RK Pharma 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.

59. On information and belief, RK Pharma's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, 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, RK Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, RK Pharma knows that the ANDA Products are especially made or adapted for use in

infringing the ’022 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

60. ARI will be irreparably harmed if RK Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products 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.

61. 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

62. ARI realleges paragraphs 1–61 as if fully set forth herein.

63. RK Pharma’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 Products 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.

64. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by RK Pharma 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 Products will occur with RK Pharma's specific intent and encouragement, and will be conduct that RK Pharma knows or should know will occur. On information and belief, RK Pharma 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.

65. On information and belief, RK Pharma's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, 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, RK Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, RK Pharma knows that the ANDA Products are especially made or adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

66. ARI will be irreparably harmed if RK Pharma is permitted to make, use, sell, offer to sell, and/or import the ANDA Products 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.

67. 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

68. ARI realleges paragraphs 1–67 as if fully set forth herein.

69. RK Pharma'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.

70. 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 RK Pharma 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 RK Pharma's specific intent and encouragement, and will be conduct that RK Pharma knows or should know will occur. On information and belief, RK Pharma 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.

71. On information and belief, RK Pharma'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, RK Pharma intends that the ANDA Product be used by patients and

medical professionals. Also, on information and belief, RK Pharma 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.

72. ARI will be irreparably harmed if RK Pharma 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.

73. 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

74. ARI realleges paragraphs 1–73 as if fully set forth herein.

75. RK Pharma’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.

76. 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 RK Pharma 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 RK Pharma’s specific intent and encouragement, and will be conduct that RK Pharma knows or should know will occur. On information and belief, RK Pharma 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.

77. On information and belief, RK Pharma’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, RK Pharma intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, RK Pharma 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.

78. ARI will be irreparably harmed if RK Pharma 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.

79. 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 RK Pharma has infringed at least one claim of the Patents-in-Suit through RK Pharma'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 Products before the expiration of the '548 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that RK Pharma's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products 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 RK Pharma, 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 Products, 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 RK Pharma, 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 RK Pharma engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products 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 attorney's fees incurred in this action; and

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

Dated: January 3, 2025

By: s/ Charles H. Chevalier

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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2025, copies of the foregoing SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT TO RK PHARMA and all exhibits were caused to be served on counsel of record via ECF and also on counsel for RK Pharma via electronic mail.

Date: January 3, 2025

s/ Charles H. Chevalier
Charles H. Chevalier