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

AMERICAN REGENT, INC., *Plaintiff*, v. XIROMED, LLC and XIROMED PHARMA ESPAÑA, S.L., *Defendants.*	Civil Action No. 25-723 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT TO XIROMED

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Xiromed, LLC and Xiromed Pharma España, S.L. (collectively, "Xiromed " 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 Xiromed's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219728 ("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, Xiromed Pharma España, S.L. is a corporation organized and existing under the laws of Spain with its principal place of business at Manuel Pombo Angulo, 28 3rd Floor, Madrid, Spain, 28050.

4. On information and belief, Xiromed, LLC is an American corporation organized and existing under the laws of New Jersey with its principal place of business at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

JURISDICTION AND VENUE

5. 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.

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

7. On information and belief, this Court has personal jurisdiction over Xiromed Pharma España, S.L., under the New Jersey state long arm statute and consistent with due process of law because Xiromed Pharma España, S.L. has extensive contacts with the State of New Jersey, including through its affiliate Xiromed, LLC, and regularly does business in this judicial district. Further, Xiromed Pharma España, S.L. plans to sell the ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction in this District .

8. This Court has personal jurisdiction over Xiromed, LLC by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Xiromed, LLC Inc.'s principal place of business is in Florham Park, New Jersey. On information and belief, Xiromed, LLC Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0600430486. On information and belief, Xiromed, 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 Xiromed, LLC.

9. This Court has personal jurisdiction over Xiromed, LLC because Xiromed, LLC derives substantial revenue from selling generic pharmaceutical products and/or active

pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

10. On information and belief, Xiromed, LLC is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this judicial district.

11. This Court has personal jurisdiction over Xiromed Pharma España, S.L. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, including Xiromed, LLC, and (2) has maintained extensive and systematic contacts with the State of New Jersey, including, directly or indirectly, preparation and submission of the ANDA to the FDA in New Jersey through Xiromed, LLC.

12. This Court has personal jurisdiction over Xiromed Pharma España, S.L. because Xiromed Pharma España, S.L. derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

13. This Court has personal jurisdiction over Xiromed Pharma España, S.L. because, *inter alia*, Xiromed Pharma España, S.L. 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.

14. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. 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.

15. On information and belief, Xiromed, LLC is the United States agent acting at the direction of, and for the benefit of, Xiromed Pharma España, S.L. regarding the ANDA.

16. On information and belief, Xiromed, LLC is a generic pharmaceutical company that, in coordination with Xiromed Pharma España, S.L. and at the direction of Xiromed Pharma España, S.L., is in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this judicial district.

17. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. operate as a single integrated business.

18. On information and belief, Xiromed, LLC has a regular and established, physical place of business in New Jersey.

19. On information and belief, Xiromed, LLC intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Product.

20. On information and belief, Xiromed Pharma España, S.L. intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Product.

21. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. actively participated in the submission of the ANDA to the FDA.

22. On information and belief, Xiromed, LLC and Xiromed Pharma España, S.L. work in privity and/or concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States, including in this judicial district, prior to the expiration of the Patents-in-Suit.

23. In the alternative, this Court has personal jurisdiction over Xiromed Pharma España, S.L. 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) Xiromed Pharma España, S.L. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Xiromed Pharma España, S.L. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the 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 Xiromed Pharma España, S.L. satisfies due process.

24. Xiromed, LLC has previously availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the place of incorporation and principal place of business for Xiromed, LLC.

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

26. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Xiromed, LLC is organized under the laws of the State of New Jersey and therefore "resides" in this judicial district, has committed acts of infringement in New Jersey, and has a regular and established place of business in New Jersey. Xiromed Pharma España, S.L 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).

27. On information and belief, Xiromed, LLC 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.

28. On information and belief, Xiromed, 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, Xiromed, LLC maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

On information and belief, Xiromed Pharma España, S.L and Xiromed, 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, Xiromed intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Product.

BACKGROUND

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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").

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

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

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

39. 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.

40. The '565 patent has been listed in connection with Tralement® in the Orange Book.

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

42. 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.

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

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

45. 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.

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

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

48. By letter dated December 10, 2024 (“the Notice Letter”), Xiromed notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Xiromed 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.

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

50. On information and belief, Xiromed 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.

51. 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.

52. In the Notice Letter, Xiromed 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.

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

54. 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

55. ARI realleges paragraphs 1–54 as if fully set forth herein.

56. Xiromed'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.

57. 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 Xiromed 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 Xiromed's

specific intent and encouragement, and will be conduct that Xiromed knows or should know will occur. On information and belief, Xiromed 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.

58. On information and belief, Xiromed'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, Xiromed intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Xiromed 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.

59. ARI will be irreparably harmed if Xiromed 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.

60. Xiromed has had knowledge of the '548 patent since at least the date Xiromed 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).

61. 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

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

63. Xiromed'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.

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

65. On information and belief, Xiromed'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, Xiromed intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Xiromed 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.

66. ARI will be irreparably harmed if Xiromed 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.

67. Xiromed has had knowledge of the '022 patent since at least the date Xiromed 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).

68. 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

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

70. Xiromed'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.

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

72. On information and belief, Xiromed'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, Xiromed intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Xiromed 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.

73. ARI will be irreparably harmed if Xiromed 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.

74. Xiromed has had knowledge of the '565 patent since at least the date Xiromed 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).

75. 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

76. ARI realleges paragraphs 1–75 as if fully set forth herein.

77. Xiromed'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.

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

79. On information and belief, Xiromed'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, Xiromed intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Xiromed 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.

80. ARI will be irreparably harmed if Xiromed 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.

81. Xiromed has had knowledge of the '956 patent since at least the date Xiromed 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).

82. 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

83. ARI realleges paragraphs 1–82 as if fully set forth herein.

84. Xiromed'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.

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

86. On information and belief, Xiromed'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, Xiromed intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Xiromed 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.

87. ARI will be irreparably harmed if Xiromed 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.

88. Xiromed has had knowledge of the '957 patent since at least the date Xiromed 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).

89. 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 Xiromed has infringed at least one claim of the Patents-in-Suit through Xiromed'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 Xiromed'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 Xiromed, 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 Xiromed,

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 Xiromed 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: January 24, 2025

By: s/ Charles H. Chevalier

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