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

FRESENIUS KABI USA, LLC Plaintiff, v. XIROMED PHARMA ESPANA, S.L. XIROMED, LLC Defendants.	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius Kabi"), by its undersigned attorneys, for its complaint against Defendants Xiromed Pharma Espana, S.L. ("Xiromed Pharma") and Xiromed, LLC ("Xiromed LLC") (collectively "Xiromed" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 9,006,289 ("the '289 patent"), 9,168,238 ("the '238 patent"), and 9,168,239 ("the '239 patent") (collectively, "patents-in-suit"), arising under the United States patent laws, Title 35 United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to the filing of Abbreviated New Drug Application ("ANDA") No. 217495 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), by Xiromed seeking U.S. Food and Drug Administration

("FDA") approval to manufacture, use, import, offer to sell and/or sell levothyroxine sodium for powder for injection, 100 mcg/vial ("Xiromed's generic products") before the expiration of the patents-in-suit.

THE PARTIES

2. Fresenius Kabi is a corporation organized and existing under the laws of the State of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. On information and belief, Xiromed Pharma is a corporation organized under the laws of Spain, having a place of business located at Manuel Pombo Angulo, 28 3rd Floor, Madrid, Spain, 28050.

4. On information and belief, Xiromed LLC is a corporation organized under the laws of New Jersey, having a place of business located at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 1 *et seq*. generally and 35 U.S.C. § 271 specifically.

6. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Xiromed Pharma because, upon information and belief, Xiromed Pharma develops and manufactures generic drugs that it, directly or indirectly, markets and sells or intends to market and sell throughout the United States and in this judicial district, including through its New Jersey-based affiliate Xiromed LLC.

8. Upon information and belief, Xiromed Pharma is the owner of ANDA No. 217495.

9. Upon information and belief, Xiromed Pharma has purposefully availed itself of the rights and benefits of the laws of the State of New Jersey, having engaged in systemic and

continuous contacts with the State of New Jersey. For its ANDA submission, Xiromed Pharma engaged Xiromed LLC in Florham Park, New Jersey, to prepare and file ANDA No. 217495 and has designated Xiromed LLC as its authorized U.S. agent to communicate with FDA on its behalf.

10. This Court has personal jurisdiction over Xiromed LLC because, upon information and belief, Xiromed LLC sells and distributes generic drugs throughout the United States and in this judicial district. In addition, on information and belief, from its office in Florham Park, New Jersey, Xiromed LLC prepared ANDA No. 217495 on behalf of Xiromed Pharma and filed the same with FDA, which is an act of patent infringement.

11. For these reasons and others that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Xiromed Pharma and Xiromed LLC.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), as to Xiromed Pharma because Xiromed Pharma is incorporated in India and may be sued in any judicial district in the United States.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), as to Xiromed LLC because Xiromed LLC is incorporated in New Jersey and prepared and filed the ANDA at issue in this case from its Florham Park, New Jersey office.

THE PATENTS IN SUIT

14. The FDA issues a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

15. Fresenius Kabi is the holder of New Drug Application ("NDA") No. 202231 for Levothyroxine Sodium powder for intravenous injection, which the FDA approved on June 24, 2011. Fresenius Kabi currently sells Levothyroxine Sodium powder for intravenous injection in the United States.

16. The '289 patent, entitled "Levothyroxine Formulations," was duly and legally

issued on April 14, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '289 patent is attached hereto as Exhibit A.

17. Fresenius Kabi is the assignee and lawfully owns all right, title, and interest in the '289 patent, including the right to sue and to recover for infringement thereof.

18. In accordance with 21 U.S.C. § 355(b)(1), the '289 patent is listed in the Orange Book in connection with approved NDA No. 202231 as a patent claiming the drug products that are the subject of Fresenius Kabi's NDA ("Fresenius Kabi's NDA Products") or a method of using that drug and "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

19. According to the Orange Book, the '289 patent is currently not due to expire until October 3, 2032.

20. The '238 patent, entitled "Levothyroxine Formulations," was duly and legally issued on October 27, 2015, naming John Zhiqiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '238 patent is attached hereto as Exhibit B.

21. Fresenius Kabi is the assignee and lawfully owns all right, title, and interest in the '238 patent, including the right to sue and to recover for infringement thereof.

22. In accordance with 21 U.S.C. § 355(b)(1), the '238 patent is listed in the Orange Book in connection with approved NDA No. 202231 as a patent claiming Fresenius Kabi's NDA Products or a method of using that drug and "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

23. According to the Orange Book, the '238 patent is currently not due to expire until August 29, 2032.

24. The ’239 patent, entitled “Levothyroxine Formulations,” was duly and legally issued on October 27, 2015, naming John Zhiqiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the ’239 patent is attached hereto as Exhibit C.

25. Fresenius Kabi is the assignee and lawfully owns all right, title, and interest in the ’239 patent, including the right to sue and to recover for infringement thereof.

26. In accordance with 21 U.S.C. § 355(b)(1), the ’239 patent is listed in the Orange Book in connection with approved NDA No. 202231 as a patent claiming Fresenius Kabi’s NDA Products or a method of using that drug and “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”

27. According to the Orange Book, the ’239 patent is currently not due to expire until August 29, 2032.

XIROMED’S ANDA NO. 217495

28. On information and belief, Xiromed submitted ANDA No. 217495 to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Xiromed’s generic products.

29. On information and belief, Xiromed Pharma is the owner of ANDA No. 217495.

30. On information and belief, Xiromed submitted a certification pursuant to Section 505(b)(2)(A)(iv) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV certification”) that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Xiromed’s ANDA No. 217495.

31. On information and belief, if ANDA No. 217495 is approved by the FDA, Xiromed

will begin marketing Xiromed's generic products for treatment of myxedema coma, and doctors and patients will use Xiromed's generic products for that indication.

32. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, Xiromed's generic products have the same strength as at least one of the approved dosages for Fresenius Kabi's NDA Products. In addition, FDA requires Xiromed's generic products to be bioequivalent to Fresenius Kabi's NDA Products.

33. Fresenius Kabi received a letter dated September 9, 2022 ("the Notice Letter"), purporting to be a Notification of Paragraph IV Certification for ANDA No. 217495 under Section 505(b)(2)(A)(iv) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2)(A)(iv). The Notice Letter alleges that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Xiromed's generic products.

34. In the Notice Letter, Xiromed indicated that the active ingredient of Xiromed's generic products is lyophilized levothyroxine sodium and the strength is 100 mcg/vial. Xiromed also stated that the proposed dosage form of Xiromed's generic products is an injection.

35. On information and belief, ANDA No. 217495 seeks approval of generic levothyroxine products that are the same, or substantially the same, as Fresenius Kabi's commercially marketed and approved NDA Products.

36. On information and belief, if ANDA No. 217495 is approved by the FDA before the expiration of the patents-in-suit, Xiromed will begin manufacturing, using, importing, offering for sale, and/or selling Xiromed's generic products in the United States despite the patents-in-suit.

37. On information and belief, Xiromed was aware of the patents-in-suit when it submitted ANDA No. 217495 to the FDA, which ANDA contained the above-described Paragraph IV certifications concerning the patents-in-suit.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 9,006,289

38. Fresenius Kabi incorporates and realleges paragraphs 1-37 above.

39. The submission of ANDA No. 217495 was an act of infringement by Xiromed of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2). In the event that Xiromed commercially manufactures, imports, uses, offers for sale, or sells Xiromed's generic products, said actions would constitute infringement of the '289 patent under 35 U.S.C. § 271(a).

40. On information and belief, Xiromed's generic products are covered by one or more claims of the '289 patent.

41. On information and belief, Xiromed's commercial importation, manufacture, use, sale, and/or offer for sale of Xiromed's generic products before the expiration of the '289 patent would directly infringe the claims of the '289 patent.

42. The '289 patent has 21 claims directed to levothyroxine compositions. Independent claim 1 of the '289 patent is directed to:

> A composition, comprising:
> about 100 or about 200 micrograms of levothyroxine sodium;
> a phosphate buffer; and
> from 2 to 4 milligrams of mannitol,
> where the composition is a lyophilized solid.

43. Upon information and belief, Xiromed's generic products contain each of the elements in claim 1 of the '289 patent, either literally or under the doctrine of equivalents. In addition, Xiromed's generic products contain each of the elements of one or more additional claims of the '289 patent, either equivalently or under the doctrine of equivalents.

44. On information and belief, unless enjoined by this Court, Xiromed plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Xiromed's generic products with its proposed labeling immediately following

approval of ANDA No. 217495 and before the expiration of the '289 patent.

45. Unless enjoined by this Court, upon FDA approval of Xiromed's NDA No. 217495, Xiromed will infringe, either literally or under the doctrine of equivalents, one or more of claims of the '289 patent by engaging in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Xiromed's generic products.

46. On information and belief, Xiromed has been aware of the existence of the '289 patent since before the submission of ANDA No. 217495.

47. On information and belief, Xiromed has no reasonable basis for believing that Xiromed's generic products will not infringe one or more valid claims of the '289 patent and no reasonable basis for believing that the infringed claims are invalid.

48. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

49. The acts of infringement by Xiromed set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

50. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Xiromed's ANDA No. 217495 to be a date which is not any earlier than the expiration date of the '289 patent, including any extensions of that date.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 9,168,238

51. Fresenius Kabi incorporates and realleges paragraphs 1-50 above.

52. The submission of ANDA No. 217495 was an act of infringement by Xiromed of one or more claims of the '238 patent under 35 U.S.C. § 271(e)(2). In the event that Xiromed commercially manufactures, imports, uses, offers for sale, or sells Xiromed's generic products,

said actions would constitute infringement of the '238 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

53. On information and belief, Xiromed's generic products are covered by each claim of the '238 patent.

54. On information and belief, Xiromed's commercial importation, manufacture, use, sale, and/or offer for sale of Xiromed's generic products before the expiration of the '238 patent would directly and/or indirectly infringe the claims of the '238 patent.

55. The '238 patent has 30 claims directed to levothyroxine compositions. Independent claim 1 of the '238 patent is directed to:

> A lyophilized solid composition, comprising:
> about 100 micrograms of levothyroxine sodium;
> a buffer; and
> between 2 to 4 milligrams of mannitol.

56. Upon information and belief, Xiromed's generic products contain each of the elements in claim 1 of the '238 patent, either literally or under the doctrine of equivalents. In addition, Xiromed's generic products contain each of the elements of one or more additional claims of the '238 patent, either equivalently or under the doctrine of equivalents.

57. The '238 patent contains dependent method claims directed to providing levothyroxine compositions. Upon information and belief, Xiromed will induce and contribute to the direct infringement of one or more of the method claims of the '238 patent, including by distributing Xiromed's generic products with a product label instructing or encouraging the use of the claimed levothyroxine product with knowledge of the '238 patent and knowing the product will be used in an infringing manner.

58. On information and belief, unless enjoined by this Court, Xiromed plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or

importation of Xiromed's generic products with its proposed labeling immediately following approval of ANDA No. 217495 and before the expiration of the '238 patent.

59. Unless enjoined by this Court, upon FDA approval of Xiromed's ANDA No. 217495, Xiromed will directly, either literally or under the doctrine of equivalents, and/or indirectly infringe one or more of claims of the '238 patent by engaging in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Xiromed's generic products.

60. On information and belief, Xiromed has been aware of the existence of the '238 patent since before the submission of ANDA No. 217495.

61. On information and belief, Xiromed has no reasonable basis for believing that Xiromed's generic products will not infringe one or more valid claims of the '238 patent and no reasonable basis for believing that the infringed claims are invalid.

62. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

63. The acts of infringement by Xiromed set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

64. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Xiromed's ANDA No. 217495 to be a date which is not any earlier than the expiration date of the '238 patent, including any extensions of that date.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 9,168,239

65. Fresenius Kabi incorporates and realleges paragraphs 1-64 above.

66. The submission of ANDA No. 217495 was an act of infringement by Xiromed of one or more claims of the '239 patent under 35 U.S.C. § 271(e)(2). In the event that Xiromed

commercially manufactures, imports, uses, offers for sale, or sells Xiromed's generic products, said actions would constitute infringement of the '239 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

67. On information and belief, Xiromed's generic products are covered by each claim of the '239 patent.

68. On information and belief, Xiromed's commercial importation, manufacture, use, sale, and/or offer for sale of Xiromed's generic products before the expiration of the '239 patent would directly infringe the claims of the '239 patent.

69. The '239 patent has 15 claims directed to levothyroxine compositions. Independent claim 1 of the '239 patent is directed to:

> A lyophilized solid composition, comprising:
> between 100 and 500 micrograms of a salt of levothyroxine;
> a buffer; and
> between 2 to 4 milligrams of mannitol.

70. Upon information and belief, Xiromed's generic products contain each of the elements in claim 1 of the '239 patent, either literally or under the doctrine of equivalents. In addition, Xiromed's generic products contain each of the elements of one or more additional claims of the '238 patent, either equivalently or under the doctrine of equivalents.

71. The '239 patent contains dependent method claims directed to providing levothyroxine compositions. Upon information and belief, Xiromed will induce and contribute to the direct infringement of one or more of the method claims of the '239 patent, including by distributing Xiromed's generic products with a product label instructing or encouraging the use of the claimed levothyroxine product with knowledge of the '239 patent and knowing the product will be used in an infringing manner.

72. On information and belief, unless enjoined by this Court, Xiromed plans and

intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Xiromed's generic products with its proposed labeling immediately following approval of ANDA No. 217495 and before the expiration of the '239 patent.

73. Unless enjoined by this Court, upon FDA approval of Xiromed's NDA No. 217495, Xiromed will directly, either literally or under the doctrine of equivalents, and/or indirectly infringe one or more of claims of the '239 patent by engaging in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Xiromed's generic products.

74. On information and belief, Xiromed has been aware of the existence of the '239 patent since before the submission of ANDA No. 217495.

75. On information and belief, Xiromed has no reasonable basis for believing that Xiromed's generic products will not infringe one or more valid claims of the '239 patent and no reasonable basis for believing that the infringed claims are invalid.

76. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

77. The acts of infringement by Xiromed set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

78. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Xiromed's ANDA No. 217495 to be a date which is not any earlier than the expiration date of the '239 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Fresenius Kabi respectfully requests the following relief:

A. Judgment in favor of Fresenius Kabi and against Xiromed;

B. Judgment, pursuant to 35 U.S.C. § 271(e)(2) and 35 U.S.C. §§ 271(a), (b), and/or (c), that Xiromed has infringed the '289 patent, the '238 patent, and the '239 patent by the submission of ANDA No. 217495, and that the importation, sale, offer for sale, use, and/or manufacture of Xiromed's generic products, in the United States, would infringe the '289 patent, the '238 patent, and the '239 patent;

C. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A) and other provisions of 35 U.S.C. § 271, that the effective date of approval of ANDA No. 217495 shall be a date not earlier than the date of expiration of the '289 patent, the '238 patent, and the '239 patent plus any additional periods of exclusivity;

D. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271 and 283 and Federal Rule of Civil Procedure 65, enjoining Xiromed, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any of Xiromed's generic products, and any product that is similar to or only colorably different from those products, before the date of expiration of the '289 patent, the '238 patent, and the '239 patent and any additional periods of exclusivity;

E. A declaration that this is an exceptional case and an award to Fresenius Kabi of its reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

F. Damages or other monetary relief, including prejudgment interest, if Xiromed engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or

importation of Xiromed's generic products, or any other products that would infringe the '289 patent, the '238 patent, and the '239 patent prior to the expiration of the '289 patent, the '238 patent, and the '239 patent, respectively;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. An award of Fresenius Kabi's taxable costs in bringing and prosecuting this action; and

I. Such other and further relief to Fresenius Kabi as this Court may deem just and proper.

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