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Fresenius Kabi USA, LLC*

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

FRESENIUS KABI USA, LLC

Plaintiff,

v.

ACCORD HEALTHCARE INC.

Defendant.

Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC (“Fresenius Kabi”), by its undersigned attorneys, for its complaint against Defendant Accord Healthcare Inc. (“Accord” or “Defendant”), 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. 217708 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), by Accord 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, 200 mcg/vial, and 500 mcg/vial, (“Accord’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, Accord is a corporation organized under the laws of North Carolina, having a place of business located at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

JURISDICTION AND VENUE

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

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

6 This Court has personal jurisdiction over Accord because, upon information and belief, Accord directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district, including Accord’s generic products. In addition, Accord, through its counsel, has consented to jurisdiction and venue in New Jersey for purposes of this action, prior to the filing of this Complaint.

7 Upon information and belief, Accord is the owner of ANDA No. 217708.

8 Upon information and belief, Accord 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. Moreover, Accord has litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey. *See, e.g., Janssen Pharmaceuticals,*

Inc. et al v. Accord Healthcare Inc. et al, C.A. No. 22-00856, Dkt. 5 (D.N.J. Feb. 18, 2022); *Eagle Pharmaceuticals, Inc. et al v. Accord Healthcare Inc.*, C.A. No. 19-09031, Dkt. 11 (D.N.J. Apr. 15, 2019).

9. For these reasons and others that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Accord.

10. Venue is proper in this Court because, among other things, Accord, through its counsel, has consented to jurisdiction and venue in New Jersey for purposes of this action, prior to the filing of this Complaint.

THE PATENTS IN SUIT

11. The FDA issues a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

12. 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.

13. 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.

14. 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.

15. 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.”

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

17. 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.

18. 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.

19. 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.”

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

21. 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.

22. 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.

23. 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.”

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

ACCORD’S ANDA NO. 217708

25. On information and belief, Accord submitted ANDA No. 217708 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 Accord’s generic products.

26. On information and belief, Accord is the owner of ANDA No. 217708.

27. On information and belief, Accord 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 Accord’s ANDA No. 217708.

28. On information and belief, if ANDA No. 217708 is approved by the FDA, Accord will begin marketing Accord’s generic products for treatment of myxedema coma, and doctors and patients will use Accord’s generic products for that indication.

29. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, Accord’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 Accord’s generic products to be bioequivalent to Fresenius Kabi’s NDA Products.

30. Fresenius Kabi received a letter dated September 13, 2022 (“the Notice Letter”), purporting to be a Notice of Certification for ANDA No. 217708 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 and/or unenforceable. The Notice Letter also states that the patents-in-suit will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Accord's generic products but provides no arguments to support this position.

31. In the Notice Letter, Accord indicated that the active ingredient of Accord's generic products is lyophilized levothyroxine sodium and the strengths are 100 mcg/vial, 200 mcg/vial, and 500 mcg/vial. Accord also stated that the proposed dosage form of Accord's generic products is an injection.

32. On information and belief, ANDA No. 217708 seeks approval of generic levothyroxine products that are the same, or substantially the same, as Fresenius Kabi's commercially marketed and approved NDA Products.

33. On information and belief, if ANDA No. 217708 is approved by the FDA before the expiration of the patents-in-suit, Accord will begin manufacturing, using, importing, offering for sale, and/or selling Accord's generic products in the United States despite the patents-in-suit.

34. On information and belief, Accord was aware of the patents-in-suit when it submitted ANDA No. 217708 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

35. Fresenius Kabi incorporates and realleges paragraphs 1-34 above.

36. The submission of ANDA No. 217708 was an act of infringement by Accord of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2). In the event that Accord commercially manufactures, imports, uses, offers for sale, or sells Accord's generic products, said actions would constitute infringement of the '289 patent under 35 U.S.C. § 271(a).

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

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

39. 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.

40. Upon information and belief, Accord'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, Accord'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.

41. On information and belief, unless enjoined by this Court, Accord plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's generic products with its proposed labeling immediately following approval of ANDA No. 217708 and before the expiration of the '289 patent.

42. Unless enjoined by this Court, upon FDA approval of Accord's NDA No. 217708, Accord 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 Accord's generic products.

43. On information and belief, Accord has been aware of the existence of the '289

patent since before the submission of ANDA No. 217708.

44. On information and belief, Accord has no reasonable basis for believing that Accord'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.

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

46. The acts of infringement by Accord 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.

47. 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 Accord's ANDA No. 217708 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

48. Fresenius Kabi incorporates and realleges paragraphs 1-47 above.

49. The submission of ANDA No. 217708 was an act of infringement by Accord of one or more claims of the '238 patent under 35 U.S.C. § 271(e)(2). In the event that Accord commercially manufactures, imports, uses, offers for sale, or sells Accord's generic products, said actions would constitute infringement of the '238 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

51. On information and belief, the commercial importation, manufacture, use, sale, and/or offer for sale of Accord's generic products by Accord before the expiration of the '238

patent would directly and/or indirectly infringe the claims of the '238 patent.

52. 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.

53. Upon information and belief, Accord'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, Accord'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.

54. The '238 patent contains dependent method claims directed to providing levothyroxine compositions. Upon information and belief, Accord will induce and contribute to the direct infringement of one or more of the method claims of the '238 patent, including by distributing Accord'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.

55. On information and belief, unless enjoined by this Court, Accord plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's generic products with its proposed labeling immediately following approval of ANDA No. 217708 and before the expiration of the '238 patent.

56. Unless enjoined by this Court, upon FDA approval of Accord's ANDA No. 217708, Accord 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 Accord's generic products.

57. On information and belief, Accord has been aware of the existence of the '238 patent since before the submission of ANDA No. 217708.

58. On information and belief, Accord has no reasonable basis for believing that Accord'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.

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

60. The acts of infringement by Accord 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.

61. 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 Accord's ANDA No. 217708 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

62. Fresenius Kabi incorporates and realleges paragraphs 1-61 above.

63. The submission of ANDA No. 217708 was an act of infringement by Accord of one or more claims of the '239 patent under 35 U.S.C. § 271(e)(2). In the event that Accord commercially manufactures, imports, uses, offers for sale, or sells Accord's generic products, said actions would constitute infringement of the '239 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

65. On information and belief, the commercial importation, manufacture, use, sale,

and/or offer for sale of Accord's generic products by Accord before the expiration of the '239 patent would directly infringe the claims of the '239 patent.

66. 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.

67. Upon information and belief, Accord'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, Accord'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.

68. The '239 patent contains dependent method claims directed to providing levothyroxine compositions. Upon information and belief, Accord will induce and contribute to the direct infringement of one or more of the method claims of the '239 patent, including by distributing Accord'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.

69. On information and belief, unless enjoined by this Court, Accord plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's generic products with its proposed labeling immediately following approval of ANDA No. 217708 and before the expiration of the '239 patent.

70. Unless enjoined by this Court, upon FDA approval of Accord's NDA No. 217708, Accord 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 Accord's generic products.

71. On information and belief, Accord has been aware of the existence of the '239 patent since before the submission of ANDA No. 217708.

72. On information and belief, Accord has no reasonable basis for believing that Accord'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.

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

74. The acts of infringement by Accord 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.

75. 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 Accord's ANDA No. 217708 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 Accord;
- B. Judgment, pursuant to 35 U.S.C. § 271(e)(2) and 35 U.S.C. §§ 271(a), (b), and/or (c), that Accord has infringed the '289 patent, the '238 patent, and the '239 patent by the submission of ANDA No. 217708, and that the importation, sale, offer for sale, use, and/or manufacture of Accord'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. 217708 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 Accord, 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 Accord'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 Accord engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of Accord'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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