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Fresenius Kabi USA, LLC

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
CUSTOPHARM, INC.,	)	C.A. No. _____
	)	
Defendant.	)	
	)	
	)	

COMPLAINT

Plaintiff Fresenius Kabi USA, LLC ("Fresenius Kabi"), by and through its undersigned attorneys, for its complaint against Defendant Custopharm, Inc. ("Custopharm"), alleges as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code Section 271, in response to Custopharm's submission of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell levothyroxine sodium solution prior to the expiration of U.S. Patent Nos. 9,782,376 ("the '376 patent") and 10,398,669 ("the '669 patent") (collectively, 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, Custopharm is a corporation organized and existing under the laws of the states of Colorado.

4. On information and belief, Custopharm is also incorporated under the laws of the state of Texas.

5. On information and belief, Custopharm has its principal place of business at 2325 Camino Vida Roble, Ste. B, Carlsbad, California 92011.

JURISDICTION AND VENUE

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

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

8. This Court has personal jurisdiction over Custopharm because this suit arises out of and relates to its activities that are, and will be, directed to the State of New Jersey. On

information and belief, Custopharm prepared and filed NDA No. 214253 with the intention of seeking to market the product covered by NDA No. 214253 nationwide, including within this Judicial District. On information and belief, following any FDA approval of NDA No. 214253, Custopharm will market and sell the product covered by NDA No. 214253 that is the subject of the infringement claims in this action in the State of New Jersey and throughout the United States, including in this Judicial District.

9. Custopharm has taken no steps to avoid marketing and selling its NDA product in this Judicial District, or to ensure that its NDA product will not be available in this Judicial District.

10. Further, upon information and belief, Custopharm, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products throughout the United States and in this Judicial District.

11. This Court also has personal jurisdiction over Custopharm because Custopharm's contacts within this Judicial District are continuous and systematic. On information and belief, Custopharm develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs that are regularly marketed, distributed, and sold in New Jersey and throughout the United States. Thus, on information and belief, Custopharm does substantial business in New Jersey, derives substantial revenue from New Jersey, and engages in other persistent courses of conduct in New Jersey. These continuous and systematic contacts, including but not limited to those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Custopharm.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, upon information and belief, Custopharm is registered to do business in New Jersey with an entity ID of 045047920. Upon information and belief, based upon Custopharm's registration

to do business in New Jersey and its current and intended sales and distribution of products in New Jersey, Custopharm also has a regular and established place of business in this Judicial District. On information and belief, Custopharm representatives make contacts to this Judicial District for the purpose of marketing and selling its pharmaceutical products.

THE PATENTS-IN-SUIT

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

14. Fresenius Kabi is the holder of NDA No. 210632 for Levothyroxine Sodium intravenous solution, which the FDA approved on April 11, 2019. Fresenius Kabi currently sells Levothyroxine Sodium intravenous solution in the United States.

15. The '376 patent, entitled "Levothyroxine Liquid Formulations," was duly and legally issued on October 10, 2017, naming Arunya Usayapant and Basma M. Ibrahim as the inventors. A true and correct copy of the '376 patent is attached hereto as Exhibit A.

16. Fresenius Kabi is the assignee and lawfully owns all right, title, and interest in the '376 patent, including the right to sue and to recover for infringement thereof.

17. In accordance with 21 U.S.C. § 355(b)(1), the '376 patent is listed in the Orange Book in connection with approved NDA No. 210632 as a patent claiming Fresenius Kabi's NDA drug product 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."

18. According to the Orange Book, the '376 patent is currently not due to expire until December 1, 2036.

19. The ’669 patent, entitled “Levothyroxine Liquid Formulations,” was duly and legally issued on September 3, 2019, naming Arunya Usayapant and Basma M. Ibrahim as the inventors. A true and correct copy of the ’669 patent is attached hereto as Exhibit B.

20. Fresenius Kabi is the assignee and lawfully owns all right, title, and interest in the ’669 patent, including the right to sue and to recover for infringement thereof.

21. In accordance with 21 U.S.C. § 355(b)(1), the ’669 patent is listed in the Orange Book in connection with approved NDA No. 210632 as a patent claiming Fresenius Kabi’s NDA drug product 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.”

22. According to the Orange Book, the ’669 patent is currently not due to expire until December 1, 2036.

CUSTOPHARM’S NDA NO. 214253

23. On information and belief, Custopharm submitted NDA No. 214253 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 a liquid levothyroxine sodium injection, 100 mcg/mL (“Custopharm’s NDA Product”).

24. On information and belief, Custopharm is the owner of NDA No. 214253.

25. In submitting its NDA No. 214253, Custopharm was required to identify any drug that the NDA relied upon for approval of Custopharm’s NDA Product, and submit a certification regarding the patents that are listed in the Orange Book for this drug. 21 U.S.C. § 355(b)(2).

26. On information and belief, Custopharm identified NDA No. 202231 as the reference listed drug upon which Custopharm’s NDA No. 214253 relied upon in seeking approval.

NDA No. 202231 is listed in the Orange Book as a "powder" formulation containing levothyroxine sodium. The Orange Book lists Fresenius Kabi as the holder of NDA No. 202231.

27. On information and belief, Custopharm 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 listed for NDA No. 202231 are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Custopharm's NDA No. 214253.

28. On information and belief, despite seeking approval of a liquid solution levothyroxine formulation, Custopharm did not submit a Paragraph IV certification that the patents listed for Fresenius Kabi's liquid "solution" levothyroxine NDA No. 210632 (specifically, the '376 patent and '669 patent) are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Custopharm's NDA No. 214253.

29. Custopharm has not provided to Fresenius Kabi any factual or legal basis for why or how it does not infringe any valid claim of the '376 or '669 patent.

30. Custopharm was required to reference Fresenius Kabi's levothyroxine liquid NDA No. 210632 in seeking approval for its liquid levothyroxine NDA No. 214253. 21 C.F.R. § 314.54(a)(1)(iii). Custopharm improperly referenced Fresenius Kabi's powder NDA No. 202231 so that it could avoid having to submit to FDA a Paragraph IV certification to the patents listed for NDA No. 210632 (specifically, the '376 patent and '669 patent) and thereby improperly deprive Fresenius Kabi from obtaining a statutory 30-month stay of approval of Custopharm's NDA if Custopharm does not change its certification. *See* 21 U.S.C. § 355(c)(3)(C).

31. Fresenius Kabi received a letter dated September 16, 2019 ("the Notice Letter"), purporting to be a Notice of Paragraph IV Certification for NDA No. 214253 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 Paragraph IV certification alleges that the claims of the patents listed in the Orange Book for powder levothyroxine formulation NDA No. 202231 are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Custopharm's NDA Product.

32. In the Notice Letter, Custopharm indicated that the dosage and active ingredient of Custopharm's NDA Product is 100 mcg/1mL levothyroxine. Custopharm also stated that the proposed dosage form of Custopharm's NDA Product is "injection."

33. Despite stating that Custopharm's NDA Product is a liquid solution levothyroxine formulation, the Notice Letter did not contain a Notice of Paragraph IV Certification for the '376 and '669 patents listed under NDA 210632.

34. The Notice Letter contained an Offer of Confidential Access ("OCA") for Fresenius Kabi to receive and review Custopharm's NDA.

35. Upon receipt of the Notice Letter, counsel for Fresenius Kabi contacted the counsel for Custopharm that sent the Notice Letter and requested a copy of Custopharm's acknowledgement letter that they should have already received from the FDA. An acknowledgment letter merely confirms the filing and acceptance for filing by the FDA as of a particular date, and contains no confidential information.

36. Counsel for Custopharm ultimately refused to provide the acknowledgment letter on October 22, 2020, and insisted that the parties discuss terms to the OCA before producing any document.

37. Counsel for Fresenius Kabi attempted to negotiate terms for the disclosures of Custopharm's NDA under the OCA, but counsel for Custopharm refused to provide the NDA under reasonable terms.

38. On information and belief, if NDA No. 214253 is approved by the FDA before the expiration of the '376 patent and '669 patent, Custopharm will begin manufacturing, using, importing, offering for sale, and/or selling Custopharm's NDA Product containing levothyroxine in a liquid formulation, despite the patents-in-suit.

39. This action is being commenced before the expiration of forty-five days from the date of Fresenius Kabi's receipt of the Notice Letter.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 9,782,376

40. Fresenius Kabi incorporates and realleges paragraphs 1-39 above.

41. The submission of NDA No. 214253 was an act of infringement by Custopharm of one or more claims of the '376 patent under 35 U.S.C. § 271(e)(2). In the event that Custopharm commercially manufactures, imports, uses, offers for sale, or sells Custopharm's NDA Product, said actions would constitute infringement of the '376 patent under 35 U.S.C. § 271(a).

42. On information and belief, Custopharm's NDA Product is covered by each claim of the '376 patent.

43. On information and belief, Custopharm's commercial importation, manufacture, use, sale, and/or offer for sale of Custopharm's NDA Product before the expiration of the '376 patent would directly infringe the claims of the '376 patent.

44. The '376 patent has 30 claims directed to a liquid formulation containing levothyroxine. Custopharm's NDA Product meets each and every limitation of claims 1-30 of the '376 patent, either literally or under the doctrine of equivalents.

45. Independent claim 1 of the '376 patent is directed to:

A liquid formulation comprising
levothyroxine or a pharmaceutically acceptable salt thereof;

about 1 mg/mL to about 50 mg/mL of tromethamine;
about 10 mcg/mL to about 500 mcg/mL of sodium iodide; and water;
wherein the formulation has a pH of about 9.0 to about 11.5, and wherein the formulation is stable for at least 12 months at 25±2° C.

46. Just as disclosed in claim 1 of the ’376 patent, Custopharm’s NDA Product is also a liquid formulation containing levothyroxine. Custopharm states in its Notice Letter that it believes the contents of the Notice Letter itself are also confidential.

47. Upon information and belief, Custopharm’s NDA Product contains each of the elements in claim 1 of the ’376 patent, either literally or under the doctrine of equivalents.

48. Like claim 1, claims 2-30 of the ’376 patent are directed to liquid formulations containing levothyroxine. Upon information and belief, Custopharm’s NDA Product contains each of the elements contained in claims 2-30 of the ’376 patent, either literally or under the doctrine of equivalents.

49. On information and belief, unless enjoined by this Court, Custopharm plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Custopharm’s NDA Product with its proposed labeling immediately following approval of NDA No. 214253 and before the expiration of the ’376 patent.

50. Unless enjoined by this Court, upon FDA approval of Custopharm’s NDA No. 214253, Custopharm will infringe, either literally or under the doctrine of equivalents, one or more of claims of the ’376 patent by engaging in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Custopharm’s NDA Product.

51. On information and belief, Custopharm has been aware of the existence of the application resulting in the ’376 patent since before the submission of NDA No. 214253.

52. On information and belief, Custopharm has no reasonable basis for believing that Custopharm's NDA Product will not infringe one or more valid claims of the '376 patent and no reasonable basis for believing that the infringed claims are invalid.

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

54. The acts of infringement by Custopharm 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.

55. 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 Custopharm's NDA No. 214253 to be a date which is not any earlier than the expiration date of the '376 patent, including any extensions of that date.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 10,398,669

56. Fresenius Kabi incorporates and realleges paragraphs 1-55 above.

57. The submission of NDA No. 214253 was an act of infringement by Custopharm of one or more claims of the '669 patent under 35 U.S.C. § 271(e)(2). In the event that Custopharm commercially manufactures, imports, uses, offers for sale, or sells Custopharm's NDA Product, said actions would constitute infringement of the '669 patent under 35 U.S.C. § 271(a).

58. On information and belief, Custopharm's NDA Product is covered by each claim of the '669 patent.

59. On information and belief, Custopharm's commercial importation, manufacture, use, sale, and/or offer for sale of the Custopharm NDA Product before the expiration of the '669 patent would directly infringe the claims of the '669 patent.

60. The ’669 patent has 17 claims directed to a liquid formulation containing levothyroxine. Custopharm’s NDA Product meets each and every limitation of claims 1-17 of the ’669 patent, either literally or under the doctrine of equivalents.

61. Independent claim 1 of the ’669 patent is directed to:

> A liquid formulation comprising
> levothyroxine or a pharmaceutically acceptable salt thereof;
> a stabilizing agent comprising tromethamine;
> not more than 2% liothyronine (T3); and
> water;
> wherein the formulation retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 12 months at 25±2° C., and retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 2 months at 40±2° C.

62. Custopharm’s NDA Product meets each and every limitation of claim 1 of the ’669 patent, either literally or under the doctrine of equivalents.

63. Just as disclosed in claim 1 of the ’669 patent, Custopharm’s NDA Product is also a liquid formulation containing levothyroxine. Custopharm states in its Notice Letter that it believes the contents of the Notice Letter itself are confidential.

64. Upon information and belief, Custopharm’s NDA Product contains each of the elements in claim 1 of the ’669 patent, either literally or under the doctrine of equivalents.

65. Like claim 1, claims 2-17 of the ’669 patent are directed to liquid formulations containing levothyroxine. Upon information and belief, Custopharm’s NDA Product contains each of the elements contained in claims 2-17 of the ’669 patent, either literally or under the doctrine of equivalents.

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

importation of Custopharm's NDA Product with its proposed labeling immediately following approval of NDA No. 214253 and before the expiration of the '669 patent.

67. Unless enjoined by this Court, upon FDA approval of Custopharm's NDA No. 214253, Custopharm will infringe, either literally or under the doctrine of equivalents, one or more of claims of the '669 patent by engaging in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Custopharm's NDA Product.

68. On information and belief, Custopharm has been aware of the existence of the application resulting in the '669 patent since before the submission of NDA No. 214253.

69. On information and belief, Custopharm has no reasonable basis for believing that Custopharm's NDA Product will not infringe one or more valid claims of the '669 patent and no reasonable basis for believing that the infringed claims are invalid.

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

71. The acts of infringement by Custopharm 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.

72. 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 Custopharm's NDA No. 214253 to be a date which is not any earlier than the expiration date of the '669 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 Custopharm;

B. Judgment, pursuant to 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), that Custopharm has infringed, literally or by the doctrine of equivalents, the ’376 patent and ’669 patent by the submission of NDA No. 214253, and that the importation, sale, offer for sale, use, and/or manufacture of Custopharm’s NDA Product, in the United States, would infringe the ’376 patent and ’669 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 NDA No. 214253 shall be a date not earlier than the date of expiration of the ’376 patent and ’669 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 Custopharm 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 NDA Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the ’376 patent and ’669 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 Custopharm engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of NDA Product, or any other products that would infringe the ’376 patent and ’669 patent prior to the expiration of the ’376 patent and ’669 patent;

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.

Respectfully submitted,

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