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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, Plaintiff, v. FERA PHARMACEUTICALS, LLC, Defendant.	)	**Civil Action No. ____**

COMPLAINT

Plaintiff Fresenius Kabi USA, LLC ("Fresenius Kabi"), by its undersigned attorneys, for its complaint against Defendant Fera Pharmaceuticals, LLC ("Fera"), 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, in response to the submission of an Abbreviated New Drug

Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell generic versions of levothyroxine sodium powder for injection prior to the expiration of U.S. Patent No. 9,006,689 ("the '689 Patent").

THE PARTIES

2. Plaintiff 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, Fera is a limited liability company organized and existing under the laws of the state of New York, having its corporate headquarters at 134 Birch Hill Road, Locust Valley, NY 11560.

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. Personal jurisdiction over Fera is proper because, upon information and belief, Fera, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. Upon information and belief, Fera has purposefully conducted and continues to conduct business in New Jersey, and, as a result, New Jersey is a likely destination of Fera's generic products. Upon information and belief, Fera has purposely availed itself of the rights and benefits of the laws of the State of New Jersey, having engaged in systematic and continuous contacts with the State of New Jersey.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

8. The ’689 Patent, entitled “Levothyroxine Formulations,” was duly and legally issued on April l4, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Mason as the inventors. A true and correct copy of the ’689 Patent is attached hereto as Exhibit A.

9. Plaintiff Fresenius Kabi is the assignee and lawfully owns all right, title, and interest in the ’689 Patent, including the right to sue and to recover for past infringement thereof.

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

11. Fresenius Kabi is the holder of New Drug Application (“NDA”) No. 202231 for Levothyroxine Sodium, which the FDA approved on June 24, 2011. In accordance with 21 U.S.C. § 355(b)(1), the ’689 Patent is listed in the Orange Book in connection with approved NDA No. 202231, as a patent “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 Fresenius Kabi’s NDA drug product.

12. Fresenius Kabi currently sells in the United States Levothyroxine Sodium. According to the Orange Book, the ’689 Patent is currently not due to expire until October 3, 2032.

FERA’S ANDA NO. 206163

13. On information and belief, Fera submitted ANDA No. 206163 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of generic 100 mcg/vial and 500 mcg/vial levothyroxine sodium powder for injection (the “ANDA Products”).

14. On information and belief, ANDA No. 206163 contains a Paragraph IV certification that the '689 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Fera's ANDA No. 206163.

15. On information and belief, Fera is the owner of ANDA No. 206163.

16. On information and belief, if ANDA No. 206163 is approved by the FDA before the expiration of the '689 Patent, Fera will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA Products, despite the patent.

17. On information and belief, if ANDA No. 206163 is approved by the FDA, Fera will begin marketing the ANDA Products for treatment of myxedema coma, and doctors and patients will use each of the dosage strengths of the ANDA Products for the indications marketed by Fera.

18. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA Products' dosage strengths must have the same strength as one of the approved dosages for Fresenius Kabi's NDA levothyroxine sodium products ("the NDA products"). In addition, the ANDA Products must be bioequivalent to the NDA products.

19. Fresenius Kabi received a letter ("the Notice Letter"), purporting to be a Notice of Certification for ANDA No. 206163 under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B), and 21 CFR § 314.95(c). The Paragraph IV certification alleged that the claims of the '689 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

20. On information and belief, ANDA No. 206163 seeks approval of a generic levothyroxine product that is the same, or substantially the same, as Fresenius Kabi's commercially marketed and approved Levothyroxine Sodium product.

21. On information and belief, Fera was aware of the '689 Patent when ANDA No. 206163 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning this specific patent.

COUNT I: INFRINGEMENT OF THE '689 PATENT – ANDA SUBMISSION

22. Fresenius Kabi incorporates and realleges paragraphs 1-21 above.

23. The submission of ANDA No. 206163 including a Paragraph IV certification regarding the '689 Patent was an act of infringement by Fera of one or more claims of the '689 Patent under 35 U.S.C. § 271(e)(2).

24. On information and belief, the use of ANDA Products in accordance with and as directed by the instructions contained in the proposed package insert of Fera's ANDA No. 206163 is covered by one or more claims of the '689 Patent.

25. On information and belief, Fera's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Products before the expiration of the '689 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '689 Patent.

26. On information and belief, the use of Fera's ANDA Products in accordance with and as directed by Fera's proposed labeling will infringe one or more claims of the '689 Patent.

27. On information and belief, by seeking approval to distribute the ANDA Products with their proposed labeling, Fera intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Fera knows will infringe one or more claims of the '689 Patent.

28. On information and belief, unless enjoined by this Court, Fera plans and intends to, and will, actively induce infringement of one or more claims of the '689 Patent immediately following approval of ANDA No. 206163.

29. On information and belief, unless enjoined by this Court, Fera plans and intends to, and will, contribute to the infringement of one or more claims of the '689 Patent immediately following approval of ANDA No. 206163.

30. On information and belief, Fera knows that its ANDA No. 206163 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '689 Patent, and that the Fera ANDA Products and their proposed labeling are not suitable for any noninfringing use.

31. On information and belief, Fera's actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 206163 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '689 patent.

32. On information and belief, Fera has been aware of the existence of the application resulting in the '689 Patent since before the submission of ANDA No. 206163.

33. On information and belief, Fera has no reasonable basis for believing that its ANDA Products will not infringe one or more valid claims of the '689 Patent and no reasonable basis for believing that the infringed claims are invalid. Fera posited no theory of non-infringement in its Notice Letter.

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

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

of the ANDA Products with their proposed labeling immediately following approval of ANDA No. 206163 and before the expiration of the '689 Patent.

36. The acts of infringement by Fera 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.

37. 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 Fera's ANDA No. 206163 to be a date which is not any earlier than the expiration date of the '689 Patent, including any extensions of that date.

COUNT II: INFRINGEMENT OF THE '689 PATENT – DECLARATORY JUDGMENT

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

39. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

40. There is an actual case or controversy such that the Court may entertain Fresenius Kabi's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

41. Fera has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Fera's generic levothyroxine sodium product before the expiration of the '689 patent, including Fera's filing of ANDA No. 206163.

42. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Fera's generic levothyroxine sodium product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '689 patent.

43. Fera has refused to stipulate that it will not launch a generic levothyroxine product while this matter is in litigation waiting to be resolved by the Court.

44. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and Fera as to liability for the infringement of the '689 patent claims. Fera's actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from Fera's threatened imminent actions.

45. Fresenius Kabi is entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or important of Fera's generic levothyroxine sodium product will constitute infringement of one or more claims of the '689 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

RELIEF SOUGHT

WHEREFORE, Fresenius Kabi respectfully requests the following relief:

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

B. Judgment that Fera has infringed, literally or by the doctrine of equivalents, the '689 Patent by the submission of ANDA No. 206163, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the '689 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. 207670 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the '689 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 Fera. 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 ANDA Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the '689 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; and

F. Damages or other monetary relief, including prejudgment interest, if Fera engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA Products, or any other products that the use of which would infringe the '689 Patent, or the inducement of or contribution to the foregoing, prior to the expiration of the '689 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.

Dated: May 29, 2015

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