UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, Plaintiff, v. MAIA PHARMACEUTICALS, INC., Defendant.	)	**C.A. No. _____**

COMPLAINT

Plaintiff Fresenius Kabi USA, LLC ("Fresenius Kabi"), by its undersigned attorneys, for its complaint against Maia Pharmaceuticals, Inc. ("Maia"), hereby 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 a generic version of levothyroxine sodium powder for injection prior to the expiration of U.S. Patent Nos. 9,006,289 ("the '289 Patent"), 9,168,238 ("the '238 Patent") and 9,168,239 ("the '239 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, Maia Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the state of Delaware, having its corporate headquarters at 707

State Road, Suite 104, Princeton, NJ 08540. On information and belief, Maia Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Maia Inc. also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") to the FDA.

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 Maia by virtue of the fact that it is a Delaware corporation and has systematic contacts with the State of Delaware. Personal jurisdiction over Maia is also proper because, upon information and belief, Maia, 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. Further, upon information and belief, Maia has committed, aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff in Delaware. Upon information and belief, Maia has purposefully conducted and continues to conduct business in Delaware, and, as a result, Delaware is a likely destination of Maia's generic products.

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

THE PATENTS-IN-SUIT

8. 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.

9. The ’238 Patent, entitled “Levothyroxine Formulations,” was duly and legally issued on October 27, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the ’238 Patent is attached hereto as Exhibit B.

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

11. Plaintiff Fresenius Kabi is the assignee and lawfully owns all rights, title, and interest in the ’289 Patent, the ’238 Patent, and the ’239 Patent (“the patents-in-suit”), including the right to sue and to recover for past infringement thereof.

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

13. 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 ’289 Patent, the ’238 Patent, and the ’239 Patent are each listed in the Orange Book in connection with approved NDA No. 202231, as patents “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.

14. Fresenius Kabi currently sells in the United States Levothyroxine Sodium. According to the Orange Book, the ’289 Patent is currently not due to expire until October 3,

2032; the ’238 Patent is currently not due to expire until August 29, 2032; and the ’239 Patent is also currently not due to expire until August 29, 2032.

MAIA’S ANDA NO. 208749

15. On information and belief, Maia submitted ANDA No. 208749 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, 200 mcg/vial, and 500 mcg/vial levothyroxine sodium for injection (the “ANDA Products”).

16. On information and belief, ANDA No. 208749 contains a Paragraph IV certification that the ’289 Patent, the ’238 Patent, and the ’239 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Maia’s ANDA No. 208749.

17. On information and belief, Maia is the owner of ANDA No. 208749.

18. On information and belief, if ANDA No. 208749 is approved by the FDA before the expiration of the ’289 Patent, the ’238 Patent, and/or the ’239 Patent, Maia will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA Products, despite the patents.

19. On information and belief, if ANDA No. 208749 is approved by the FDA, Maia will begin marketing the ANDA Products for treatment of myxedema coma, and doctors and patients will use the ANDA Products for the indications marketed by Maia.

20. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, 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.

21. Fresenius Kabi received a letter ("the Notice Letter"), purporting to be a Notice of Certification for ANDA No. 208749 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 certifications alleged that the claims of the '289 Patent, the '238 Patent, and the '239 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

22. On information and belief, ANDA No. 208749 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.

23. On information and belief, Maia was aware of the '289 Patent, the '238 Patent, and the '239 Patent when ANDA No. 208749 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning the patents-in-suit.

COUNT I: INFRINGEMENT OF THE '289 PATENT – ANDA SUBMISSION

24. Fresenius Kabi incorporates and realleges paragraphs 1-23 above.

25. The submission of ANDA No. 208749, including a Paragraph IV certification regarding the '289 Patent, was an act of infringement by Maia of one or more claims of the '289 Patent under 35 U.S.C. § 271(e)(2).

26. On information and belief, the use of the ANDA Products in accordance with and as directed by the instructions contained in the proposed package insert of Maia's ANDA No. 208749 is covered by one or more claims of the '289 Patent.

27. On information and belief, Maia's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Products before the expiration of the '289 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '289 Patent.

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