IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC. and EMP LEVO US B.V., Plaintiffs, v. ACCORD HEALTHCARE, INC. Defendant.	Civil Action No.: _____ COMPLAINT FOR PATENT INFRINGEMENT *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Azurity Pharmaceuticals, Inc. ("Azurity") and EMP Levo US B.V. ("EMP") (collectively, "Plaintiffs"), by and through their attorneys, bring this Complaint against Defendant Accord Healthcare, Inc. ("Accord" or "Defendant"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 9,050,307 ("the '307 patent" or the "Asserted Patent") under the patent laws of the United States of America, Title 35, United States Code, arising out of the submission by Accord of Abbreviated New Drug Application ("ANDA") No. 218234 to the United States Food and Drug Administration ("FDA") seeking approval of a generic version of Plaintiffs' oral solution that is the subject of New Drug Application ("NDA") No. 214047, hereinafter referred to as Plaintiffs' "Thyquidity® Product" or "Thyquidity®." Plaintiffs seek all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and other applicable laws for Accord's infringement of the Asserted Patent.

THE PARTIES

2. Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, Massachusetts, 01801.

3. EMP is a Dutch corporation with a principal place of business at Onze Lieve Vrouweplein 8, 6211HD Maastricht, the Netherlands.

4. On information and belief, Accord is a corporation organized and existing under the laws of the State of North Carolina, with a principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 22703.

5. On information and belief, Accord is in the business of, among other things, developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and from Accord's submission of ANDA No. 218234 ("Accord's ANDA").

7. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e)(2).

8. This Court has personal jurisdiction over Accord because Accord specifically consented prior to suit to jurisdiction in Delaware.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b) and because Accord specifically consented prior to suit to venue in Delaware.

PLAINTIFFS' THYQUIDITY® PRODUCT

10. Azurity holds approved NDA No. 214047 for an oral solution of levothyroxine sodium, which is prescribed and sold under the trade name Thyquidity®.

11. Plaintiffs' Thyquidity® Product is an FDA approved and labeled levothyroxine sodium (T4) product indicated for hyperthyroidism as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hyperthyroidism and Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression as an adjunct to surgery and radioiodine therapy and in the management of thyrotropin-dependent well-differentiated thyroid cancer.

PATENT-IN-SUIT

12. The '307 patent, entitled "Method for the Preparation of Levothyroxine Solution" was duly and legally issued on June 9, 2015 from United States Patent Application No. 14/003,598. A true and correct copy of the '307 patent is attached to this Complaint as Exhibit A.

13. The face of the '307 patent names Yannis Psarrakis and Konstantinos I. Lioumis as inventors and EMP Pharma GmBH as assignee. EMP Pharma GmBH assigned all interest to EMP. EMP, as assignee, owns all rights, title, and interest in the '307 patent.

14. Pursuant to 21 U.S.C. § 355, the '307 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 214047 and Plaintiffs' Thyquidity® Product.

15. Plaintiffs' Thyquidity® Product is covered by at least one claim of the '307 patent.

INFRINGEMENT BY ACCORD

16. By letter dated February 14, 2023 (the "Notice Letter"), Accord notified Plaintiffs that it had submitted ANDA No. 218234 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Plaintiffs' Thyquidity® Product (the "Accord ANDA Product") before the expiration of the '307 patent.

17. The ’307 patent expires on August 6, 2031.

18. On information and belief, Accord is seeking FDA approval to engage in the commercial manufacture, use, and sale of the Accord ANDA Product before the expiration of the ’307 patent.

19. On information and belief, Accord intends to engage in commercial manufacture, use, and sale of the Accord ANDA Product promptly upon receiving FDA approval of its ANDA.

20. By submitting ANDA No. 218234, Accord has represented to FDA that the Accord ANDA Product has the same active ingredients as Plaintiffs’ Thyquidity® Product; has the same route of administration, dosage form, use, and strength as Plaintiffs’ Thyquidity® Product; and is bioequivalent to Plaintiffs’ Thyquidity® Product.

21. Following receipt of the Notice Letter, Azurity negotiated confidential access to review Accord’s ANDA and evaluate statements made in Accord’s Notice Letter.

22. Azurity received confidential access to Accord’s ANDA on March 16, 2023.

23. Azurity sent a letter to Accord on March 24, 2023 requesting that Accord clarify certain statements made in its Notice Letter in view of certain documents in Accord’s ANDA. Accord responded on March 27, 2023 via email, but failed to fully respond to Azurity’s request. Azurity again requested clarity on March 29, 2023 via email. On March 30, 2023 via email, Accord indicated that it had no further information to provide at that time.

24. Confidential access to ANDA No. 218234 did not provide confirmation of certain statements in Accord’s Notice Letter.

25. This action is being filed within forty-five (45) days of Plaintiffs’ receipt of Accord’s Notice Letter.

CLAIMS FOR RELIEF

Count I—Infringement of the '307 Patent Under 35 U.S.C. § 271(e)(2)

26. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

27. Accord submitted ANDA No. 218234 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product throughout the United States before the expiration of the '307 patent. By submitting that ANDA, Accord has committed an act of infringement of one or more claims of the '307 patent under 35 U.S.C. § 271(e)(2)(A).

28. If Accord's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Accord ANDA Product will constitute acts of direct and indirect infringement, either literally or under the doctrine of equivalents, of the '307 patent under 35 U.S.C. § 271(a)-(c) and (g) unless enjoined by the Court.

29. On information and belief, Accord has actual and constructive knowledge of the '307 patent, and is aware that submission of ANDA No. 218234 to FDA constituted an act of infringement of the '307 patent. In addition, upon information and belief, Accord has specific intent to infringe the '307 patent when it filed ANDA No. 218234. Moreover, there are no substantial non-infringing uses for the Accord ANDA Product other than as the pharmaceutical claimed in the '307 patent.

30. The commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product in violation of Plaintiffs' patent rights will cause substantial and irreparable harm to Plaintiffs for which damages are inadequate.

PRAYER FOR RELIEF

Plaintiffs respectfully request the following relief:

a) A judgment that Accord has infringed the '307 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 218234 under Section 505(j) of the FDCA, and that Accord's making, using, offering to sell, or selling in the United States or importing into the United States the Accord ANDA Product will infringe one or more claims of the '307 patent;

b) A finding that the '307 patent is valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 218234 shall be a date which is not earlier than the latest expiration date of the '307 patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Accord, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States, of any drug product the use of which is covered by the '307 patent, including the Accord ANDA Product;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

DATED: March 31, 2023

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI, P.C.

/s/ Ian R. Liston

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