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Eisai Co., Ltd. and
Eisai Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI CO., LTD.; EISAI INC.; and NOVARTIS PHARMA AG,

Plaintiffs,

v.

AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,

Defendants.

Civil Action No. 21-20723

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively, "Eisai") and Novartis Pharma AG ("Novartis," and together with Eisai, "Plaintiffs"), for their Complaint against Defendants Aurobindo Pharma Limited ("Aurobindo Ltd.") and Aurobindo Pharma USA, Inc. ("Aurobindo USA," and together with Aurobindo Ltd., "Aurobindo") hereby allege as follows:

THE PARTIES

1. Plaintiff Eisai Co., Ltd. is a Japanese corporation having a principal place of business at 6-10 Koishikawa, 4-Chome, Bunkyo-ku, Tokyo 112-8088, Japan.

2. Plaintiff Eisai Inc. is a Delaware corporation having a principal place of business at 200 Metro Boulevard, Nutley, New Jersey 07110.

3. Plaintiff Novartis is a Swiss corporation having a principal place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

4. Upon information and belief, Defendant Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India. Upon information and belief, Defendant Aurobindo Ltd., itself and through its wholly-owned subsidiary and agent, Aurobindo USA, develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district.

5. Upon information and belief, Defendant Aurobindo USA is a Delaware corporation and wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a principal place of business at 279 Princeton Highstown Road, East Windsor, New Jersey 08520.

6. Upon information and belief, Defendant Aurobindo USA develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

NATURE OF THE ACTION

7. This is a civil action concerning the infringement of United States Patent No. 6,740,669 ("the '669 patent" or "the patent-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq*.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and/or 35 U.S.C. § 271.

9. This Court has personal jurisdiction over Aurobindo USA by virtue of, *inter alia*, Aurobindo USA's having a principal place of business in the State of New Jersey.

10. This Court has personal jurisdiction over both Aurobindo Ltd. and Aurobindo USA by virtue of, *inter alia*, the fact that they have availed themselves of the rights and benefits of the laws of New Jersey by engaging in systematic and continuous contacts with New Jersey and because they intend to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 216549. This Court has personal jurisdiction over Aurobindo Ltd. and Aurobindo USA for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. This Court also has personal jurisdiction over both Aurobindo Ltd. and Aurobindo USA by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including by sending via Federal Express a written notification ("Aurobindo's Paragraph IV Notice Letter"), dated November 18, 2021, of Aurobindo's ANDA No. 216549 and its accompanying certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) to Eisai Inc. in New Jersey.

12. This Court also has personal jurisdiction over both Aurobindo Ltd. and Aurobindo USA because they have previously been sued in this District and have not challenged personal jurisdiction, and have also affirmatively availed themselves of the jurisdiction of this Court by filing claims and counterclaims in this District. *See, e.g., Medicure Int'l., Inc. v. Aurobindo Pharma Ltd.*, Civil Action No. 21-17534, ECF No. 6 (D.N.J.); *Merck Sharp & Dohme Corp. v. Aurobindo Pharma USA, Inc.*, Civil Action No. 20-10444, ECF No. 21 (D.N.J.).

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

THE PATENT-IN-SUIT

14. On May 25, 2004, the '669 patent, titled "Crystal Modification of 1-(2,6-Difluorobenzyl)-1H-1,2,3-Triazole-4-Carboxamide and its Use as Antiepileptic," was duly and legally issued. A copy of the '669 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

15. Plaintiffs re-allege paragraphs 1-14 as if fully set forth herein.

16. Novartis owns the '669 patent. Eisai holds an exclusive license to the '669 patent in the United States and also holds New Drug Application ("NDA") No. 201367 for an oral suspension containing 40 mg/mL of the active pharmaceutical ingredient rufinamide. Eisai markets and sells this oral suspension in the United States under the brand name "Banzel®."

17. The FDA approved Eisai's NDA No. 201367 on March 3, 2011.

18. Pursuant to 21 U.S.C. § 355(b)(1), the '669 patent is listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering the oral suspension form of Banzel® or its use.

19. Upon information and belief, Aurobindo submitted ANDA No. 216549 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Aurobindo's ANDA No. 216549 seeks FDA approval to engage in the commercial manufacture, use, offer for sale, or sale of an oral suspension containing 40 mg/mL of rufinamide ("the Aurobindo Generic Product") prior to the expiration of the patent-in-suit.

20. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Aurobindo certified in ANDA No. 216549 that the claims of the patent-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the Aurobindo Generic Product.

21. Upon information and belief, by filing ANDA No. 216549, Aurobindo has represented to the FDA that the Aurobindo Generic Product has the same active ingredient as the oral suspension form of Banzel® and has the same or substantially the same proposed labeling as the oral suspension form of Banzel®.

22. This action was commenced within 45 days of Plaintiffs receiving Aurobindo's Paragraph IV Notice Letter, dated November 18, 2021.

CLAIM FOR RELIEF
INFRINGEMENT BY AUROBINDO OF U.S. PATENT NO. 6,740,669

23. Plaintiffs re-allege paragraphs 1-22 as if fully set forth herein.

24. Aurobindo's submission of ANDA No. 216549 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '669 patent under 35 U.S.C. § 271(e)(2)(A).

25. Separate and apart from certain contentions regarding patent validity, Aurobindo's Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of Claims 1-6, 9-11, and 18 of the '669 patent.

26. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the Aurobindo Generic Product, if approved by the FDA, prior to the expiration of the '669 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '669 patent.

27. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Aurobindo's ANDA No. 216549 be a date that is not earlier than the expiration of the '669 patent, or any later expiration of exclusivity for the '669 patent to which Plaintiffs are or become entitled.

28. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

29. Upon information and belief, Aurobindo was aware of the existence of the '669 patent and was aware that the filing of its ANDA and certification with respect to the '669 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Aurobindo has infringed one or more claims of the '669 patent by submitting ANDA No. 216549;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Aurobindo's ANDA No. 216549 shall not be a date that is earlier than the latest expiration date of the '669 patent, including any applicable exclusivities and extensions;

C. That Aurobindo, its officers, agents, servants and employees, and those persons acting in concert, participation, or in privity with any of them, and their successors or assigns, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing into the United States the Aurobindo Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '669 patent prior their expiration, including any exclusivities and extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: December 27, 2021
Newark, New Jersey

Of Counsel:

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