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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

HETERO USA INC.;
HETERO LABS LIMITED; and
HETERO LABS LIMITED UNIT-III,

Defendants.

Civil Action No. 22-1795 (CPO) (AMD)

Document Electronically Filed

**AMENDED 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 Amended Complaint against

Defendants Hetero USA Inc. (“Hetero USA”), Hetero Labs Limited (“Hetero Labs”), and Hetero

Labs Limited Unit-III (“Hetero Unit-III,” and together with Hetero USA and Hetero Labs,

“Hetero”) 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 Hetero USA is a Delaware corporation having a principal place of business at 1035 Centennial Ave., Piscataway, New Jersey 08854. Upon information and belief, Defendant Hetero USA is a subsidiary of Defendant Hetero Labs and is the U.S. regulatory agent for Defendant Hetero Labs Unit-III. Upon information and belief, Defendant Hetero 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 Hetero Labs is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Andhra Pradesh, India. Upon information and belief, Defendant Hetero Labs develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

6. Upon information and belief, Defendant Hetero Unit-III is a division of Defendant Hetero Labs and has a place of business at #22-110, IDA Jeedimetla, Hyderabad – 500 055, Telangana, India. Upon information and belief, Defendant Hetero Unit-III 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 Hetero USA by virtue of, *inter alia*, Hetero USA’s having a principal place of business in the State of New Jersey.

10. This Court has personal jurisdiction over Hetero USA, Hetero Labs, and Hetero Unit-III 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. 216841. This Court has personal jurisdiction over Hetero USA, Hetero Labs, and Hetero Unit-III 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 Hetero USA, Hetero Labs, and Hetero Unit-III 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 United Parcel Service a written notification (“Hetero’s Paragraph IV Notice Letter”), dated February 17, 2022, of Hetero’s ANDA No. 216841 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 Hetero USA, Hetero Labs, and Hetero Unit-III 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 counterclaims in this District. *See, e.g., AstraZeneca AB v. Hetero USA Inc.*, Civil Action No. 15-03385, ECF No. 31 (D.N.J.); *Janssen Products, L.P. v. Hetero Labs, Ltd.*, Civil Action No. 13-01444, ECF No. 10 (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, Hetero submitted ANDA No. 216841 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Hetero's ANDA No. 216841 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 Hetero 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), Hetero certified in ANDA No. 216841 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 Hetero Generic Product.

21. Upon information and belief, by filing ANDA No. 216841, Hetero has represented to the FDA that the Hetero 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 Hetero’s Paragraph IV Notice Letter, dated February 17, 2022.

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

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

24. Hetero’s submission of ANDA No. 216841 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, Hetero’s Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of the claims of the ’669 patent.

26. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the Hetero 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 Hetero's ANDA No. 216841 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 Hetero'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, Hetero 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. Hetero has infringed one or more claims of the '669 patent by submitting ANDA No. 216841;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Hetero's ANDA No. 216841 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 Hetero, 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 Hetero 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 to its 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: June 23, 2022
Newark, New Jersey

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