IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EISAI CO., LTD., EISAI INC. and NOVARTIS PHARMA AG,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

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

THE PARTIES

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

2. Plaintiff Eisai Inc. is a Delaware corporation having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. Plaintiff Novartis is a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Upon information and belief, Defendant Lupin Ltd. is an Indian corporation having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Defendant Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharma, 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 Lupin Pharma is a Delaware corporation and wholly owned subsidiary and agent of Defendant Lupin Ltd., having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief Defendant Lupin Pharma sells various drug products in the United States, including in this judicial district.

NATURE OF THE ACTION

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

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharma because of, *inter alia*, the incorporation of Lupin Pharma in the State of Delaware and the fact that they have availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware 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. 213457.

9. This Court also has personal jurisdiction over Lupin Ltd. and Lupin Pharma 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 Eisai Inc., a Delaware corporation.

10. This Court also has personal jurisdiction over Lupin Ltd. and Lupin Pharma because they have previously been sued in this district and have not challenged personal jurisdiction, and they have affirmatively availed themselves of the jurisdiction of this Court by filing claims and counterclaims in this district. *See, e.g*, *Cosmo Techs. Ltd. v. Lupin Ltd.*, No. 15-669 (D. Del. Aug. 25, 2016); *Alcon Research Ltd. v. Lupin Ltd.*, No. 16-195 (Apr. 25, 2016); *Vanda Pharm. Inc. v. Lupin Ltd.*, No. 15-1073 (D. Del. Dec. 14, 2015).

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

THE PATENT-IN-SUIT

12. 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 issued. A copy of the '669 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

13. Novartis owns the '669 patent. Eisai holds an exclusive license to the '669 patent in the United States and 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®."

14. 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.

15. Upon information and belief, Lupin submitted ANDA No. 213457 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Lupin's ANDA No. 213457 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of an oral

suspension containing 40 mg/mL of rufinamide ("the Lupin Generic Product") prior to the expiration of the '669 patent.

16. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Lupin certified in ANDA No. 213457 that the claims of the '669 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Lupin Generic Product.

17. Upon information and belief, by filing ANDA No. 213457, Lupin has represented to the FDA that the Lupin 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®.

18. Plaintiffs received written notification of Lupin's ANDA No. 213457 and its accompanying certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) by overnight mail dated June 24, 2019 ("Lupin's Notice Letter").

19. This action was commenced within 45 days of Plaintiffs receiving Lupin's Notice Letter.

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

20. Plaintiffs re-allege paragraphs 1-19 as if fully set forth herein.

21. Lupin's submission of ANDA No. 213457 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '669 patent under 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Lupin 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.

23. In Lupin's Notice Letter, Lupin has not contested infringement of any of the claims of the '669 patent.

24. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin's ANDA No. 213457 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.

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

26. Upon information and belief, Lupin 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. Lupin has infringed one or more claims of the '669 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's ANDA No. 213457 shall not be a date that is earlier than the latest expiration date of the '669 patent, including any applicable exclusivities or extensions;

C. That Lupin, 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 Lupin 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 or 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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