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. _____
ALKEM LABORATORIES LTD. and ASCEND LABORATORIES, LLC,	)	
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 Alkem Laboratories Ltd. ("Alkem Labs") and Ascend Laboratories, LLC ("Ascend Labs," and together with Alkem Labs, "Alkem"), 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 Alkem Labs is an Indian corporation having a place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400013, Maharashtra, India.

5. Upon information and belief, Defendant Alkem Labs, itself and through its wholly owned subsidiaries and agents, 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 Ascend Labs is a New Jersey corporation having a place of business at 339 Jefferson Road, Suite 101, Parsippany, NJ 07054. Upon information and belief, Defendant Ascend Labs is a wholly owned subsidiary of Alkem Labs acting as an agent of Alkem Labs with respect to Abbreviated New Drug Application ("ANDA") No. 213410.

7. Upon information and belief, Defendant Ascend Labs, itself and through its wholly owned subsidiaries and agents, develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district.

8. Upon information and belief, Defendant Ascend Labs assisted in the preparation and submission of ANDA No. 213410, which was done at the direction of, under the control of, in concert with, and for the direct benefit of Defendant Alkem Labs.

NATURE OF THE ACTION

9. 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

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

11. This Court has personal jurisdiction over Alkem Labs and Ascend Labs 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. This Court has personal jurisdiction over Alkem Labs and Ascend Labs for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

12. This Court has personal jurisdiction over Alkem Labs for the additional reasons that, *inter alia*, Alkem Labs (1) has substantial, continuous, and systematic contacts with this State, including by virtue of incorporating at least one subsidiary company in this State, S&B Pharma, Inc. and (2) intends to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic product that is the subject of ANDA No. 213410.

13. This Court also has personal jurisdiction over Alkem Labs because it has previously been sued in this district and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this district. *See, e.g., Shire Dev. LLC et al. v. Alkem Labs. Ltd.*, 16-747 (D. Del. Oct. 24, 2016); *Acorda Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, 14-917 (D. Del. Aug. 1, 2014); *Sanofi et al. v. Alkem Labs. Ltd. et al.*, 14-292 (D. Del. May 22, 2014); *Medicis Pharm. Corp. v. Alkem Labs. Ltd.*, 12-1663 (D. Del. Aug. 12, 2013); *Pfizer Inc. et al. v. Alkem Labs. Ltd.*, 13-1110 (D. Del. July 15, 2013).

14. This Court has personal jurisdiction over Ascend Labs for the additional reasons that, *inter alia*, Ascend Labs (1) has substantial, continuous, and systematic contacts with this

State and (2) intends to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic product that is the subject of ANDA No. 213410.

15. This Court also has personal jurisdiction over Ascend Labs because it has been sued previously in this district and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by litigating in this district. *See, e.g., Acorda Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, 14-0917 (D. Del. Aug. 1, 2014); *Sanofi et al. v. Alkem Labs. Ltd. et al.*, 14-292 (D. Del. May 22, 2014); *Medicis Pharm. Corp. v. Alkem Labs. Ltd.*, 12-1663 (D. Del. Aug. 12, 2013).

16. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Alkem Labs in this action, this Court may exercise jurisdiction over Alkem Labs pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Alkem Labs is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem Labs has sufficient contacts with the United States as a whole, including but not limited to submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem Labs satisfies due process.

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

THE PATENT-IN-SUIT

18. 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

19. Novartis owns the patent-in-suit. Eisai holds an exclusive license to the patent-in-suit 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®."

20. 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.

21. Upon information and belief, Alkem submitted ANDA No. 213410 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Alkem's ANDA No. 213410 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 Alkem Generic Product") prior to the expiration of the patent-in-suit.

22. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Alkem certified in ANDA No. 213410 that the claims of the patent-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Alkem Generic Product.

23. Upon information and belief, by filing ANDA No. 213410, Alkem has represented to the FDA that the Alkem 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®.

24. Plaintiffs received written notification of Alkem's ANDA No. 213410 and its accompanying certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) by overnight mail dated May 15, 2019 ("Alkem's Notice Letter").

25. This action was commenced within 45 days of Plaintiffs receiving Alkem's Notice Letter.

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

26. Plaintiffs re-allege paragraphs 1-25 as if fully set forth herein.

27. Alkem's submission of ANDA No. 213410 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).

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

29. 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 Alkem's ANDA No. 213410 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.

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

31. Upon information and belief, Alkem 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. Alkem 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 Alkem’s ANDA No. 213410 shall not be a date that is earlier than the latest expiration date of the patent-in-suit, including any applicable exclusivities or extensions;

C. That Alkem, 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 Alkem 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 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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