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. _____
BIONPHARMA INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively, "Eisai") and Novartis Pharma AG ("Novartis," and together with Eisai, "Plaintiffs"), for their Complaint against Defendant Bionpharma Inc. ("Bionpharma"), 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-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 Pharma AG is a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Upon information and belief, Defendant Bionpharma is a Delaware corporation having a place of business at 600 Alexander Road, Suite 2-4B, Princeton, NJ 08540. Upon information and belief, Defendant Bionpharma 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

5. This is a civil action concerning the infringement of United States Patent Nos. 6,740,669 ("the '669 patent") and 7,750,028 ("the '028 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Bionpharma by virtue of, *inter alia*, the fact that it has committed, or 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 Bionpharma for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. This Court has personal jurisdiction over Bionpharma for the additional reasons that, *inter alia*, Bionpharma (1) is incorporated in Delaware, (2) has substantial, continuous, and systematic contacts with this State, and (3) 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 Abbreviated New Drug Application ("ANDA") No. 211388.

9. This Court also has personal jurisdiction over Bionpharma because it has previously been sued in this district and has not challenged personal jurisdiction, and it has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this district. *See, e.g.*, *Patheon Softgels Inc. et al. v. Apotex Inc. et al.*, 18-cv-00003 (D. Del. Jan. 2, 2018); *Bristol-Myers Squibb Company et al. v. Bionpharma Inc.*, 17-cv-00400 (D. Del. Apr.

10, 2017); *Silvergate Pharmaceuticals Inc. v. Bionpharma Inc.*, 16-cv-00876 (D. Del. Sept. 28, 2016).

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

THE PATENTS-IN-SUIT

11. 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.

12. On July 6, 2010, the '028 patent, titled "Crystal Modifications of 1-(2,6-Difluorobenzyl)-1H-1,2,3-Triazole-4-Carboxamide," was issued. A copy of the '028 patent is attached as Exhibit B.

ACTS GIVING RISE TO THIS ACTION

13. Novartis owns the patents-in-suit. Eisai is an exclusive licensee to the patents-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®," which is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome.

14. Pursuant to 21 U.S.C. § 355(b)(1), the '669 and '028 patents are 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, Bionpharma submitted ANDA No. 211388 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Bionpharma's ANDA No. 211388 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 Bionpharma Generic Product") prior to the expiration of the patents-in-suit.

16. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Bionpharma certified in ANDA No. 211388 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Bionpharma Generic Product.

17. Upon information and belief, by filing ANDA No. 211388, Bionpharma has represented to the FDA that the Bionpharma 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 Bionpharma's ANDA No. 211388 and its accompanying certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) by a letter dated March 12, 2018 ("Notice Letter").

19. This action was commenced within 45 days of the Bionpharma Notice Letter.

FIRST COUNT
INFRINGEMENT BY BIONPHARMA OF U.S. PATENT NO. 6,740,669

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

21. In its Notice Letter, Bionpharma did not set forth an opinion of noninfringement of claims 1-21 of the '669 patent separate and apart from any assertions regarding the validity of those claims.

22. Bionpharma's submission of ANDA No. 211388 to the FDA, including its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '669 patent under 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Bionpharma Generic Product, if approved by the FDA, prior to the expiration of the '669 patent, would infringe the '669 patent under 35 U.S.C. § 271.

24. 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 Bionpharma's ANDA No. 211388 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 Bionpharma'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, Bionpharma 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.

SECOND COUNT
INFRINGEMENT BY BIONPHARMA OF U.S. PATENT NO. 7,750,028

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

28. In its Notice Letter, Bionpharma did not set forth an opinion of noninfringement of claims 1-8 of the '028 patent separate and apart from any assertions regarding the validity of those claims.

29. Bionpharma's submission of ANDA No. 211388 to the FDA, including its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Bionpharma Generic Product, if approved by the FDA, prior to the

expiration of the ’028 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the ’028 patent.

31. 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 Bionpharma’s ANDA No. 211388 be a date that is not earlier than the expiration of the ’028 patent , or any later expiration of exclusivity for the ’028 patent to which Plaintiffs are or become entitled.

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

33. Upon information and belief, Bionpharma was aware of the existence of the ’028 patent and was aware that the filing of its ANDA and certification with respect to the ’028 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Bionpharma has infringed one or more claims of the ’669 patent;

B. Bionpharma has infringed one or more claims of the ’028 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Bionpharma’s ANDA No. 211388 shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

D. That Bionpharma, 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 Bionpharma Generic Product and any other product that infringes or induces or contributes to the infringement of one or more

claims of the '669 and '028 patents prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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