

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. _____
MSN PHARMACEUTICALS 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 MSN Pharmaceuticals Inc. (“MSN”) 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 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
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 MSN is a Delaware corporation having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.
5. Upon information and belief, Defendant MSN 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

6. 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

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

8. This Court has personal jurisdiction over MSN by virtue of, *inter alia*, MSN’s incorporation in the State of Delaware and the fact that it has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware and because it 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. 214817. This Court has personal jurisdiction over MSN for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. This Court also has personal jurisdiction over MSN by virtue of, *inter alia*, the fact that it has 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 written notification dated May 15, 2020 of MSN’s ANDA No. 214817 and its accompanying certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) (“MSN’s Notice Letter”) to Eisai Inc., a Delaware corporation.

10. This Court also has personal jurisdiction over MSN 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., Vanda Pharms. Inc. v. MSN Pharms. Inc. et al.*, No. 20-0235 (D. Del. Mar. 13, 2020).

11. Venue is proper in this Court pursuant to 28 U.S.C. § 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 duly and legally issued. A copy of the '669 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

13. Plaintiffs re-allege paragraphs 1-12 as if fully set forth herein.

14. 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®."

15. 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.

16. Upon information and belief, MSN submitted ANDA No. 214817 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, MSN's ANDA No. 214817 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 MSN Generic Product") prior to the expiration of the patent-in-suit.

17. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), MSN certified in ANDA No. 214817 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 MSN Generic Product.

18. Upon information and belief, by filing ANDA No. 214817, MSN has represented to the FDA that the MSN 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®.

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

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

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

21. MSN's submission of ANDA No. 214817 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).

22. Separate and apart from certain contentions regarding patent validity, MSN's Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of the claims of the patent-in-suit.

23. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the MSN 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.

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 MSN's ANDA

No. 214817 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 MSN'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, MSN 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.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. MSN has infringed one or more claims of the '669 patent by submitting ANDA No. 214817;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of MSN's ANDA No. 214817 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 MSN, 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 MSN 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

OF COUNSEL:

Bruce M. Wexler
Melanie R. Rupert
Young J. Park
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

*Attorneys for Plaintiffs Eisai Co., Ltd.
and Eisai Inc.*

Jack B. Blumenfeld (#1014)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
araucci@mnat.com

*Attorneys for Plaintiffs Eisai Co., Ltd., Eisai
Inc., and Novartis Pharma AG*

June 10, 2020