

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

EISAI INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
BANNER PHARMACAPS INC.,	)	
	)	
Defendant.	)	

**COMPLAINT**

Plaintiff Eisai Inc. (“Eisai”), for its Complaint against Defendant Banner Pharmacaps Inc. (“Banner”), hereby alleges as follows:

**THE PARTIES**

1. Plaintiff Eisai is a Delaware corporation having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
2. Upon information and belief, Defendant Banner is a Delaware corporation having a principal place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, North Carolina 27265.

**NATURE OF THE ACTION**

3. This is a civil action concerning the infringement of United States Patent Nos. 5,780,676 C1 (“the ’676 patent”) and 5,962,731 (“the ’731 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**

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

5. This Court has personal jurisdiction over Defendant Banner by virtue of the fact that Banner is a resident and citizen of Delaware and has availed itself of the rights and benefits of the laws of Delaware by incorporating in Delaware and engaging in systematic and continuous contacts with Delaware.

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

### **THE PATENTS-IN-SUIT**

7. Eisai is the lawful owner of the '676 patent, titled "Compounds Having Selective Activity for Retinoid X Receptors, and Means for Modulation of Processes Mediated by Retinoid X Receptors," which was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 14, 1998. On March 16, 1999, an *ex parte* request for reexamination of the '676 patent was submitted to the USPTO. On February 11, 2003, the USPTO issued a reexamination certificate and confirmed the patentability of the claims of the '676 patent. A copy of the '676 patent, including its reexamination certificate, is attached as Exhibit A.

8. Eisai is the lawful owner of the '731 patent, titled "Compounds Having Selective Activity for Retinoid X Receptors, and Means for Modulation of Processes Mediated by Retinoid X Receptors," which was duly and legally issued by the USPTO on October 5, 1999. A copy of the '731 patent is attached as Exhibit B.

9. Eisai holds New Drug Application ("NDA") No. 21-055 for oral capsules containing 75 mg of the active pharmaceutical ingredient bexarotene. Eisai markets and sells these capsules in the United States under the brand name "Targretin®."

10. Pursuant to 21 U.S.C. § 355(b)(1), the '676 and '731 patents are listed in the United States Food and Drug Administration's ("FDA") publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Targretin<sup>®</sup>.

**ACTS GIVING RISE TO THIS ACTION**

11. Upon information and belief, Defendant Banner submitted Abbreviated New Drug Application ("ANDA") No. 203-174 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Banner's ANDA No. 203-174 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of generic capsules containing 75 mg of bexarotene ("the Banner Generic Product") prior to the expiration of the '676 and '731 patents.

12. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Defendant Banner certified in ANDA No. 203-174 that the claims of the '676 and '731 patents are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Banner Generic Product.

13. Plaintiff Eisai received written notification of Defendant Banner's ANDA No. 203-174 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated August 25, 2011 and sent via U.S. mail ("Notice Letter"). In its Notice Letter, Banner alleged that Claim 1 of the '676 patent and Claim 4 of the '731 patent would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Banner Generic Product. Banner further alleged that Claims 2-99 of the '676 patent and Claims 1-3 and 5-26 of the '731 patent are invalid under 35 U.S.C. § 112. Banner did not allege noninfringement of Claims 2-99 of the '676 patent or

Claims 1-3 and 5-26 of the '731 patent, separate and apart from its assertions that those claims are invalid under 35 U.S.C. § 112.

14. Defendant Banner's submission of ANDA No. 203-174 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '676 patent and the '731 patent under 35 U.S.C. § 271(e)(2)(A).

15. Moreover, if Defendant Banner manufactures, uses, sells, offers for sale, or imports into the United States any of the Banner Generic Product, or induces or contributes to any such conduct, Defendant Banner would further infringe the '676 patent and the '731 patent under 35 U.S.C. § 271(a), (b), and/or (c).

16. Upon information and belief, Defendant Banner was aware of the existence of both the '676 and '731 patents prior to filing ANDA No. 203-174.

17. Plaintiff Eisai will be irreparably harmed by Defendant Banner's infringing activities unless those activities are enjoined by this Court. Plaintiff Eisai does not have an adequate remedy at law.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment as follows:

A. That Defendant Banner has infringed one or more claims of the '676 patent;

B. That Defendant Banner has infringed one or more claims of the '731 patent;

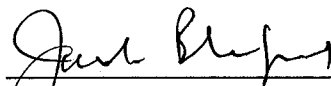
C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Banner's ANDA No. 203-174 shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

D. That Defendant Banner, 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 Banner Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '676 patent prior to its expiration or one or more claims of the '731 patent prior its expiration, including any exclusivities or extensions to which Plaintiff Eisai is or becomes entitled;

E. That Plaintiff Eisai be awarded the attorney fees, costs, and expenses that it incurs in prosecuting this action; and

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

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