IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EISAI INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 11-901 (GMS)
	)	
BANNER PHARMACAPS INC. and MYLAN PHARMACEUTICALS INC.,	)	**REDACTED – PUBLIC VERSION**
	)	
Defendants.	)	

PLAINTIFFS' SECOND AMENDED COMPLAINT

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IN THE UNITED STATES DISTRICT COURT
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EISAI INC. and VALEANT PHARMACEUTICALS LUXEMBOURG S.À.R.L.	)	
Plaintiffs,	)	C.A. No. 11-901 (GMS)
v.	)	REDACTED - PUBLIC VERSION
BANNER PHARMACAPS INC. and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

PLAINTIFFS' SECOND AMENDED COMPLAINT

Plaintiffs Eisai Inc. ("Eisai") and Valeant Pharmaceuticals Luxembourg S.à.r.l. ("Valeant") (collectively, "Plaintiffs'"), for their Complaint against Defendants Banner Pharmacaps Inc. ("Banner") and Mylan Pharmaceuticals Inc. ("Mylan") (collectively, "Defendants"), hereby allege 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. Plaintiff Valeant is a Luxembourg société à responsabilité limitée having a principal place of business at 208 Val des Bons Malades, L-2121 Luxembourg.

3. 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.

4. Upon information and belief, Defendant Mylan is a West Virginia corporation having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Defendant Mylan manufactures

numerous generic drugs for sale and use 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. 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

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 Defendant Banner by virtue of the fact that Defendant Banner has consented to jurisdiction in this action in its December 18, 2012 Answer and Counterclaims to Eisai's First Amended Complaint (D.I. 24). Furthermore, 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.

8. This Court has personal jurisdiction over Defendant Mylan by virtue of the fact that it has consented to jurisdiction in this action in its December 18, 2012 Answer and Counterclaims to Eisai's First Amended Complaint (D.I. 24). Furthermore, Mylan has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware. Defendant Mylan also previously represented to Plaintiff Eisai that it would consent to personal jurisdiction in this District for purposes of this action only.

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

THE PATENTS-IN-SUIT

10. The '676 patent, titled "Compounds Having Selective Activity for Retinoid X Receptors, and Means for Modulation of Processes Mediated by Retinoid X Receptors," was duly and legally issued by the 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.

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

12. At the time that 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)), and at the time Plaintiff Eisai filed its Complaint and First Amended Complaint in this action, Plaintiff Eisai was the lawful owner of the entire right, title and interest in the patents-in-suit.

13. On February 5, 2013, Plaintiff Eisai and Valeant Pharmaceuticals International, Inc. ("VPII") executed an agreement ("Eisai/VPII Asset Purchase Agreement"), whereby Plaintiff Eisai agreed to assign all of its right, title, and interest in the patents-in-suit to VPII with respect to the U.S. market for Targretin®. [redacted]

[redacted]

[redacted]

14. Plaintiff Valeant is presently the lawful owner of the entire right, title and interest in the patents-in-suit as a result of this assignment.

15. At the time that Defendant Banner submitted ANDA No. 203-174 to the FDA, and at the time Plaintiff Eisai filed its Complaint and First Amended Complaint in this action, Plaintiff Eisai was the lawful owner of the entire right, title and interest in New Drug Application ("NDA") No. 21-055.

16. Pursuant to the Eisai/VPII Asset Purchase Agreement, VPII purchased all of Plaintiff Eisai's right, title and interest in NDA No. 21-055. [redacted]

17. Plaintiff Valeant presently holds NDA No. 21-055 for oral capsules containing 75 mg of the active pharmaceutical ingredient bexarotene. [redacted]

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

ACTS GIVING RISE TO THIS ACTION

19. Upon information and belief, Defendant Banner submitted ANDA No. 203-174 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Defendant 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.

20. 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.

21. 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, Defendant 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. Defendant 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. Defendant 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.

22. [redacted]

23. 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).

24. 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).

25. Defendant Mylan is jointly and severally liable for an infringement of the '676 patent and the '731 patent. Upon information and belief, Defendant Mylan participated in, contributed to, aided, abetted, and/or induced Defendant Banner to submit and/or maintain its submission of ANDA No. 203-174 and its § 505(j)(2)(A)(vii)(IV) allegations with the FDA.

26. Defendant Mylan's participation in, contribution to, aiding, abetting and/or inducement of the submission and/or maintenance of ANDA No. 203-174 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '676 patent and the '731 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan 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 Mylan would further infringe the '676 patent and the '731 patent under 35 U.S.C. § 271(a), (b), and/or (c).

27. 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.

28. Upon information and belief, Defendant Mylan was aware of the existence of both the '676 and '731 patents prior to executing the Mylan Agreement.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed one or more claims of the '676 patent;

B. That Defendants have 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 Defendants, their 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 Plaintiffs are or become entitled;

E. That Plaintiffs be awarded the attorney fees, costs, and expenses that it incurs 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

/s/ Maryellen Noreika

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