IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No.
EAGLE PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bone Care International, LLC and Genzyme Corporation, by and through their attorneys, and for their Complaint herein against Defendant Eagle Pharmaceuticals, Inc. hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Bone Care International LLC ("Bone Care") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

3. Plaintiff Genzyme Corporation ("Genzyme") is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142. Genzyme is the sole member of Bone Care.

4. On information and belief, Defendant Eagle Pharmaceuticals, Inc. ("Eagle") is a corporation organized and existing under the laws of the State of Delaware, having

a principal place of business at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677-7604.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. On information and belief, Eagle is a corporation organized and existing under the laws of the State of Delaware. This Court has personal jurisdiction over Eagle.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIMS FOR RELIEF

8. Genzyme holds approved New Drug Application ("NDA") No. 021-027 for Hectorol® injectable (2 μg/mL), which product contains the active ingredient doxercalciferol.

9. Hectorol® injectable was approved by the U.S. Food and Drug Administration ("FDA") on April 6, 2000, and is currently indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

10. On information and belief, Eagle submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 91-101 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of a generic product containing 2 μg/mL doxercalciferol ("Eagle's Proposed Generic Product").

Count I – Infringement Of The '116 Patent

11. Plaintiffs repeat and reallege the allegations of paragraphs 1-10 as though fully set forth herein.

12. On February 11, 1997, United States Patent No. 5,602,116 ("'116 patent"), titled "Method For Treating And Preventing Secondary Hyperparathyroidism" was duly and legally issued by the United States Patent and Trademark Office. The '116 patent claims a method for lowering or maintaining lowered serum parathyroid hormone in human patients suffering from hyperparathyroidism secondary to end stage renal disease by administering doxercalciferol. A copy of the '116 patent is attached hereto as Exhibit A.

13. Bone Care is the owner of the '116 patent. Genzyme is the sole member of Bone Care.

14. On information and belief, Eagle submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Eagle's Proposed Generic Product prior to the expiration of the '116 patent.

15. By submitting ANDA No. 91-101 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Eagle's Proposed Generic Product prior to the expiration of the '116 patent, Eagle has infringed the '116 patent under 35 U.S.C. § 271(e)(2)(A).

16. On information and belief, the commercial manufacture, use, sale, offer for sale and/or importation of Eagle's Proposed Generic Product, if approved by the FDA, would infringe one or more claims of the '116 patent under 35 U.S.C. § 271.

17. On information and belief, the sale or offer for sale of Eagle's Proposed Generic Product, if approved by the FDA, would induce infringement of, and/or be contributory infringement of, one or more claims of the '116 patent under 35 U.S.C. § 271.

18. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 91-101 be a date which is not earlier than the expiration of the '116 patent, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that Defendant has infringed one or more claims of the '116 patent by filing its ANDA No. 91-101;

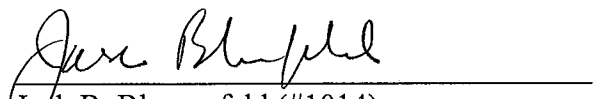
B. An Order that the effective date of any FDA approval of Defendant's ANDA No. 91-101 be no earlier than the date on which the '116 patent expires, and any other exclusivity to which Plaintiffs are or become entitled;

C. Preliminary and permanent injunctions enjoining Defendant, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Eagle's Proposed Generic Product until after the expiration of the '116 patent, and any other exclusivity to which Plaintiffs are or become entitled;

D. The costs and reasonable attorney fees of Plaintiffs in this action; and

E. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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