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FEBRUARY 21, 2008
MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,

Plaintiffs,

v.

PENTECH PHARMACEUTICALS, INC.,

Defendant.

08 C 1083

Civil Action No.:

JUDGE DOW
MAGISTRATE JUDGE ASHMAN

Complaint For Patent Infringement

Plaintiffs Bone Care International, LLC and Genzyme Corporation (collectively "Plaintiffs"), by and through their attorneys, and for their Complaint herein against Defendant Pentech Pharmaceuticals, Inc. ("Pentech"), 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.

4. On information and belief, Pentech is a corporation organized and existing under the laws of the state of Illinois, having a principal place of business at 3315 Algonquin Road, Rolling Meadows, Illinois 60008.

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, Pentech is an Illinois corporation and has a principal place of business in the Northern District of Illinois. Pentech does business throughout the United States, including within this judicial district. This Court has personal jurisdiction over Pentech by virtue of, *inter alia*, the above-mentioned facts.

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).

Claim For Relief – Patent Infringement

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. Doxercalciferol is known chemically as 1α-OH-vitamin D_2, 1-alpha-hydroxyvitamin D_2, 1α-OH-D_2 and 1α-hydroxyergocalciferol.

10. 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.

11. On information and belief, Pentech submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 90-040 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of a generic product containing 2 μg/mL doxercalciferol ("Pentech's Proposed Generic Product").

Count I – Infringement Of The '116 Patent

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

13. On February 11, 1997, United States Patent No. 5,602,116 ("the '116 patent"), entitled "Method For Treating And Preventing Secondary Hyperparathyroidism" was duly and legally issued. 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.

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

15. On information and belief, Pentech submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Pentech's Proposed Generic Product before the expiration of the '116 patent.

16. By filing the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Pentech's Proposed Generic Product before the expiration of the '116 patent, Pentech has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Pentech's Proposed Generic Product will infringe one or more claims of the '116 patent.

17. On information and belief, Pentech made, and included in its ANDA, a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which states that, in Pentech's opinion, the claims of the '116 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Pentech's Proposed Generic Product.

18. The offer for sale and sale of Pentech's Proposed Generic Product, if approved by the FDA, will induce infringement of, and be contributory infringement of, the '116 patent.

19. On information and belief, Pentech had notice of the '116 patent prior to undertaking its acts of infringement.

20. 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 the aforementioned ANDA relating to Pentech's Proposed Generic Product be a date which is not earlier than February 11, 2014, the expiration date of the '116 patent, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled, and an award of damages for any commercial sale or use of Pentech's Proposed Generic Product and any act committed by Pentech with respect to the subject matter claimed in the '116 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

Count II – Infringement Of The '083 Patent

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

22. On June 7, 2005, United States Patent No. 6,903,083 ("the '083 patent"), entitled "Stabilized Hydroxyvitamin D" was duly and legally issued. The '083 patent claims a stabilized form of doxercalciferol and pharmaceutical compositions containing that stabilized form. A copy of the '083 patent is attached hereto as Exhibit B.

23. Bone Care is the owner of the '083 patent. Genzyme is the sole member of Bone Care.

24. On information and belief, Pentech submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Pentech's Proposed Generic Product before the expiration of the '083 patent.

25. By filing the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Pentech's Proposed Generic Product before the

expiration of the ‘083 patent, Pentech has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Pentech’s Proposed Generic Product will infringe one or more claims of the ‘083 patent.

26. On information and belief, Pentech made, and included in its ANDA, a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which states that, in Pentech’s opinion, the claims of the ‘083 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Pentech’s Proposed Generic Product.

27. On information and belief, Pentech’s ANDA seeks approval to manufacture and sell Pentech’s Proposed Generic Product, which product infringes the ‘083 patent.

28. On information and belief, Pentech had notice of the ‘083 patent prior to undertaking its acts of infringement.

29. 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 the aforementioned ANDA relating to Pentech’s Proposed Generic Product be a date which is not earlier than July 18, 2021, the expiration date of the ‘083 patent, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled, and an award of damages for any commercial sale or use of Pentech’s Proposed Generic Product and any act committed by Pentech with respect to the subject matter claimed in the ‘083 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

Prayer For Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

30. A Judgment declaring that Pentech has infringed one or more claims of the ‘116 patent by filing the aforesaid ANDA relating to Pentech’s Proposed Generic Product;

31. A Judgment declaring that Pentech has infringed one or more claims of the '083 patent by filing the aforesaid ANDA relating to Pentech's Proposed Generic Product;

32. An Order that the effective date of any FDA approval of Pentech's ANDA No. 90-040 relating to Pentech's Proposed Generic Product be no earlier than the date on which the '116 patent expires, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled;

33. An Order that the effective date of any FDA approval of Pentech's ANDA No. 90-040 relating to Pentech's Proposed Generic Product be no earlier than the date on which the '083 patent expires, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled;

34. Preliminary and permanent injunctions enjoining Pentech and 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 State or importation into the United States of Pentech's Proposed Generic Product until after the expiration of the '116 patent, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled;

35. Preliminary and permanent injunctions enjoining Pentech and 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 State or importation into the United States of Pentech's Proposed Generic Product until after the expiration of the '083 patent, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled;

36. If Pentech engages in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Pentech's Proposed Generic Product prior to the expiration of the '116 patent, and any other exclusivity to which Genzyme and/or

Bone Care are or become entitled, a Judgment awarding damages to Plaintiffs resulting from such infringement;

37. If Pentech engages in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Pentech's Proposed Generic Product prior to the expiration of the '083 patent, and any other exclusivity to which Genzyme and/or Bone Care are or become entitled, a Judgment awarding damages to Plaintiffs resulting from such infringement;

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

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

Dated: February 21, 2008

Respectfully submitted,

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION, *Plaintiffs*

By: /s/ Jennifer Yule DePriest

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