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

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION, *Plaintiffs,* v. **PENTECH PHARMACEUTICALS, INC.,** *Defendant.*	No. 08 C 1083 The Honorable Robert M. Dow, Jr., Judge Presiding Magistrate Judge Martin C. Ashman

PLAINTIFFS' REPLY TO DEFENDANT'S COUNTERCLAIMS

Bone Care International LLC ("Bone Care") and Genzyme Corporation ("Genzyme") (collectively, "Plaintiffs") for their reply to the Counterclaims of Pentech Pharmaceuticals, Inc. ("Pentech") hereby state as follows:

COUNTERCLAIMS

1. Plaintiffs admit that Pentech purports to incorporate by reference its Answer and Affirmative Defenses to the Complaint, but deny the allegations of those Answers and Affirmative Defenses, consistent with Plaintiffs' reply to Defendant's Counterclaims below.

THE PARTIES

2. Plaintiffs admit the allegations of paragraph 2.

3. Plaintiffs admit the allegations of paragraph 3.

4. Plaintiffs admit the allegations of paragraph 4.

5. Plaintiffs admit the allegations of paragraph 5.

6. Plaintiffs admit the allegations of paragraph 6.

7. Plaintiffs admit the allegations of paragraph 7.

8. Plaintiffs admit that doxercalciferol is known chemically as 1α-OH-vitamin D2, 1-alpha-hydroxyvitamin D2, 1α-OH-D2 and 1α-hyrdoxyergocalciferol.

9. Plaintiffs admit that 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, admitted.

11. Plaintiffs admit the allegations of paragraph 11, and state further that United States Patent No. 5,602,116 (the "'116 patent") was duly and legally issued.

12. Plaintiffs admit that Bone Care is the owner of the '116 patent, and further admit that Genzyme is the sole member of Bone Care.

13. On information and belief, admitted.

14. Plaintiffs admit that in their Complaint against Pentech, filed in the United States District Court for the Northern District of Illinois on February 21, 2008 (the "Complaint"), they allege that 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), and further admit that in their Complaint they allege that 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.

15. On information and belief, admitted.

16. On information and belief, admitted.

17. Plaintiffs admit that in their Complaint against Pentech, they allege that they 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 no 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).

18. Plaintiffs admit the allegations of paragraph 18, and state further that United States Patent No. 6,903,083 (the "'083 patent") was duly and legally issued.

19. Plaintiffs admit that Bone Care is the owner of the '083 patent, and further admit that Genzyme is the sole member of Bone Care.

20. On information and belief, admitted.

21. Plaintiffs admit that in their Complaint against Pentech, they allege that 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), and further admit that in their Complaint they allege that 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.

22. On information and belief, admitted.

23. Plaintiffs admit that in their Complaint, they alleged that Pentech had notice of the '083 patent prior to undertaking its acts of infringement.

24. Plaintiffs admit that Bone Care is the owner of the '116 patent, the '083 patent, and United States Patent No. 5,707,980 (the "'980 patent"), including the right to sue and collect damages, but otherwise deny the allegations of Paragraph 24.

25. Plaintiffs admit that Pentech sent its notice letter with a Paragraph IV Certification for non-infringement and/or invalidity of United States Patent Nos. 5,602,116; 5,707,980; and 6,903,083 dated January 8, 2007 on or about January 8, 2008, but otherwise deny the allegations of Paragraph 25.

26. Plaintiffs admit the allegations of paragraph 26.

JURISDICTION AND VENUE

27. Plaintiffs admit that Pentech has alleged counterclaims that purportedly arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but deny that there is any factual or legal basis for such counterclaims or that Pentech is entitled to any relief.

28. Plaintiffs admit that this Court has subject matter jurisdiction over Pentech's counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), but deny that there is any factual or legal basis for such counterclaims or that Pentech is entitled to any relief.

29. Plaintiffs admit that Bone Care is the owner of the '116 and '083 patents, and further admit that they filed a Complaint in the United States District Court for the Northern District of Illinois on February 21, 2008, alleging Pentech infringes the '116 and '083 patents.

30. Plaintiffs admit that by filing an ANDA (No. 90-040) with the FDA seeking approval for its Proposed Generic Product, and including in that ANDA a paragraph IV certification to the '116 and '083 patents, Pentech has created an actual and justiciable controversy between itself and Plaintiffs. Plaintiffs otherwise deny any remaining allegation of paragraph 30.

COUNT I

31. Plaintiffs deny the allegations of paragraph 31.

COUNT II

32. Plaintiffs deny the allegations of paragraph 32.

COUNT III

33. Plaintiffs deny the allegations of paragraph 33.

COUNT IV

34. Plaintiffs deny the allegations of paragraph 34.

COUNT V

35. Plaintiffs deny the allegations of paragraph 35.

COUNT VI

36. Plaintiffs deny the allegations of paragraph 36.

COUNT VII

37. Plaintiffs deny the allegations of paragraph 37.

COUNT VIII

38. Plaintiffs deny the allegations of paragraph 38.

PRAYER FOR RELIEF

Plaintiffs deny that Pentech is entitled to any relief from the Plaintiffs or the Court, either as prayed for in their Counterclaims or otherwise.

GENERAL DENIAL

Plaintiffs further deny each allegation contained in Pentech's Counterclaims that was not specifically admitted, denied or otherwise responded to in this Reply to Defendant's Counterclaims.

Dated: May 14, 2008

Respectfully submitted,

/s/ Jennifer Yule DePriest

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2008, I electronically filed the **PLAINTIFFS' REPLY TO DEFENDANT'S COUNTERCLAIMS** with the Clerk of the Court using the ECF system, which will send notification of such filing to the following:

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