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

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,	)	
	)	**Civil Action No. 08 C 1083**
Plaintiffs,	)	
	)	**JUDGE DOW**
v.	)	**MAGISTRATE JUDGE ASHMAN**
	)	
PENTECH PHARMACEUTICALS, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	
	)	

AMENDED ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant, Pentech Pharmaceuticals, Inc. ("Defendant"), pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, hereby provides its Amended Answer, Affirmative Defenses and Counterclaims to respond to the Complaint of Plaintiffs, Bone Care International LLC and Genzyme Corporation (collectively "Plaintiffs"), as follows:

Nature of the Action

1. This is an action for patent infringement.

RESPONSE: Admitted.

Parties

2. Defendant 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.

RESPONSE: Defendant is without sufficient information as to the truth of the allegations of Paragraph 2 and, therefore, denies those allegations.

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.

RESPONSE: Defendant is without sufficient information as to the truth of the allegations of Paragraph 3 and, therefore, denies those allegations.

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.

RESPONSE: Admitted.

Jurisdiction

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).

RESPONSE: Admitted that there is jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies that Defendant committed any infringing acts.

6. On information and believe, 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.

RESPONSE: Admitted that Pentech is an Illinois corporation and has a principal place of business in the Northern District of Illinois. Denied that Pentech does business throughout the United States, including within this judicial district.

Admitted that there is jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies that Defendant committed any infringing acts.

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).

RESPONSE: Admitted.

Claim for Relief – Patent Infringement

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

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 9 and, therefore, denies those allegations.

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

RESPONSE: Admitted.

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.

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 10 and, therefore, denies those allegations.

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 2µg/mL doxercalciferol ("Pentech's Proposed Generic Product").

RESPONSE: Admitted.

Count I – Infringement of the '116 Patent

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

RESPONSE: Defendant repeats its responses to 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 fully 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.

RESPONSE: Admitted that the '116 patent issued on February 11, 1997 as entitled, and that a copy of the '116 patent was attached as Exhibit B to the Complaint. Denied that the '116 patent was duly and legally issued.

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

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 14 and, therefore, denies those allegations.

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.

RESPONSE: Admitted.

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.

RESPONSE: Admitted 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 a "highly artificial act" of infringement under 35 U.S.C. § 271(e)(2), otherwise denied, since one cannot infringe an invalid 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.

RESPONSE: Admitted.

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.

RESPONSE: Subject to any claim construction ruling having a bearing on this issue, denied, since one cannot infringe an invalid patent.

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

RESPONSE: Defendant admits that Defendant was aware of the '116 patent at the time of filing its ANDA.

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).

RESPONSE: Defendant denies that Plaintiffs are entitled to such relief.

Count II – Infringement of the '083 Patent

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

RESPONSE: Defendant repeats its responses to 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.

RESPONSE: Admitted that the '083 patent issued on June 7, 2005 as entitled and that a copy of the '083 patent was attached Exhibit B to the Complaint. Denied that the '083 patent was duly and legally issued.

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

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 23 and, therefore, denies those allegations.

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.

RESPONSE: Admitted.

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.

RESPONSE: Admitted that the filing of a Paragraph IV certification is deemed a "highly artificial act" of infringement to provide the court with jurisdiction. Denied that 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.

RESPONSE: Admitted.

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.

RESPONSE: Denied.

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

RESPONSE: Defendant admits that Defendant was aware of the '083 patent at the time of filing its ANDA, otherwise denied.

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).

RESPONSE: Defendant denies that Plaintiffs are entitled to such relief.

Affirmative Defenses

1. The '083 patent would not be infringed by Defendant's commercial manufacture, use, offer for sale, sale and/or importation of its product covered by ANDA No. 90-040.

2. The '116 patent would not be infringed by Defendant's commercial manufacture, use, offer for sale, sale and/or importation of its product covered by ANDA No. 90-040 since an invalid patent cannot be infringed.

3. Plaintiffs have failed to state a claim upon which relief may be granted.

4. The '083 patent would not be infringed by a product made in accordance with ANDA No. 90-040.

5. The '116 and '083 patents are invalid under 35 U.S.C. §100, *et seq.*

6. The '116 and '083 patents are invalid under 35 U.S.C. §102.

7. The '116 and '083 patents are obvious over the prior art under 35 U.S.C. §103 and, thus, are invalid.

WHEREFORE, Defendant requests that this Honorable Court:

(a) Deny Plaintiffs all requested relief and dismiss the Complaint with prejudice;

(b) Order that the effective date of the approval of Defendant's ANDA No. 90-040 is immediate under §505(j) of the Federal Food and Cosmetic Act, 21 U.S.C. §355(j), upon a statement by the FDA that it is otherwise ready to approve the ANDA;

(c) Declare that the '083 and '116 patents are not infringed; and

(d) Declare that the '116 and '083 patents are invalid.

(e) Defendant further requests that this Court award its attorneys' fees, costs and all other relief this Court deems just.

COUNTERCLAIMS

1. Defendant, Counterclaim-Plaintiff, incorporates by reference herein its Answer and Affirmative Defenses to the Complaint.

THE PARTIES

2. Counterclaim-Plaintiff Pentech is a corporation organized under the laws of the State of Illinois, having its principal place of business at 315 West Algonquin Road, Suite 310, Rolling Meadows, Illinois 60008.

3. On information and belief, Counterclaim-Defendant Bone Care International LLC ("Bone Care") is a Delaware corporation having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

4. On information and belief, Counterclaim-Defendant Genzyme Corporation is a Massachusetts corporation having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

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

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

8. On information and belief, doxercalciferol is known chemically as 1α-OH-vitamin D_2, 1-alpha-hydroxyvitamin D_2, 1α-OH-D2 and1α-hydroxyergocalciferol.

9. On information and belief, 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 patents with chronic kidney disease on dialysis.

10. 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").

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

12. On information and belief, Bone Care is the owner of the '116 patent. On information and belief, Genzyme is the sole member of Bone Care.

13. 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.

14. In its Complaint, Counterclaim-Defendants alleged 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). Counterclaim-Defendant further alleged 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. 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.

16. Pentech had notice of the '116 patent prior to filing its ANDA.

17. In their Complaint against Counterclaim-Plaintiff, Counterclaim-Defendants alleged 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 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).

18. On June 7, 2005, United States Patent No. 6,903,083 ("the '083 patent) entitled "Stabilized Hydroxyvitamin D" issued. On information and belief, the '083 patent claims a stabilized form of doxercalciferol and pharmaceutical compositions containing that stabilized form.

19. On information and belief, Bone Care is the owner of the '083 patent. On information and belief, Genzyme is the sole member of Bone Care.

20. 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.

21. In their Complaint against Pentech, Counterclaim-Defendants alleged 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 committed an act of infringement under 35 U.S.C. §271(e)(2). Counterclaim-Defendants further alleged 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. 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.

23. Counterclaim-Defendants alleged in their Complaint that Pentech had notice of the '083 patent prior to undertaking its acts of infringement.

24. On information and belief, Counterclaim-Defendants allege that they are the owners of 5,602,116 ('116 patent), 5,707,980 ('980 patent), 6,903,083 ('083 patent), including the right to sue and collect damages.

25. On January 8, 2007, Counterclaim-Plaintiff 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.

26. On February 21, 2008, Counterclaim-Defendants sued Counterclaim-Plaintiff but did not sue Counterclaim-Plaintiff on U.S. Patent No. 5,707,980 ("the '980 patent").

JURISDICTION AND VENUE

27. These counterclaims constitute an action for a declaratory judgment under 28 U.S.C. §§2201 and 2202, and arise under the Patent Laws of the United States, Title 35, United States Code.

28. This Court has jurisdiction of these counterclaims under 28 U.S.C. §§1331 and 1338(a) and the Patent Laws of the United States, Title 35, United States Code.

29. In the Complaint, Counterclaim-Defendants allege that they are the owner of the '116 and '083 patents and allege that Counterclaim-Plaintiff has infringed the '116 and '083 patents.

30. As evidenced by the Complaint and this pleading in response thereto, an actual controversy exists between the parties with respect to the alleged infringement of the '116 and '083 patents.

COUNT I

31. The '083 patent is not infringed.

COUNT II

32. The '083 patent would not be infringed by a product made in accordance with ANDA No. 90-040.

COUNT III

33. The '116 patent is invalid under one or more provisions of 35 U.S.C. §101, *et seq.* and thus cannot be infringed.

COUNT IV

34. The '116 patent is invalid under 35 U.S.C. §102.

COUNT V

35. The '116 patent is obvious over the prior art under 35 U.S.C. §103 and, thus, is invalid.

COUNT VI

36. The '083 patent is invalid under one or more provisions of 35 U.S.C. §101, *et seq.*

COUNT VII

37. The '083 patent is invalid under 35 U.S.C. §102.

COUNT VIII

38. The '083 patent is obvious over the prior art under 35 U.S.C. §103 and, thus, is invalid.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff requests that this Honorable Court:

(a) Deny Counterclaim-Defendants all requested relief and dismiss the Complaint with prejudice;

(b) Adjudge and decree that the '083 and '116 patents are not infringed.

(c) Adjudge and decree that the '116 and '083 patents are invalid.

(d) Order that the effective date of the approval of Pentech's Abbreviated New Drug Application (ANDA) No. 90-040 is immediate under §505(j) of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. §355(j), upon a statement by the FDA that it is otherwise ready to approve the ANDA;

(e) Award Counterclaim-Plaintiff with its attorneys' fees, interest and costs; and

(f) Grant such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

Counterclaim-Plaintiff requests a jury trial on all issues so triable.

Dated: May 7, 2008

Respectfully submitted,

By: s/ Robert B. Breisblatt

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Attorneys for Defendant, Pentech Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of May, 2008, a true and correct copy of the **AMENDED ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** is being mailed, via United States Postal Services, first class mail, postage prepaid in an envelope addressed to:

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