Exhibit 1

PTO/SB/43 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## DISCLAIMER IN PATENT UNDER 37 CFR 1.321(a)

| Name of Patentee | Docket Number (Optional) |
|---|---|
| Bone Care International, LLC | 017620-9282 US01 |
| **Patent Number** | **Date Patent Issued** |
| 6,903,083 | June 7, 2005 |

Title of Invention

STABILIZED HYDROXYVITAMIN D

I hereby disclaim the following complete claims in the above identified patent: 1-19

The extent of my interest in said patent is (if assignee of record, state liber and page, or reel and frame, where assignment is recorded): assignee of record - Reel 020518/Frame 0909

The fee for this disclaimer is set forth in 37 CFR 1.20(d).

- [ ] Patentee claims small entity status. See 37 CFR 1.27.
- [ ] Small entity status has already been established in this case, and is still proper.
- [ ] A check in the amount of the fee is enclosed.
- [X] Payment by credit card. Form PTO-2038 is attached.
- [X] The Director is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 50-0842.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

Signed at Madison, State of Wisconsin, this 3rd day of August 20 09.

Signature

49,038
Registration Number, if applicable

Jeffrey D. Peterson, Attorney of Record
Typed or printed name of patentee/ attorney or agent of record

608-257-3501
Telephone Number

Michael Best & Friedrich LLP, 1 S. Pinckney Street, P.O. Box 1806
Address

Madison, WI 53701-1806 USA
City, State, Zip Code or Foreign Country as applicable

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

Exhibit 2

**Orange Book Search Results on patent number '6903083' in the OB_Rx list.**

| Appl No | Prod No | Active Ingredient | Patent No | Patent Expire | Drug Substance Claim | Drug Product Claim | Patent Use Code | Delist Requested |
|---|---|---|---|---|---|---|---|---|
| 020862 | 001 | DOXERCALCIFEROL | 6903083 | Jul 18, 2021 | Y | Y | | Y |
| 020862 | 002 | DOXERCALCIFEROL | 6903083 | Jul 18, 2021 | Y | Y | | Y |
| 021027 | 001 | DOXERCALCIFEROL | 6903083 | Jul 18, 2021 | Y | Y | | Y |

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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View a list of all patent use codes

Return to Electronic Orange Book Home Page

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through September, 2009

Patent and Generic Drug Product Data Last Updated: November 06, 2009

Exhibit 3

**Orange Book Search Results on patent number '5707980' in the OB_Rx list.**

| Appl No | Prod No | Active Ingredient | Patent No | Patent Expire | Drug Substance Claim | Drug Product Claim | Patent Use Code | Delist Requested |
|---|---|---|---|---|---|---|---|---|
| 021027 | 001 | DOXERCALCIFEROL | 5707980 | Aug 17, 2010 | | | U-321 | Y |

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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View a list of all patent use codes

Return to Electronic Orange Book Home Page

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through September, 2009
Patent and Generic Drug Product Data Last Updated: November 06, 2009

Exhibit 4

SANDOZ

**Alison Sherwood, Manager**
Regulatory Affairs

**Sandoz Inc.**
2555 W. Midway Blvd.
P.O. Box 446
Broomfield, CO 80038-0446

Tel +1 303 438-4513
Fax +1 303 438-4600
Email:
alison.sherwood@sandoz.com

JUN 1 2009

RECEIVED
2009 JUN -2 A 10:09
FITZPATRICK, CELLA, HARPER & SCINTO

**VIA UPS OVERNIGHT DELIVERY**
***Return Receipt Requested***

Genzyme Corporation
Attention: Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

✓ Robert L. Baechtold, Esq.
FITZPATRICK CELLA HARPER& SCINTO
30 Rockefeller Plaza
New York, New York 10112-3800

Bone Care International
Attention: Chief Executive Officer
500 Kendall Street
Cambridge, MA 02142

Bone Care International
Attn: Chief Executive Officer
1600 Aspen Commons
Middleton, WI 53562

Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B)) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95
Sandoz, Inc.'s Doxercalciferol Injectable, 2 microg/mL
Sandoz, Inc.'s ANDA 91-333

Dear Sir or Madam:

Sandoz, Inc. ("Sandoz") of 506 Carnegie Center, Suite 400, Princeton, NJ 08540, U.S.A., hereby gives notice to the NDA holder and/or listed patent owner for the reference listed drug that the FDA has received an Abbreviated New Drug Application ("ANDA") for Doxercalciferol Injectable, 2 microg/mL ("the Sandoz Product"), which contains data or information from required bioequivalence and/or bioavailability studies.

The FDA has assigned the Sandoz ANDA the number 91-333.

The following U.S. Patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluation* (the "Orange Book") as having the indicated expiration date:

| Patent No. | Patent Owner | Patent Expiry | PED expiry[1] |
|---|---|---|---|
| 5,602,116 | Bone Care International LLC | 11 Feb 2014 | N/A |
| 5,707,980 | Bone Care International, Inc. | 02 Aug 2008[2] | N/A |
| 6,903,083 | Bone Care International LLC | 18 July 2021 | N/A |
| 7,148,211 | Bone Care International, Inc. | 07 Dec 2024[3] | N/A |

1. There is no pediatric exclusivity associated with this product.

2. The patent expiration date of 17 Aug 2010 listed in the Orange Book for the 5,707,980 patent is incorrect; the correct expiration date is 02 Aug 2008.

3. The expiration date of 14 Sept 2023 listed in the Orange Book for the 7,148,211 patent is incorrect; the correct expiration date is 07 Dec 2024 which includes 361 days of Patent Term Adjustment.

The purpose of this communication is to provide the notice and information required by 21 U.S.C. §355(j)(2)(B)(i) and/or (ii) (Sections 505(j)(2)(B)(i) and/or (ii) of the Food, Drug and Cosmetics Act) and to inform you that the Sandoz ANDA contains a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV),which asserts that the claims of said U.S. Patent Nos. 5,707,980, 5,602,116, 6,903,083, and 7,148,211 are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of the Sandoz Product. Sandoz, by submitting its ANDA, seeks to obtain approval to engage in commercial manufacture, use and sale of the Sandoz Product prior to the expiration of U.S. Patent Nos. 5,602,116, 6,903,083, and 7,148,211.

A Detailed Statement of the factual and legal basis for Sandoz's opinion that the Listed Patents will not be infringed by the manufacture, use or sale of the Sandoz Products is attached hereto.

Offer for Confidential Access

An Offer of Confidential Access to relevant sections of the Sandoz ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) is attached hereto.

Anticompetitive Behavior Warning

Please be warned of the following. It is an antitrust violation to assert a patent known not to be infringed. *Loctite v. Ultraseal*, 781 F.2nd 861 (Fed. Cir. 1985). As such, the attached Detailed Statement has outlined in the necessary detail that your patents are not, and cannot be, infringed by the subject matter described in the Sandoz ANDA. As such, your pursuit of an infringement action may be deemed to be an antitrust violation. In addition, it is an antitrust violation to assert a patent known not to be valid. *Handgards v. Ethicon*, 601 F.2nd 986 (9th Cir. 1979). If you launch any patent infringement lawsuit, either now or later, Sandoz may pursue the appropriate remedies against you, including seeking fees, costs, and sanctions for potential violations of Rule 11 (of the Civil Procedure Rules), exceptional case and frivolous suit statutes under the patent laws, and for violations of the antitrust laws, plus any remedy the court deems fit to award.

Reservation of Legal Rights

We reserve the right to allege the same, similar, different or new theories of non-infringement and/or invalidity and nothing in this Notice Letter or Detailed Statement shall be construed as to limit our rights to make any allegation in any subsequent litigation regarding any issue.

Relevant Contact Information

If you have any inquiries concerning this notice or for any service of process or legal information, please contact:

Stephen R. Auten, Esq.
Vice-President, Legal – Intellectual Property
Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Very truly yours,

ASherwood 5-29-09

Alison Sherwood
Regulatory Affairs
Sandoz, Inc.

Attachments:

1. Offer of Confidential Access
2. Detailed Statement

Exhibit 5

EDA
FILED
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,** | ) | **08 C 1083** |
| *Plaintiffs*, | ) | |
| **v.** | ) | **Civil Action No.:** **JUDGE DOW** **MAGISTRATE JUDGE ASHMAN** |
| **PENTECH PHARMACEUTICALS, INC.,** | ) | |
| *Defendant.* | ) | |

**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

Sarah R. Wolff (IL Bar No. 03123733)
Jennifer Yule DePriest (IL Bar No. 6272137)
REED SMITH LLP
10 South Wacker Drive, 40th Floor
Chicago, Illinois 60606-7507
Phone: (312) 207-1000
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*Attorneys for Plaintiffs Bone Care International LLC and Genzyme Corporation*

Of Counsel:
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30 Rockefeller Plaza
New York, New York 10112-3800
Phone: (212) 218-2100
Facsimile: (212) 218-2200

CHILIB-2161545.1-999906-00700

Exhibit 6

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

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

**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 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

30. 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-Defendant requests a jury trial on all issues so triable.

Dated: April 25, 2008

Respectfully submitted,

By _____

Robert S. Silver
William J. Castillo
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COHEN & POKOTILOW, LTD.
1635 Market Street, 11th Floor
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Robert B. Breisblatt
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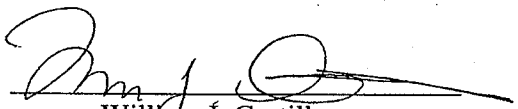
Robert.Breisblatt@kattenlaw.com
*Attorneys for Defendant, Pentech Pharmaceuticals, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on this 25th day of April, 2008, a true and correct copy of the **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:

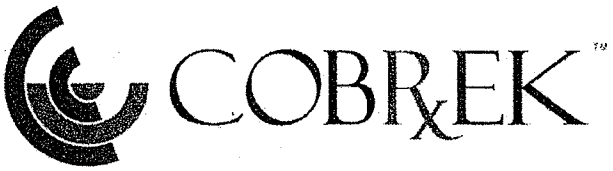
Sarah R. Wolff
Jennifer Yule
REED SMITH LLP
10 South Wacker Drive, 40th Floor
Chicago, IL 60606-7507

Robert L. Baechtold
Scott K. Reed
Filko Prugo
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3800



William J. Castillo

Exhibit 7




**Pharmaceuticals, Inc.**
**A Subsidiary of Pentech Pharmaceuticals, Inc.**
**Corporate and Administrative Offices**

**3315 Algonquin Road, Suite 310**
**Rolling Meadows, IL 60008**
**Phone 847-225-0303**
**Fax 847-255-2112**

February 20, 2009

***SENT VIA FEDERAL EXPRESS***

Genzyme Corporation
Attention: Henri A. Termeer, President, Chairman & CEO
500 Kendall Street
Cambridge, MA 02142

Genzyme Corporation
(Bone Care International, Inc.)
1600 Aspen Commons
Middleton, WI 53562

**Re: Certification of Non-Infringement and/or Invalidity of United States Patent No. 7,148,211**

To Whom it May Concern:

Pursuant to Section 505(j)(2)(B)(i) and (ii) of the Federal Food, Drug and Cosmetic Act ("the Act"), notice is hereby given that the Food and Drug Administration ("FDA") has received an Abbreviated New Drug Application ("ANDA") submitted by Cobrek Pharmaceuticals, Inc. ("Cobrek").

Furthermore, the following information is herein provided:

REDACTED

4. The ANDA contains a certification pursuant to Section 505(j)(2)(A)(vii)(IV) of the Act ("Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of Cobrek's ANDA product before the expiration of U.S. Patent No. 7,148,211 (the "'211 patent"). This patent was listed in the Orange Book for New Drug Application No. 021027 for Hectorol® injection.

5. As stated in the Paragraph IV Patent Certification, the claims of the '211 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Cobrek's ANDA product.

REDACTED

Exhibit 8

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

| | |
|---|---|
| **BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,** | |
| **Plaintiffs,** | **Civil Action No. 08 C 1083** |
| **v.** | **JUDGE DOW** |
| | **MAGISTRATE JUDGE ASHMAN** |
| **PENTECH PHARMACEUTICALS, INC., and COBREK PHARMACEUTICALS, INC.** | |
| **Defendants.** | |

**CONSENT JUDGMENT**

The parties stipulate that judgment should be entered for Defendants with respect to Plaintiffs' claims of infringement of U.S. Patent No. 6,903,083 in accordance with the Plaintiffs' March 13, 2009 Covenant Not To Sue on that patent in relation to Defendants' ANDA 90-040.

Dated: April 28, 2009

By /s/ Robert Stevenson
Robert S. Silver
Robert W. Stevenson, *Ill. Reg. No. 6195238*
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Mona Gupta
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*rstevenson@crbcp.com*
*bjchasan@crbcp.com*
*mgupta@crbcp.com*

and

By /s/ Christopher E. Loh
Robert L. Baechtold, Esq.
Scott K. Reed, Esq.
Filko Prugo, Esq.
Christopher E. Loh, Esq.
Fitzpatrick, Cella, Harper & Scinto
30 Rockefeller Plaza
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*Attorneys for Defendants, Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc.*

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*brian.fagel@goldbergkohn.com*

*Attorneys for Plaintiffs, Bone Care International LLC and Genzyme Corporation*

SO ORDERED:

Robert M. Dow, Jr. U.S.D.J.

May 12, 2009

Exhibit 9

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FIONA DARKIN
DIRECT DIAL (212) 218-2286
E-MAIL fdarkin@fchs.com

August 25, 2009

***Via E-mail***

Richard W. Riley, Esq.
Duane Morris LLP
1100 N. Market Street, Ste. 1200
Wilmington, DE 19801

Re: *Bone Care Int'l LLC and Genzyme Corporation v. Sandoz, Inc.* (09-CV-524)

Dear Mr. Riley:

I write to inform you that Genzyme is the owner of United States Patent Nos. 6,903,083 ("the '083 patent") and 7,148,211 ("the '211 patent"). Genzyme has delisted the '083 patent from the Orange Book and dedicated it to the public. Additionally, Genzyme has authorized the attached covenant not to sue Sandoz, Inc. in connection with the '211 patent. We trust these actions resolve any potential controversy between the parties in connection with the '083 and '211 patents. If Sandoz disagrees, we look forward to hearing upon what basis it believes there is any live issue here.

Very truly yours,

Fiona Darkin

*Attachment*

cc: Jack Blumenfeld, Esq.

FCHS_WS 3728920_1.DOC

Exhibit 10

**Thomas J. Filarski**
**312·321·4243**
**tfilarski@brinkshofer.com**

BRINKS HOFER GILSON & LIONE®
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October 5, 2009
***Via Email***

Fiona Darkin, Esq.
Fitzpatrick Cella Harper & Scinto
30 Rockefeller Plaza
New York, New York 10112-3800
fdarkin@fchs.com

**Re:** ***Bone Care Int'l LLC and Genzyme Corp. v. Sandoz Inc.***
**Civil Action No: 09-cv-524**
**Our Ref No: 13132/23**

Dear Ms. Darkin:

We represent Sandoz Inc. in connection with this matter and I am writing in response to your letter of August 25, 2009 to Richard Riley.

Today, Sandoz will submit a responsive pleading that includes declaratory judgment counts against U.S. Patent Nos. 6,903,083, 7,148,211, 5,707,980, and 5,602,116. Sandoz desires to retain its full right to timely approval of its ANDA No. 91-333, yet each of these patents forms the basis for eligibility for 180-day exclusivity pursuant to the Hatch-Waxman statute. A declaratory judgment against each of these patents is required to prevent significant harm to Sandoz.

For example, the following actions do not remove the harm of Genzyme's listing of the four identified patents in the Orange Book to Sandoz:

- Genzyme's request to delist the '083 patent from the Orange Book and its effort to dedicate the patent to the public,
- Genzyme's offer to Sandoz of a covenant not to sue in connection with the '211 patent, and
- Genzyme's request to delist the '980 patent from the Orange Book in view of the patent's current, incorrectly listed expiration date.

It is our desire to litigate this case efficiently while protecting the rights of Sandoz. We would be happy to discuss with you at your convenience opportunities to resolve these claims.

Sincerely,

Tom Filarski
TJF:mi

Exhibit 11

**From:** Loh, Christopher
**Sent:** Monday, October 19, 2009 8:47 PM
**To:** #Hectorol Internal
**Subject:** FW: Bone Care Int'l LLC and Genzyme Corp. v. Sandoz Inc. (09-CV-524)
**Attachments:** 8_25_2009 Darkin ltr to Riley.PDF; 8_25_2009 Darkin covenant to Riley.PDF

---

**From:** Loh, Christopher
**Sent:** Monday, October 19, 2009 8:42 PM
**To:** RWRiley@duanemorris.com
**Cc:** jblumenfeld@mnat.com; Prugo, Filko; Darkin, Fiona
**Subject:** Bone Care Int'l LLC and Genzyme Corp. v. Sandoz Inc. (09-CV-524)

Dear Richard,

Further to my colleague Fiona Darkin's August 25, 2009 letter (attached), please let us know whether Sandoz still intends to pursue its counterclaims concerning Genzyme's '083 and '211 patents.

As we have indicated, the '083 patent has been delisted, and Genzyme remains willing to execute the attached covenant not to sue Sandoz on the '211 patent. Thus, we do not believe that there is any live controversy between Genzyme and Sandoz over the '083 and '211 patents. Nevertheless, if Sandoz will not voluntarily withdraw its counterclaims against those patents, we will move to dismiss them.

So that we may move to dismiss Sandoz's '083 and '211 patent counterclaims in a timely manner, please let us know Sandoz's intentions by this Friday. Thank you.

Best regards,

**Christopher E. Loh**
**FITZPATRICK, CELLA, HARPER & SCINTO**
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F 212-218-2200
CLoh@fchs.com
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Exhibit 12

**Thomas J. Filarski**
(312) 321-4243
tfilarski@brinkshofer.com

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Intellectual Property Law Worldwide

October 23, 2009
***Via Email***

Mr. Christopher E. Loh, Esq.
FITZPATRICK, CELLA, HARPER AND SCINTO
30 Rockefeller Plaza
New York, NY 10112-3280
cloh@fchs.com

***Re:*** ***Bone Care Int'l LLC and Genzyme Corp. v. Sandoz Inc.***
**Civil Action No. 09-cv-524**
**Our Ref No. 13132/23**

Dear Mr. Loh:

In response to your October 19, 2009 email to Rich Riley, and as previously stated in the October 5, 2009 letter to Ms. Darkin, Sandoz has properly asserted declaratory judgment counterclaims under the express authorization of 21 U.S.C. § 355(j)(5)(C).

Genzyme's actions, including its attempt to delist the '083 and '980 patents, have failed to remove the harm to Sandoz or to divest the Court of jurisdiction. Similarly, Genzyme's offer to provide a covenant not to sue for the '211 patent does not remove the harm to Sandoz. *See Caraco Pharm. Labs, Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008) (reversing the district court's dismissal of declaratory judgment counterclaims in spite of a unilateral covenant not to sue). Nor does the Federal Circuit's more recent, yet distinguishable, opinion deprive the Court of jurisdiction of Sandoz's claim. *See Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008) ("[W]hile the harm that created a justiciable Article III controversy in *Caraco* was present when Apotex filed its counterclaims [], that harm ceased to exist upon Apotex's stipulation [of infringement and validity].").

Genzyme can remove this harm by agreeing to enter into a consent decree or settlement order on each of these patents.[1] Please advise whether Genzyme will agree to enter into these consent judgments or settlement orders, and if not, why it believes the statute or other authority support its position in view of the harm it has created to Sandoz.

[1] This would give Sandoz a concrete date under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB).

We look forward to further discussions regarding a settlement order or consent decree to resolve the controversy regarding the '083, '211 and the '980 patents.

Sincerely,

Thomas J. Filarski
TJF:all

Exhibit 13

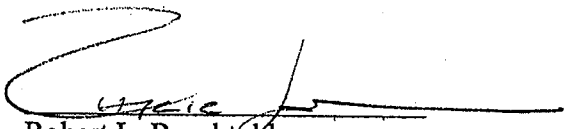
**COVENANT NOT TO SUE**

WHEREAS Genzyme Corporation ("Genzyme") owns United States Patent No. 7,148,211 ("the '211 patent''), titled "Formulation for Lipophilic Agents" and has full and exclusive right to enforce the '211 patent;

WHEREAS Sandoz Inc. ("Sandoz") filed Abbreviated New Drug Application ("ANDA") No. 91-333 seeking approval to engage in the commercial manufacture, use and/or sale of a generic injectable product containing 2 μg/mL doxercalciferol;

NOW THEREFORE Genzyme, Bone Care, their subsidiaries, successors and assigns, agree, promise and covenant not to sue, assert any claim of infringement of, or otherwise enforce or attempt to enforce against Sandoz, including each of Sandoz's current and future parents, subsidiaries, affiliates, officers, directors, employees, customers, distributors, suppliers, representatives and agents of any kind, and its successors and assigns, if any, (i) the '211 patent; (ii) any patents issuing from continuation or divisional applications of the '211 patent; and/or (iii) any patent resulting from a re-examination or re-issue proceeding involving the '211 patent, based upon either the submission of Sandoz's ANDA No. 91-333 to the United States Food and Drug administration or the importation, manufacture, use, sale or offer for sale of the product that is the subject of and described in Sandoz's ANDA No. 91-333, provided that, in either case, the formulation remains substantially identical to that described in the portion of Sandoz's ANDA sent on June 15, 2009 to counsel for Genzyme and Bone Care by counsel for Sandoz (attached hereto as Exhibit A).

Dated: November 9, 2009

By: 

Robert L. Baechtold
Scott K. Reed
Filko Prugo
Christopher E. Loh
Fiona E. Darkin
Daniel J. Minion
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Exhibit 14

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

| | |
|---|---|
| BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>PENTECH PHARMACEUTICALS, INC. and COBREK PHARMACEUTICALS, INC.,<br><br>Defendants. | Civil Action No.: 08-cv-1083<br><br>Honorable Robert M. Dow Jr.<br>Magistrate Judge Martin C. Ashman |

**STIPULATION REGARDING INFRINGEMENT OF PLAINTIFFS' U.S. PATENT NO. 5,602,116**

Plaintiffs Bone Care International, LLC and Genzyme Corporation (collectively, "Genzyme") and Defendants Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc. (collectively, "Pentech"), through their counsel, hereby stipulate and agree to the following:

WHEREAS Plaintiff Bone Care International LLC ("Bone Care") owns United States Patent No. 5,602,116 ("the '116 patent"), titled "Method For Treating And Preventing Secondary Hyperparathyroidism," and claiming methods of treating hyperparathyroidism secondary to end stage renal disease using 1α-OH-vitamin $D_2$;

WHEREAS Plaintiff Genzyme Corporation is the sole member of Bone Care, and holds approved New Drug Application ("NDA") No. 021-027 for Hectorol® injectable (2 μg/mL), which product contains the active ingredient 1α-OH-vitamin $D_2$;

WHEREAS Defendant Pentech Pharmaceuticals, Inc. filed Abbreviated New Drug Application ("ANDA") No. 90-040 seeking approval to engage in the commercial

manufacture, use and/or sale of a generic injectable product containing 2 μg/mL of 1α-OH-vitamin $D_2$ for the treatment of hyperparathyroidism secondary to end stage renal disease;

WHEREAS Defendant Cobrek Pharmaceuticals, Inc. presently holds ANDA No. 90-040;

NOW THEREFORE, the parties, their successors and assigns hereby stipulate, and will not contest before this Court or on appeal, that:

(i) the submission of ANDA No. 90-040 to the United States Food and Drug Administration infringed claim 7 of the '116 patent pursuant to 35 U.S.C. § 271(e)(2)(A);

(ii) upon final approval of ANDA No. 90-040, the use of the product that is the subject of and described in ANDA No. 90-040 for the indication described in ANDA No. 90-040 would infringe claim 7 of the '116 patent; and

(iii) upon final approval of ANDA No. 90-040, the commercial manufacture, use, sale, offer for sale in the United States, and/or importation into the United States by Pentech of the product and/or active ingredient that is the subject of and described in ANDA No. 90-040, accompanied with a package insert including the indication described in ANDA No. 90-040, would induce the infringement of, and would contributorily infringe, claim 7 of the '116 patent.

(iv) Should Defendants succeed in demonstrating the invalidity of claim 7 of the '116 patent or the unenforceability of the '116 patent, Plaintiffs agree that thereafter they shall not assert any of the claims of the '116 patent (or any

reissue or re-examination thereof) against Defendants, their manufacturers, customers, distributors, successors, assigns or anyone in privity therewith, in connection with any doxercalciferol product that is the subject of any ANDA submitted by Defendants, or in connection with any product that is marketed, offered for sale or sold by Defendants, their distributors, customers, successors, assigns or anyone in privity therewith that contains doxercalciferol.

**AGREED TO:**

Dated: 3/24/09

By: _____

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Dated: March 24, 2009

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