

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

GENZYME CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ANCHEN PHARMACEUTICALS, INC.	)	
and ANCHEN INCORPORATED,	)	
	)	
Defendants.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Genzyme Corporation (“Plaintiff”), by and through its attorneys, and for its Complaint against Defendants Anchen Pharmaceuticals, Inc. (“Anchen Pharmaceuticals”) and Anchen Incorporated (“Anchen Inc.”) (collectively, “Defendants” or “Anchen”), hereby alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement.

**THE PARTIES**

2. Plaintiff 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.

3. Upon information and belief, Anchen Pharmaceuticals is a corporation organized and existing under the laws of the State of California, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618. Upon information and belief, Anchen Pharmaceuticals is in the business of, among other things, manufacturing and selling generic

copies of branded pharmaceutical products throughout the United States including in the State of Delaware.

4. Upon information and belief, Anchen Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

5. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. are closely related entities in the same corporate family that act in concert, including with respect to collaborating in the development, manufacturing, marketing, and sale of generic copies of branded pharmaceutical products pursuant to Abbreviated New Drug Applications. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. share the same principal place of business. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. have at least one officer and/or director in common.

6. Upon information and belief, Anchen has represented to the United States Patent and Trademark Office that Anchen Pharmaceuticals and Anchen Inc. “constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods.”

#### **JURISDICTION AND VENUE**

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Anchen Pharmaceuticals because, *inter alia*, of its continuous and systematic contacts with the State of Delaware. Anchen Pharmaceuticals directly and/or through Anchen Inc. manufactures, markets, and sells drugs throughout the United States, including the State of Delaware, and therefore derives substantial

revenue from Delaware drug sales and has availed itself of the privilege of conducting business within the State of Delaware such that it should reasonably anticipate being haled into court here. Specifically, on information and belief, revenue sheets indicate that Anchen Pharmaceuticals sold at least \$1,079,202 worth of drug product in Delaware between June 2007 and May 2009.

9. This Court has personal jurisdiction over Anchen Inc. Anchen Inc. has submitted to personal jurisdiction in this Court because, *inter alia*, it is a resident and citizen of the State of Delaware and has availed itself to the rights and benefits of the laws of Delaware by virtue of incorporating in Delaware and engaging in systematic and continuous contacts with the State of Delaware such that it should reasonably anticipate being haled into court here.

10. On information and belief, Anchen Pharmaceuticals and Anchen Inc. have sold millions of dollars worth of pharmaceutical products, including Bupropion and Divalproex generic drugs, within the United States generally, and the State of Delaware specifically, under its stylized “Anchen” trademark (serial no. 77037779).

11. In addition, this Court previously determined that it has personal jurisdiction over Anchen Pharmaceuticals and Anchen Inc. in its March 12, 2010 decision *In re: Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, MDL No. 09-2118 (consolidated).

12. This Court has personal jurisdiction over Anchen by virtue of, *inter alia*, the above-mentioned facts.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

**CLAIMS FOR RELIEF**

14. Plaintiff holds approved New Drug Application (“NDA”) No. 020-862 for Hectorol<sup>®</sup> oral capsules (0.5 µg, 1 µg, and 2.5 µg), which products contain the active ingredient doxercalciferol.

15. Hectorol<sup>®</sup> oral capsules were approved by the U.S. Food and Drug Administration (“FDA”) on June 9, 1999 (2.5 µg), April 23, 2004 (0.5 µg), and July 13, 2009 (1.0 µg), and are currently indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease, including patients on dialysis.

16. On information and belief, Anchen Pharmaceuticals submitted to the FDA Abbreviated New Drug Application (“ANDA”) No 20-1518 under § 505(j) of the Federal Food Drug, and Cosmetic act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic doxercalciferol capsules in 0.5, 1.0, and 2.5 µg strengths (“Anchen’s Proposed Generic Products”).

**Count 1: Infringement By Anchen**

17. Plaintiff repeats and realleges the allegations of paragraphs 1-16 as though fully set forth herein.

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

19. Plaintiff is the owner of the '116 Patent.

20. By letter dated April 26, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) (the "Notice Letter"), Anchen Pharmaceuticals notified Plaintiff that it had submitted ANDA No. 20-1518 to the FDA seeking the approval of the FDA to commercially manufacture, use, sell, and/or import into the United States, Anchen's Proposed Generic Products prior to the expiration of the '116 Patent.

21. Upon information and belief, Anchen Inc. initiates, directs, and controls the activities of Anchen Pharmaceuticals with regard to ANDA No. 20-1518 and Anchen's Proposed Generic Products described therein.

22. Upon information and belief, Anchen Inc., through Anchen Pharmaceuticals as its agent, initiated, directed, and controlled the preparation and filing of ANDA No. 20-1518 with the FDA.

23. By submitting ANDA No. 20-1518 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Anchen's Proposed Generic Products prior to the expiration of the '116 Patent, Anchen Inc. and its agent Anchen Pharmaceuticals have infringed the '116 Patent under 35 U.S.C. § 271(e)(2).

24. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of Anchen's Proposed Generic Products by Anchen, if approved by the FDA, would infringe one or more claims of the '116 Patent under 35 U.S.C. § 271(a).

25. On information and belief, the sale or offer for sale of Anchen's Proposed Generic Products, if approved by the FDA, would induce infringement of, and/or be contributory infringement of, one or more claims of the '116 Patent under 35 U.S.C. §§ 271(b) or (c).

26. Plaintiff is entitled to full relief provided by 35 U.S.C. §§ 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 20-1518 be a date which is not earlier than the expiration of the '116 Patent, and any other exclusivity to which Plaintiff is or becomes entitled.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A Judgment declaring that the '116 Patent remains valid and enforceable, and that Anchen has infringed one or more claims of the '116 Patent by filing its ANDA No. 20-1518.

(b) An Order that the effective date of any FDA approval of Anchen's ANDA No. 20-1518 be no earlier than the date on which the '116 Patent expires, and any other exclusivity to which Plaintiff is or becomes entitled;

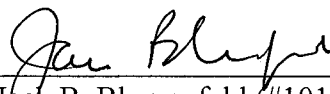
(c) Preliminary and permanent injunctions enjoining Anchen, its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Anchen's Proposed Generic Products until after the expiration of the '116 Patent, and any other exclusivity to which Plaintiff is or becomes entitled;

(d) If Anchen engages in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Anchen's Proposed Generic Products prior to the expiration of the '116 Patent, and any other exclusivity to which Plaintiff is or becomes entitled, a Judgment awarding damages to Plaintiff resulting from such infringement;

(e) The costs and reasonable attorney fees of Plaintiff in this action; and

(f) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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Jack B. Blumenfeld (#1014)  
Karen Jacobs Louden (#3778)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
[jblumenfeld@mnat.com](mailto:jblumenfeld@mnat.com)  
[klouden@mnat.com](mailto:klouden@mnat.com)

*Attorneys for Plaintiff*

OF COUNSEL:

Scott K. Reed  
Filko Prugo  
FITZPATRICK CELLA HARPER & SCINTO  
1290 Avenue of the Americas  
New York, NY 10104-3800  
(212) 218-2100

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