IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION,	)	
	)	
Plaintiff,	)	
v.	)	C.A. No.: _____
	)	
ROXANE LABORATORIES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Genzyme Corporation ("Genzyme"), by and through its attorneys, and for its Complaint herein against Defendant Roxane Laboratories, Inc. ("Roxane"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement.

PARTIES

2. 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.

3. On information and belief, Roxane is a corporation organized and existing under the laws of the state of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

JURISDICTION AND VENUE

4. On information and belief, Roxane markets and sells pharmaceutical products throughout the United States, including in the State of Delaware.

5. Roxane agreed not to contest personal jurisdiction in Delaware in connection with a related action, *Genzyme Corporation v. Roxane Laboratories, Inc.*, C.A. No.

09-567 (GMS) (the "Related Action"), noting in its answer that Genzyme alleges infringement of United States Patent No. 5,602,116 ("'116 patent") which Genzyme has asserted against other ANDA filers in this judicial district, and names only Roxane as a defendant (D.I. 9 at ¶¶5-6).

6. Based on the above facts, this Court has personal jurisdiction over Roxane.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF

8. Genzyme holds approved New Drug Application ("NDA") No. 020-862 for Hectorol® oral capsules (0.5 μg, 1.0 μg and 2.5 μg strengths), which products contain the active ingredient doxercalciferol.

9. The U.S. Food and Drug Administration ("FDA") approved Hectorol® oral capsules (1.0 μg) on July 13, 2009 for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease, including patients on dialysis.

10. In a letter dated June 17, 2009, Roxane notified Genzyme that it had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 91-433 under 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 and 2.5 μg strengths, which contained a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("a paragraph IV certification") directed to the '116 patent.

11. In response to Roxane's submission of its ANDA and paragraph IV certification, Genzyme filed the Related Action against Roxane in this Court on July 31, 2009, alleging infringement of the '116 patent. This action is related to that action.

12. In a letter dated June 9, 2010, Roxane notified Genzyme that it had amended ANDA No. 91-433 under 21 U.S.C. §355(j) seeking approval to engage in the

commercial manufacture, use and/or sale of a generic capsule product containing 1μg doxercalciferol ("Roxane's Proposed Generic Product").

Infringement Of The '116 Patent

13. Genzyme repeats and realleges the allegations of paragraphs 1-12 as though fully set forth herein.

14. On February 11, 1997, 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.

15. Genzyme is the owner of the '116 patent.

16. On information and belief, Roxane submitted its ANDA 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 Roxane's Proposed Generic Product prior to the expiration of the '116 patent.

17. By submitting ANDA No. 91-433 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 Roxane's Proposed Generic Product prior to the expiration of the '116 patent, Roxane committed an act of infringement under 35 U.S.C. § 271(e)(2).

18. On information and belief, Roxane made, and included in its ANDA, a, paragraph IV certification stating that, in Roxane's opinion, the claims of the '116 patent are invalid and unenforceable.

19. On information and belief, the commercial manufacture, use, sale, offer for sale and/or importation of Roxane's Proposed Generic Product prior to the expiration of the '116 patent, if approved by the FDA, would infringe one or more claims of the '116 patent under 35 U.S.C. §§ 271(a).

20. On information and belief, the sale or offer for sale of Roxane's Proposed Generic Product prior to the expiration of the '116 patent, 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).

21. Roxane had notice of the '116 patent prior to undertaking its acts of infringement.

22. Genzyme is 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 ANDA No. 91-433 be a date which is not earlier than the expiration of the '116 patent, and any other exclusivity to which Genzyme is or becomes entitled, and an award of damages for any commercial sale or use of Roxane's Proposed Generic Product and any act committed by Roxane with respect to the subject matter of the claims in the '116 patent, which act is not within the limited exclusions of 35 U.S.C. §271(e)(1).

PRAYER FOR RELIEF

WHEREFORE, Genzyme respectfully requests the following relief:

A. A Judgment declaring that Roxane committed an act of intringement under 35 U.S.C. § 271(e)(2) by filing its ANDA No. 91-433;

B. An Order that the effective date of any FDA approval of Roxane's ANDA No. 91-433 be no earlier than the date on which the '116 patent expires, and any other exclusivity to which Genzyme is or becomes entitled;

C. Preliminary and permanent injunctions enjoining Roxane, 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 Roxane's Proposed Generic Product until after the expiration of the '116 patent, and any other exclusivity to which Genzyme is or becomes entitled;

D. A Judgment declaring that, if Roxane engages in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Roxane's Proposed Generic Product prior to the expiration of the '116 patent, such action constitutes infringement, induced infringement and/or contributory infringement, of the '116 patent.

E. If Roxane engages in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of Roxane's Proposed Generic Product prior to the expiration of the '116 patent, and any other exclusivity to which Genzyme is or becomes entitled, a Judgment awarding damages to Genzyme resulting from such infringement;

F. Genzyme's costs and reasonable attorney fees in this action; and

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

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July 23, 2010