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

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| GENZYME CORPORATION<br>500 Kendall Street<br>Cambridge, Massachusetts 02142<br><br>Plaintiff,<br><br>v.<br><br>LUPIN LTD.<br>Laxmi Towers, B Wing<br>Bandra Kurla Complex<br>Bandra (East)<br>Mumbai, Maharashtra 400 051, India<br><br>SERVE ON:<br>Resident Agent<br>William A. Rakoczy, Esquire<br>Rakoczy Molino Mazzochi Siwik LLP<br>6 West Hubbard Street, Suite 500<br>Chicago, Illinois 60654<br><br>and<br><br>LUPIN PHARMACEUTICALS INC.<br>Harborplace Tower<br>111 South Calvert Street, 21st Floor<br>Baltimore, Maryland 21202<br><br>SERVE ON: Resident Agent<br>Vinita Gupta<br>Harborplace Tower<br>111 South Calvert Street, 21st Floor<br>Baltimore, Maryland 21202<br><br>Defendants. | ) | Civil Action No.: |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Genzyme Corporation, by and through its undersigned counsel, and for its Complaint herein against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., hereby alleges as follows:

## NATURE OF THE ACTION

1. This is an action for patent infringement.

## PARTIES

2. 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.

3. On information and belief, Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

4. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

5. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary, agent and alter ego of Lupin Ltd. Lupin Pharmaceuticals, Inc. and Lupin Ltd. herein are referred to collectively as "Lupin."

6. On information and belief, Lupin Pharmaceuticals, Inc. is the United States agent for Lupin Ltd. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

7. On information and belief, Lupin Pharmaceuticals, Inc. is the United States sales and marketing agent for Lupin Ltd., such that, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Lupin Ltd. manufactures and supplies the ANDA pharmaceutical product to Lupin Pharmaceuticals, Inc., which then sells and markets the product in Maryland and throughout the United States.

8. On information and belief, the acts of Lupin Pharmaceuticals, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, assistance of, and at least in part for the benefit of, Lupin Ltd.

## JURISDICTION AND VENUE

9. 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).

10. On information and belief, Lupin Ltd. manufactures bulk pharmaceuticals and pharmaceutical products that are sold by Lupin Pharmaceuticals, Inc. and others in Maryland and throughout the United States. On information and belief, Lupin Pharmaceuticals, Inc. markets and sells pharmaceuticals and pharmaceutical products and does business in Maryland and throughout the United States. On information and belief, Lupin engages and has engaged in continuous and systematic contacts with Maryland.

11. This Court has personal jurisdiction over Lupin by virtue of, *inter alia*, the abovementioned facts.

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

## CLAIM FOR RELIEF

13. Genzyme holds approved New Drug Application ("NDA") No. 022-127 for Renvela® tablets, 800 mg, which product contains the active ingredient sevelamer carbonate.

14. Renvela® tablets were approved by the FDA on October 9, 2007, and currently are indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

15. Genzyme owns United States Patent No. 5,496,545 ("'545 patent"), titled "Phosphate-Binding Polymers for Oral Administration." The '545 patent was duly and legally issued on March 5, 1996, and was originally assigned to GelTex Pharmaceuticals, Inc., which

was acquired by Genzyme in 2000. A true copy of the '545 patent is attached hereto as Exhibit A.

16. Genzyme owns United States Patent No. 5,667,775 ("'775 patent"), titled "Phosphate-Binding Polymers for Oral Administration." The '775 patent was duly and legally issued on September 16, 1997, and was originally assigned to GelTex Pharmaceuticals, Inc., which was acquired by Genzyme in 2000. A true copy of the '775 patent is attached hereto as Exhibit B.

17. Genzyme owns United States Patent No. 6,509,013 ("'013 patent"), titled "Method of Making Phosphate-Binding Polymers for Oral Administration." The '013 patent was duly and legally issued on January 21, 2003, and was originally assigned to GelTex Pharmaceuticals, Inc., which was acquired by Genzyme in 2000. A true copy of the '013 patent is attached hereto as Exhibit C.

18. Genzyme owns United States Patent No. 6,858,203 ("'203 patent"), titled "Method of Making Phosphate-Binding Polymers for Oral Administration." The '203 patent was duly and legally issued on February 22, 2005, and assigned to Genzyme. A true copy of the '203 patent is attached hereto as Exhibit D.

19. Genzyme owns United States Patent No. 7,014,846 ("'846 patent"), titled "Phosphate-Binding Polymers For Oral Administration." The '846 patent was duly and legally issued on March 21, 2006, and assigned to Genzyme. A true copy of the '846 patent is attached hereto as Exhibit E.

20. Genzyme owns United States Patent No. 7,459,151 ("'151 patent"), titled "Phosphate-Binding Polymers for Oral Administration." The '151 patent was duly and legally

issued on December 2, 2008, and assigned to Genzyme. A true copy of the '151 patent is attached hereto as Exhibit F.

**PATENT INFRINGEMENT BY LUPIN**

21. Genzyme repeats and realleges the allegations of paragraphs 1-20 as if fully set forth herein.

22. By a letter dated April 1, 2009 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) ("Lupin's Notice Letter"), Lupin informed Genzyme that it had submitted to the FDA ANDA No. 91-026 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 800 mg sevelamer carbonate tablets ("Lupin's Sevelamer Carbonate Tablets") prior to the expiration of the '545, '775, '013, '203, '846 and '151 patents.

23. Lupin's Notice Letter informed Genzyme that, as part of ANDA No. 91-026 , Lupin had filed a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), and opined that the '545, '775, '013, '203, '846 and '151 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of Lupin's Sevelamer Carbonate Tablets.

24. By submitting ANDA No. 91-026 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Lupin's Sevelamer Carbonate Tablets prior to the expiration of the '545, '775, '013, '203, '846 and '151 patents, Lupin has infringed those patents under 35 U.S.C. § 271(e)(2)(A).

25. On information and belief, the commercial manufacture, use, sale, offer for sale and/or importation of Lupin's Sevelamer Carbonate Tablets, if approved by the FDA, would

infringe one or more claims of the '545, '775, '013, '203, '846 and '151 patents under 35 U.S.C. § 271.

26. On information and belief, the offer for sale or sale of Lupin's Sevelamer Carbonate Tablets, if approved by the FDA, would induce infringement of, and/or be contributory infringement of, one or more claims of the '545, '775, '203, '846 and '151 patents under 35 U.S.C. § 271.

27. 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. 91-026 be a date which is not earlier than the expiration of the last of the'545, '775, '013, '203, '846 and '151 patents, and any other exclusivity to which Genzyme is or becomes entitled.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff respectfully requests the following relief:

A. A Judgment declaring that Lupin has infringed one or more claims of the '545, '775, '013, '203, '846 and '151 patents by filing its ANDA No. 91-026;

B. An Order that the effective date of any FDA approval of Lupin's ANDA No. 91-026 be no earlier than the date on which the last of the '545, '775, '013, '203, '846 and '151 patents expires, and any other exclusivity to which Genzyme is or becomes entitled;

C. Preliminary and permanent injunctions enjoining Lupin, 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 Lupin's Sevelamer Carbonate Tablets until after the expiration of the last of the '545, '775, '013,

'203, '846 and '151 patents, and any other exclusivity to which Genzyme is or becomes entitled;

D. The costs and reasonable attorney fees of Genzyme in this action; and

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

/s/ George E. Brown

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