IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
LUPIN LTD., *et al.*	)	Civil Action No.: 09-cv-00563-JFM
	)	
Defendants.	)	
	)	
	)	

FIRST AMENDED 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 above-mentioned 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. 021-179 for Renagel® tablets, 400 mg and 800 mg, which products contain the active ingredient sevelamer hydrochloride.

14. Renagel® tablets were approved by the FDA on July 12, 2000, 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. 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 D.

19. 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 was assigned to Genzyme. A true copy of the '151 patent is attached hereto as Exhibit E.

Patent Infringement By Lupin

20. Genzyme repeats and realleges the allegations of paragraphs 1-19 as if fully set forth herein.

21. By a letter dated January 20, 2009 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) ("Lupin's First Notice Letter"), Lupin informed Genzyme that it had submitted to the FDA ANDA No. 90-569 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 400 mg and 800 mg sevelamer hydrochloride tablets ("Lupin's Sevelamer Hydrochloride Tablets") prior to the expiration of the '545, '775, '013 and '846 patents.

22. By a letter dated April 7, 2009 purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) ("Lupin's Second Notice Letter"), Lupin informed Genzyme that it had submitted to the FDA ANDA No. 90-569 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 Lupin's Sevelamer Hydrochloride Tablets prior to the expiration of the '151 patent. Lupin's First Notice Letter and Lupin's Second Notice Letter herein are referred to collectively as "Lupin Notice Letters."

23. Lupin's Notice Letters informed Genzyme that, as part of ANDA No. 90-569, 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, '151 and '846 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 Hydrochloride Tablets.

24. By submitting ANDA No. 90-569 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 Hydrochloride Tablets prior to the expiration of the '545, '775, '013, '151 and '846 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 Hydrochloride Tablets, if approved by the FDA, would infringe one or more claims of the '545, '775, '013, '151 and '846 patents under 35 U.S.C. § 271.

26. On information and belief, the offer for sale or sale of Lupin's Sevelamer Hydrochloride Tablets, if approved by the FDA, would induce infringement of, and/or be

contributory infringement of, one or more claims of the '545, '775, '151 and '846 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. 90-569 be a date which is not earlier than the expiration of the last of the '545, '775, '013, '151 and '846 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, '151 and '846 patents by filing its ANDA No. 90-569;

B. An Order that the effective date of any FDA approval of Lupin's ANDA No. 90-569 be no earlier than the date on which the last of the '545, '775, '013, '151 and '846 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 Hydrochloride Tablets until after the expiration of the last of the '545, '775, '013, '151 and '846 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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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 22nd day of May, 2009, a copy of the foregoing First Amended Complaint for Patent Infringement, Exhibit E and Redlined Amended Complaint for Patent Infringement were sent via ECF filing to:

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Attorneys for Defendants
Lupin Ltd. and Lupin Pharmaceuticals, Inc.

/s/ George E. Brown