IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION, 500 Kendall Street Cambridge, Massachusetts 02142 Plaintiff, v. IMPAX LABORATORIES, INC. 30831 Huntwood Avenue Hayward, California 94544 SERVE ON: Resident Agent The Prentice-Hall Corporation System, Inc. 2711 Centerville Road, Suite 400 Wilmington, Delaware 19808 Defendant.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Genzyme Corporation, by and through its attorneys, and for its Complaint herein against Defendant Impax Laboratories, 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, Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544.

JURISDICTION AND VENUE

4. 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).

5. On information and belief, Impax formulates, manufactures, packages, markets, and sells branded and generic pharmaceuticals and pharmaceutical products to customers including wholesalers, drug store chains, distributors, and managed health care organizations in Maryland and throughout the United States.

6. On information and belief, Impax has negotiated and entered into a co-marketing agreement with Shire Pharmaceuticals, a Maryland-based corporation. On information and belief, Impax's largest selling branded pharmaceutical is manufactured in the state of Maryland. On information and belief, Impax has a 66 person national sales force that markets and sells drugs in the state of Maryland and throughout the United States.

7. On information and belief, Impax engages and has engaged in continuous and systematic contacts with the state of Maryland, and has purposely availed itself of the benefits and protections of the laws of the state of Maryland. This Court has personal jurisdiction over Impax by virtue of, *inter alia*, the above-mentioned facts.

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

CLAIM FOR RELIEF

9. 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.

10. Renagel® tablets were approved by the Food and Drug Administration (the "FDA") on July 12, 2000, and currently are indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

11. 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 A.

Patent Infringement By Impax

12. Genzyme repeats and realleges the allegations of paragraphs 1-11 as if fully set forth herein.

13. By a letter dated January 27, 2009 purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) ("Impax's Notice Letter"), Impax informed Genzyme that it had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 90-846 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 ("Impax's Sevelamer Hydrochloride Tablets") prior to the expiration of the '775 patent.

14. Impax's Notice Letter informed Genzyme that, as part of ANDA No. 90-846, Impax had filed a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and opined that the '775 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of Impax's Sevelamer Hydrochloride Tablets.

15. By submitting ANDA No. 90-846 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of

Impax's Sevelamer Hydrochloride Tablets prior to the expiration of the '775 patent, Impax has infringed that patent under 35 U.S.C. § 271(e)(2)(A).

16. On information and belief, the offer for sale or sale of Impax'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 '775 patent under 35 U.S.C. § 271.

17. 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. 90-846 be a date which is not earlier than the expiration of the '775 patent, 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 Impax has infringed one or more claims of the '775 patent by filing its ANDA No. 90-846;

B. An Order that the effective date of any FDA approval of Impax's ANDA No. 90-846 be no earlier than the date on which the '775 patent expires, and any other exclusivity to which Genzyme is or becomes entitled;

C. Preliminary and permanent injunctions enjoining Impax, 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 Impax's Sevelamer Hydrochloride Tablets until after the expiration of the '775 patent, 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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