

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

GENZYME CORPORATION
500 Kendall Street
Cambridge, Massachusetts 02142

Plaintiff,

v.

ENDO PHARMACEUTICALS INC.
100 Endo Boulevard
Chadds Ford, Pennsylvania 19317

SERVE ON:

Resident Agent
The Corporation Trust Incorporated
300 E. Lombard Street
Baltimore, Maryland 21202

Defendant.

Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Genzyme Corporation, by and through its attorneys, and for its Complaint herein against Defendant Endo 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, Endo Pharmaceuticals Inc. (“Endo”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

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, Endo engages and has engaged in systematic and continuous contacts with Maryland, and has purposely availed itself of the benefits and protections of the laws of the state of Maryland.

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

7. Furthermore, Endo counsel has consented to personal jurisdiction in the District of Maryland for purposes of this litigation.

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 (“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 Endo

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

13. By a letter dated August 18, 2009 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) (“Endo’s Notice Letter”), Endo informed Genzyme that it had amended its ANDA No. 90-112 to seek 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 (“Endo’s Sevelamer Hydrochloride Tablets”) prior to the expiration of the ‘775 patent.

14. Endo’s Notice Letter informed Genzyme that, as part of ANDA No. 90-112, Endo had filed a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”), 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 Endo’s Sevelamer Hydrochloride Tablets.

15. By amending ANDA No. 90-112 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Endo’s Sevelamer Hydrochloride Tablets prior to the expiration of ‘775 patent, Endo has infringed that patent under 35 U.S.C. § 271(e)(2)(A).

16. On information and belief, the commercial manufacture, use, sale, offer for sale and/or importation of Endo's Sevelamer Hydrochloride Tablets, if approved by the FDA, would infringe the '775 patent under 35 U.S.C. § 271.

17. On information and belief, the offer for sale or sale of Endo's Sevelamer Hydrochloride Tablets, if approved by the FDA, would induce infringement of, and/or be contributory infringement of, the '775 patent under 35 U.S.C. § 271.

18. 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. 90-112 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 Endo has infringed one or more claims of the '775 patent by filing its ANDA No. 90-112;

B. An Order that the effective date of any FDA approval of Endo's ANDA No. 90-112 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 Endo, 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 Endo'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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