

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

GENZYME CORPORATION	)	
500 Kendall Street	)	
Cambridge, Massachusetts 02142	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.:
	)	
SANDOZ, INC.	)	
506 Carnegie Center	)	
Princeton, New Jersey 08540	)	
	)	
SERVE ON:	)	
Resident Agent	)	
Corporate Service Company	)	
1560 Broadway	)	
Suite 2090	)	
Denver, Colorado 80202	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Genzyme Corporation, by and through its attorneys, and for its Complaint herein against Defendant Sandoz, 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, Sandoz, Inc. (“Sandoz”) is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

**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, Sandoz markets and sells pharmaceuticals and pharmaceutical products and does business in the State of Maryland and throughout the United States. On information and belief, Sandoz 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.

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

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

**CLAIM FOR RELIEF**

8. Genzyme holds approved New Drug Application (“NDA”) No. 022-127 for Renvela<sup>®</sup> tablets, 800 mg, which product contains the active ingredient sevelamer carbonate.

9. Renvela<sup>®</sup> tablets were approved by the Food and Drug Administration (the “FDA”) on October 9, 2007, and currently are indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

10. 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 SANDOZ**

11. Genzyme repeats and realleges the allegations of paragraphs 1-10 as if fully set forth herein.

12. By a letter dated May 14, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) (“Sandoz’s Notice Letter”), Sandoz informed Genzyme that it had submitted to the FDA Abbreviated New Drug Application (“ANDA”) No. 200959 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 (“Sandoz’s Sevelamer Carbonate Tablets”) prior to the expiration of the ‘775 patent.

13. Sandoz’s Notice Letter informed Genzyme that, as part of ANDA No. 200959, Sandoz 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 Sandoz’s Sevelamer Carbonate Tablets.

14. By submitting ANDA No. 200959 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz’s Sevelamer Carbonate Tablets prior to the expiration of the ‘775 patent, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

15. On information and belief, the offer for sale or sale of Sandoz’s Sevelamer Carbonate 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.

16. 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. 200959 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 Sandoz's filing of ANDA No. 200959 is an act of infringement under 35 U.S.C. § 271(e)(2)(A);
- B. A Judgment declaring that the offer for sale or sale of Sandoz's Sevelamer Carbonate 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;
- C. An Order that the effective date of any FDA approval of Sandoz's ANDA No. 200959 be no earlier than the date on which the '775 patent expires, and any other exclusivity to which Genzyme is or becomes entitled;
- D. Preliminary and permanent injunctions enjoining Sandoz, 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 Sandoz's Sevelamer Carbonate Tablets until after the expiration of the '775 patent, and any other exclusivity to which Genzyme is or becomes entitled;
- E. The costs and reasonable attorney fees of Genzyme in this action; and
- F. Such further and other relief as this Court may deem just and proper.

/s/ Geoffrey H. Genth  
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