

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

GENZYME CORPORATION
500 Kendall Street
Cambridge, Massachusetts 02142

Plaintiff,

v.

INVAGEN PHARMACEUTICALS, INC.
7 Oser Avenue
Hauppauge, New York 11788

Defendant.

CV 12 - 1164

Civil Action No.:

**WEINSTEIN, J.
GOLD, M.J.**

SUMMONS ISSUED

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U.S. DISTRICT COURT
EASTERN DISTRICT
OF NEW YORK

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Genzyme Corporation, by and through its attorneys, and for its Complaint herein against Defendant InvaGen 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, InvaGen Pharmaceuticals Inc. ("InvaGen") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.

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, InvaGen is a New York corporation with a principal place of business in Hauppauge, New York.

6. This Court has personal jurisdiction over InvaGen 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. 021-179 for Renagel[®] tablets, 400 and 800 mg, which products contain the active ingredient sevelamer hydrochloride.

9. 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.

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 INVAGEN

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

12. By a letter dated January 27, 2012 purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) (“InvaGen’s Purported Notice Letter”), InvaGen informed Genzyme that it had submitted to the FDA Abbreviated New Drug Application (“ANDA”) No. 203758 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 and 800 mg sevelamer hydrochloride tablets (“InvaGen’s Sevelamer Hydrochloride Tablets”) prior to the expiration of the ’775 patent.

13. InvaGen’s Purported Notice Letter informed Genzyme that, as part of ANDA No. 203758, InvaGen 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 InvaGen’s Sevelamer Hydrochloride Tablets.

14. InvaGen’s Purported Notice Letter does not state whether ANDA No. 203758 contained any bioavailability or bioequivalence data or information, as required by 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c).

15. InvaGen’s Purported Notice Letter does not contain the expiration dates of each patent for which it submitted a Paragraph IV Certification, as required by 21 C.F.R. § 314.95(c)(5).

16. InvaGen’s Purported Notice Letter does not contain a full and detailed explanation of the alleged factual and legal basis that the patents to which it submitted Paragraph IV Certifications are invalid and/or not infringed, as required by 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

17. By submitting ANDA No. 203758 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of InvaGen's Sevelamer Hydrochloride Tablets prior to the expiration of the '775 patent, InvaGen has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

18. On information and belief, the offer for sale or sale of InvaGen'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.

19. 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. 203758 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

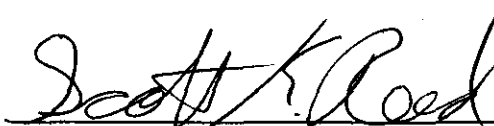
WHEREFORE, Plaintiff respectfully requests the following relief:

- A. A Judgment that InvaGen's filing of ANDA No. 203758 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 InvaGen'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;
- C. An Order that the effective date of any FDA approval of InvaGen's ANDA No. 203758 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 InvaGen, 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 InvaGen's Sevelamer Hydrochloride 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.

Dated: March 8, 2012



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