IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FRESENIUS MEDICAL CARE HOLDINGS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. _____
INVAGEN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Fresenius Medical Care Holdings, Inc. ("FMCH") for its Complaint against InvaGen Pharmaceuticals, Inc. ("InvaGen") alleges as follows:

THE PARTIES

1. FMCH is a New York corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

2. InvaGen is a New York corporation having its principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.

NATURE OF ACTION

3. This is a civil action for declaratory and injunctive relief against InvaGen for patent infringement under the Food and Drug and Patent Laws of the United States, arising from InvaGen's submission of Abbreviated New Drug Application ("ANDA") No. 20-3135 to the Food and Drug Administration ("FDA") for approval to market a generic copy of FMCH's PhosLo® GelCaps calcium acetate drug product.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Specifically, InvaGen included in ANDA No. 20-3135 a certification under Paragraph IV of Section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"), with respect to United States Patent No. 6,576,665 (the "'665 patent"). *See* 21 U.S.C. § 355(j)(2)(A)(vii). Under the Hatch-Waxman Act, the filing of a so-called "Paragraph IV certification" with respect to a patent constitutes an act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Accordingly, this case presents a question of federal law over which the Court has exclusive subject matter jurisdiction.

5. InvaGen is a drug company that is in the business of manufacturing, marketing and distributing prescription drug products throughout the United States, including in the Commonwealth of Massachusetts, including through exclusive contractual arrangements with other companies.

6. InvaGen filed ANDA No. 20-3135 and issued a certification under 21 U.S.C. § 355(j)(2)(A)(vii) – the acts which give rise to the instant litigation – with knowledge that FMCH was located in the Commonwealth and therefore would be injured by such actions in the Commonwealth.

7. This Court has personal jurisdiction over InvaGen, at least by virtue of the fact that it conducts business in the Commonwealth, and has engaged in substantial and continuing contacts with the Commonwealth.

8. Venue is proper in this jurisdiction under 28 U.S.C. §§ 1391 and 1400(b).

INFRINGEMENT OF FMCH'S '665 PATENT

9. FMCH is the assignee of the '665 patent and holder of New Drug Application ("NDA") No. 21-160, upon which ANDA No. 20-3135 is based. A copy of the '665 patent is attached as Exhibit A.

10. The submission of ANDA No. 20-3135 by InvaGen constitutes infringement of the '665 patent. InvaGen included within the ANDA a Paragraph IV certification to the effect that the '665 patent is invalid and/or would not be infringed by its proposed generic copy of FMCH's PhosLo® GelCaps calcium acetate drug product. The submission of this certification by InvaGen constitutes an act of infringement of one or more claims of the '665 patent under the Hatch-Waxman Act and the Patent Act. *See* 35 U.S.C. § 271(e)(2)(A).

11. By letter dated August 4, 2011, and received August 5, 2011, InvaGen provided notice to FMCH of the ANDA filing and Paragraph IV certification alleging that the '665 patent is invalid and/or would not be infringed by InvaGen's proposed generic calcium acetate drug product.

12. Upon information and belief, InvaGen intends to, and will, engage in the commercial manufacture, use and sale of its generic calcium acetate drug product promptly upon receiving FDA approval to do so.

13. Upon FDA approval of ANDA No. 20-3135, InvaGen will infringe one or more claims of the '665 patent by making, offering to sell, importing, or selling its proposed generic calcium acetate drug product in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

14. FMCH has the right and standing to enforce the '665 patent and bring this action.

15. InvaGen had notice of the '665 patent at the time of its infringement. Its infringement has been, and continues to be, willful and deliberate.

16. FMCH will be substantially and irreparably damaged and harmed if infringement by InvaGen is not enjoined. FMCH does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, FMCH respectfully requests the following relief:

(a) A judgment declaring that InvaGen has infringed the ’665 patent, and that the making, using, selling, offering to sell, or importing of its generic calcium acetate drug product will infringe the ’665 patent;

(b) A judgment providing that the effective date of any FDA approval for InvaGen to make, use or sell its generic calcium acetate drug product be no earlier than the date on which the ’665 patent expires;

(c) A judgment permanently enjoining InvaGen from making, using, selling, offering to sell, or importing its generic calcium acetate drug product until after the expiration of the ’665 patent;

(d) If InvaGen engages in the commercial manufacture, use, offer to sell, or sale of its generic calcium acetate drug product prior to the expiration of the ’665 patent, a judgment awarding FMCH damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(e) Attorney’s fees in this action pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as the Court may deem just and proper.

FRESENIUS MEDICAL CARE HOLDINGS, INC.

By its attorneys,

James M. Flaherty, Jr.

Stephen B. Deutsch, BBO # 122000
sdeutsch@foleyhoag.com
Sarah Cooleybeck, BBO # 631161
scooleybeck@foleyhoag.com
James M. Flaherty, Jr., BBO # 653643
jflaherty@foleyhoag.com
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210-2600
Telephone: 617 832 1000
Facsimile: 617 832 7000

Attorneys for Plaintiff
Fresenius Medical Care Holdings, Inc.

Dated: September 16, 2011