

NO SUMMONS ISSUED

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

FRESENIUS MEDICAL CARE)
HOLDINGS, INC.,)
)
Plaintiff,)
)
v.)
)
INVAGEN PHARMACEUTICALS, INC.,)
)
Defendants.)

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y.
★ SEP 16 2011 ★

Civil Action No. LONG ISLAND OFFICE

CV-11 4505

COMPLAINT FOR PATENT INFRINGEMENT

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

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. This Court has general jurisdiction over InvaGen by virtue of the fact that InvaGen is a New York corporation having its principal place of business in the State of New York. This Court thus has personal jurisdiction over InvaGen.

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

INFRINGEMENT OF FMCH’S ‘665 PATENT

7. 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.

8. 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).

9. 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.

10. 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.

11. 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.

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

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

14. 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.

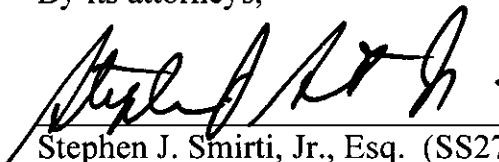
PRAYER FOR RELIEF

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,



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