IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FRESENIUS MEDICAL CARE HOLDINGS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. _____
NOSTRUM LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Fresenius Medical Care Holdings, Inc. ("FMCH") for its Complaint against Nostrum Laboratories, Inc. ("Nostrum") 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. Nostrum is a Missouri corporation having its principal place of business at 1800 North Topping Avenue, Kansas City, Missouri 55427.

NATURE OF ACTION

3. This is a civil action for declaratory and injunctive relief against Nostrum for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Nostrum's submission of Abbreviated New Drug Application ("ANDA") No. 20-3179 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, Nostrum included in ANDA No. 20-3179 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, Nostrum's 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 personal jurisdiction over Nostrum at least by virtue of the fact that Nostrum conducts business in the Commonwealth of Massachusetts, has availed itself of the rights and benefits of Massachusetts law, and has engaged in substantial and continuing contacts with the Commonwealth.

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

NOSTRUM'S 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 Nostrum's ANDA No. 20-3179 is based. A copy of the '665 patent is attached as Exhibit A.

8. Nostrum's submission of ANDA No. 20-3179 constitutes infringement of the '665 patent. Nostrum included within its ANDA a Paragraph IV certification to the effect that the '665 patent would not be infringed by Nostrum's proposed generic copy of FMCH's PhosLo® GelCaps calcium acetate drug product. Nostrum's submission of this certification

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 November 29, 2011, and received on December 2, 2011, Nostrum provided notice to FMCH of the ANDA filing and Paragraph IV certification alleging that the ’665 patent would not be infringed by Nostrum’s proposed generic calcium acetate drug product.

10. Upon information and belief, Nostrum 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 Nostrum’s ANDA No. 20-3179, Nostrum will infringe one or more claims of the ’665 patent by making, offering to sell, importing, or selling Nostrum’s 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. Nostrum had notice of the ’665 patent at the time of its infringement. Nostrum’s infringement has been, and continues to be, willful and deliberate.

14. FMCH will be substantially and irreparably damaged and harmed if Nostrum’s infringement 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 Nostrum has infringed the ’665 patent, and that Nostrum’s 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 Nostrum to make, use or sell Nostrum's generic calcium acetate drug product be no earlier than the date on which the '665 patent expires;

(c) A judgment permanently enjoining Nostrum 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 Nostrum 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.

Dated: January 13, 2012

Respectfully submitted,

/s/ James M. Flaherty, Jr.
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