IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Fresenius Medical Care Holdings, Inc. ("Fresenius") for its Complaint against Paddock Laboratories, Inc. ("Paddock") alleges as follows:

THE PARTIES

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

2. Paddock is a Minnesota corporation having its principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

NATURE OF ACTION

3. This is a civil action for declaratory and injunctive relief against Paddock for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Paddock's submission of Abbreviated New Drug Application ("ANDA") No. 91-312 to the Food and Drug Administration ("FDA") for approval to market a generic copy of Fresenius'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, Paddock included in ANDA No. 91-312 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, Paddock'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 Paddock at least by virtue of the fact that Paddock 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).

PADDOCK'S INFRINGEMENT OF FRESENIUS'S '665 PATENT

7. Fresenius is the assignee of the '665 patent and holder of New Drug Application ("NDA") No. 21-160, upon which Paddock's ANDA No. 91-312 is based. A copy of the '665 patent is attached as Exhibit A.

8. Paddock's submission of ANDA No. 91-312 constitutes infringement of the '665 patent. Paddock included within its ANDA a Paragraph IV certification to the effect that the '665 patent is invalid, unenforceable, or would not be infringed by Paddock's proposed generic copy of Fresenius's PhosLo® GelCaps calcium acetate drug product. Paddock'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 May 18, 2009, and received May 19, 2009, Paddock provided notice to Fresenius of its ANDA filing and Paragraph IV certification alleging that the '665 patent is invalid, unenforceable, or would not be infringed by Paddock's proposed generic calcium acetate drug product.

10. Upon information and belief, Paddock 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 Paddock's ANDA No. 91-312, Paddock will infringe one or more claims of the '665 patent by making, offering to sell, importing, or selling Paddock'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. Fresenius has the right and standing to enforce the '665 patent and bring this action.

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

14. Fresenius will be substantially and irreparably damaged and harmed if Paddock's infringement is not enjoined. Fresenius does not have an adequate remedy at law.

PADDOCK'S INFRINGEMENT OF FRESENIUS'S '455 PATENT

15. Upon information and belief, Paddock 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.

16. Paddock's intended commercial manufacture, use and sale of its generic calcium acetate drug product will constitute infringement under 35 U.S.C. § 271 of United States Patent No. 6,875,445 (the "'445 patent"), assigned to Fresenius, which has the right and standing to enforce the '445 patent. A copy of the '445 patent is attached as Exhibit B.

17. There is a justiciable controversy between the parties hereto as to infringement of the '445 patent. Paddock's submission of ANDA No. 91-312 to the FDA constitutes activity directed toward infringing and a refusal to change course in the face of acts sufficient to create reasonable apprehension of forthcoming suit. Accordingly, there is a sufficient case or controversy under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

18. Fresenius will be substantially and irreparably damaged and harmed if Paddock's infringement is not enjoined. Fresenius does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

(a) A judgment declaring that Paddock has infringed the '665 patent and the '445 patent, and that Paddock's making, using, selling, offering to sell, or importing of its generic calcium acetate drug product will infringe the '665 patent and '445 patent;

(b) A judgment providing that the effective date of any FDA approval for Paddock to make, use or sell Paddock's generic calcium acetate drug product be no earlier than the later of the dates on which the '665 patent and the '445 patent expire;

(c) A judgment permanently enjoining Paddock from making, using, selling, offering to sell, or importing its generic calcium acetate drug product until after the expiration of the '665 patent and the '445 patent;

(d) If Paddock 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 and the '445 patent, a judgment awarding Fresenius 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: July 2, 2009

Respectfully submitted,

/s/ Sarah Cooleybeck

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