IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FRESENIUS MEDICAL CARE HOLDINGS, INC. Plaintiff, v. LOTUS PHARMACEUTICAL CO., LTD. and ALVOGEN PINE BROOK, INC. Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Fresenius Medical Care Holdings, Inc. ("FMCHI") for its Complaint against Lotus Pharmaceutical Co., Ltd. ("Lotus") and Alvogen Pine Brook, Inc. ("Alvogen") alleges as follows:

THE PARTIES

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

2. Upon information and belief, Lotus is a Taiwanese company having its principal place of business at No. 30, Chenggong 1st Rd., Nantou City, Nantou County 540, Taiwan.

3. Upon information and belief, Alvogen is a Delaware corporation with a principal place of business at 10B Bloomfield Ave, Pine Brook, NJ 07058.

4. On information and belief, Lotus and Alvogen acted collaboratively in the preparation and submission of Abbreviated New Drug Application ("ANDA") No. 203298 to the Food and Drug Administration ("FDA"). On information and belief, Lotus appointed Alvogen as its authorized U.S. agent for purposes of making that ANDA submission, and Alvogen acted

as such. On information and belief, Alvogen's submission of ANDA No. 203298 to the FDA was done at the direction, under the control, and for the direct benefit of Lotus.

NATURE OF ACTION

5. This is a civil action for declaratory and injunctive relief against Lotus and Alvogen for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Alvogen's submission of ANDA No. 203298 to FDA for approval to market a generic copy of Fresenius's PhosLo® GelCaps calcium acetate drug product.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.§§ 1331, 1338(a), 2201 and 2202. Specifically, on information and belief, Lotus and Alvogen included in ANDA No. 203298 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 ("'665 patent"), a patent assigned to FMCHI. 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.

7. This Court has personal jurisdiction over both Lotus and Alvogen at least by virtue of the fact that Alvogen sent a letter dated October 22, 2014 as the U.S. agent for Lotus to FMCHI's corporate offices in Massachusetts notifying FMCHI of its Paragraph IV certification ("the Notice Letter"). Upon information and belief, Lotus and/or Alvogen conduct business in the Commonwealth of Massachusetts, have availed themselves of the rights and benefits of

Massachusetts law, and/or have engaged in substantial and continuing contacts with the Commonwealth.

8. Lotus and Alvogen, jointly, are in the business of making and selling drug products in the United States.

9. Lotus and Alvogen, jointly, participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of the ANDA at issue in this case.

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

COUNT I: INFRINGEMENT BY LOTUS AND ALVOGEN

11. FMCHI is the assignee of the ’665 patent and holder of New Drug Application (“NDA”) No. 21-160, upon which Lotus and Alvogen’s ANDA No. 203298 is based. A copy of the ’665 patent is attached as Exhibit A. The claims of the ’665 patent are valid and enforceable.

12. The FDA’s official publication of approved drugs (“the Orange Book”) lists the ’665 patent under PhosLo®.

13. By operation of law, Lotus and Alvogen’s submission constitutes infringement of the ’665 patent because Lotus and Alvogen included within their ANDA a Paragraph IV certification to the effect that the ’665 patent is invalid, unenforceable, and/or would not be infringed by their proposed generic copy of FMCHI’s PhosLo® GelCaps calcium acetate drug product. Their submission of this certification constitutes an act of infringement of one or more claims of the ’665 patent because the proposed generic drug is covered by one or more claims of the ’665 patent, and/or because its use is covered by the ’665 patent. *See* 35 U.S.C. § 271(e)(2)(A).

14. By their Notice Letter, Lotus and Alvogen notified FMCHI of the ANDA filing seeking approval to engage in the commercial manufacture, use, and sale of generic calcium acetate product before the expiration dates of the ’665 patent.

15. In the Notice Letter, Lotus and Alvogen notified FMCHI that their ANDA contained a Paragraph IV certification alleging that in their opinion no valid claim of the '665 patent would be infringed by their proposed generic calcium acetate drug product.

16. Upon information and belief, Lotus and Alvogen intend to, and will, engage in the commercial manufacture, use, and sale of their generic calcium acetate drug product promptly upon receiving FDA approval to do so.

17. Upon FDA approval of Lotus and Alvogen's ANDA No. 203298, Lotus and Alvogen will infringe one or more claims of the '665 patent by making, offering to sell, importing, or selling their 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.

18. FMCHI has the right and standing to enforce the '665 patent and bring this action.

19. Lotus and Alvogen had notice of the '665 patent at the time of their infringement. Lotus and Alvogen's infringement has been, and continues to be, willful and deliberate.

20. FMCHI will be substantially and irreparably damaged and harmed if Lotus and Alvogen's infringement is not enjoined. FMCHI does not have an adequate remedy at law.

21. This Complaint is being filed before the expiration of the forty-five days from the date FMCHI received the Notice Letter.

PRAYER FOR RELIEF

Accordingly, plaintiff respectfully requests the following relief:

a. A judgment declaring that defendants have infringed the '665 patent, and that Lotus and Alvogen's making, using, selling, offering to sell, or importing of their generic calcium acetate drug product will infringe the '665 patent;

b. A judgment providing that the effective date of any FDA approval for Lotus and Alvogen to make, use or sell their generic calcium acetate drug product be no earlier than the date on which the ’665 patent expires;

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

d. If defendants engage in the commercial manufacture, use, offer to sell, or sale of their generic calcium acetate drug product prior to the expiration of the ’665 patent, a judgment awarding FMCHI damages or other monetary relief, increased to treble the amount found or assessed, together with interest;

e. Attorney’s fees 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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Dated: December 5, 2014