IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LYNE LABORATORIES, INC., FRESENIUS USA MANUFACTURING, INC., and FRESENIUS MEDICAL CARE HOLDINGS, INC. Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Lyne Laboratories, Inc. ("Lyne"), Fresenius USA Manufacturing, Inc. (FUSA), and Fresenius Medical Care Holdings, Inc. ("FMCHI") (together, "plaintiffs") for their Complaint against Roxane Laboratories ("Roxane") allege as follows:

THE PARTIES

1. Lyne is a Massachusetts corporation having its principal place of business at 10 Burke Drive, Brockton, Massachusetts.

2. FUSA is a Delaware corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts.

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

4. On information and belief, Defendant Roxane is a Nevada corporation, having its principal place of business at 1809 Wilson Road, Columbus, OH 43228. On information and belief, Roxane is engaged in the manufacture and sale of pharmaceutical products throughout the United States including the Commonwealth of Massachusetts.

NATURE OF ACTION

5. This is a civil action for declaratory and injunctive relief against Roxane for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Roxane's submission of Abbreviated New Drug Application ("ANDA") No. 205027 to the Food and Drug Administration ("FDA") for approval to market a generic copy of FMCHI's Phoslyra® calcium acetate oral solution.

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, Roxane included in ANDA No. 205027 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 Nos. 8,591,938 B2 and 8,592,480 B2. *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.

7. This Court has personal jurisdiction over Roxane, at least by virtue of the fact that it conducts business within the Commonwealth of Massachusetts. Roxane markets and sells pharmaceutical products throughout the United States, including the Commonwealth of Massachusetts. Roxane has availed itself of the rights and benefits of Massachusetts law, and has engaged in substantial and continuing contacts with the Commonwealth.

8. Roxane participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of the ANDA at issue in this case.

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

INFRINGEMENT BY ROXANE

10. Lyne is the assignee of U.S. Patent No. 8,591,938 B2 (the ’938 patent) entitled “Liquid Compositions of Calcium Acetate,” which the U.S Patent and Trademark Office duly and legally issued on November 26, 2013. A true and correct copy of the ’938 patent is attached as Exhibit A. The claims of the ’938 patent are valid and enforceable. FUSA is an exclusive licensee of the ’938 patent.

11. Lyne is the assignee of U.S. Patent No. 8,592,480 B2 (the ’480 patent) entitled “Liquid Compositions of Calcium Acetate,” which the U.S Patent and Trademark Office duly and legally issued on November 26, 2013. A true and correct copy of the ’480 patent is attached as Exhibit B. The claims of the ’480 patent are valid and enforceable. FUSA is an exclusive licensee of the’480 patent.

12. FMCHI, d/b/a Fresenius Medical Care North America, is the holder of New Drug Application (“NDA”) No. 022581 for Phoslyra®, upon which ANDA No. 205027 is based.

13. The FDA’s official publication of approved drugs (“the Orange Book”) lists the ’938 and ’480 patents under Phoslyra®.

14. By operation of law, the submission of ANDA No. 205027 by Roxane constitutes infringement of the ’938 and ’480 patents, because Roxane included within the ANDA a Paragraph IV certification to the effect that the ’938 and ’480 patents are invalid, unenforceable, or would not be infringed by its proposed generic copy of FMCHI’s Phoslyra® calcium acetate oral solution. The submission of this certification by Roxane constitutes an act of infringement of one or more claims of the ’938 and ’480 patents under the Hatch-Waxman Act and the Patent Act, because the proposed generic drug is covered by one or more claims of the ‘938 and/or ‘480

patents, and/or because its use is covered by one or both of those patents. *See* 35 U.S.C. § 271(e)(2)(A).

15. Upon information and belief, Roxane intends to, and will, engage in the commercial manufacture, use and sale of its generic calcium acetate oral solution promptly upon receiving FDA approval to do so.

16. By letter sent to FMCHI and Lyne ("the Notice Letter"), Roxane notified FMCHI and Lyne of the ANDA filing seeking approval to engage in the commercial manufacture, use, and sale of generic calcium acetate oral solution before the expiration dates of the '938 and '480 patents.

17. In the Notice Letter, Roxane notified FMCHI and Lyne that its ANDA contained a Paragraph IV certification alleging that in its opinion the '938 and '480 patents are invalid and/or unenforceable and/or would not be infringed by Roxane's proposed commercial manufacture, use or sale of its generic calcium acetate oral solution.

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

Count I (Infringement of the '938 Patent)

19. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth herein.

20. Roxane's submission of ANDA No. 205027 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic calcium acetate oral solution prior to the expiration of the '938 patent constitutes infringement of one or more claims of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

21. Upon FDA approval of ANDA No. 205027, Roxane will further infringe one or more claims of the '938 patent by making, offering to sell, importing, or selling its proposed

generic calcium acetate oral solution in the United States, and importing such solution into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

22. Roxane had notice of the ’938 patent prior to the filing at the time of its infringement. Its infringement has been, and continues to be, willful and deliberate.

23. Plaintiffs will be substantially and irreparably damaged and harmed if infringement of the ’938 patent by Roxane is not enjoined. Plaintiffs do not have an adequate remedy at law.

Count II (Infringement of the ’480 Patent)

24. Each of the preceding paragraphs 1 to 31 is incorporated as if fully set forth herein.

25. Roxane’s submission of ANDA No. 205027 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic calcium acetate oral solution prior to the expiration of the ’480 patent constitutes infringement of one or more claims of the ’480 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon FDA approval of ANDA No. 205027, Roxane will further infringe one or more claims of the ’480 patent by making, offering to sell, importing, or selling its proposed generic calcium acetate oral solution in the United States, and importing such solution into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

27. Roxane had notice of the ’480 patent prior to the filing at the time of its infringement. Its infringement has been, and continues to be, willful and deliberate.

28. Plaintiffs will be substantially and irreparably damaged and harmed if infringement of the ’480 patent by Roxane is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Accordingly, plaintiffs respectfully request the following relief:

a. A judgment declaring that Roxane has infringed the ’938 and ’480 patents, and that the making, using, selling, offering to sell, or importing of its generic calcium acetate oral solution will infringe the ’938 patent and ’480 patents;

b. A judgment providing that the effective date of any FDA approval for Roxane to make, use or sell its generic calcium acetate oral solution be no earlier than the later of the dates on which the ’938 and ’480 patents expire;

c. A judgment permanently enjoining Roxane from making, using, selling, offering to sell, or importing its generic calcium acetate oral solution until after the expiration of the ’938 and ’480 patents;

d. If Roxane engages in the commercial manufacture, use, offer to sell, or sale of its generic calcium acetate oral solution prior to the expiration of the’938 or ’480 patents, a judgment awarding plaintiffs damages or other monetary relief, 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.

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Dated: February 27, 2014