JUDGE GARDEPHE 09 CV 3987

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

SEPRACOR INC., Plaintiff, v. ALPHAPHARM PTY. LTD. and MYLAN INC., Defendants.	Civil Action No. _____

Plaintiff Sepracor Inc. ("Sepracor"), for its Complaint for Patent Infringement against Defendants Alphapharm Pty. Ltd. ("Alphapharm") and Mylan Inc. ("Mylan"), (collectively, "Defendants"), hereby alleges as follows:

PARTIES

1. Plaintiff Sepracor is a Delaware corporation having its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

2. Upon information and belief, Defendant Alphapharm is an Australian corporation having a place of business at Chase Building 2, 1 Wentworth Park Road, Glebe NSW 2037, Australia. Upon information and belief, Defendant Alphapharm derives substantial revenue from interstate and/or international commerce. Upon information and belief, Defendant Alphapharm has received FDA approval to sell drug products throughout the United States, including into this judicial district. Upon information and belief, Defendant Alphapharm conducts business in this judicial district. Upon information and belief, Defendant Alphapharm manufactures, sells and/or markets generic drugs for sale and use throughout the United States,

including in this judicial district. Upon information and belief, Defendant Alphapharm is a wholly owned subsidiary of Mylan Australia Pty., Ltd., which is a wholly owned subsidiary of Defendant Mylan. Upon information and belief, Defendant Alphapharm has previously consented to personal jurisdiction in this Court.

3. Upon information and belief, Defendant Mylan is a corporation organized under the laws of Pennsylvania having a place of business at 1500 Corporate Drive, Canonsburg, PA 15317. Upon information and belief, Defendant Mylan, itself and through Defendant Alphapharm, manufactures generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Defendant Mylan has a place of business at 405 Lexington Ave, New York, NY 10174 and does business in this judicial district.

NATURE OF THE ACTION

4. This is a civil action for the infringement of United States Patent No. 6,864,257 ("the '257 patent"), United States Patent No. 6,319,926 ("the '926 patent"), United States Patent No. 6,444,673 ("the '673 patent") and United States Patent No. 7,381,724 ("the '724 patent"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*

STATEMENT REGARDING PRIOR-FILED SUIT

5. This is not the first-filed action involving Sepracor and Defendants, the patents in suit, and the counts of patent infringement set forth below. Sepracor previously filed, on March 20, 2009, an identical action seeking to enjoin Alphapharm and Mylan (along with nine other groups of defendants) from infringing the '257, '926, '673, and '724 patents in the District of New Jersey, and that action has been assigned Civil Action No. 2:09-cv-01302 ("the New Jersey action"). Defendants Alphapharm and Mylan have previously consented to personal jurisdiction in the District of New Jersey and in the New Jersey action Mylan has now consented

to personal jurisdiction. Judicial economy would be promoted, and Plaintiff Sepracor's choice of forum respected, if the claims related to Sepracor's action for infringement of the '257, '926, '673, and '724 patents against Alphapharm and Mylan are addressed in the New Jersey action.

6. Sepracor filed this action as a protective measure in order to avoid waiving any rights under 21 U.S.C. and 35 U.S.C. Both before and after the New Jersey action was filed, Alphapharm and Mylan had refused to give consent to personal jurisdiction in New Jersey, but Mylan has now consented to personal jurisdiction in its Answer in the New Jersey action. Sepracor expects that personal jurisdiction will be maintained over Alphapharm (despite its denial) in the District of New Jersey and that the action will proceed in that forum against all defendants, in which case this second action would be unnecessary and voluntarily dismissed.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court as to each Defendant pursuant to 28 U.S.C. §§ 1391(b), (c) and/or (d) and 1400(b).

8. This Court has personal jurisdiction over each of Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, aided, abetted, contributed to and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Sepracor. This Court has personal jurisdiction over each of Defendants for the additional reasons set forth above and below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. This Court has personal jurisdiction over Defendant Alphapharm.

10. This Court has personal jurisdiction over Defendant Mylan.

THE PATENTS

11. On March 8, 2005, the '257 patent, titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the '257 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '257 patent is attached hereto as Exhibit A.

12. On September 3, 2002, the '673 patent, titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the '673 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '673 patent is attached hereto as Exhibit B.

13. On November 20, 2001, the '926 patent, titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the '926 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '926 patent is attached hereto as Exhibit C.

14. On June 3, 2008, the '724 patent, titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing Same," was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the '724 patent and the sole owner of the right to sue and to

recover for any infringement of that patent. A copy of the '724 patent is attached hereto as Exhibit D.

ACTS GIVING RISE TO THIS ACTION

INFRINGEMENT OF THE '257 PATENT

COUNT I – INFRINGEMENT OF THE '257 PATENT BY DEFENDANTS

15. Sepracor re-alleges paragraphs 1-14 as if fully set forth herein.

16. Upon information and belief, Defendants submitted ANDA No. 91-151 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(i)). ANDA No. 91-151 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '257 patent. ANDA No. 91-151 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '257 patent.

17. ANDA No. 91-151 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '257 patent are invalid. Sepracor received written notification of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations on March 10, 2009.

18. Defendants' submission to the FDA of ANDA No. 91-151, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '257 patent under 35 U.S.C. § 271(e)(2)(A).

19. Alphapharm and Mylan are jointly and severally liable for any infringement of the '257 patent. This is because, upon information and belief, Alphapharm and Mylan actively and knowingly caused to be submitted, assisted with, participated in, contributed

to and/or directed the submission of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

20. Defendants' active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '257 patent under 35 U.S.C. § 271(e)(2)(A). Defendants' commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '257 patent under 35 U.S.C. § 271(a), (b) and/or (c).

21. Upon information and belief, Defendants were aware of the existence of the '257 patent and were aware that filing of the ANDA and certification with respect to the '257 patent constituted an act of infringement of that patent.

22. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

23. Sepracor will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

INFRINGEMENT OF THE '673 PATENT

COUNT II – INFRINGEMENT OF THE '673 PATENT BY DEFENDANTS

24. Sepracor re-alleges paragraphs 1-23 as if fully set forth herein.

25. Upon information and belief, Defendants submitted ANDA No. 91-151 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(i)). ANDA No. 91-151 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient

eszopiclone prior to the expiration of the '673 patent. ANDA No. 91-151 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '673 patent.

26. ANDA No. 91-151 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '673 patent are invalid. Sepracor received written notification of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations on March 10, 2009.

27. Defendants' submission to the FDA of ANDA No. 91-151, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '673 patent under 35 U.S.C. § 271(e)(2)(A).

28. Alphapharm and Mylan are jointly and severally liable for any infringement of the '673 patent. This is because, upon information and belief, Alphapharm and Mylan actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

29. Defendants' active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '673 patent under 35 U.S.C. § 271(e)(2)(A). Defendants' commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '673 patent under 35 U.S.C. § 271(a), (b) and/or (c).

30. Upon information and belief, Defendants were aware of the existence of the '673 patent and were aware that filing of the ANDA and certification with respect to the '673 patent constituted an act of infringement of that patent.

31. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

32. Sepracor will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

INFRINGEMENT OF THE '926 PATENT

COUNT III– INFRINGEMENT OF THE '926 PATENT BY DEFENDANTS

33. Sepracor re-alleges paragraphs 1-32 as if fully set forth herein.

34. Upon information and belief, Defendants submitted ANDA No. 91-151 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(i)). ANDA No. 91-151 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '926 patent. ANDA No. 91-151 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '926 patent.

35. ANDA No. 91-151 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '926 patent are invalid. Sepracor received written notification of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations on March 10, 2009.

36. Defendants' submission to the FDA of ANDA No. 91-151, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '926 patent under 35 U.S.C. § 271(e)(2)(A).

37. Alphapharm and Mylan are jointly and severally liable for any infringement of the '926 patent. This is because, upon information and belief, Alphapharm and Mylan actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-151 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

38. Defendants' active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '926 patent under 35 U.S.C. § 271(e)(2)(A). Defendants' commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '926 patent under 35 U.S.C. § 271(a), (b) and/or (c).

39. Upon information and belief, Defendants were aware of the existence of the '926 patent and were aware that filing of the ANDA and certification with respect to the '926 patent constituted an act of infringement of that patent.

40. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

41. Sepracor will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

INFRINGEMENT OF THE '724 PATENT

COUNT IV – INFRINGEMENT OF THE '724 PATENT BY DEFENDANTS

42. Sepracor re-alleges paragraphs 1-41 as if fully set forth herein.

43. Upon information and belief, Defendants submitted ANDA No. 91-151 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(i)). ANDA No. 91-151 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '724 patent. ANDA No. 91-151 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '724 patent.

44. ANDA No. 91-151 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are invalid. Sepracor received written notification of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations on March 10, 2009.

45. Defendants' submission to the FDA of ANDA No. 91-151, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

46. Alphapharm and Mylan are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Alphapharm and Mylan actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-151 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

47. Defendants' active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-151 and the

§ 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A). Defendants' commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to any such conduct, would further infringe the '724 patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. Upon information and belief, Defendants were aware of the existence of the '724 patent and were aware that filing of the ANDA and certification with respect to the '724 patent constituted an act of infringement of that patent.

49. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

50. Sepracor will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Sepracor requests that:

A. A Judgment be entered declaring that Defendants Alphapharm and Mylan have infringed the '257, '673, '926, and '724 patents by submitting the aforesaid ANDA;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of Defendants' ANDA identified in this Complaint be a date that is not earlier than the expiration dates of the '257 patent, '673 patent, '926 patent and '724 patent, or any later expiration of exclusivity for the '257 patent, '673 patent, '926 patent or '724 patent to which Plaintiff is or becomes entitled;

C. An Order be issued that Defendants Alphapharm and Mylan, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, importing or selling the proposed generic versions of Sepracor's Lunesta® brand products identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '257, '673, '926 and '724 patents, prior to the expiration of the '257, '673, '926 and '724 patents, including any extensions to which Plaintiff is or becomes entitled;

D. Sepracor be awarded monetary relief if any Defendant commercially manufactures, uses, offers for sale, or sells a generic version of Sepracor's Lunesta® brand product, or any other product that infringes or induces or contributes to the infringement of the '257, '673, '926 or '724 patent, within the United States prior to the

expiration of those patents, including any extensions, and that any such monetary relief be awarded to Sepracor with prejudgment interest;

E. A Judgment be entered against each Defendant that this case is exceptional and that Sepracor is entitled to its reasonable attorney fees, costs and expenses that it incurs prosecuting this action as to that Defendant; and

F. Sepracor be awarded such other and further relief as this Court deems just and proper.

Dated: April 22, 2009

Respectfully submitted,

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