IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC. and ORION CORPORATION, Plaintiffs, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Hospira, Inc. ("Hospira") and Orion Corporation ("Orion") (collectively, "Plaintiffs"), for their Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Defendants"), hereby allege as follows:

PARTIES

1. Hospira is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

2. Orion is a corporation organized under the laws of Finland with its principal place of business at Orionintie lA, FI-02200 Espoo, Finland.

3. On information and belief, Aurobindo Pharma Ltd. ("Aurobindo Ltd.") is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad 500 038, Andhra Pradesh, India.

4. On information and belief, Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware, having

its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent No. 6,716,867 (the "'867 patent"). The '867 patent is attached as Exhibit A.

6. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to manufacture, use and/or sell dexmedetomidine hydrochloride injection 100 mcg base/ml prior to the expiration of the '867 patent, which is assigned to and/or exclusively licensed by Plaintiffs and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") as covering PRECEDEX™.

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Aurobindo USA is subject to personal jurisdiction in this District by virtue of its incorporation under the laws of the State of Delaware. In addition, Aurobindo USA has engaged in substantial and continuing contacts with the State of Delaware by virtue of, *inter alia*, its conduct of business in this District. On information and belief, Aurobindo USA is in the business of, *inter alia*, formulating, developing, manufacturing, marketing, and selling pharmaceutical drugs for the U.S. market, including in this District.

10. Aurobindo Ltd. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, through various directly- or indirectly-

owned operating subsidiaries, including its wholly-owned subsidiary Aurobindo USA. On information and belief, Aurobindo Ltd. and Aurobindo USA work in concert for purposes of developing, formulating, manufacturing, marketing, and selling drug products throughout the United States, including Delaware, and Delaware is a likely destination of the products. On information and belief, Aurobindo Ltd. has purposely availed itself of the rights and benefits of the laws of the State of Delaware, and has engaged in substantial and continuous contacts with the State of Delaware.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

12. The ‘867 patent, entitled “Use of Dexmedetomidine for ICU Sedation,” was duly and legally issued by the USPTO on April 6, 2004. Hospira and Orion are co-assignees of the ‘867 patent and share ownership of the ‘867 patent.

13. Hospira is the exclusive licensee in the United States of Orion’s ownership interest in the ‘867 patent.

14. Hospira is the holder of New Drug Application (“NDA”) No. 21-038, for dexmedetomidine hydrochloride injection 100 mcg base/ml, sold in the United States under the trademark PRECEDEX™. The United States Food and Drug Administration (“FDA”) approved NDA No. 21-038 on December 17, 1999.

15. The ‘867 patent is duly listed in the Orange Book as covering PRECEDEX™. The claims of the ‘867 patent cover various methods of using PRECEDEX™.

ACTS GIVING RISE TO THIS ACTION

16. On information and belief, Defendants reviewed the '867 patent and certain commercial and economic information regarding Hospira's PRECEDEX™ and decided to file an ANDA seeking approval to market a generic version of PRECEDEX™.

17. On information and belief, Defendants collaborated in the research, development, preparation, and filing of ANDA No. 205867 for generic dexmedetomidine hydrochloride injection 100 mcg base/ml.

18. Plaintiffs received a letter dated March 5, 2014, from Aurobindo Ltd. notifying them that Defendants had filed ANDA No. 205867 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use and/or sell a generic version of Hospira's PRECEDEX™ prior to the expiry of the '867 patent.

19. The stated purpose of Defendants' letter was to notify Plaintiffs that ANDA No. 205867 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '867 patent are invalid or will not be infringed by the commercial manufacture, use, and/or sale of Defendants' product. Attached to the March 5, 2014, letter was a "Detailed Statement" of the factual and legal basis for Defendants' Paragraph IV Certification.

20. On information or belief, Defendants were aware of the '867 patent when they filed ANDA No. 205867 with a Paragraph IV Certification.

21. Plaintiffs received the March 5, 2014, letter on March 7, 2014. Plaintiffs commenced this action within 45 days of receipt of the letter.

FIRST CLAIM FOR RELIEF

(Infringement)

22. Paragraphs 1 through 21 are incorporated herein as set forth above.

23. Defendants submitted ANDA No. 205867 with a Paragraph IV Certification to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, and/or sale of dexmedetomidine hydrochloride injection 100 mcg base/ml prior to the expiration of the '867 patent. By submitting this ANDA, Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2).

24. Moreover, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the proposed generic dexmedetomidine hydrochloride product described in ANDA 205867 would infringe the '867 patent under 35 U.S.C. § 271(a), (b), and/or (c).

25. Defendants' actions and conduct will encourage direct infringement of the '867 patent by others.

26. Defendants' "Detailed Statement" asserts only the alleged invalidity of the '867 patent as the basis for their belief that the '867 patent will not be infringed by the product described in ANDA 205867.

27. Defendants were aware of the existence of the '867 patent prior to the filing of ANDA No. 205867, and took such action knowing it would constitute infringement of the '867 patent.

28. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '867 patent.

SECOND CLAIM FOR RELIEF

(Inducement by Aurobindo USA of Infringement of the '867 patent)

29. Paragraphs 1 through 28 are incorporated herein as set forth above.

30. On information and belief, Aurobindo USA knowingly encouraged, directed, and actively induced Aurobindo Ltd. to prepare and file ANDA No. 205867 with a Paragraph IV Certification.

31. Aurobindo USA has knowingly and actively induced Aurobindo Ltd. to, through the conduct alleged above, infringe and continue to infringe one or more claims of the '867 patent.

32. By reason of Aurobindo USA's inducement of Aurobindo Ltd.'s infringement of the '867 patent, Aurobindo USA has caused and continues to cause irreparable harm to Plaintiffs.

33. On information and belief, Aurobindo USA's inducement of Aurobindo Ltd.'s infringement of the '867 patent will continue unless enjoined by this Court.

34. Plaintiffs have no adequate remedy at law for Aurobindo USA's inducement of Aurobindo Ltd.'s infringement of the '867 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. An order decreeing that Defendants' submission to the FDA of ANDA No. 205867 with a Paragraph IV Certification was an act of infringement;

B. An order decreeing that Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 205867 prior to the expiration of the '867 patent, including any regulatory extensions, will infringe the '867 patent;

C. An order pursuant to 21 U.S.C. § 355(c)(3)(C) that the effective date of any approval of ANDA No. 205867 shall be no earlier than thirty months after the date on which Hospira received Defendants' March 5, 2014, letter, and, if the court rules that the product proposed in ANDA No. 205867 infringes the '867 patent, shall be no earlier than the expiration date of the '867 patent, including any applicable extensions;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4) restraining and enjoining Defendants, their officers, agents, attorneys, and employees and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the generic dexmedetomidine hydrochloride product described in ANDA No. 205867, or any other ANDA not colorably different from ANDA No. 205867, until the expiration of the '867 patent, including any applicable extensions;

E. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: April 18, 2014

Respectfully Submitted,

By: */s/ R. Eric Hutz*

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