IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HOSPIRA, INC. and ORION CORPORATION, Plaintiffs, v. AKORN, INC., Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Hospira, Inc. ("Hospira") and Orion Corporation ("Orion") (collectively, "Plaintiffs"), for their Complaint against Defendant Akorn, Inc. ("Akorn"), hereby allege as follows:

PARTIES

1. Hospira is a Illinois 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, Akorn is a corporation organized and existing under the laws of the State of Louisiana, having a principal place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

NATURE OF THE ACTION

4. 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.

5. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and arises out of Akorn's 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

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

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

8. Akorn is subject to personal jurisdiction in this District by virtue of having its principal place of business in this District. In addition, Akorn has engaged in substantial and continuous contacts with the State of Illinois by virtue of, *inter alia*, its conduct of business in this District. On information and belief, Akorn develops, formulates, manufactures, markets, and sells drug products throughout the United States, including Illinois, and Illinois is a likely destination of the products.

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

THE PATENT-IN-SUIT

10. 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.

11. Hospira is the exclusive licensee in the United States of Orion's ownership interest in the '867 patent.

12. 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.

13. 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

14. On information and belief, Akorn 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™.

15. Plaintiffs received a letter dated June 20, 2012, from Akorn notifying them that Akorn had filed ANDA No. 202585 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to manufacture, use, and/or sell a generic version of Hospira's PRECEDEX™ prior to the expiry of the '867 patent.

16. The stated purpose of Akorn's letter was to notify Plaintiffs that ANDA No. 202585 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, sale, offer for sale, and/or importation into the United States of Akorn's product. Included in the June 20, 2012, letter was a "Detailed Statement" of the factual and legal basis for Akorn's Paragraph IV Certification.

17. On information or belief, Akorn was aware of the '867 patent when it filed ANDA No. 202585 with a Paragraph IV Certification.

CLAIM FOR RELIEF

(Infringement)

18. Paragraphs 1 through 17 are incorporated herein as set forth above.

19. Akorn submitted ANDA No. 202585 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, Akorn committed an act of infringement under 35 U.S.C. § 271(e)(2).

20. Moreover, Akorn's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the proposed generic dexmedetomidine hydrochloride product described in ANDA 202585 would infringe the '867 patent under 35 U.S.C. § 271(a), (b), and/or (c).

21. Akorn's actions and conduct will encourage direct infringement of the '867 patent by others.

22. Akorn's "Detailed Statement" asserts only the alleged invalidity of the '867 patent as the basis for its belief that the '867 patent will not be infringed by the product described in ANDA 202585.

23. Akorn was aware of the existence of the '867 patent prior to the filing of ANDA No. 202585, and took such action knowing it would constitute infringement of the '867 patent.

24. Plaintiffs will be irreparably harmed if Akorn is not enjoined from infringing the '867 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. An order decreeing that Akorn's submission to the FDA of ANDA No. 202585 with a Paragraph IV Certification was an act of infringement;

B. An order decreeing that Akorn's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 202585 prior to the expiration of the '867 patent, including any regulatory extensions, will infringe the '867 patent;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 202585 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 Akorn, its officers, agents, attorneys, and employees and those acting in privity or concert with it, 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. 202585, or any other ANDA not colorably different from ANDA No. 202585, 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,

HOSPIRA, INC. and ORION CORPORATION.

By: */s/ Bradford P. Lyerla*

Bradford P. Lyerla
Sara T. Horton
Yusuf Esat
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654-3456
Telephone: 312 222-9350
Facsimile: 312 527-0484
blyerla@jenner.com
shorton@jenner.com
yesat@jenner.com

Attorneys for Plaintiffs Hospira, Inc. and Orion Corp.