IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

HOSPIRA, INC. and ORION CORPORATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
Caraco Pharmaceutical Laboratories, Ltd.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Hospira, Inc. ("Hospira") and Orion Corporation ("Orion") (collectively "Plaintiffs") for their Complaint against Defendant Caraco Pharmaceutical Laboratories, Ltd. ("Defendant") 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 1A, FI-02200 Espoo, Finland.

3. On information and belief, Defendant is a corporation organized and existing under the laws of the State of Michigan with a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

4. On information and belief, Defendant owns and operates a packing facility at 24700 Crestview Court, Farmington Hills, Michigan 48335.

5. On information and belief, Defendant manufactures, distributes, markets, and sells generic drug products throughout the United States, including the State of Michigan.

NATURE OF THE ACTION

6. 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.

7. This action is based upon the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises out of Defendant's filing of Abbreviated New Drug Application ("ANDA") No. 20-2126, seeking approval to sell dexmedetomidine hydrochloride injection 100 mcg base/ml prior to the expiration of a patent 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

8. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

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

10. On information and belief, Defendant is subject to personal jurisdiction in this District by virtue of, *inter alia*, the location of its principal place of business in the State of Michigan, its incorporation in the State of Michigan, its business activity within Michigan, its purposeful availment of the rights and benefits of Michigan law, including its previous assertions that it is subject to personal jurisdiction in Michigan, *see, e.g.*, *Schering Corp. v. Zydus Pharms. USA, Inc. et al.*, No. 06-cv-04715 (D.N.J. Jan. 18, 2007), and its substantial and continuous contacts with the State of Michigan.

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

PRECEDEX™ PATENTS

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. U.S. Patent No. 4,910,214 (the "'214 patent"), U.S. Patent No. 5,344,840 (the "'840 patent"), and the '867 patent are duly listed in the Orange Book as covering PRECEDEX™. The claims of the '214, '840, and '867 patents cover, *inter alia*, PRECEDEX™, including formulations of PRECEDEX™ and various methods of using PRECEDEX™.

14. The '214 patent, entitled "Optical Isomer of an Imidazole Derivative Medetomidine as an Alpha-2-Receptor Agonist," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on March 20, 1990. On information and belief, Defendant does not challenge the validity of, or assert non-infringement of, the '214 patent.

15. The '840 patent, entitled "4-Substituted Imidazole Derivatives Useful in Perioperative Care," was duly and legally issued by the USPTO on September 6, 1994. On information and belief, Defendant does not challenge the validity of, or assert non-infringement of, the '840 patent.

16. On information and belief, Defendant does not seek approval to market a generic version of Hospira's PRECEDEX™ prior to the expiry of the '214 and '840 patents.

17. 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.

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

ACTS GIVING RISE TO THIS ACTION

19. On information and belief, Defendant 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™.

20. On information and belief, Defendant undertook research, development, and preparation for the filing of ANDA No. 20-2126 for generic dexmedetomidine hydrochloride injection 100 mcg base/ml.

21. On information and belief, Defendant submitted ANDA No. 20-2126 to the FDA to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic dexmedetomidine hydrochloride injection 100 mcg base/ml.

22. On October 4, 2010, Plaintiffs received a letter dated October 1, 2010 from Defendant notifying them that Defendant had filed ANDA No. 20-2126 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of Hospira's PRECEDEX™ prior to the expiry of the '867 patent.

23. The stated purpose of Defendant's October 1, 2010 letter was to notify Plaintiffs that Defendant's ANDA included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of generic dexmedetomidine hydrochloride injection 100 mcg base/ml before the expiration of the '867 patent.

24. Attached to the October 1, 2010 letter was a "Detailed Statement" of the factual and legal bases for Defendant's opinion that the '867 patent was invalid for obviousness.

25. On information or belief, Defendant was necessarily aware of the '867 patent when Defendant filed ANDA No. 20-2126 with a Paragraph IV Certification.

26. Plaintiffs received the October 1, 2010 letter on October 4, 2010. Plaintiffs commenced this action within 45 days of the date they received Defendant's notice of the Paragraph IV Certification filing with the FDA.

CLAIM FOR RELIEF

(Infringement of the '867 Patent by Defendant)

27. Paragraphs 1 through 26 are incorporated herein as set forth above.

28. Defendant submitted ANDA No. 20-2126 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, sale, offer for sale, and/or importation into the United States of dexmedetomidine hydrochloride injection 100 mcg base/ml prior to the expiration of the '867 patent. By submitting this ANDA, Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2).

29. Moreover, Defendant's actions and conduct, including Defendant'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 20-2126, as well as its proposed instructions for use of such product, would contribute to the infringement of, and/or induce others to infringe, the '867 patent under 35 U.S.C. § 271.

30. Defendant was aware of the existence of the '867 patent prior to the filing of ANDA No. 20-2126 but took such action knowing it would constitute infringement of the '867 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. An order decreeing that Defendant has infringed the '867 patent;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 20-2126 be no earlier than the expiration date of the '867 patent, including any applicable extensions;

C. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4) restraining and enjoining Defendant, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, offer for sale within the United States, and/or importation into the United States of the generic dexmedetomidine hydrochloride product described in ANDA No. 20-2126 or any other ANDA not colorably different from ANDA No. 20-2126 until the expiration of the '867 patent, including any applicable extensions;

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

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

Dated: November 12, 2010

Respectfully Submitted,

DICKINSON WRIGHT PLLC
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Hospira Inc. and Orion Corporation

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