IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC. and ORION CORPORATION	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
SANDOZ INTERNATIONAL GmbH and SANDOZ, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Hospira, Inc. ("Hospira") and Orion Corporation ("Orion") (collectively "Plaintiffs") for their Complaint against Defendants Sandoz International GmbH and Sandoz, Inc. (collectively "Defendants" or "Sandoz") 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 Sandoz International GmbH is a German corporation with a principal place of business at Industriestrasse 25, Holzkirchen 83607, Germany.

4. On information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado with places of business at 2555 West Midway Boulevard, Broomfield, Colorado, 80020 and at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

5. On information and belief, Defendant Sandoz, Inc. is the United States arm of Defendant Sandoz International GmbH.

6. On information and belief, Defendant Sandoz International GmbH conducts its United States business operations, in part, through Defendant Sandoz, Inc.

7. On information and belief, Defendant Sandoz, Inc. is a subsidiary of Defendant Sandoz International GmbH, and the two companies have at least one common officer and/or director.

8. On information and belief, Defendant Sandoz, Inc. is controlled and/or dominated by Defendant Sandoz International GmbH.

9. On information and belief, the acts of Defendant Sandoz, Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation and awareness of, and at least in part for the benefit of, Defendant Sandoz International GmbH.

NATURE OF THE ACTION

10. This is a civil action for infringement of U.S. Patent Nos. 4,910,214 (the "'214 patent") and 6,716,867 (the "'867 patent"). The '214 and '867 patents are attached as Exhibits A and B, respectively.

11. 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 sell dexmedetomidine hydrochloride injection 100 mcg base/ml prior to the expiration of patents 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

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

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

14. Defendant Sandoz, Inc. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial and continuing contacts with the state of Delaware.

15. Defendant Sandoz International GmbH is subject to personal jurisdiction in this District by virtue of, *inter alia*, its direction and control of the business of Sandoz, Inc., through which it conducts business in this District, purposefully avails itself of the rights and benefits of Delaware law, and has substantial and continuing contacts with the state of Delaware.

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d), and 1400(b).

THE PATENTS-IN-SUIT

17. 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. Orion is the current assignee of the '214 patent and owns the entire right, title, and interest in the '214 patent.

18. Hospira is the exclusive licensee in the United States of the '214 patent.

19. 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.

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

21. 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.

22. The '214 and '867 patents (collectively "the patents-in-suit") are duly listed in the Orange Book as covering PRECEDEX™. The claims of the '214 and '867 patents cover, *inter alia*, PRECEDEX™, including formulations of PRECEDEX™ and various methods of using PRECEDEX™.

ACTS GIVING RISE TO THIS ACTION

23. On information and belief, Defendants reviewed the patents-in-suit 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™.

24. On information and belief, Defendants undertook research, development, preparation, and filing of ANDA No. 91-465 for generic dexmedetomidine hydrochloride injection 100 mcg base/ml.

25. On information and belief Defendant Sandoz, Inc. submitted ANDA No. 91-465 to the FDA to seek approval to engage in the commercial manufacture, use, sale, offer for

sale, and importation into the United States of generic dexmedetomidine hydrochloride injection 100 mcg base/ml.

26. Plaintiffs received a letter dated July 27, 2009 from Defendant Sandoz, Inc. notifying them that Defendant Sandoz, Inc. had filed ANDA No. 91-465 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 patents-in-suit.

27. The stated purpose of Defendant Sandoz, Inc.'s July 27, 2009 letter was to notify Plaintiffs that Defendant Sandoz, Inc.'s ANDA included a certification under 21 U.S.C. §355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the patents-in-suit would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' product.

28. Attached to the July 27, 2009 letter was a "Detailed Statement" of the factual and legal basis for Defendant Sandoz, Inc.'s opinion that the patents-in-suit would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Sandoz, Inc. product. The Detailed Statement alleged that the patents-in-suit were invalid and therefore not infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' product.

29. On information and belief, Defendant Sandoz International GmbH knowingly encouraged, directed, and actively induced Defendant Sandoz, Inc. to file ANDA No. 91-465 with a Paragraph IV Certification.

30. On information or belief, Defendants were necessarily aware of the patents-in-suit when Defendant Sandoz, Inc. filed ANDA No. 91-465 with a Paragraph IV Certification.

31. Hospira received the July 27, 2009 letter on July 28, 2009. Orion received the July 27, 2009 letter on July 29, 2009. Plaintiffs commenced this action within 45 days of the date they received Defendant Sandoz, Inc.'s notice of the Paragraph IV Certification filing with the FDA.

FIRST CLAIM FOR RELIEF

(Infringement of the '214 Patent by Defendants)

32. Paragraphs 1 through 31 are incorporated herein as set forth above.

33. Defendant Sandoz, Inc. submitted ANDA No. 91-465 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 '214 patent. By submitting this ANDA, Defendant Sandoz, Inc. has committed an act of infringement under 35 U.S.C. § 271(e)(2).

34. 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 91-465 would infringe the '214 patent under 35 U.S.C. § 271(a), (b) and/or (c).

35. Defendants were aware of the existence of the '214 patent prior to the filing of ANDA No. 91-465, but took such action knowing it would constitute infringement of the '214 patent.

36. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '214 patent.

SECOND CLAIM FOR RELIEF

(Infringement of the '867 Patent by Defendants)

37. Paragraphs 1 through 36 are incorporated herein as set forth above.

38. Defendant Sandoz, Inc. submitted ANDA No. 91-465 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 Sandoz, Inc. has committed an act of infringement under 35 U.S.C. § 271(e)(2).

39. 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 91-465 would infringe the '867 patent under 35 U.S.C. § 271(a), (b) and/or (c).

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

41. Defendants were aware of the existence of the '867 patent prior to the filing of ANDA No. 91-465, but took such action knowing it would constitute infringement of the '867 patent.

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

THIRD CLAIM FOR RELIEF

(Inducement of Infringement of the Patents-in-Suit by Sandoz International GmbH)

43. Paragraphs 1 through 42 are incorporated herein as set forth above.

44. Through the conduct alleged above, Defendant Sandoz International GmbH has knowingly and actively induced Defendant Sandoz, Inc. to infringe and continue to infringe one or more claims of the patents-in-suit.

45. By reason of Defendant Sandoz International GmbH's inducement of Defendant Sandoz, Inc.'s direct infringement of the patents-in-suit, Defendant Sandoz International GmbH has caused and continues to cause irreparable harm to Plaintiffs.

46. On information and belief, Defendant Sandoz International GmbH's inducement of Defendant Sandoz Inc.'s direct infringement of patents-in-suit will continue unless enjoined by this Court.

47. Plaintiffs have no adequate remedy at law for Defendant Sandoz International GmbH's inducement of Defendant Sandoz Inc.'s direct infringement of patents-in-suit.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. An order decreeing that Defendants have infringed the patents-in-suit;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 91-465 be no earlier than the expiration date of the last to expire of the patents-in-suit including any applicable extensions;

C. 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 within the United States, and/or importation into the United States of the generic dexmedetomidine hydrochloride product described in ANDA No. 91-465 or any other ANDA

not colorably different from ANDA No. 91-465 until the expiration of the last to expire of the patents-in-suit 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.

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
D. Fon Muttamara-Walker (#4646)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, Delaware 19801
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@pottersanderson.com
fmuttamara-walker@potteranderson.com

Attorneys for Plaintiffs Hospira, Inc. and Orion Corporation

OF COUNSEL:

Thomas J. Meloro
Colman B. Ragan
Heather M. Schneider
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, N.Y. 10019-6099
Tel: (212) 728-8000

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