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

HOSPIRA, INC., Plaintiff, v. FRESENIUS KABI USA, LLC Defendant.	Civil Action No. _____

COMPLAINT

Plaintiff Hospira, Inc. ("Hospira"), for its Complaint against Defendant Fresenius Kabi USA, LLC ("Defendant"), hereby alleges 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. On information and belief, Defendant is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, IL 60047.

NATURE OF THE ACTION

3. This is a civil action for infringement of U.S. Patent Nos. 8,242,158 (the "'158 patent") (Ex. A); 8,338,470 (the "'470 patent") (Ex. B); 8,455,527 (the "'527 patent") (Ex. C); and 8,648,106 (the "'106 patent") (Ex. D) (collectively, the "Patents-in-suit").

4. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and arises out of the Defendant's filing of Abbreviated New Drug Application ("ANDA") No. 208129 seeking approval to market dexmedetomidine hydrochloride products

("Proposed Fresenius Dexmedetomidine Products") prior to the expiration of the Patents-in-suit, which are assigned to Hospira and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") as covering PRECEDEX™.

JURISDICTION AND VENUE

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

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

7. Defendant is subject to personal jurisdiction in this District by virtue of, *inter alia*, its residence and conduct of business in this District. On information and belief, Defendant's principal place of business is located in this District at Three Corporate Drive, Lake Zurich, IL 60047. On information and belief, among Defendant's operations located in this District are its Corporate Headquarters, a Science, Production and Technology Center, a Manufacturing facility, and a Distribution Center. On information and belief, Defendant develops, formulates, manufactures, markets, and sells drug products throughout the United States, including Illinois, and Illinois is a likely destination of Defendant's products. On information and belief, Defendant has purposely availed itself of the rights and benefits of the laws of the State of Illinois, and has engaged in substantial and continuous contacts with the State of Illinois. Defendant has a registered agent for service in the State of Illinois. Defendant has also previously filed Counterclaims in this District. *See, e.g.*, *Mylan Pharma Acquisition Ltd. v. Fresenius Kabi USA, LLC*, No. 1:15-cv-06700.

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

THE PATENTS-IN-SUIT

9. The '158 patent, entitled "Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on August 14, 2012. Hospira is the assignee and owner of the '158 patent.

10. The '470 patent, entitled "Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on December 25, 2012. Hospira is the assignee and owner of the '470 patent.

11. The '527 patent, entitled "Methods of Treatment Using a Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on June 4, 2013. Hospira is the assignee and owner of the '527 patent.

12. The '106 patent, entitled "Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on February 11, 2014. Hospira is the assignee and owner of the '106 patent.

13. The Patents-in-suit are duly listed in the Orange Book as covering PRECEDEX™. The claims of the Patents-in-suit cover various presentations of PRECEDEX™ and methods of using PRECEDEX™.

14. Hospira is the holder of New Drug Application ("NDA") No. 21-038 for dexmedetomidine hydrochloride injection, sold in the United States under the trademark PRECEDEX™. The United States Food and Drug Administration ("FDA") originally approved NDA No. 21-038 on December 17, 1999. On March 13, 2013 and November 14, 2014, the FDA approved amendments to Hospira's NDA No. 21-038 for a premix formulation of PRECEDEX™.

ACTS GIVING RISE TO THIS ACTION

15. On information and belief, Defendant 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 the Proposed Fresenius Dexmedetomidine Products.

16. On December 7, 2015, Hospira received a letter dated December 4, 2015, from Defendant ("the Notice Letter"), notifying Hospira that Defendant had filed ANDA No. 208129 with the FDA under 21 U.S.C. § 355(j) (*i.e.*, section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA")), seeking approval to market the Proposed Fresenius Dexmedetomidine Products prior to the expiry of the Patents-in-suit.

17. The stated purpose of the Notice Letter was to notify Hospira that ANDA No. 208129 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '158 patent, the '470 patent, the '527 patent, and the '106 patent are invalid and/or that certain claims will not be infringed by Defendant.

18. Included in the Notice Letter was a "detailed statement" of the alleged factual and legal basis for Defendant's Paragraph IV Certification. With the exception of certain claims of the '527 patent, the sole basis set forth in the detailed statement for Defendant's Paragraph IV Certification is alleged invalidity.

19. As described in the Notice Letter, the Proposed Fresenius Dexmedetomidine Products are Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection, 4 mcg/mL, in 20 mL, 50 mL, and 100 mL vials.

20. On information and belief, Defendant was aware of the Patents-in-suit when it filed ANDA No. 208129 with a Paragraph IV Certification.

21. Hospira received the Notice Letter on December 7, 2015. Hospira commenced this action within 45 days of receipt of the Notice Letter.

COUNT I FOR INFRINGEMENT OF PATENT NO. 8,242,158

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

23. Defendant submitted ANDA No. 208129 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 the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '158 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

24. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products described in ANDA No. 208129 would infringe the '158 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Fresenius Dexmedetomidine Products—which, according to the Notice Letter, contain 4 mcg/mL dexmedetomidine hydrochloride and 0.9% sodium chloride in 20 mL, 50 mL, and 100 mL vials—meet each limitation of at least one claim of the '158 patent. The Notice Letter does not allege non-infringement of any claim of the '158 patent.

25. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '158 patent by others.

26. On information and belief, Defendant was aware of the existence of the '158 patent prior to the filing of ANDA No. 208129, and took such action knowing it would constitute infringement of the '158 patent.

27. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '158 patent.

COUNT II FOR INFRINGEMENT OF PATENT NO. 8,338,470

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

29. Defendant submitted ANDA No. 208129 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 the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '470 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

30. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products described in ANDA No. 208129 would infringe the '470 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Fresenius Dexmedetomidine Products meet each limitation of at least one claim of the '470 patent. The Notice Letter does not allege non-infringement of any claim of the '470 patent.

31. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '470 patent by others.

32. On information and belief, Defendant was aware of the existence of the '470 patent prior to the filing of ANDA No. 208129, and took such action knowing it would constitute infringement of the '470 patent.

33. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '470 patent.

COUNT III FOR INFRINGEMENT OF PATENT NO. 8,455,527

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

35. Defendant submitted ANDA No. 208129 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 the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '527 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

36. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products described in ANDA No. 208129 would infringe the '527 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Fresenius Dexmedetomidine Products meet each limitation of at least one claim of the '527 patent. With respect to most claims of the '527 patent, the Notice Letter does not allege non-infringement.

37. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '527 patent by others.

38. On information and belief, Defendant was aware of the existence of the '527 patent prior to the filing of ANDA No. 208129, and took such action knowing it would constitute infringement of the '527 patent.

39. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '527 patent.

COUNT IV FOR INFRINGEMENT OF PATENT NO. 8,648,106

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

41. Defendant submitted ANDA No. 208129 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 the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '106 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

42. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products described in ANDA No. 208129 would infringe the '106 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Fresenius Dexmedetomidine Products meet each limitation of at least one claim of the '106 patent. The Notice Letter does not allege non-infringement of any claim of the '106 patent.

43. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '106 patent by others.

44. On information and belief, Defendant was aware of the existence of the '106 patent prior to the filing of ANDA No. 208129, and took such action knowing it would constitute infringement of the '106 patent.

45. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '106 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. An order decreeing that the submission to the FDA of ANDA No. 208129 with a Paragraph IV Certification was an act of infringement by Defendant;

B. An order decreeing that Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius

Dexmedetomidine Products prior to the expiration of the '158 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '158 patent;

C. An order decreeing that Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '470 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '470 patent;

D. An order decreeing that Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '527 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '527 patent;

E. An order decreeing that Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine Products prior to the expiration of the '106 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '106 patent;

F. An order pursuant to 21 U.S.C. § 355(c)(3)(C) that the effective date of any approval of ANDA No. 208129 shall be no earlier than thirty months after the date on which Hospira received the Notice Letter, and, if the Court rules that the Proposed Fresenius Dexmedetomidine Products infringe any Patent-in-suit, shall be no earlier than the expiration date of the infringed Patent(s)-in-suit, including any applicable extensions;

G. 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 it, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Fresenius Dexmedetomidine

Products described in ANDA No. 208129, or any other ANDA not colorably different from ANDA No. 208129, until the expiration of the Patents-in-suit, including any applicable extensions;

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

I. Costs and expenses in this action; and

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

Dated: January 15, 2016

Respectfully Submitted,

HOSPIRA, INC.

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 Plaintiff Hospira, Inc.