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. 17-cv-7903

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 No. 9,616,049 (the "'049 patent") (Ex. A) (the "Patent-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 Patent-in-suit,

which is 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. Moreover, there is existing litigation between Defendant and Hospira related to patents covering certain dexmedetomidine hydrochloride products in this District.

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

THE PATENT-IN-SUIT

9. The ’049 patent, entitled “Dexmedetomidine Premix Formulation,” was duly and legally issued by the USPTO on April 11, 2017. Hospira is the assignee and owner of the ’049 patent.

10. The Patent-in-suit is duly listed in the Orange Book as covering PRECEDEX™. The claims of the Patent-in-suit cover various presentations of PRECEDEX™.

11. 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

12. On October 10, 2017, Hospira received a letter dated October 9, 2017, from Defendant (“the Notice Letter”), notifying Hospira that Defendant had previously 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 Patent-in-suit.

13. 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 ’049 patent are invalid.

14. Included in the Notice Letter was a description of the Proposed Fresenius Dexmedetomidine Products as well as a “detailed statement” of the alleged factual and legal

basis for Defendant's Paragraph IV Certification. The sole basis set forth in the detailed statement for Defendant's Paragraph IV Certification is alleged invalidity.

15. The Proposed Fresenius Dexmedetomidine Products meet each limitation of at least one claim of the '049 patent.

16. On information and belief, Defendant was aware of Hospira's patents related to dexmedetomidine products when it filed ANDA No. 208129. Defendant was further aware of the '049 patent when it submitted its updated Paragraph IV Certification.

COUNT I FOR INFRINGEMENT OF PATENT NO. 9,616,049

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

18. 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 '049 patent. Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

19. 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 '049 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Notice Letter does not allege non-infringement of any claim of the '049 patent. The Proposed Fresenius Dexmedetomidine Products, according to the Notice Letter, meet each limitation of at least one claim of the '049 patent.

20. 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 '049 patent by others.

21. Defendant was aware of the existence of the Hospira patents related to dexmedetomidine products prior to the filing of ANDA No. 208129, and provided Hospira with Defendant's Paragraph IV Certification knowing it would constitute infringement of the '049 patent.

22. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '049 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 '049 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '049 patent;

C. An order pursuant to 35 U.S.C. 271(e)(4) that the effective date of any approval of ANDA No. 208129 shall be no earlier than the expiration date of the Patent-in-suit, including any applicable extensions;

D. 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 Patent-in-suit, 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: November 1, 2017

Respectfully Submitted,

HOSPIRA, INC.

By: /s/ *Bradford P. Lyerla*

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