

Exhibit 2

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

Hon. Thomas M. Durkin

**FRESENIUS KABI'S ANSWER TO COMPLAINT,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Fresenius Kabi USA, LLC, by and through its counsel, answers the Complaint of Plaintiff Hospira, Inc. as follows.

PARTIES

1. Hospira is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

ANSWER: On information and belief, Fresenius Kabi admits the allegations in paragraph 1.

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.

ANSWER: Admitted.

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").

ANSWER: Fresenius Kabi admits that Hospira's Complaint is for patent infringement of U.S. Patent No. 9,616,049 ("the '049 patent"), a copy of which appears to be attached to the

Complaint as Exhibit A, but denies that Hospira is entitled to relief and denies any remaining allegations.

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™.

ANSWER: Fresenius Kabi admits that Hospira's Complaint arises under the Patent Laws of the United States based on Fresenius Kabi's lawful filing within the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to commercially market its ANDA product which references the NDA for PRECEDEX™.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 5 contains conclusions of law for which no response is required. To the extent that a response is required, Fresenius Kabi admits that Hospira's Complaint arises under the Patent Laws of the United States.

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

ANSWER: Paragraph 6 contains conclusions of law for which no response is required. To the extent that a response is required, Fresenius Kabi admits that this court has subject matter jurisdiction for this matter.

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.

ANSWER: Paragraph 7 contains conclusions of law for which no response is required.

To the extent that a response is required, Fresenius Kabi does not object to personal jurisdiction for this particular action. Fresenius Kabi admits that it has a principal place of business located at Three Corporate Drive, Lake Zurich, IL 60047. Fresenius Kabi admits that there is existing litigation between Fresenius Kabi and Hospira related to patents listed in the Orange Book by Hospira as covering the same product at issue in this litigation. Fresenius Kabi denies the remaining allegations in paragraph 7.

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

ANSWER: Paragraph 8 contains conclusions of law for which no response is required.

To the extent that a response is required, Fresenius Kabi does not contest venue for this particular action.

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.

ANSWER: Fresenius Kabi admits that on its face, the '049 patent is titled "Dexmedetomidine Premix Formulation," and that the issue date of the '158 patent is shown as April 11, 2017—after Fresenius Kabi submitted its ANDA No. 208129 to the FDA. Fresenius Kabi admits that the assignee on the face of the patent is HOSPIRA, INC. Fresenius Kabi denies all remaining allegations in paragraph 9.

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™.

ANSWER: Fresenius Kabi admits that the '049 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluation" ("the Orange Book"), with respect to dexmedetomidine hydrochloride injection. Fresenius Kabi denies all remaining allegations in paragraph 10.

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™.

ANSWER: Fresenius Kabi admits that, according to the Orange Book, Hospira, Inc. is listed as the current applicant for NDA No. 21-138, which was approved December 17, 1999. Fresenius Kabi lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11, and therefore denies them.

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.

ANSWER: Fresenius Kabi admits that on or about October 9, 2017 it sent a letter notifying Hospira that Fresenius Kabi had previously submitted ANDA No. 208129 with the FDA, seeking approval to market a dexmedetomidine hydrochloride injection product before expiry of the '049 patent. Fresenius Kabi denies all remaining allegations of paragraph 12.

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.

ANSWER: Fresenius Kabi admits that the stated purpose of the Notice Letter was to notify that ANDA No. 208129 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV)

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