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

HOSPIRA, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	
	:	C.A. No. 1:16-cv-00651
FRESENIUS KABI USA, LLC	:	
	:	The Hon. Rebecca R. Pallmeyer, U.S.D.J.
Defendant.	:	
	:	
_____	:	

ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Fresenius Kabi USA, LLC ("Fresenius Kabi") by and through its counsel, answers the Complaint of Plaintiff Hospira, Inc., ("Plaintiff") 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: Fresenius Kabi admits the allegations in paragraph 2.

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").

ANSWER: Fresenius Kabi admits that Plaintiff's Complaint is for patent infringement of United States Patent Nos. 8,242,158 ("the '158 patent," a copy of which appears to be

attached to the Complaint as Exhibit A); 8,338,470 ("the '470 patent," a copy of which appears to be attached to the Complaint as Exhibit B); 8,455,527 ("the '527 patent," a copy of which appears to be attached to the Complaint as Exhibit C); and 8,648,106 ("the '106 patent," a copy of which appears to be attached to the Complaint as Exhibit D), but denies that Plaintiff 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 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™.

ANSWER: Fresenius Kabi admits that Plaintiff's Complaint arises under the Patent Laws of the United States based on Fresenius Kabi's filing with the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to commercially market a generic version of PRECEDEX™, but denies that Plaintiff is entitled to relief and denies any remaining allegations.

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 Plaintiff'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, Manufacturing facility, and 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.

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 it filed claims or counterclaims in *Mylan Pharma Acquisition Ltd. v. Fresenius Kabi USA, LLC*, No. 1:15-cv-06700. 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 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.

ANSWER: Fresenius Kabi admits that on its face the '158 patent is titled "Dexmedetomidine Premix Formulation," and that the issue date of the '158 patent is shown as August 14, 2012. Fresenius Kabi denies all remaining allegations in paragraph 9.

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.

ANSWER: Fresenius Kabi admits that on its face the '470 patent is titled "Dexmedetomidine Premix Formulation," and that the issue date of the '470 patent is shown as December 25, 2012. Fresenius Kabi denies all remaining allegations in paragraph 10.

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.

ANSWER: Fresenius Kabi admits that on its face the '527 patent is titled "Methods of Treatment Using a Dexmedetomidine Premix Formulation," and that the issue date of the '527 patent is shown as June 4, 2013. Fresenius Kabi denies all remaining allegations in paragraph 11.

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.

ANSWER: Fresenius Kabi admits that on its face the '106 patent is titled "Dexmedetomidine Premix Formulation," and that the issue date of the '106 patent is shown as February 11, 2014. Fresenius Kabi denies all remaining allegations in paragraph 12.

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

ANSWER: Fresenius Kabi admits that the '106 patent, the '527 patent, the '470 patent, and the '158 patent are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to dexmedetomidine hydrochloride injection. Fresenius Kabi denies all remaining allegations in paragraph 13.

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™.

ANSWER: Fresenius Kabi admits that, according to the Orange Book, Hospira, Inc. is listed as the applicant for NDA No. 21-038, 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 14, and therefore denies them.

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.

ANSWER: Fresenius Kabi admits that it reviewed the '106 patent, the '527 patent, the '470 patent, and the '158 patent and submitted an ANDA to the FDA seeking approval to market a dexmedetomidine hydrochloride injection product. Fresenius Kabi denies the remaining allegations in paragraph 15.

16. On December 17, 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.

ANSWER: Fresenius Kabi admits that, on December 4, 2015, it sent a letter notifying Plaintiff that Fresenius Kabi submitted ANDA No. 208129 with the FDA, seeking approval to market a dexmedetomidine hydrochloride injection product prior to the expiration of the '106 patent, the '527 patent, the '470 patent, and the '158 patent. Fresenius Kabi denies all remaining allegations in paragraph 16.

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)9a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '158 patent, the '470 patent,

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.