IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXTER HEALTHCARE CORPORATION, Plaintiff, v. HOSPIRA, INC. and ORION CORP., Defendants.	)))))))))	C.A. No. 18-303-RGA **PUBLIC VERSION**

PLAINTIFF'S ANSWER TO DEFENDANTS' COUNTERCLAIM

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Plaintiff Baxter Healthcare Corporation ("Baxter"), through counsel, hereby answers the March 20, 2018 Counterclaim of Defendants Hospira, Inc. ("Hospira") and Orion Corp. ("Orion") (collectively, "Defendants").

Parties, Jurisdiction, and Venue

1. Baxter has filed a Complaint against Defendants seeking, among other things, a judgment that Baxter does not infringe U.S. Patent No. 6,716,867 ("the '867 Patent"). An immediate and justiciable controversy exists between Baxter and Defendants regarding the infringement and validity of the '867 patent.

RESPONSE: Baxter admits that it filed a Complaint against Defendants seeking a judgment of noninfringement regarding U.S. Patent No. 6,716,867 ("the '867 Patent"), and that an immediate and justiciable controversy exists between Baxter and Defendants regarding infringement of the '867 Patent. Baxter denies that a controversy exists regarding the validity of the '867 Patent.

2. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Federal Food, Drug and Cosmetic Act.

RESPONSE: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Baxter admits that Defendants' Counterclaim purports to arise under the laws cited in this paragraph.

3. Subject matter jurisdiction in this Court is proper under, among other things, 28 U.S.C. §§ 1331 and 1338.

RESPONSE: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, admitted.

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

RESPONSE: Admitted, on information and belief.

5. Orion is a corporation organized under the laws of Finland, with its principal place of business at Orionintie IA, FI-02200 Espoo, Finland.

RESPONSE: Admitted, on information and belief.

6. On information and belief, Baxter Healthcare Corporation is a corporation incorporated in Delaware with its principal place of business at One Baxter Parkway, Deerfield, IL 60015.

RESPONSE: Admitted.

7. This Court has personal jurisdiction over Baxter because, among other things, Baxter is incorporated in this District and Baxter has submitted to the jurisdiction of this Court by filing its Complaint with this Court.

RESPONSE: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Baxter admits that this Court has personal jurisdiction for purposes of this action only.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400 because, among other things, Baxter is incorporated in this District and selected this venue by filing its Complaint with this Court.

RESPONSE: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Baxter admits that venue is proper for purposes of this action only.

The ‘867 Patent

9. The ‘867 patent, entitled “Use of Dexmedetomidine for ICU Sedation,” was duly and legally issued by the USPTO on April 6, 2004.

RESPONSE: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Baxter admits that the ’867 Patent is entitled “Use of Dexmedetomidine for ICU Sedation,” and that the ’867 Patent was issued by the U.S. Patent and Trademark Office on April 6, 2004. All other allegations not expressly admitted are denied.

10. Hospira and Orion are co-assignees of the ‘867 patent and share ownership of the patent.

RESPONSE: Baxter admits that, according to the records at the U.S. Patent and Trademark Office, Hospira and Orion are co-assignees of the ’867 Patent. Baxter lacks information sufficient

to admit or deny the remaining allegations in this paragraph and, therefore, denies all allegations not expressly admitted.

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.

RESPONSE: Admitted, upon information and belief.

12. The '867 patent is duly listed in the Orange Book as covering PRECEDEX®. The claims of the '867 patent cover various methods of using PRECEDEX®.

RESPONSE: This paragraph contains conclusions of law and a characterization of the '867 Patent, which speaks for itself, to which no response is required. To the extent a response is required, Baxter admits that the '867 Patent is listed in the Orange Book by Hospira as covering PRECEDEX® with a current use code only for "intensive care unit sedation, including sedation of non-intubated patients prior to and/or during surgical and other procedures." **Attach. A**, Declaration of Jon Clark, M.S. ¶ 44 [hereinafter Clark Decl.]. All other allegations not expressly admitted are denied.

Count I: Infringement Of The '867 Patent

13. Defendants re-allege herein the foregoing paragraphs of their Counterclaim.

RESPONSE: Baxter incorporates herein its responses to the foregoing paragraphs of the Counterclaim.

14. On information and belief, Celerity Pharmaceuticals, LLC ("Celerity") submitted ANDA No. 208532 to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of its generic dexmedetomidine hydrochloride in 0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL ("Baxter ANDA Product") prior to the expiry of the '867 patent.

RESPONSE: Admitted. *See* **Attach. B**, Declaration of Jonathan M. Edwards ¶ 12 [hereinafter Edwards Decl.].

15. Celerity was aware of the '867 patent when it submitted its ANDA.

RESPONSE: Baxter lacks information sufficient to admit or deny the allegations in this paragraph and, therefore, denies all allegations.

16. On information and belief, Baxter has assumed all rights and responsibilities with respect to ANDA No. 208532.

RESPONSE: Admitted.

17. The '867 patent covers, among other things, a method of sedating a patient in an intensive care unit comprising administering to the patient an effective amount of dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the patient remains arousable and orientated.

RESPONSE: This paragraph contains a characterization of the '867 Patent, which speaks for itself, and to which no response is required. To the extent a response is required, Baxter admits that claim 1 of the '867 Patent claims "[a] method of sedating a patient in an intensive care unit, which comprises administering to the patient an effective amount of dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the patient remains arousable and orientated." All other allegations not expressly admitted are denied.

18. Celerity was not required by the FDA to maintain a Paragraph IV Certification as to the '867 patent because its ANDA did not seek approval for the Precedex® indication that covers "sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting."

RESPONSE: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Baxter admits that Celerity did not provide a Paragraph IV certification to the '867 Patent. All other allegations not expressly admitted are denied.

19. However, on information and belief, while Baxter's ANDA omits this indication, Baxter knows that its product will be used for this indication, which keeps ICU patients arousable and orientated. Medical professionals use dexmedetomidine drug products for this indication even when the drug products are not approved by the FDA for the indication.

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