EXHIBIT 1

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 DEMAND FOR JURY TRIAL

DEFENDANTS' FIRST AMENDED COUNTERCLAIM

Pursuant to the Court's Scheduling Order (D.I. 21 ¶ 3), Defendants Hospira, Inc. ("Hospira") and Orion Corp. ("Orion") (collectively, "Defendants"), through counsel, hereby file this amended counterclaim against Plaintiff Baxter Healthcare Corporation ("Baxter").

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 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.

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

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

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

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.

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.

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.

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.

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

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.

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®.

Count I: Infringement Of The '867 Patent

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

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

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

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.

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."

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.

20. Moreover, on information and belief, Baxter's ANDA seeks approval to market the Baxter ANDA Product for the Precedex® indication of "sedation of non-intubated patients prior

to and/or during surgical and other procedures." Such sedation often occurs in an intensive care unit, and allows the patient to remain arousable and orientated.

21. Therefore, the Baxter ANDA seeks approval to market the Baxter ANDA Product for uses covered by the '867 patent.

22. By submitting this ANDA, Baxter committed an act of infringement under 35 U.S.C. § 271(e)(2).

23. Moreover, on information and belief, at least as early as August 28, 2018, Baxter began to manufacture, sell, offer for sale, and/or import in to the United States its Baxter ANDA Product, which constitutes an act of infringement under 35 U.S.C. § 271(b) and/or (c). *See e.g.*, http://ecatalog.baxter.com/ecatalog/loadproduct.html?cid=20016&lid=10001&hid=20001&pid=982028;

http://ecatalog.baxter.com/ecatalog/loadproduct.html?cid=20016&lid=10001&hid=20001&pid=982026, attached hereto as Exhibit A.

24. Baxter's actions and conduct will encourage direct infringement of the '867 patent by others.

25. On information and belief, Baxter acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. Further, on information and belief, Baxter actually knew or should have known that its actions constituted infringement of a valid patent. Baxter's infringement is therefore willful.

26. Defendants will be irreparably harmed if Baxter is not enjoined from infringing the '867 patent.

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