

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAXTER HEALTHCARE	)	
CORPORATION,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 18-303-RGA
v.	)	
	)	DEMAND FOR JURY TRIAL
HOSPIRA, INC. and ORION CORP.,	)	
	)	
Defendants.	)	

**ANSWER TO BAXTER’S FIRST AMENDED COMPLAINT**

Defendants Hospira, Inc. (“Hospira”) and Orion Corp. (“Orion”) (collectively, “Defendants”), through counsel, hereby answer the October 15, 2018 Complaint of Plaintiff Baxter Healthcare Corporation (“Baxter”).

**I. NATURE OF THE SUIT**

1. This is a civil action brought by Baxter against Defendants seeking declaratory judgment, treble damages, and other relief for harms arising out of Defendants’ unlawful misuse of an invalid patent. United States Patent No. 6,716,867 (the “’867 Patent”) is invalid as obvious, as originally determined by the United States District Court for the District of New Jersey in Civil Action No. 3:09-cv-04591 (2012). Despite the invalidity of the ’867 Patent, Defendants have misused the ’867 Patent to unlawfully exclude generic competition from the market for dexmedetomidine hydrochloride injection, 200 mcg base/50mL and 400 mcg base/100mL, a drug manufactured and marketed by Defendants under the brand name Precedex. As alleged below, Defendants devised a scheme using a variety of illegal and deceptive acts to unlawfully preclude or delay generic competition for Precedex. Through these acts, Defendants have unlawfully monopolized and attempted to monopolize the dexmedetomidine hydrochloride market in violation of numerous antitrust laws, including but not limited to the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15 and 26.

**ANSWER:** No answer is required because the allegations of this paragraph relate solely to the counts that Defendants have moved to dismiss.<sup>1</sup>

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<sup>1</sup> Defendants reserve the right to answer the allegations subject to the motion to dismiss in the event the motion is denied.

2. Specifically, Defendants have engaged in a pattern and scheme to abuse the patent system and have engaged in sham litigation to restrain competition from Baxter and other generic manufacturers of premix dexmedetomidine hydrochloride. Defendants' unlawful conduct includes, inter alia:

(a) Conspiring to monopolize and restrain trade by entering into a settlement agreement with Sandoz in Case No. 3:09-cv-04591 (D.N.J.) to vacate the district court's judgment declaring the '867 Patent invalid. Vacatur of this judgment through settlement enabled Defendants to improperly manipulate the use codes for the '867 Patent and to continue monopolizing the dexmedetomidine hydrochloride market by asserting against Baxter and other generic manufacturers a patent that they knew was invalid. The vacatur occurred after a full bench trial on the merits and while the case was awaiting oral argument at the United States Court of Appeals for the Federal Circuit;

(b) Continuing to list the '867 Patent in the Orange Book despite knowledge of the patent's fraudulent procurement and invalidity;

(c) Misrepresenting and improperly altering the use code for the '867 Patent to preclude generic competition despite knowing that the claims in the '867 Patent do not extend to the new use code;

(d) Asserting the '867 Patent against Baxter despite knowing that this patent is unenforceable and invalid as obvious, and that the patent was obtained through fraudulent misrepresentations; and

(e) Filing a sham counterclaim against Baxter for infringement of the '867 Patent, despite knowing that such claim is objectively baseless, asserted in bad faith, and brought for an anti-competitive purpose in violation of § 2 of the Sherman Act (as interpreted in *Handgards Inc. v. Ethicon Inc.*, 743 F.2d 1282 (9th Cir. 1984)) to unlawfully restrain competition in a relevant market causing antitrust injury to Baxter and other generic premix dexmedetomidine hydrochloride manufacturers.

**ANSWER:** No answer is required because the allegations of this paragraph relate solely to the counts that Defendants have moved to dismiss.

3. Baxter seeks judgment, damages, injunctive, and other relief for Defendants' unlawful conduct with respect to the '867 Patent and monopolization of the market for premix dexmedetomidine hydrochloride injection.

**ANSWER:** No answer is required because the allegations of this paragraph relate solely to the counts that Defendants have moved to dismiss.

## II. PARTIES

4. Baxter Healthcare Corporation is a corporation incorporated in Delaware with its principal place of business at One Baxter Parkway, Deerfield, IL 60015.

**ANSWER:** Admitted, on information and belief.

5. Upon information and belief, Hospira, Inc. is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

**ANSWER:** Admitted.

6. Upon information and belief, Orion Corp. is a corporation organized under the laws of Finland with its principal place of business at Orionintie 1, FIN-02200 Espoo, Finland.

**ANSWER:** Admitted.

### **III. JURISDICTION AND VENUE**

7. This First Amended Complaint arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq., the antitrust laws of the United States, 15 U.S.C. § 2, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as amended, based upon an actual controversy between the parties.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted that Baxter's Amended Complaint purports to arise under the laws cited in this paragraph and there is a controversy as to patent infringement by Baxter's ANDA pursuant to the cited statutes. Otherwise denied.

8. This Court has subject matter jurisdiction over Baxter's claims under 28 U.S.C. §§ 1331, 1337(a), and 1338, and 15 U.S.C. § 15.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted.

9. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 15 U.S.C. § 22, at least because Hospira resides in this District and the Court may exercise personal jurisdiction over Hospira.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted that venue is proper for purposes of this action only.

10. This Court has personal jurisdiction over Hospira because, among other things, Hospira is a Delaware corporation that, having availed itself of Delaware's corporate laws, is subject to personal jurisdiction in Delaware.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted that this Court has personal jurisdiction over Hospira for purposes of this action only.

11. Hospira is also engaged in the sale of Precedex in interstate commerce and in this judicial District.

**ANSWER:** Admitted.

12. This Court has personal jurisdiction over Orion because, among other things, on information and belief, Orion does business in this District by co-owning a patent covering Precedex (i.e., the '867 Patent), licensing in the United States its interest in that patent to Hospira—a Delaware corporation—and receiving royalty payments from Hospira for the sale of Precedex, which is sold in Delaware.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted that this Court has personal jurisdiction over Orion for purposes of this action only. Otherwise denied.

13. This Court also has personal jurisdiction over Orion because Orion has regularly and purposefully availed itself of the privileges and benefits of this forum, having brought multiple suits in this District, including suits specifically alleging infringement of the '867 Patent: *Hospira, Inc. & Orion Corp. v. Sandoz Int'l GmbH, et al.*, Civ. No. 09-00665 (D. Del.);

*Hospira, Inc. & Orion Corp. v. Aurobindo Pharma Ltd., et al.*, Civ. No. 14-00486 (D. Del.); *Hospira, Inc. & Orion Corp. v. Ben Venue Labs, Inc.*, Civ. No. 14-00487 (D. Del.); *Hospira, Inc. & Orion Corp. v. Actavis LLC et al.*, Civ. No. 14-00488 (D. Del.); *Hospira, Inc. & Orion Corp. v. Ben Venue Labs., Inc., et al.*, Civ. No. 14-1008 (D. Del.).

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted that this Court has jurisdiction over Orion for the purposes of this action only. Otherwise denied.

14. Upon information and belief, the license agreement between Orion and Hospira obliges Orion to participate in the enforcement or defense of the '867 Patent with Hospira, which is engaged in exploiting the patent rights in Delaware through its sale of Precedex.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, denied.

15. By repeatedly asserting infringement of the '867 Patent in this District, Orion has waived any argument that it is not subject to specific personal jurisdiction in this District for actions relating to the '867 Patent.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent this paragraph is directed towards Counts 3-9, no answer is required because Defendants have moved to dismiss those counts. To the extent this paragraph is directed towards Counts 1-2, admitted that this Court has personal jurisdiction over Orion for purposes of this action only. Otherwise denied.

16. Venue is proper in this district for Orion pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) and 15 U.S.C. § 22 because, inter alia, Orion is a corporation organized and existing under the laws of Finland and is subject to personal jurisdiction in this judicial District.

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