

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

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

**(PROPOSED) FIRST AMENDED COMPLAINT**

Plaintiff Baxter Healthcare Corporation (“Baxter”), through counsel, hereby files its First Amended Complaint against Hospira, Inc. (“Hospira”) and Orion Corp. (“Orion”) (collectively, “Defendants”), and alleges as follows:

**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.

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.

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.

## 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.

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.

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.

## 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.

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.

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.

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.

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

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.

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.).

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.

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.

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.

#### IV. FACTUAL BACKGROUND

##### A. The '867 Patent

17. On its face, the '867 Patent, entitled "Use of Dexmedetomidine for ICU Sedation," indicates it was issued by the U.S. Patent and Trademark Office ("PTO") on April 6, 2004. A copy of the '867 Patent is attached as **Exhibit A**.

18. According to records at the PTO, Hospira and Orion are co-assignees of the '867 Patent.

19. On information and belief, Hospira is the exclusive licensee in the United States of Orion's interest in the '867 Patent.

20. The '867 Patent contains twelve claims.

21. The '867 Patent contains two independent claims.

22. Each independent claim of the '867 Patent recites "[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 therefor, wherein the patient remains arousable and orientated." (emphasis added).

# 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.