IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Baxter Healthcare Corporation ("Baxter"), through counsel, hereby brings its Complaint for Declaratory Judgment against Hospira, Inc. ("Hospira") and Orion Corp. ("Orion"), and alleges as follows:

NATURE OF THE SUIT

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent Nos. 6,716,867 (the "'867 Patent"), 8,242,158 (the "'158 Patent"), 8,338,470 (the "'470 Patent"), and 8,455,527 (the "'527 Patent") (collectively, "the Patents-in-Suit") to enable Baxter to bring its generic dexmedetomidine hydrochloride in 0.9% sodium chloride injection 200 mcg/50 mL and 400 mcg/100mL (the "Baxter ANDA Product") to market at the earliest possible date under the applicable statutory and Food and Drug Administration ("FDA") regulatory provisions, and to allow the public to enjoy the benefits of generic competition for these products.

THE PARTIES

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

3. 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.

4. 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.

JURISDICTION, VENUE AND JOINDER

5. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984 (codified as amended at 21 U.S.C. § 355)) (the "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) (the "MMA"), based upon an actual controversy between the parties to declare that Baxter is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed product as described in Abbreviated New Drug Application ("ANDA") No. 208532.

6. This Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 1400(b), at least because Hospira resides in this District within the meaning of 28 U.S.C. § 1400(b).

8. 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.

9. 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), exclusively licensing in the United States its ownership interest in said patent to Hospira—a Delaware corporation—and receiving royalty payments from Hospira for the sale of Precedex®, which is sold in Delaware.

10. 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 at issue in this suit: *Hospira Inc. and Orion Corp v. Sandoz International GmbH, et al.*, Civ. No. 09-00665 (D. Del.); *Hospira, Inc. and Orion Corp. v. Aurobindo Pharma Ltd., at al.*, Civ. No. 14-00486 (D. Del.); *Hospira, Inc. and Orion Corp. v. Ben Venue Labs, Inc.*, Civ. No. 14-00487 (D. Del.); *Hospira, Inc. and Orion Corp. v. Actavis LLC et. Al.*, Civ. No. 14-00488 (D. Del.); *Hospira, Inc. and Orion Corp. v. Ben Venue Labs., Inc., et al.*, Civ. No. 14-1008 (D. Del.).

11. Upon information and belief, the license agreement between Orion and Hospira imposes an obligation on 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®.

12. By virtue of its repeated assertion of 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 infringement thereof.

13. Venue is proper in this district for Orion pursuant to 28 U.S.C. §§ 1391 and 1400(b) 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.

THE PATENTS-IN-SUIT

The ’867 Patent

14. 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 on April 6, 2004. A copy of the ’867 Patent is attached as Exhibit A.

15. According to records at the U.S. Patent and Trademark Office, Hospira and Orion are co-assignees of the ’867 Patent.

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

17. The ’867 Patent contains twelve claims.

18. The ’867 Patent contains two independent claims.

19. Each independent claim of the ’867 Patent recites “[a] method of sedating a patient in an intensive care unit.”

20. The ’867 Patent’s ten dependent claims incorporate the limitations of the claims from which they depend. Thus, all claims of the ’867 Patent require “[a] method of sedating a patient in an intensive care unit.”

The ’158 Patent

21. On its face the ’158 Patent, entitled “Dexmedetomidine Premix Formulation,” indicates it was issued by the U.S. Patent and Trademark Office on August 14, 2012. A copy of the ’158 Patent is attached as Exhibit B.

22. The ’158 Patent issued from application number 13/343,672 (the “’672 Application”).

23. According to records at the U.S. Patent and Trademark Office, Hospira is the

assignee of the ’158 Patent.

24. The ’158 Patent contains four claims.

25. The ’158 Patent contains one independent claim.

26. The independent claim of the ’158 Patent recites “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

27. The ’158 Patent’s three dependent claims incorporate the limitations of the claims from which they depend. Thus, all claims of the ’158 Patent require “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

28. When the ’672 Application was initially filed, its claims did not require that the sealed container be made of glass.

29. On March 13, 2012, in response to an office action rejecting the originally-filed claims of the ’672 Application, Hospira amended the sole pending independent claim to include the present requirement that the sealed container be “a sealed glass container.”

30. In its March 13, 2012 filing with the U.S. Patent and Trademark Office, Hospira argued that it discovered that using glass containers resulted in unexpectedly superior stability compared to using plastic containers. Response to Office Action, at 7-8 (Mar. 13, 2012) (arguing it was surprising that “a 4µg/mL premixture formulation stored in glass vials and ampoules maintained a higher level of potency after a 5 month storage period compared to storage in plastic, CR3, or PVC containers”).

31. On April 18, 2012, the U.S. Patent and Trademark Office issued a notice of allowance for the ’672 Application. In this notice, the examiner stated that “requiring the composition to be disposed within a sealed glass container[] was effective to overcome the previous rejection under 35 U.S.C[. §] 102(b).” Notice of Allowance, ¶ 3 (Apr. 18, 2012)

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