

**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.)

CONSENT JUDGMENT

On February 22, 2018, Plaintiff Baxter Healthcare Corporation (“Baxter”) filed its Complaint for Declaratory Judgment against Defendants Hospira, Inc. (“Hospira”) and Orion Corp. (“Orion”) (collectively, “Defendants”). The Complaint seeks 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”). Defendants filed their Answer and Counterclaim on March 20, 2018.

Baxter and Defendants have agreed to the entry of this Consent Judgment regarding the ’158 Patent, the ’470 Patent, and the ’527 Patent upon the following findings of fact and conclusions of law. No claim, counterclaim, affirmative defense, or demand related to the ’867 Patent is affected by this Consent Judgment. Each party has waived the right to appeal from this Consent Judgment. Should judicial enforcement of any of the terms of this Consent Judgment become necessary in the future, the prevailing party will be entitled to its attorneys’ fees and costs. It is therefore found, adjudged, and decreed as follows:

FINDINGS OF FACT

1. Baxter is a corporation incorporated in Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

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

3. Orion is a corporation organized under the laws of Finland with its principal place of business at Orionintie 1, FIN-02200 Espoo, Finland.

4. On August 14, 2012, the U.S. Patent and Trademark Office issued United States Patent No. 8,242,158, entitled “Dexmedetomidine Premix Formulation.” Hospira is the assignee of the ’158 Patent.

5. On December 25, 2012, the U.S. Patent and Trademark Office issued United States Patent No. 8,338,470, entitled “Dexmedetomidine Premix Formulation.” Hospira is the assignee of the ’470 Patent.

6. On June 4, 2013, the U.S. Patent and Trademark Office issued United States Patent No. 8,455,527, entitled “Methods of Treatment Using a Dexmedetomidine Premix Formulation.” Hospira is the assignee of the ’527 Patent.

7. Celerity Pharmaceuticals, LLC (“Celerity”) submitted and later transferred to Baxter ANDA No. 208532 (“Baxter ANDA”) for a proposed drug product containing dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL. Baxter’s ANDA seeks approval from the Food and Drug Administration (“FDA”) for the commercial manufacture, use, importation, offer for sale and sale of generic dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL in flexible plastic containers (“Baxter ANDA Product”).

8. Hospira received a Notice Letter informing Hospira of Baxter's ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Baxter's ANDA Product before the expiration of three of the patents-in-suit, the '158 Patent, the '470 Patent, or the '527 Patents, and that the Baxter ANDA contained a section viii statement regarding the '867 patent, but Hospira did not file suit in connection with ANDA No. 208532 or otherwise object to ANDA No. 208532 within 45 days of receipt of the Notice Letter.

9. On January 22, 2018, FDA issued a letter tentatively approving Baxter's ANDA No. 208532.

CONCLUSIONS OF LAW

10. This is an action for declaratory judgment arising 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), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003).

11. This Court has subject matter jurisdiction over this lawsuit pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

12. This Court has personal jurisdiction over Baxter and the Defendants for purposes of this action, and venue is proper in this district pursuant to 28 U.S.C. § 1400(b) for purposes of this action.

13. Orion has no ownership interest in the '158 Patent, the '470 Patent, or the '527 Patent.

14. Baxter does not infringe the '158 Patent through the manufacture, marketing, use, offer for sale, sale, and/or importation of the Baxter ANDA Product.

15. Baxter does not infringe the '470 Patent through the manufacture, marketing, use, offer for sale, sale, and/or importation of the Baxter ANDA Product.

16. Baxter does not infringe the '527 Patent through the manufacture, marketing, use, offer for sale, sale, and/or importation of the Baxter ANDA Product.

17. Baxter does not contest the validity or enforceability of the '158 Patent, the '470 Patent, and '527 Patent for purposes of this action.

18. This Consent Judgment shall finally conclude and dispose of all claims related to the '158 Patent, the '470 Patent, and the '527 Patent as to Baxter and Defendants with respect to the Baxter ANDA Product. All claims, counterclaims, affirmative defenses, and demands related to these three patents are dismissed with prejudice. All claims, counterclaims, affirmative defenses, and demands related to the '867 Patent are not affected by this Consent Judgment and remain active in this litigation.

19. This Consent Judgment is a final adjudication on the merits with respect to all claims related to the '158 Patent, the '470 Patent, and the '527 Patent as to Baxter and Defendants with respect to the Baxter ANDA Product.

20. This Consent Judgment constitutes a final, non-appealable judgment that the '158 Patent, the '470 Patent, and the '527 Patent are not infringed as provided in 21 U.S.C § 355(j)(5)(D)(i)(bb)(AA) and (BB) by Baxter with respect to the Baxter ANDA Product.

21. The Court retains jurisdiction to enforce or supervise performance under this Consent Judgment.

ORDER

IT IS HEREBY FOUND, ORDERED, ADJUDGED, AND DECREED THAT:

A. Baxter's request for declaratory judgment is GRANTED with respect to United States Patent Nos. 8,242,158 (the "'158 Patent"), 8,338,470 (the "'470 Patent"), and 8,455,527 (the "'527 Patent"). The Court finds that Baxter's ANDA Product does not infringe these three patents.

B. This Court retains exclusive jurisdiction of this action for the purpose of (1) ensuring compliance with this Consent Judgment, and (2) determining whether Baxter's ANDA Product infringes United States Patent No. 6,716,867.

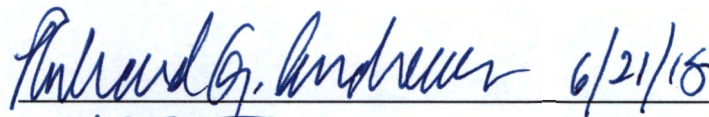
C. No appeal shall be taken by any party from this Consent Judgment.

D. This Consent Judgment shall finally conclude and dispose of all claims against Defendants by Baxter related to the '158 Patent, the '470 Patent, and the '527 Patent with respect to the Baxter ANDA Product.

E. This Consent Judgment shall be entered without further notice.

IT IS SO ORDERED.

Dated:


Richard G. Andrews 6/21/18
USDS