

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC. and ORION  
CORPORATION,

Plaintiffs,

v.

BEN VENUE LABORATORIES, INC.  
formerly d/b/a BEDFORD LABORATORIES,  
HIKMA PHARMACEUTICALS PLC, and  
WEST-WARD PHARMACEUTICAL CORP.,

Defendants.

Civil Action No. \_\_\_\_\_

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**COMPLAINT**

Plaintiffs Hospira, Inc. (“Hospira”) and Orion Corporation (“Orion”) (collectively, “Plaintiffs”), for their Complaint against Defendant Ben Venue Laboratories, Inc. formerly d/b/a Bedford Laboratories, Hikma Pharmaceuticals PLC, and West-Ward Pharmaceutical Corp., hereby allege as follows:

**PARTIES**

1. Hospira is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.
2. Orion is a corporation organized under the laws of Finland with its principal place of business at Orionintie 1A, FI-02200 Espoo, Finland.
3. On information and belief, Bedford Laboratories (“Bedford”) was an unincorporated division of Ben Venue Laboratories, Inc. (“BVL”), a corporation organized and

existing under the laws of the State of Delaware, both having a place of business at 300 Northfield Road, Bedford, Ohio 44146.

4. On information and belief, Hikma Pharmaceuticals PLC (“Hikma”) is a company incorporated in the United Kingdom with a place of business at 13 Hanover Square, London, W1S 1HW, United Kingdom. Hikma is a worldwide pharmaceutical company in the business of developing and manufacturing branded and generic drugs. According to Hikma’s website, Hikma’s generics business in the United States “operates as West-Ward Pharmaceuticals, a domestic marketer and manufacturer of generic pharmaceutical products.”

5. On information and belief, West-Ward Pharmaceutical Corp. (“West-Ward”) is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724. Upon information and belief, West-Ward acts as a domestic marketer, manufacturer, and distributor of drug products for sale and use throughout the United States for entities affiliated with Hikma. West-Ward’s website states that it is “the US agent and subsidiary of Hikma PLC.” West-Ward’s website also indicates that it has a sales representative for the State of Delaware. Upon information and belief, West-Ward is a wholly-owned subsidiary of Eurohealth (U.S.A.) Inc., and its parent, Hikma.

6. On information and belief, Hikma acquired the assets of Bedford on or about July 15, 2014. Hikma’s website states that it acquired Bedford’s “large product portfolio, intellectual property rights, contracts for products marketed under license, raw material inventories, a strong R&D and business development pipeline and a number of employees across key business functions.” The website also states that the Bedford acquisition “brings a unique and attractive R&D pipeline of 27 products, of which 16 are filed and pending approval from the

US FDA. The pipeline assets focus on higher value, medically necessary and acute care products, including numerous Paragraph IV opportunities.”

7. On information and belief, Bedford’s assets will be integrated into West Ward’s existing US operations. Regarding Hikma’s acquisition of Bedford, West-Ward’s website states that “[a]fter the fulfillment of customary closing and regulatory conditions all of these [Bedford] products will be integrated into West-Ward’s existing US operations.”

### **NATURE OF THE ACTION**

8. This is a civil action for infringement of U.S. Patent No. 6,716,867 (the “‘867 patent”). The ‘867 patent is attached as Exhibit A.

9. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and arises out of BVL and Bedford’s filing of Abbreviated New Drug Application (“ANDA”) No. 206407 seeking approval to market dexmedetomidine hydrochloride prior to the expiration of the ‘867 patent, which is assigned to and/or exclusively licensed by Plaintiffs and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the “Orange Book”) as covering PRECEDEX™.

### **JURISDICTION AND VENUE**

10. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

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

12. BVL and Bedford are subject to personal jurisdiction in this District by virtue of, *inter alia*, BVL’s incorporation under the laws of the State of Delaware, and its conduct of business in this District. On information and belief, BVL develops, formulates, manufactures, markets, and sells drug products throughout the United States, including

Delaware, and Delaware is a likely destination of BVL's and Bedford's products. On information and belief, BVL has purposely availed itself of the rights and benefits of the laws of the State of Delaware, and has engaged in substantial and continuous contacts with the State of Delaware.

13. West-Ward is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation under the laws of the State of Delaware, and its conduct of business in this District. On information and belief, West-Ward develops, formulates, manufactures, markets, and sells drug products throughout the United States, including Delaware, and Delaware is a likely destination of West-Ward's products. On information and belief, West-Ward has purposely availed itself of the rights and benefits of the laws of the State of Delaware, and has engaged in substantial and continuous contacts with the State of Delaware.

14. Hikma is subject to personal jurisdiction in this District because, *inter alia*, together with West-Ward which is incorporated under the laws of the State of Delaware, Hikma has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Hikma regularly and continuously transacts business within the State of Delaware, including, but not limited to, shipping pharmaceuticals to West-Ward from locations outside the United States for distribution by West-Ward within the United States generally, and within this District specifically.

15. In the alternative, this Court has personal jurisdiction over Hikma under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law and, upon information and belief, Hikma is not subject to the jurisdiction of the courts of general jurisdiction of any state

and the exercise of personal jurisdiction over Hikma is consistent with the Constitution and the laws of the United States.

16. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **THE PATENT-IN-SUIT**

17. The '867 patent, entitled "Use of Dexmedetomidine for ICU Sedation," was duly and legally issued by the USPTO on April 6, 2004. Hospira and Orion are co-assignees of the '867 patent and share ownership of the '867 patent.

18. Hospira is the exclusive licensee in the United States of Orion's ownership interest in the '867 patent.

19. 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.

20. 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™.

### **ACTS GIVING RISE TO THIS ACTION**

21. On information and belief, BVL and Bedford reviewed the '867 patent and certain commercial and economic information regarding Hospira's PRECEDEX™ and decided to file an ANDA seeking approval to market a generic version of PRECEDEX™.

22. Plaintiffs received a letter dated June 17, 2014, from BVL and Bedford notifying them that BVL and Bedford had filed ANDA No. 206407 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to market a generic version of Hospira's PRECEDEX™ prior to the expiry of the '867 patent.

23. The stated purpose of BVL and Bedford's letter was to notify Plaintiffs that ANDA No. 206407 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '867 patent are invalid. Included in the June 17, 2014, letter was a "detailed statement" of the factual and legal basis for BVL and Bedford's Paragraph IV Certification.

24. On information or belief, BVL and Bedford were aware of the '867 patent when they filed ANDA No. 206407 with a Paragraph IV Certification.

25. Hospira received the June 17, 2014, letter on June 20, 2014. Plaintiffs commenced this action within 45 days of receipt of the letter.

26. On information belief, following its acquisition by Hikma, Bedford will continue to pursue the approval of ANDA No. 206407 under the direction and control of Hikma and its U.S. subsidiary West-Ward.

### **FIRST CLAIM FOR RELIEF**

#### **(BVL and Bedford)**

27. Paragraphs 1 through 26 are incorporated herein as set forth above.

28. BVL and Bedford submitted ANDA No. 206407 with a Paragraph IV Certification to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of dexmedetomidine hydrochloride prior to the expiration of the '867 patent. By submitting this ANDA, BVL and Bedford committed an act of infringement under 35 U.S.C. § 271(e)(2).

29. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the proposed generic dexmedetomidine hydrochloride product described in ANDA No. 206407 by BVL and Bedford would infringe the '867 patent under 35 U.S.C. § 271(a), (b), and/or (c).

30. BVL and Bedford's actions and conduct will encourage direct infringement of the '867 patent by others.

31. BVL and Bedford's "detailed statement" asserts only the alleged invalidity, and specifically obviousness, of the '867 patent as the basis for their belief that the '867 patent will not be infringed by the product described in ANDA No. 206407.

32. BVL and Bedford were aware of the existence of the '867 patent prior to the filing of ANDA No. 206407, and took such action knowing it would constitute infringement of the '867 patent.

33. Plaintiffs will be irreparably harmed if BVL and Bedford are not enjoined from infringing the '867 patent.

### **SECOND CLAIM FOR RELIEF**

#### **(Hikma and West-Ward)**

34. Paragraphs 1 through 33 are incorporated herein as set forth above.

35. On information and belief, Hikma and West-Ward, based on the submission of ANDA No. 206407 with a Paragraph IV Certification, intend to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of dexmedetomidine hydrochloride prior to the expiration of the '867 patent.

36. By submitting this ANDA, as Bedford's assets have transferred to Hikma, Hikma has committed an act of infringement under 35 U.S.C. § 271(e)(2).

37. By submitting this ANDA, as Bedford's assets will be integrated into West-Ward's existing US operations, West-Ward has committed an act of infringement under 35 U.S.C. § 271(e)(2).

38. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the proposed generic dexmedetomidine hydrochloride

product described in ANDA No. 206407 by Hikma and West-Ward would infringe the '867 patent under 35 U.S.C. § 271(a), (b), and/or (c).

39. In addition, on information and belief, Hikma and West-Ward knowingly encourage, direct, and actively induce Bedford to seek approval for ANDA No. 206407 prior to the expiry of the '867 patent.

40. Hikma and West-Ward knowingly and actively induce Bedford to, through the conduct alleged above, infringe one or more claims of the '867 patent.

41. In addition, on information and belief, Hikma and West-Ward's actions and conduct will encourage direct infringement of the '867 patent by others.

42. By reason of inducement by Hikma and West-Ward of infringement of the '867 patent by Bedford and others, Hikma and West-Ward have caused and continue to cause irreparable harm to Plaintiffs.

43. On information and belief, inducement by Hikma and West-Ward of infringement of the '867 patent by Bedford and others will continue unless enjoined by this Court.

44. Plaintiffs have no adequate remedy at law for Hikma and West-Ward's inducement of infringement of the '867 patent by Bedford and others.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

A. An order decreeing that the submission to the FDA of ANDA No. 206407 with a Paragraph IV Certification was an act of infringement by BVL, Bedford, West-Ward and/or Hikma;

B. An order decreeing that BVL's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No.

206407 prior to the expiration of the '867 patent, including any regulatory extensions, will infringe the '867 patent;

C. An order decreeing that Bedford's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 206407 prior to the expiration of the '867 patent, including any regulatory extensions, will infringe the '867 patent;

D. An order decreeing that Hikma's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 206407 prior to the expiration of the '867 patent, including any regulatory extensions, will infringe the '867 patent;

E. An order decreeing that West-Ward's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 206407 prior to the expiration of the '867 patent, including any regulatory extensions, will infringe the '867 patent;

F. An order pursuant to 21 U.S.C. § 355(c)(3)(C) that the effective date of any approval of ANDA No. 206407 shall be no earlier than thirty months after the date on which Hospira received BVL and Bedford's June 17, 2014, letter, and, if the Court rules that the product proposed in ANDA No. 206407 infringes the '867 patent, shall be no earlier than the expiration date of the '867 patent, including any applicable extensions;

G. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4) restraining and enjoining BVL, Bedford, Hikma, and West-Ward, their officers, agents, attorneys, and employees and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the

generic dexmedetomidine hydrochloride product described in ANDA No. 206407, or any other ANDA not colorably different from ANDA No. 206407, until the expiration of the '867 patent, including any applicable extensions;

H. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such other and further relief as the Court may deem just and proper.

Dated: August 1, 2014

/s/ Mary B. Matterer

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