

### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

BEN VENUE LABORATORIES, INC., d/b/a BEDFORD LABORATORIES, 200 Northfield Road	1°05CV1787
Bedford, Ohio 44146	Judge:
Plaintiff, )	JUDGE NUGENT
vs.	
HOSPIRA, INC., 275 N. Field Drive  Lake Forest, Illinois 60045	COMPLAINT MAG. JUDGE MCHARGH
Defendant.	

Ben Venue Laboratories, Inc. ("Ben Venue"). d/b/a Bedford Laboratories ("Bedford"), hereby complains against defendant Hospira Inc. ("Hospira"), for actions as described below, and requests that the Court declare at least claim 18 of United States Patent No. 6,140,373 ("the '373 patent") invalid for failing to meet the requirements of 35 U.S.C. §§ 102. 103 and/or 112. declare that Bedford's Propofol Injectable Emulsion product does not infringe any valid claim of the '373 patent, and grant such other relief as it deems just and proper.

#### **PARTIES**

1. Bedford is an unincorporated division of Ben Venue and, like Ben Venue, has its principal place of business within the Northern District of Ohio, in Bedford, Ohio. Ben Venue is incorporated in the State of Delaware.

2. Hospira is a Delaware corporation, and has its principal place of business in Lake Forest, Illinois.

#### **BACKGROUND**

- 3. On October 21, 2000, the United States Patent and Trademark Office issued United States Patent No. 6,140,373. A copy of the '373 patent is attached hereto as Exhibit A. Abbott Laboratories is identified as the assignee on the face of the '373 patent. While the information available on the United States Patent And Trademark Office's internet website does not reflect the recordation of an assignment of the '373 patent to Hospira, Hospira's Vice President, Patents and Trademarks, Brian R. Woodworth has, in a July 1, 2005 letter to Bedford, represented that Hospira is now the assignee of the '373 patent. A copy of Mr. Woodworth's letter is attached hereto as Exhibit B.
- 4. On February 2, 1996, Bedford filed in the United States Food and Drug Administration ("FDA") an abbreviated new drug application ("ANDA") seeking approval to market its Propofol Injectable Emulsion products (10 ml, 20 ml, 50 ml and 100 ml vials).
- 5. On April 19, 2005, FDA issued to Bedford Laboratories an "Approval Letter" approving Bedford's ANDA on Bedford's Propofol Injectable Emulsion products.
- 6. On June 27, 2005, Bedford announced the launch of its Propofol Injectable Emulsion products.
- 7. Propofol is an intravenous sedative-hypnotic agent used for induction or maintenance of anesthesia or sedation. To the best of Bedford's knowledge, neither Hospira nor Abbott is making, using or selling any Propofol product covered by the '373 patent.

8. In his July 1, 2005 letter (Exhibit B) to Thomas Murphy, President of Ben Venue, Brian R. Woodworth, Vice President, Patents and Trademarks at Hospira, alleges that Bedford's manufacture, importation, sale and/or use of its Propofol Injectable Emulsion products is within the scope of one or more claims of the '373 patent.

9. Mr. Woodworth's letter further states that "Hospira hereby demands that Bedford cease and desist its direct infringement, contributory infringement, and/or inducement of infringement of U.S. Patent No. 6,140,373."

#### **JURISDICTION**

- 10. This is an action for a declaratory judgment pursuant to the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202. This action arises, in part, under the patent laws of the United States, 35 U.S.C. §1, et seq. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1338(a).
- 11. Bedford is located within, and actively manufactures, markets and sells pharmaceutical products within, the Northern District of Ohio, including the Propofol Injectable Emulsion products that Hospira has accused of infringement.
- 12. In view of the threatening nature of Hospira's July 1, 2005 "cease and desist" letter to Bedford. Bedford reasonably believes that there is an imminent threat of a lawsuit by Hospira and/or Abbott against Bedford alleging infringement of the '373 patent.
- 13. There is therefore an actual controversy between the parties with respect to the validity of the '373 patent and its infringement by Bedford.

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## COUNT 1 - DECLARATORY JUDGMENT THAT THE CLAIMS OF THE '373 PATENT ARE INVALID

- 14. Bedford repeats and realleges the allegations in Paragraphs 1-13 as if fully set forth herein.
- 15. Claims of the '373 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 102, 103, and/or 112.

# COUNT 2 - DECLARATORY JUDGMENT THAT BEDFORD'S PROPOFOL INJECTABLE EMULSION DOES NOT INFRINGE ANY CLAIM OF THE '373 PATENT

- 16. Bedford repeats and realleges the allegations in Paragraphs 1-15 as if fully set forth herein.
- 17. Bedford's Propofol Injectable Emulsion products do not infringe any valid claim of the '373 patent.

#### PRAYER FOR RELIEF

WHEREFORE, Bedford prays for the following relief:

- a) That the Court issue a judgment declaring that claims of the '373 patent are invalid;
- b) That the Court issue a judgment declaring that Bedford's Propofol Injectable Emulsion products do not infringe any valid claim of the '373 patent:
- c) That Hospira, its officers, agents, servants, employees, and attorneys, and those persons active in concert or participation with it, be enjoined from asserting or threatening to assert any rights under the '373 patent against Bedford, its customers, suppliers, licensees, agents, employees or others acting for, on behalf of, or in concert with Bedford:

- d) That Bedford be awarded its costs and disbursements in this action;
- e) That the Court declare this case to be "exceptional" pursuant to 35 U.S.C. § 285, and award Bedford its attorneys fees; and
- f) That Bedford be awarded such other and further relief as this Court may deem just and proper.

Dated: July 14, 2005

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