IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| ABBOTT LABORATORIES and WISCONSIN ALUMNI RESEARCH FOUNDATION, | ) | |
| Plaintiffs, | ) | C.A. No._____ |
| v. | ) | |
| BEN VENUE LABORATORIES, INC. | ) | |
| Defendant. | ) | |

**COMPLAINT**

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") (collectively "Plaintiffs"), for their Complaint against Defendant Ben Venue Laboratories, Inc., ("Ben Venue") allege as follows:

**NATURE OF THE ACTION**

1. This is an action for infringement of U.S. Patent Nos. 5,587,497 ("the '497 patent"), 6,136,799 ("the '799 patent"), and 6,361,758 ("the '758 patent"). This action arises out of Ben Venue's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott's highly-successful Zemplar® injectable products, in 2 μg/ml and 5 μg/ml formulations, prior to the expiration of the patents owned by and exclusively licensed to Plaintiffs.

**THE PARTIES**

2. Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Wisconsin Alumni Research Foundation ("WARF") is a nonprofit Wisconsin corporation, having its principal place of business at 614 Walnut Street, Madison, Wisconsin 53726. WARF is the designated technology transfer organization for the University of Wisconsin-Madison ("University"). WARF's mission is to support research at the University, to transfer technology, and to ensure that the inventions and discoveries of the University benefit humankind. WARF carries out this mission by patenting and licensing University inventions and by returning a portion of the proceeds of that licensing to fund additional research at the University. To date, WARF's contributions to the University have included funds to support research, build facilities, purchase land and equipment, and provide many faculty and graduate student fellowships.

4. On information and belief, Defendant Ben Venue is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 300 Northfield Road, Bedford, Ohio 44146.

## JURISDICTION AND VENUE

5. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Ben Venue is subject to personal jurisdiction in this district because it is a Delaware corporation, and, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, directing the operations and management of Bedford Laboratories, as well as shipping pharmaceuticals to Bedford Laboratories from locations outside the United States for distribution by Bedford Laboratories

within the United States generally, and within this District specifically. Additionally, Ben Venue has agreed that it will not contest personal jurisdiction over it in this district for purposes of this action.

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

**FACTS PERTINENT TO ALL COUNTS**

8. On December 24, 1996, the United States Patent and Trademark Office ("the PTO") issued the '497 patent, entitled "19-nor-Vitamin D Compounds," to Plaintiff WARF, the assignee of the named inventors Hector F. DeLuca, Heinrich K. Schnoes, Kato L. Perlman, Rafal R. Sicinski, and Jean M. Prahl. Plaintiff Abbott is the exclusive licensee of the '497 patent. A copy of the '497 patent is attached hereto as Exhibit A.

9. The '497 patent expires on December 24, 2013.

10. On October 24, 2000, the PTO issued the '799 patent, entitled "Cosolvent Formulations," to Plaintiff Abbott, the assignee of the named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier. A copy of the '799 patent is attached hereto as Exhibit B.

11. The '799 patent expires on April 8, 2018.

12. On March 26, 2002, the PTO issued the '758 patent, entitled "Cosolvent Formulations," to Plaintiff Abbott, the assignee of the named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier. A copy of the '758 patent is attached hereto as Exhibit C.

13. The '758 patent expires on April 8, 2018.

14. The ’497, ’799, and ’758 patents (collectively, the “patents-in-suit”) are listed in the United States Food and Drug Administration (“FDA”) publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”) as covering paricalcitol, which is marketed by Abbott under the brand name Zemplar®.

15. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of each of the ’497, ’799, and ’758 patents.

16. On information and belief, Ben Venue prepared and submitted ANDA No. 202-465 to the FDA, seeking approval to engage in the commercial manufacture, use, and sale of generic paricalcitol injection products, prior to the expiration of the patents-in-suit.

17. On or about April 11, 2011, Plaintiffs received a letter (“Paragraph IV Notice”) dated April 7, 2011, from Ben Venue notifying Plaintiffs that Ben Venue had filed ANDA No. 202-465 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”), and stating that, in Ben Venue’s opinion, the patents-in-suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the generic paricalcitol injection products described in ANDA No. 202-465.

18. On information and belief, Ben Venue was necessarily aware of the patents-in-suit when it filed ANDA No. 202-465 containing the Paragraph IV certification with the FDA.

19. Plaintiffs are commencing this action within forty-five days of the date they received Ben Venue’s Paragraph IV Notice of ANDA No. 202-465 containing the Paragraph IV certification.

20. Ben Venue has committed and will commit acts of infringement of the patents-in-suit that create a justiciable case or controversy between Plaintiffs and Ben Venue.

Pursuant to 35 U.S.C. § 271(e)(2)(A), Ben Venue committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Ben Venue's generic versions of Abbott's paricalcitol injection products prior to expiration of the patents-in-suit. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the patents-in-suit.

## COUNT 1
### INFRINGEMENT OF THE '497 PATENT

21. Paragraphs 1-20 are incorporated herein by reference.

22. Under 35 U.S.C. § 271 (e)(2)(A), Ben Venue infringed one or more claims of the '497 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '497 patent, of generic paricalcitol injection products labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, products the use or sale of which would infringe and contribute to and induce infringement of one or more claims of the '497 patent by ultimate purchasers.

23. Plaintiffs will be substantially and irreparably damaged and harmed if Ben Venue's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## COUNT 2
### DECLARATORY JUDGMENT AS TO '497 PATENT

24. Paragraphs 1-23 are incorporated herein by reference.

25. Upon information and belief, Ben Venue has made substantial preparations to sell generic paricalcitol injection products labeled for the same indications and the same dosage and method of use as the Zemplar® products sold by Abbott.

26. Upon further information and belief, Ben Venue intends to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

27. The manufacture, importation, sale, and offer for sale of such generic paricalcitol injection products, once approved by the FDA, would infringe one or more claims of the '497 patent.

28. Ben Venue's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol injection products would infringe and contribute to or induce infringement of one or more claims of the '497 patent.

29. Plaintiffs will be substantially and irreparably damaged and harmed if Ben Venue's threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## COUNT 3
## INFRINGEMENT OF THE '799 PATENT

30. Paragraphs 1-29 are incorporated herein by reference.

31. Under 35 U.S.C. § 271 (e)(2)(A), Ben Venue infringed one or more claims of the '799 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '799 patent, of generic paricalcitol injection products labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, products the use or sale of which would infringe and contribute to and induce infringement of one or more claims of the '799 patent by ultimate purchasers.

32. Plaintiffs will be substantially and irreparably damaged and harmed if Ben Venue's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## COUNT 4
### DECLARATORY JUDGMENT AS TO THE '799 PATENT

33. Paragraphs 1-32 are incorporated herein by reference.

34. Upon information and belief, Ben Venue has made substantial preparations to sell generic paricalcitol injection products labeled for the same indications and the same dosage and method of use as the Zemplar® products sold by Abbott.

35. Upon further information and belief, Ben Venue intends to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

36. The manufacture, importation, sale, and offer for sale of such generic paricalcitol injection products, once approved by the FDA, would infringe one or more claims of the '799 patent.

37. Ben Venue's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol injection products would infringe and contribute to or induce infringement of one or more claims of the '799 patent.

38. Plaintiffs will be substantially and irreparably damaged and harmed if Ben Venue's threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## COUNT 5
### INFRINGEMENT OF THE '758 PATENT

39. Paragraphs 1-38 are incorporated herein by reference.

40. Under 35 U.S.C. § 271 (e)(2)(A), Ben Venue infringed one or more claims of the '758 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '758 patent, of generic paricalcitol injection products

labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, products the use or sale of which would infringe and contribute to and induce infringement of one or more claims of the '758 patent by ultimate purchasers.

41. Plaintiffs will be substantially and irreparably damaged and harmed if Ben Venue's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## COUNT 6
### DECLARATORY JUDGMENT AS TO THE '758 PATENT

42. Paragraphs 1-41 are incorporated herein by reference.

43. Upon information and belief, Ben Venue has made substantial preparations to sell generic paricalcitol injection products labeled for the same indications and the same dosage and method of use as the Zemplar® products sold by Abbott.

44. Upon further information and belief, Ben Venue intends to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

45. The manufacture, importation, sale, and offer for sale of such generic paricalcitol injection products, once approved by the FDA, would infringe one or more claims of the '758 patent.

46. Ben Venue's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol injection products would infringe and contribute to or induce infringement of one or more claims of the '758 patent.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Ben Venue's threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## EXCEPTIONAL CASE

48. Paragraphs 1-47 are incorporated herein by reference.

49. This is an exceptional case warranting imposition of attorney fees against Defendants under 35 U.S.C. § 285.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against Ben Venue as follows:

(a) declaring the ’497, ’799, and ’758 patents valid and enforceable;

(b) declaring that Ben Venue would infringe one or more claims of the ’497, ’799, and ’758 patents by the threatened acts of using, offering to sell, or selling its generic paricalcitol injection products prior to the expiration of said patents;

(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Ben Venue’s ANDA No. 202-465 relating to generic paricalcitol injection products before the expiration of the six-month period of market exclusivity for the ’497, ’799, and ’758 patents granted under 21 U.S.C. § 355(a);

(d) enjoining Ben Venue from using, offering to sell, or selling its generic paricalcitol injection products, in accordance with 35 U.S.C. § 271(e)(4)(B);

(e) declaring this to be an exceptional case and awarding Plaintiffs attorney fees under 35 U.S.C. §§ 285 and 271(e)(4); and

(f) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

Mary B. Graham (#2256)
Erich W. Struble (#5394)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
estruble@mnat.com
*Attorneys forAbbott Laboratories and Wisconsin Alumni Research Foundation*

OF COUNSEL:

Michael A. Morin
David P. Frazier
Robert F. Shaffer
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4000

May 26, 2011
4283464.1