IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ABBVIE INC. and WISCONSIN ALUMNI RESEARCH FOUNDATION, | ) | |
| Plaintiffs, | ) | C.A. No. _____ |
| v. | ) | |
| BANNER PHARMACAPS INC., | ) | |
| Defendant. | ) | |

**COMPLAINT**

Plaintiffs AbbVie Inc. ("AbbVie") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendant Banner Pharmacaps Inc. ("Banner") allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for infringement of U.S. Patent No. 5,597,815 ("the '815 patent"). This action arises out of Banner's filing of an amended Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott Laboratory's ("Abbott")[1] highly successful Zemplar® paricalcitol capsules, in 1 mcg, 2 mcg, and 4 mcg formulations, prior to the expiration of the patent owned by and exclusively licensed to Plaintiffs.

[1] Zemplar® is currently marketed by Abbott Laboratories, who was the exclusively licensee of the '815 patent and holder of the NDA until August 1, 2012, when the licensing agreement and NDA were transferred to Plaintiff AbbVie.

## THE PARTIES

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

3. 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 support many faculty and graduate student fellowships.

4. On information and belief, Defendant Banner is a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, North Carolina 27265.

## 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. Banner is subject to personal jurisdiction in this District because it regularly and continuously transacts business within the State of Delaware. Banner markets and

sells pharmaceutical products throughout the United States, including the State of Delaware. Banner derives substantial revenue from Delaware drug sales and has availed itself of the privilege of conducting business within the State of Delaware.

7. Banner did not challenge personal jurisdiction in this District in *Eisai Inc. v. Banner Pharmacaps Inc.*, No. 1:11-cv-901 (GMS), a patent infringement action involving Banner's filing of an ANDA for generic bexarotine capsules.

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

**FACTS PERTINENT TO ALL COUNTS**

9. On January 28, 1997, the PTO issued the '815 patent, entitled "Prevention of Hyperphosphatemia in Kidney Disorder Patients," to Plaintiff WARF, the assignee of the named inventors Hector F. Deluca and Eduardo Slatopolsky. AbbVie is the exclusive licensee of the '815 patent. A copy of the '815 patent is attached hereto as Exhibit A.

10. The '815 patent expires on July 13, 2015.

11. The '815 patent (the "patent-in-suit") is 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®.

12. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of the '815 patent.

13. On information and belief, Banner manufactures, markets, and sells pharmaceutical products (including generic drug products manufactured and sold pursuant to

approved ANDAs) for distribution within the United States generally, and into the State of Delaware specifically.

14. On information and belief, Banner actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

15. On information and belief, Banner prepared and submitted to the FDA ANDA No. 202-539, seeking approval to engage in the commercial manufacture, use, and sale of paricalcitol capsule products, in 1 mcg, 2 mcg, and 4 mcg formulations, prior to the expiration of the patent-in-suit.

16. On or about August 15, 2012, Plaintiffs[2] received a letter dated August 14, 2012, from Banner notifying Plaintiffs that Banner had filed ANDA No. 202-539 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), and stating that, in Banner's opinion, the patent-in-suit is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the generic paricalcitol capsule products described in ANDA No. 202-539.

17. Banner was necessarily aware of the patent-in-suit when it filed ANDA No. 202-539 containing the Paragraph IV Certification with the FDA.

18. Upon information and belief, Plaintiffs allege that at least claim 4 of the '815 patent directed to "[a] method of treating a patient having renal osteodystrophy while avoiding hyperphosphatemia comprising administering to said patient a vitamin D compound that has minimal effect on blood serum phosphorus of said patient, said vitamin D compound

[2] The letter was addressed to Abbott and WARF, rather than Plaintiffs AbbVie and WARF.

selected from a 19-nor-vitamin $D_2$ compound [wherein the vitamin D compound is paricalcitol]" reads on the proposed label of Banner's amended paricalcitol capsule ANDA No. 202-539.

19. Upon information and belief, Banner seeks FDA-marketing approval under 21 U.S.C. § 355(j) *et. seq.* of paricalcitol capsule drug products for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease ("CKD"). This use is the only FDA-authorized use of paricalcitol capsule, and, if approved, would induce infringement of at least claim 4 of the '815 patent prior to its expiration.

20. Secondary hyperparathyroidism, characterized by parathyroid hyperplasia, persistently elevated parathyroid ("PTH") levels in the blood, and systemic mineral and bone abnormalities, is a common consequence of reduced kidney function in patients with CKD. Paricalcitol is a vitamin D analog proven effective, at appropriate dosage strengths, in suppressing elevated levels of blood PTH, the defining characteristic of secondary hyperparathyroidism found in patients suffering from CKD and its corresponding abnormalities in bone metabolism. PTH is a major regulator of bone turnover and skeletal cellular activity.

21. Clinical studies of renal osteodystrophy have generally utilized the levels of PTH as a marker for bone turnover. Obtaining direct evidence of bone effects requires highly invasive techniques, for example bone biopsy, which are intrusive for patients as well as difficult and expensive for investigators. Thus, newer vitamin D analogs, including paricalcitol, have largely obtained FDA approval for use in the control of intact PTH and do not contain bone biopsy data to document their direct effect on bone histology. However, limited data does exist to show that features of hyperparathyroid bone disease are improved by vitamin D treatment, such as paricalcitol. Moreover, physicians and medical professionals understand that because

intact PTH levels correlate with bone turnover, avoidance of very high intact PTH levels prevents renal osteodystrophy.

22. Paricalcitol at appropriate dosage strengths suppresses PTH levels with minor effects on calcium and phosphate metabolism, which is critical to maintaining mineral homeostasis and proper parathyroid functioning. (Exhibit B, Approved Labeling of Zemplar®, "Clinical Studies".) By suppressing elevated PTH levels and encouraging proper phosphorus metabolism, paricalcitol has been shown to have positive impact on serum markers associated with renal osteodystrophy.

23. Numerous studies have shown that renal osteodystrophy is associated with high serum levels of intact PTH. The approved labeling of Zemplar® recommends paricalcitol in CKD patients who have elevated plasma levels of intact PTH to reduce PTH levels, which, left untreated results in a greater chance of brittle bones due to high bone turnover.

24. Upon information and belief, Banner's proposed drug label contains descriptions indicating that secondary hyperparathyroidism is characterized by elevated levels of PTH, and further indicates that elevated PTH levels often precede abnormalities in serum calcium and phosphorus levels, and affect bone turnover and may result in renal osteodystrophy. (*See, e.g.,* Exhibit B, Approved Labeling of Zemplar®, "Clinical Pharmacology".) Accordingly, a treating physician or healthcare professional following Banner's proposed labeled indication would intend that the use of paricalcitol capsule to treat secondary hyperparathyroidism in patients with CKD would necessarily also treat bone abnormalities associated with elevated PTH; that is, would thus also treat renal osteodystrophy as described and claimed in the '815 patent.

25. The specification of the ’815 patent discloses that secondary hyperparathyroidism is a “universal complication” in patients with chronic renal failure, (’815 patent, col. 1, ll. 26-27), and that paricalcitol is an “ideal tool” for the treatment of secondary hyperparathyroidism and renal osteodystrophy because it suppresses PTH with “minimal effect on calcium and phosphorus,” (*id.*, col. 9, ll. 63-66). This use and effect is reflected in the approved dosage and use of paricalcitol capsules described in the Zemplar® label, which, on information and belief, will be copied by Banner with respect to its ANDA products and included with Banner’s proposed paricalcitol capsule products.

26. Based on the Zemplar® label, physicians and healthcare professionals prescribing and administering paricalcitol capsules understand and intend that treating secondary hyperparathyroidism by suppressing PTH will treat renal osteodystrophy while avoiding hyperphosphatemia. Indeed, some of the advantages in treating patients with paricalcitol over other vitamin D analogs are reduced calcemic and phosphatemic activities of paricalcitol treatment, which can be attributed to lower potency in stimulating intestinal calcium and phosphate absorption.

27. Upon information and belief, Banner has knowledge of the claims and disclosures of the ’815 patent, and has knowledge that its proposed label directs physicians and healthcare professionals to prescribe paricalcitol capsules for the prevention and treatment of secondary hyperparathyroidism in patients with CKD with the effect of treating renal osteodystrophy while avoiding hyperphosphatemia. Therefore, the proposed products and labeling in ANDA No. 202-539, if approved and marketed in the United States, would result in Banner knowingly and intentionally encouraging, promoting, and inducing infringement of the ’815 patent.

28. Moreover, there is no substantial non-infringing use of paricalcitol capsules that is authorized in the United States. The proposed products and labeling in ANDA No. 202-539 constitute a material part of the claimed method, are knowingly and especially made and adapted for use in that method, and, if approved and marketed in the United States, will unavoidably contribute to the infringement of the '815 patent.

29. Plaintiffs are commencing this action within forty-five days of the date they received Banner's Paragraph IV Notice of ANDA No. 202-539 containing the Paragraph IV Certification.

30. Banner purported to include an "Offer of Confidential Access" to Plaintiffs[3] to ANDA No. 202-539 along with its Paragraph IV Notice. Under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(III), restrictions to an Offer of Confidential Access must serve the purpose of protecting trade secrets and other confidential business information. Restrictions may not be made based on counsel's status as in-house. *U.S. Steel Corp. v. U.S.*, 730 F.2d 1465, 1468 (Fed. Cir. 1984); *see also Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 936 (N.D. Ill. 2010) (applying *U.S. Steel* to an Offer of Confidential Access).

31. Banner's Offer of Confidential Access restricted disclosure to outside counsel and certain of their support staff, and required that the outside counsel (a) not be involved in patent prosecution matters for the Plaintiffs, (b) not be responsible for competitive decision making with respect to any product containing paricalcitol, and (c) not be involved in any current or potential matters with the FDA for the Plaintiffs. Banner's Offer of Confidential Access also provided remedies for violation of the Offer of Confidential Access that were above

[3] The Offer of Confidential Access was directed to Abbott and WARF.

those allowed under the law, and restricted disclosure to unspecified sections of ANDA No. 202-539 that Banner in its sole discretion would choose to make available to Plaintiffs at some point in the future.

32. The proposed terms of Banner's Offer of Confidential Access to Plaintiffs did not allow any of Plaintiffs' in-house litigation team members, who are crucial decision-makers in the process of filing any infringement action, access to the necessary information with which to decide whether Banner's proposed generic copy of Abbott's paricalcitol capsule likely infringed Plaintiffs' patent. The restrictions to other work performed by those having access to the ANDA were not directed to the purpose of protecting trade secrets and other confidential business information. Additionally, the remedies Banner sought for violation of the Offer of Confidential Access were above those allowed under the law. Furthermore, under the proposed terms of Banner's Offer of Confidential Access, Banner could have technically complied by making very minimal disclosures to Plaintiffs.

33. After a series of negotiations between Banner and Plaintiffs' outside counsel, the parties have reached some agreement on the terms of Banner's Offer of Confidential Access. Plaintiffs, however, cannot agree to all of the restrictions Banner continues to place on its Offer of Confidential Access, and, therefore, are necessarily filing this Complaint without having had any access to any portion of Banner's ANDA.

34. Banner has committed and will commit acts of infringement of the patent-in-suit that create a justiciable case or controversy between Plaintiffs and Banner. Pursuant to 35 U.S.C. § 271(e)(2)(A), Banner committed an act of infringement by filing an ANDA with a Paragraph IV Certification that seeks FDA-marketing approval for Banner's generic versions of Abbott's paricalcitol capsule products prior to expiration of the patent-in-suit. This Court has

subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the patent-in-suit.

## COUNT I
## INFRINGEMENT OF THE '815 PATENT

35. Paragraphs 1-36 are incorporated herein by reference.

36. Under 35 U.S.C. § 271(e)(2)(A), Banner infringed one or more claims of the '815 patent by submitting to the FDA an ANDA seeking approval to commercially market, before the expiration date of the '815 patent, generic paricalcitol capsule products labeled for the prevention and treatment of secondary hyperparathyroidism associated with CKD, products the use or sale of which would infringe and contribute to and induce direct infringement of one or more claims of the '815 patent by ultimate purchasers.

37. Upon information and belief, Banner has infringed, induced or contributed to and will infringe, induce or contribute to infringement of at least claim 4 of the '815 patent by (1) filing ANDA No. 202-539 seeking approval to introduce into interstate commerce generic paricalcitol capsule products in 1 mcg, 2 mcg, and 4 mcg formulations; (2) preparing to sell generic paricalcitol capsule products pursuant to its ANDA; and (3) intending to sell such generic paricalcitol capsule products, upon FDA approval, together with instructions and labeling which will result in direct infringement of at least claim 4 of the '815 patent by ultimate purchasers and users.

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

## COUNT II
## DECLARATORY JUDGMENT AS TO THE '815 PATENT

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

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

41. Upon further information and belief, Banner intends to commence sales of such generic paricalcitol capsule products immediately upon receiving approval from the FDA.

42. The manufacture, importation, use, sale, and offer for sale of such generic paricalcitol capsule products, once approved by the FDA, would infringe one or more claims of the ’815 patent.

43. Banner’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such generic paricalcitol capsule products would infringe and contribute to or induce direct infringement of one or more claims of the ’815 patent.

44. Plaintiffs will be substantially and irreparably damaged and harmed if Banner’s threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

## EXCEPTIONAL CASE

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

46. This is an exceptional case warranting imposition of attorneys’ fees against Defendant Banner under 35 U.S.C. § 285.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Banner as follows:

(a) declaring the ’815 patent valid and enforceable;

(b) finding that Banner has infringed one or more claims of the ’815 patent by filing ANDA No. 202-539 under 21 U.S.C. § 355(j)(2);

(c) finding that Banner has infringed one or more claims of the '815 patent by the threatened acts of making, importing, using, offering to sell, or selling its generic paricalcitol capsule products prior to the expiration of said patent;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Banner's ANDA No. 202-539 relating to generic paricalcitol capsule products before the expiration of the six-month period of market exclusivity for the '815 patent granted under 21 U.S.C. § 355A;

(e) enjoining Banner from commercially making, importing, using, offering to sell, or selling its generic paricalcitol capsule products, in accordance with 35 U.S.C. § 271(e)(4)(B);

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

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