IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and WISCONSIN ALUMNI RESEARCH FOUNDATION,	)	
Plaintiffs,	)	C.A. No._____
v.	)	
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs AbbVie Inc. ("AbbVie") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendants Aurobindo Pharma Ltd. ("Aurobindo Ltd.") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively, "Defendants" or "Aurobindo") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 5,597,815 ("the '815 patent"); 6,136,799 ("the '799 patent"); and 6,361,758 ("the '758 patent"). This action arises out of Aurobindo's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of AbbVie'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. AbbVie is a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 1 N. Waukegan Road, North Chicago, 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 provide faculty and graduate student fellowships.

4. On information and belief, Defendant Aurobindo Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad - 500 038, Andhra Pradesh, India.

5. On information and belief, Defendant Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

JURISDICTION AND VENUE

6. 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).

7. Aurobindo Ltd. is subject to personal jurisdiction in this district because, *inter alia*, together with Aurobindo USA, Aurobindo Ltd. has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement against AbbVie, a Delaware corporation.

8. This Court also has personal jurisdiction over Aurobindo Ltd. because, *inter alia*, together with Aurobindo USA (a Delaware corporation), Aurobindo Ltd. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware and by having previously submitted itself to personal jurisdiction in this Court. Upon information and belief, Aurobindo Ltd. develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States including this judicial district, through various directly- or indirectly-owned operating subsidiaries, including its wholly-owned subsidiary Aurobindo USA. Upon information and belief, Aurobindo Ltd. and Aurobindo USA work in concert for purposes of developing, formulating, manufacturing, marketing, and selling Aurobindo Ltd.'s generic drug products throughout the United States, including Delaware, and Delaware is a likely destination of Aurobindo Ltd.'s generic products.

9. Aurobindo USA 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, the regular sales of pharmaceutical products within the State of Delaware. On information and belief, Aurobindo USA is in the business of, among other things, formulating, developing, manufacturing,

marketing, and selling generic copies of branded pharmaceutical products for the United States market, including in this district. On information and belief, Aurobindo USA holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0001270. On information and belief, Aurobindo USA holds a Distributor/Manufacturer License No. DM-0006550. On information and belief, Aurobindo USA has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware and by having previously submitted itself to personal jurisdiction in this Court.

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

FACTS PERTINENT TO ALL COUNTS

11. The ’815 patent, entitled “Prevention of Hyperphosphatemia in Kidney Disorder Patients,” issued on January 28, 1997, and a copy is attached hereto as Exhibit A. Named inventors Hector DeLuca and Eduardo Slatopolsky assigned the ’815 patent to WARF and Washington University, respectively, and Washington University transferred all substantial rights in the ’815 patent to WARF. AbbVie is the exclusive licensee of the ’815 patent.

12. The ’815 patent expires on July 13, 2015.

13. On October 24, 2000, the PTO issued the ’799 patent, entitled “Cosolvent Formulations,” to Plaintiff AbbVie, 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.

14. The ’799 patent expires on April 8, 2018.

15. On March 26, 2002, the PTO issued the ’758 patent, entitled “Cosolvent Formulations,” to Plaintiff AbbVie, 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.

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

17. The '815, '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 or the use of paricalcitol, which is marketed by AbbVie under the brand name Zemplar®. The '815 patent claims an approved use of paricalcitol as set forth in the FDA's Orange Book, Patent Use Code U-1195, which recites the use of paricalcitol for "Prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5, which may result in renal osteodystrophy, while avoiding hyperphosphatemia."

18. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of each of the '815, '799, and '758 patents.

19. On information and belief, Aurobindo Ltd. and Aurobindo USA collaborate in the development, manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) within the United States generally, and the State of Delaware specifically.

20. On information and belief, Defendants actively review pharmaceutical patents and seeks opportunities to challenge those patents.

21. On information and belief, Aurobindo Ltd. and Aurobindo USA collaborated in the research, development, preparation, and filing of ANDA No. 205982 for generic paricalcitol injection products.

22. Upon information and belief, Aurobindo prepared and submitted ANDA No. 205982 to the FDA, seeking approval to engage in the commercial manufacture, use, and sale of generic paricalcitol injection products in 0.002 mg/mL and 0.005 mg/mL formulations, prior to the expiration of the patents-in-suit.

23. On or about January 6, 2014, AbbVie and WARF received letters dated January 3, 2014, from Aurobindo Ltd. ("Paragraph IV Notice") notifying Plaintiffs that Aurobindo Ltd. had filed ANDA No. 205982 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), and stating that, in Aurobindo's opinion, the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the generic paricalcitol injection products described in ANDA No. 205982.

24. On information and belief, Aurobindo Ltd. and Aurobindo USA collaborated and acted in concert in the decision to file and the filing of ANDA No. 205982 containing the Paragraph IV certification.

25. On information and belief, Aurobindo Ltd. and Aurobindo USA were necessarily aware of the patents-in-suit when they filed ANDA No. 205982 containing the Paragraph IV certification with the FDA.

26. 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 selected from a 19-nor-vitamin D_2 compound [where the vitamin D compound is paricalcitol]" reads on the proposed label of Aurobindo's paricalcitol injection ANDA No. 205982.

27. On information and belief, Aurobindo seeks FDA-marketing approval under 21 U.S.C. § 355(j) *et. seq.* for paricalcitol injection drug products for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5. This use is the only FDA authorized use of paricalcitol injection, and, if approved, would induce infringement of at least claim 4 of the '815 patent prior to its expiration.

28. 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 chronic kidney disease. 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 chronic kidney disease and its corresponding abnormalities in bone metabolism. PTH is a major regulator of bone turnover and skeletal cellular activity.

29. 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.

30. 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 D, 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.

31. Numerous studies have shown that renal osteodystrophy is associated with high serum levels of intact PTH. The approved labeling of Zemplar® recommends paricalcitol in chronic kidney disease (CKD) Stage 5 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.

32. Upon information and belief, Aurobindo'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 D, Approved Labeling of Zemplar®, "Clinical Pharmacology".) Accordingly, a treating physician or healthcare professional following Aurobindo's proposed labeled indication would intend that the use of paricalcitol injection to treat secondary hyperparathyroidism in patients with late stage renal failure 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.

33. At the time the '815 patent was filed, renal osteodystrophy was understood as a broad term that encompasses secondary hyperparathyroidism such that treatment of

secondary hyperparathyroidism was understood to be treatment of renal osteodystrophy. For example, a 1988 publication by Dr. DeLuca, described how the discovery of the active form of vitamin D led to "an immediate application" to renal osteodystrophy in that oral treatment with a synthetic form of the drug resulted in, inter alia, "a suppression of secondary hyperparathyroidism." (H. DeLuca, The Vitamin D Story, 2 FASEB J 224 (1988).) The same article noted that injection of synthetic active vitamin D was "extremely effective in suppressing secondary hyperparathyroidism found in renal osteodystrophy." (*Id.* at 226.) A 1991 treatise chapter co-authored by Dr. Slatopolsky described the treatment of secondary hyperparathyroidism as an objective under the general heading of "Prevention and Management of Renal Osteodystrophy." These publications reflect the understanding of skilled artisans in the field that treatment of renal osteodystrophy would encompass treatment of secondary hyperparathyroidism such that the '815 patent claims would cover the approved indication for Zemplar and Aurobindo's generic paricalcitol products.

34. 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 injection described in the Zemplar® label, which, upon information and belief, will be copied by Aurobindo with respect to its ANDA products and included with every vial of Aurobindo's proposed paricalcitol injectable drug products.

35. Based on the Zemplar® label, physicians and healthcare professionals prescribing and administering paricalcitol injection 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.

36. Upon information and belief, Defendants have knowledge of the claims and disclosures of ’815 patent, and have knowledge that their proposed label directs physicians and healthcare professionals to prescribe paricalcitol injection for the prevention and treatment of secondary hyperparathyroidism in patients with chronic kidney disease Stage 5 with the effect of treating renal osteodystrophy while avoiding hyperphosphatemia. Therefore, the proposed products and labeling in ANDA No. 205982, if approved and marketed in the United States, would result in Defendants knowingly and intentionally encouraging, promoting, and inducing infringement of the ’815 patent.

37. Moreover, there is no substantial non-infringing use of paricalcitol injection that is authorized in the United States. The proposed products and labeling in ANDA No. 205982, if approved and marketed in the United States, will unavoidably contribute to the infringement of the ’815 patent.

38. Plaintiffs are commencing this action within forty-five days of the date they received Aurobindo’s Paragraph IV Notice of ANDA No. 205982 containing the Paragraph IV certification.

39. Aurobindo has committed and will commit acts of infringement of the patents-in-suit that create a justiciable case or controversy between Plaintiffs and Aurobindo. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo committed an act of infringement by filing an

ANDA with a Paragraph IV certification that seeks FDA-marketing approval for Aurobindo's generic versions of AbbVie'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.

40. Upon information and belief, Aurobindo Ltd. and Aurobindo USA continue to collaborate in seeking approval of ANDA No. 205982 from the FDA and intend to collaborate in the commercial manufacturing, marketing, and sale of a generic paricalcitol injection (including commercial marketing and sale of such products in the State of Delaware) in the event that the FDA approves ANDA No. 205982.

COUNT 1
INFRINGEMENT OF THE '815 PATENT

41. Paragraphs 1–40 are incorporated herein by reference.

42. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo 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 injectable drug 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 direct infringement of one or more claims of the '815 patent by ultimate purchasers.

43. Upon information and belief, Aurobindo 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. 205982 seeking approval to introduce into interstate commerce paricalcitol injectable drug products in 0.002 mg/mL and 0.005 mg/mL formulations; (2) preparing to sell generic paricalcitol injectable drug products pursuant to ANDA No. 205982;

and (3) intending to sell such generic paricalcitol injectable drug 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.

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

COUNT 2
DECLARATORY JUDGMENT AS TO THE ’815 PATENT

45. Paragraphs 1–44 are incorporated herein by reference.

46. Upon information and belief, Defendants have acted in concert and made substantial preparations to sell generic paricalcitol injection products labeled for the same indication and the same dosage and method of use as the Zemplar® products sold by AbbVie.

47. Upon further information and belief, Defendants intend to commence sales of such generic paricalcitol injectable drug products immediately upon receiving approval from the FDA.

48. The manufacture, importation, use, sale, or offer for sale of such generic paricalcitol injectable drug products, once approved by the FDA, will infringe one or more claims of the ’815 patent.

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

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

COUNT 3
INFRINGEMENT OF THE '799 PATENT

51. Paragraphs 1–50 are incorporated herein by reference.

52. Under 35 U.S.C. § 271 (e)(2)(A), Aurobindo infringed one or more claims of the '799 patent by submitting to the FDA an ANDA seeking approval to commercially market, before the expiration date of the '799 patent, 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.

53. AbbVie will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 4
DECLARATORY JUDGMENT AS TO THE '799 PATENT

54. Paragraphs 1–53 are incorporated herein by reference.

55. Upon information and belief, Defendants have 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 AbbVie.

56. Upon further information and belief, Defendants intend to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

57. The manufacture, importation, use, 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.

58. Defendants' 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.

59. AbbVie will be substantially and irreparably damaged and harmed if Defendants' threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 5
INFRINGEMENT OF THE '758 PATENT

60. Paragraphs 1–59 are incorporated herein by reference.

61. Under 35 U.S.C. § 271 (e)(2)(A), Aurobindo infringed one or more claims of the '758 patent by submitting to the FDA an ANDA seeking approval to commercially market, before the expiration date of the '758 patent, 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.

62. AbbVie will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. AbbVie does not have an adequate remedy at law.

COUNT 6
DECLARATORY JUDGMENT AS TO THE '758 PATENT

63. Paragraphs 1–62 are incorporated herein by reference.

64. Upon information and belief, Defendants have 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 AbbVie.

65. Upon further information and belief, Defendants intend to commence sales of such generic paricalcitol injection products immediately upon receiving approval from the FDA.

66. The manufacture, importation, use, 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.

67. Defendants' 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.

68. AbbVie will be substantially and irreparably damaged and harmed if Defendants' threatened infringement is not enjoined. AbbVie does not have an adequate remedy at law.

EXCEPTIONAL CASE

69. Paragraphs 1–68 are incorporated herein by reference.

70. 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 Aurobindo as follows:

(a) declaring the '815, '799, and '758 patents valid and enforceable;

(b) finding that Aurobindo has infringed one or more claims of the '815, '799, and '758 patents by filing ANDA No. 205982 under 21 U.S.C. § 355(j)(2);

(c) declaring that Aurobindo has infringed one or more claims of the '815, '799, and '758 patents by the threatened acts of making, importing, 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 Aurobindo's ANDA No. 205982 relating to generic paricalcitol injection products before the expiration of the six-month period of market exclusivity for the '815, '799, and '758 patents granted under 21 U.S.C. § 355A;

(d) enjoining Aurobindo from commercially making, importing, 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)(C); 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)
Derek J. Fahnestock (#4705)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
dfahnestock@mnat.com
Attorneys for AbbVie Inc. 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

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