IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and WISCONSIN ALUMNI RESEARCH FOUNDATION, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL FZE, and SUN PHARMACEUTICAL INDUSTRIES, INC. Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs AbbVie Inc. ("AbbVie") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendants Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global FZE ("Sun FZE"), and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively "Sun" or "Defendants"), 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 Sun's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of AbbVie's highly successful Zemplar® paricalcitol capsules in 1 mcg, 2 mcg, and 4 mcg formulations, prior to the expiration of the '815 patent.

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 support many faculty and graduate student fellowships.

4. On information and belief, Defendant Sun Ltd. is a company organized and existing under the laws of India with a principal place of business at Acme Plaza, Andheri Kurla Rd., Andheri East, Mumbai 400 059, India. On information and belief, Sun Ltd. manufactures generic drug products for sale and use throughout the United States, including in this judicial district, including through its wholly-owned subsidiary Sun Inc. Sun Ltd. has been a named party in lawsuits filed in the United States District Court for the District of Delaware where it has not contested jurisdiction.

5. On information and belief, Defendant Sun FZE is a company organized and existing under the laws of the United Arab Emirates with a principal place of business at Executive Suite #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, U.A.E. On information

and belief, Sun FZE is a wholly owned subsidiary of Sun Pharma Global Inc., which is a company incorporated under the laws of the British Virgin Islands and a wholly-owned subsidiary of Sun Ltd. Sun FZE has been a named party in lawsuits filed in the United States District Court for the District of Delaware where it has not contested jurisdiction.

6. On information and belief, Defendant Sun Inc. is a company organized and existing under the laws of Michigan, having a place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. On information and belief, Sun Inc. manufactures generic drug products for sale and use throughout the United States, including in this judicial district. Sun Inc. is a wholly owned subsidiary of Sun Ltd. Sun Inc. has been a named party in lawsuits filed in the United States District Court for the District of Delaware where it has not contested jurisdiction.

JURISDICTION AND VENUE

7. 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).

8. Defendants are each subject to personal jurisdiction in this district because, *inter alia*, they committed or aided, abetted, contributed to, and/or participated in the commission of an act of patent infringement against AbbVie, a Delaware corporation. This Court also has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Delaware. For example, Defendants regularly and continuously transact business within the State of Delaware, including, but not limited to, the regular sale of drug products within the State of Delaware.

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

FACTS PERTINENT TO ALL COUNTS

10. 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 F. 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.

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

12. The ’815 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”) as covering 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.”

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

14. On information and belief, Defendants manufacture, market, and sell pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs, for distribution with the United States generally, and into the State of Delaware specifically.

15. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

16. On information and belief, Defendants prepared and submitted with the FDA ANDA No. 20-4564, 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 '815 patent.

17. On information and belief, Defendants acted collaboratively in developing the generic drug products that are the subject of ANDA No. 20-4564 and in preparing and submitting ANDA No. 20-4564. On information and belief, Sun FZE's preparation and submission of ANDA No. 20-4564 was done at the direction, under the control, and for the direct benefit of Sun Ltd.

18. On or about December 11, 2012, Plaintiffs[1] received a letter dated December 10, 2012, from Defendants notifying Plaintiffs that Defendants had filed ANDA No. 20-4564 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), and stating that, in Defendants' opinion, the '815 patent is "not infringed, invalid and/or unenforceable."

19. Defendants were necessarily aware of the '815 patent when they filed ANDA No. 20-4564 containing the Paragraph IV Certification with the FDA.

20. 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

[1] The letter was addressed to Abbott Laboratories rather than Plaintiff AbbVie.

that has minimal effect on blood serum phosphorus of said patient, said vitamin D compound selected from a 19-nor-vitamin D_2 compound [wherein the vitamin D compound is paricalcitol]" reads on the proposed label of Defendants' ANDA No. 20-4564.

21. On information and belief, Defendants seek 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.

22. 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.

23. 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 have assumed that because

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

24. 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.

25. 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.

26. Upon information and belief, Defendants' 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 Defendants' proposed labeled indication would intend that the use of paricalcitol capsules to treat secondary hyperparathyroidism in patients with CKD would also treat bone abnormalities associated with elevated PTH; that is, would thus also treat renal osteodystrophy as described and claimed in the '815 patent.

27. 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.* at 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 Defendants with respect to their ANDA product and included with every vial of Defendants' proposed paricalcitol capsule products.

28. 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.

29. 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 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. 20-4564, if approved and marketed in the United States, would result in Defendants knowingly and intentionally encouraging, promoting, and inducing infringement of the '815 patent.

30. 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. 20-4564, if approved and marketed in the United States, will unavoidably contribute to the infringement of the ’815 patent.

31. Plaintiffs are commencing this action within forty-five days of the date they received Defendants’ Notice of ANDA No. 20-4564 containing the Paragraph IV Certification.

32. Plaintiffs and Defendants have agreed to a revised Offer of Confidential Access to Defendants’ ANDA, but Defendants have not yet provided a copy of any portion of the ANDA.

33. Defendants have committed and will commit acts of infringement of the ’815 patent that create a justiciable case or controversy between Plaintiffs and Defendants. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants committed an act of infringement by filing an ANDA with a Paragraph IV Certification that seeks FDA-marketing approval for Defendants’ generic versions of AbbVie’s paricalcitol capsule products prior to expiration of the ’815 patent.

34. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs’ rights under the ’815 patent.

COUNT 1
INFRINGEMENT OF THE ’815 PATENT

35. Paragraphs 1-34 are incorporated herein by reference.

36. Under 35 U.S.C. § 271(e)(2)(A), Defendants 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, Defendants have 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. 20-4564 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 their 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 Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT 2
DECLARATORY JUDGMENT AS TO THE '815 PATENT

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

40. Upon information and belief, Defendants have 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 AbbVie.

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

42. The manufacture, importation, use, sale, or 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. Defendants' 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 Defendants' threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

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

(b) finding that Defendants have infringed one or more claims of the '815 patent by filing ANDA No. 20-4564;

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

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Defendants' ANDA No. 20-4564 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 Defendants from commercially making, importing, using, offering to sell, or selling their 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.

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/s/ Mary B. Graham

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