IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and WISCONSIN ALUMNI RESEARCH FOUNDATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
HOSPIRA, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") (collectively, "Plaintiffs"), for their Complaint against Defendant Hospira, Inc., ("Hospira"), 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 Hospira's filing of a New Drug Application ("NDA") under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(b)(2), with the U.S. Food and Drug Administration ("FDA") for approval to manufacture and sell paricalcitol injectable drug products prior to the expiration of the '815 patent.

THE PARTIES

2. Abbott is a corporation organized 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. WARF is a not-for-profit 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 has contributed more than a billion dollars to the University, including money to fund research, build facilities, purchase land and equipment, and support many faculty and graduate student fellowships.

4. On information and belief, Defendant Hospira is a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 275 Field Drive, Lake Forest, Illinois 60045.

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. Hospira 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 sale of pharmaceutical products within the State of Delaware.

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

FACTS PERTINENT TO ALL COUNTS

8. 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. A copy of the '815 patent is attached hereto as Exhibit A.

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

10. 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 Abbott 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."

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

12. On information and belief, Hospira prepared and submitted with the FDA NDA No. 201-657 under § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), (also known as a 505(b)(2) application), seeking approval to engage in the commercial manufacture, use, and sale of paricalcitol injectable drug products in 2 mcg/ml, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations, prior to the expiration of the patent-in-suit.

13. On or about June 8, 2011, Abbott received a letter ("First Paragraph IV Notice") dated June 7, 2011, from Hospira notifying Abbott that Hospira had filed NDA No. 201-657 containing a certification under § 505(b)(2)(A)(iv) of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv), ("Paragraph IV Certification"), and stating that two patents listed in the Orange Book as covering paricalcitol, U.S. Patent Nos. 6,136,799 ("the '799 patent") and 6,361,758 ("the '758 patent"), are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, offer for sale or sale of the [paricalcitol injectable] drug product[s] described in Hospira's NDA."

14. Abbott filed a Complaint (C.A. No. 11-648-GMS, D.I. 1) against Hospira on July 21, 2011, for infringement of the '799 and '758 patents within forty-five days of the date it received Hospira's Paragraph IV Notice of NDA No. 201-657 containing the Paragraph IV Certification, pursuant to § 505(b)(3)(B) of the FFDCA.

15. Hospira filed an Answer to Plaintiff's Complaint (C.A. No. 11-648-GMS, D.I. 7) admitting that it submitted NDA No. 201-657 to the FDA under the provisions of § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), seeking approval to introduce into interstate commerce paricalcitol injectable drug products in 2 mcg/ml, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations, prior to the expiration of the '799 patent and the '758 patent. (C.A. No. 11-648-GMS, D.I. 7, Answer at ¶ 13.)

16. Hospira's Answer in C.A. No. 11-648-GMS further admitted that an actual, justiciable controversy exists within this jurisdiction regarding the infringement of the '799 patent and the '758 patent by Hospira's proposed generic paricalcitol injectable drug products, as evidenced by Abbott's Complaint and Abbott's listing of the '799 patent and

the '758 patent in the Orange Book with respect to Abbott's NDA No. 020-819. (C.A. No. 11-648-GMS, D.I. 7, Counterclaims at ¶ 9.)

17. On or about July 27, 2011, Abbott and WARF received a second letter ("Second Paragraph IV Notice") dated July 26, 2011, from Hospira notifying Abbott and WARF that Hospira had amended its Paragraph IV Certification stating that an additional patent listed in the Orange Book as covering paricalcitol, U.S. Patent No. 5,587,497 ("the '497 patent"), is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, offer for sale or sale of the [paricalcitol injectable] drug product[s] described in Hospira's NDA."

18. Plaintiffs filed a Complaint (C.A. No. 11-795-GMS, D.I. 1) against Hospira on September 9, 2011, for infringement of the '497 patent within forty-five days of the date they received Hospira's Second Paragraph IV Notice containing the amended Paragraph IV Certification against the '497 patent pursuant to § 505(b)(3)(B) of the FFDCA.

19. Hospira filed an Answer to Plaintiffs' Complaint (C.A. No. 11-795-GMS, D.I. 6) admitting that it submitted NDA No. 201-657 to the FDA under the provisions of § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), seeking approval to introduce into interstate commerce paricalcitol injectable drug products in 2 mcg/ml, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations, prior to the expiration of the '497 patent. (C.A. No. 11-795-GMS, D.I. 6, Answer at ¶ 12.)

20. Hospira's Answer in C.A. No. 11-795-GMS further admitted that an actual, justiciable controversy exists within this jurisdiction regarding the infringement of the '497 patent by Hospira's proposed generic paricalcitol injectable products, as evidenced by Plaintiffs' Complaint and Abbott's listing of the '497 patent in the Orange Book with respect to Abbott's NDA No. 020-819. (C.A. No. 11-795-GMS, D.I. 6, Counterclaims at ¶ 9.)

21. The ’815 patent was listed in the Orange Book no later than December 6, 2011, and the Plaintiffs provided notice of the ’815 patent listing to Hospira on December 7, 2011.

22. This action is being commenced by Abbott and WARF without Hospira having provided a Paragraph IV Notice addressing the ’815 patent.

23. 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 [wherein the vitamin D compound is paricalcitol] . . . .” reads on the proposed label of Hospira’s paricalcitol injection NDA No. 201-657.

24. Upon information and belief, Hospira seeks FDA marketing approval under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2) of 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.

25. 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.

26. 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.

27. 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.

28. 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 (Stage 5) 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.

29. Upon information and belief, Hospira'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 Hospira'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.

30. 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." ('815 patent, 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, on information and belief, will be copied by Hospira with respect to its NDA product and included with every vial of Hospira's proposed paricalcitol injection products.

31. 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.

32. Upon information and belief, Hospira has knowledge of the claims and disclosures of '815 patent, and has knowledge that its 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 NDA No. 201-657, if approved and marketed in the United States, would result in Hospira knowingly and intentionally encouraging, promoting, and inducing infringement of the '815 patent.

33. Moreover, there is no substantial non-infringing use of paricalcitol injection that is authorized in the United States. The proposed products and labeling in NDA No. 201-657 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.

34. By filing NDA No. 201-657 prior to expiration of the '815 patent and by its continued approval to market a generic version of Zemplar® injection, Hospira committed and will commit acts of infringement pursuant to 35 U.S.C. § 271.

35. This Court has subject matter jurisdiction with respect to this action to declare Abbott's rights under the '815 patent.

COUNT 1
INFRINGEMENT OF THE '815 PATENT

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

37. Under 35 U.S.C. § 271(e)(2)(A), Hospira infringed one or more claims of the '815 patent by submitting to the FDA an NDA under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2), seeking approval for the commercial marketing, before the expiration date of the '815 patent, of its paricalcitol injectable drug products, the using, selling, or offering for sale of which would infringe one or more claims of the '815 patent.

38. Upon information and belief, Hospira 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 NDA No. 201-657 seeking approval to introduce into interstate commerce paricalcitol injectable drug products in 2 mcg/ml, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations; (2) preparing to sell paricalcitol injection products pursuant to the NDA; and (3) intending to sell such paricalcitol injection 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.

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

COUNT 2
DECLARATORY JUDGMENT AS TO THE '815 PATENT

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

41. Upon information and belief, Hospira has made substantial preparations to sell the paricalcitol injectable drug products described in NDA No. 201-657.

42. Upon further information and belief, Hospira intends to commence sales of such paricalcitol injectable drug products immediately upon receiving approval from the FDA.

43. The manufacture, importation, use, sale, or offer for sale of paricalcitol injectable drug products, once approved by the FDA, would infringe and/or induce and/or contribute to infringement of one or more claims of the '815 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Hospira as follows:

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

(b) finding that Hospira has infringed one or more claims of the '815 patent by filing NDA No. 201-657 under § 505(b)(2) of the of the FFDCA, 21 U.S.C. § 355(b)(2);

(c) declaring that Hospira would infringe one or more claims of the '815 patent by the threatened acts of making, importing, using, offering to sell, or selling its paricalcitol injectable products prior to the expiration of said patent;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Hospira's NDA No. 201-657 relating to paricalcitol injectable 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 Hospira from commercially making, importing, using, offering to sell, or selling its paricalcitol injectable products, in accordance with 35 U.S.C. § 271(e)(4)(B);

(f) finding this to be an exceptional case and awarding Plaintiffs attorney 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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