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. 5,587,497 ("the '497 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 '497 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 December 24, 1996, 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. The '497 patent is one of the patents listed in the 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®.

11. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of the '497 patent.

12. On information and belief, Hospira prepared and submitted to 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 '497 patent.

13. On or about June 8, 2011, Abbott received a letter ("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 other 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. 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 with respect to the '497 patent, and stating that "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."

16. This action is being commenced by Abbott and WARF within forty-five days of the date it received Hospira's Second Paragraph IV Notice of NDA No. 201-657 containing the amended Paragraph IV Certification, pursuant to § 505(b)(3)(B) of the FFDCA.

17. On information and belief, Hospira was necessarily aware of the '497 patent when it filed NDA No. 201-657 containing the Paragraph IV Certification with the FDA, and when it amended its Paragraph IV Certification.

18. Hospira has committed and will commit acts of infringement of the '497 patent that create a justiciable case or controversy between Plaintiffs and Hospira. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hospira committed an act of infringement by filing an NDA under § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), with a Paragraph IV Certification that seeks FDA marketing approval for Hospira's paricalcitol injectable drug products prior to expiration of

the ’497 patent. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs’ rights under the ’497 patent.

COUNT 1
INFRINGEMENT OF THE ’497 PATENT

19. Paragraphs 1-18 are incorporated herein by reference.

20. Under 35 U.S.C. § 271(e)(2)(A), Hospira infringed one or more claims of the ’497 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 ’497 patent, of its paricalcitol injectable drug products, the making, using, selling, offering for sale, or importing of which would one or more claims of the ’497 patent.

21. 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 ’497 PATENT

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

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

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

25. The manufacture, use, importation, sale, or offer for sale of paricalcitol injectable drug products, once approved by the FDA, would infringe one or more claims of the ’497 patent.

26. 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.

EXCEPTIONAL CASE

27. Paragraphs 1-26 are incorporated herein by reference.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Hospira as follows:

(a) declaring the ’497 patent is valid and enforceable;

(b) finding that Hospira has infringed one or more claims of the ’497 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 ’497 patent by the threatened acts of making, using, importing, 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 ’497 patent granted under 21 U.S.C. § 355A;

(e) enjoining Hospira from commercially manufacturing, 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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