IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") (collectively "Plaintiffs"), for their Complaint against Defendant Sandoz Inc., a Colorado corporation, ("Sandoz") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 5,587,497 ("the '497 patent"). This action arises out of Sandoz's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott's highly successful Zemplar® Paricalcitol Capsules, in a 4 mcg formulation, prior to the expiration of the '497 patent owned by and exclusively licensed to Plaintiffs.

THE PARTIES

2. Abbott Laboratories ("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. Wisconsin Alumni Research Foundation ("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 many faculty and graduate student fellowships.

4. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the state of Colorado having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

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. Sandoz is subject to personal jurisdiction in this district because it regularly and continuously transacts business within the State of Delaware. Sandoz markets and sells pharmaceutical products throughout the United States, including the State of Delaware. Sandoz derives substantial revenue from Delaware drug sales and has availed itself of the privilege of conducting business within the State of Delaware.

7. Sandoz did not challenge personal jurisdiction in this District in *Abbott Laboratories and Wisconsin Alumni Research Foundation v. Sandoz Inc. and Sandoz Canada Inc.*, No. 09-215 (GMS), an action involving Sandoz's finding of an ANDA seeking approval to sell a generic copy of Abbott's Zemplar® injectable products.

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

FACTS PERTINENT TO ALL COUNTS

9. On December 24, 1996, the United States Patent and Trademark Office ("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.

10. The '497 patent 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®. The '497 patent expires on December 24, 2013.

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

12. On information and belief, Sandoz manufactures, markets, and sells pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) within the United States generally, and the State of Delaware specifically.

13. On information and belief, Sandoz actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

14. On information and belief, Sandoz prepared and submitted ANDA No. 202-658 to the FDA, seeking approval to engage in the commercial manufacture, use, and sale of generic paricalcitol capsules, prior to the expiration of the patent-in-suit.

15. On or about March 29, 2011, Plaintiffs received a letter ("Paragraph IV Notice") dated March 28, 2011, from Sandoz notifying Plaintiffs that Sandoz had filed ANDA No. 202-658 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), and stating that, in Sandoz's opinion, the patent-in-suit is invalid or will not be infringed by the commercial manufacture, use, or sale of the generic paricalcitol capsules described in ANDA No. 202-658.

16. On information and belief, Sandoz was necessarily aware of the patent-in-suit when ANDA No. 202-658 containing the Paragraph IV certification was filed with the FDA.

17. This action is being commenced by Plaintiffs within forty-five days of the date they received Sandoz's Paragraph IV Notice of ANDA No. 202-658 containing the Paragraph IV certification.

18. Sandoz has committed and will commit acts of infringement of the '497 patent that create a justiciable case or controversy between Plaintiffs and Sandoz. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sandoz committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Sandoz's generic copies of Abbott's paricalcitol capsules 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), Sandoz infringed one or more claims of the '497 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '497 patent, of generic Paricalcitol Capsules labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stages 3 and 4, and the prevention and treatment of secondary hyperparathyroidism associated with CKD Stage 5 in patients on hemodialysis (HD) or peritoneal dialysis (PD), a product the use or sale of which would infringe and contribute to and induce the direct infringement of one or more claims of the '497 patent by ultimate purchasers.

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

COUNT 2
DECLARATORY JUDGMENT AS TO '497 PATENT

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

23. Upon information and belief, Sandoz has made substantial preparations to sell Paricalcitol Capsules labeled for the same indications and the same dosage and method of use as the Zemplar® product sold by Abbott.

24. Upon further information and belief, Sandoz intends to commence sales of such Paricalcitol Capsules immediately upon receiving approval from the FDA.

25. The manufacture, importation, sale, and offer for sale of Paricalcitol Capsules, once approved by the FDA, would infringe one or more claims of the '497 patent.

26. Sandoz's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such Paricalcitol Capsules would infringe and contribute to or induce infringement of one or more claims of the '497 patent.

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

EXCEPTIONAL CASE

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

29. 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 Sandoz as follows:

(a) declaring the '497 patent valid and enforceable;

(b) declaring that Sandoz would infringe one or more claims of the '497 patent by the threatened acts of using, offering to sell, or selling its paricalcitol capsule drug products prior to the expiration of said patent;

(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Sandoz's ANDA No. 202-658 relating to paricalcitol capsules before the expiration of the six-month period of market exclusivity for the '497 patent granted under 21 U.S.C. § 355(a);

(d) enjoining Sandoz from using, offering to sell, or selling its paricalcitol for capsule drug 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); and

(f) 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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