IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") (collectively "Plaintiffs"), for their Complaint against Defendant Roxane Laboratories, Inc. ("Roxane"), 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 Roxane'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 1 mcg, 2 mcg, and 4 mcg formulations, 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 Roxane is a Nevada corporation, having its principal place of business at 1809 Wilson Road, Columbus, OH 43228. On information and belief, Roxane is engaged in the manufacture and sale of pharmaceutical products throughout the United States including the state of Delaware.

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

7. Roxane did not challenge personal jurisdiction in this District in either *Genzyme Corp. v. Roxane Laboratories, Inc.*, No. 09-567 or *Genzyme Corp. v. Roxane Laboratories, Inc.*, No. 10-627.

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®.

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

12. On information and belief, Roxane 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, Roxane actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

14. On information and belief, Roxane prepared and submitted ANDA No. 202-069 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 October 8, 2010, Plaintiffs received a letter ("Paragraph IV Notice") dated October 5, 2010, from Roxane notifying Plaintiffs that Roxane had filed ANDA No. 202-069 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), and stating that, in Roxane'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. 202-069.

16. On information and belief, Roxane was necessarily aware of the patent-in-suit when ANDA No. 202-069 containing the Paragraph IV certification was filed with the FDA.

17. Plaintiffs commenced this action within forty-five days of the date they received Roxane's Paragraph IV Notice of ANDA No. 202-069 containing the Paragraph IV certification.

18. Roxane has committed and will commit acts of infringement of the '497 patent that create a justiciable case or controversy between Plaintiffs and Roxane. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Roxane'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), Roxane 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 Roxane'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, Roxane 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, Roxane 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. Roxane'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 Roxane'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, Abbott demands judgment against Roxane as follows:

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

(b) declaring that Roxane 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 Roxane's ANDA No. 202-069 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 Roxane 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 Abbott attorney fees under 35 U.S.C. §§ 285 and 271(e)(4); and

(f) awarding Abbott any further and additional relief as this Court deems just and proper.

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