IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, and WISCONSIN ALUMNI RESEARCH FOUNDATION, a Wisconsin nonprofit corporation,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PARENTERAL MEDICINES, INC., a Delaware corporation, TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., a foreign corporation organized under the laws of Israel,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") (collectively "Plaintiffs"), for their Complaint against Defendants Teva Parenteral Medicines, Inc. ("Teva Parenteral"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively "Teva"), allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 5,246,925 ("the '925 patent"); 5,587,497 ("the '497 patent"); and 6,136,799 ("the '799 patent"). This action arises out of Teva's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott's highly successful Zemplar® injectable products prior to the expiration of patents 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 Teva Parenteral is a Delaware corporation, having its principal place of business at 19 Hughes, Irvine, California 92618. On information and belief, Teva Parenteral manufactures injectable pharmaceuticals.

5. On information and belief, Defendant Teva USA is a Delaware corporation, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is engaged in the manufacture and sale of pharmaceutical products.

6. On information and belief, Defendant Teva Industries is an Israeli corporation, having a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. On information and belief, Teva Industries manufactures bulk pharmaceutical products.

7. On information and belief, Teva Parenteral is a wholly owned subsidiary of Teva USA.

8. On information and belief, Teva Industries owns 100% of the ownership and voting interest in Teva USA.

9. On information and belief, Teva USA is controlled and/or dominated by Teva Industries.

10. On information and belief, Teva Industries conducts its North American operations, in part, through Teva USA.

JURISDICTION AND VENUE

11. 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).

12. Teva Parenteral 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.

13. Teva USA 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.

14. Teva Industries is subject to personal jurisdiction in this District because, on information and belief, it regularly and continuously transacts business within the State of

Delaware, including, but not limited to, directing the operations and management of Teva USA, as well as shipping pharmaceuticals to Teva USA from locations outside the United States for distribution by Teva USA within the United States generally, and within this District specifically.

15. On information and belief, Teva Parenteral is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Teva USA and Teva Industries for the purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

16. On information and belief, Teva Parenteral acts as an agent of Teva USA and Teva Industries with respect to the acts complained of herein.

17. On information and belief, the acts of Teva Parenteral complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of, and, in part, for the benefit of Teva USA and Teva Industries.

18. Teva Parenteral's acts and contacts with this District, as an agent of Teva USA and Teva Industries, are attributable to Teva USA and Teva Industries for jurisdictional purposes.

19. 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

20. On September 21, 1993, the United States Patent and Trademark Office ("the PTO") issued the '925 patent, entitled "19-nor-Vitamin D Compounds for Use in Treating Hyperparathyroidism," 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 ’925 patent. A copy of the ’925 patent is attached hereto as Exhibit A.

21. 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 B.

22. On October 24, 2000, the PTO issued the ’799 patent, entitled “Cosolvent Formulations,” to Plaintiff Abbott, the assignee of the named inventors Lukchiu Li, Edward Anthony Pec, Daniel H. Robinson, Dennis A. Stephens, Kathee Jantzi, Thomas Barton May, and John Paul Oberdier. A copy of the ’799 patent is attached hereto as Exhibit C.

23. The ’925, ’497, and ’799 patents (collectively “the patents-in-suit”) are listed in a 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®.

24. Zemplar® has received pediatric exclusivity of six months beginning from the expiration of each of the ’925, ’497, and ’799 patents.

25. On information and belief, Teva Parenteral, Teva USA, and Teva Industries collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) within the United States generally, and the State of Delaware specifically.

26. On information and belief, Teva Industries actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

27. On information and belief, Teva Parenteral, Teva USA, and Teva Industries collaborated in the research, development, preparation, and filing of ANDA No. 91-583 for a generic paricalcitol injection.

28. On information and belief, Teva Parenteral submitted ANDA No. 91-583 to the FDA, seeking approval to engage in the commercial manufacture, use, and sale of a generic paricalcitol injection, prior to the expiration of the patents-in-suit.

29. Plaintiffs received a letter ("Paragraph IV Notice") dated October 9, 2009, from Teva Parenteral notifying Plaintiffs that Teva Parenteral had filed ANDA No. 91-583 containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), and stating that, in Teva Parenteral's opinion, the patents-in-suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the generic paricalcitol injection described in ANDA No. 91-583.

30. On information and belief, Teva Parenteral, Teva USA, and Teva Industries collaborated and acted in concert in the decision to file and the filing of ANDA No. 91-583 containing the Paragraph IV certification with the FDA.

31. On information and belief, Teva Parenteral, Teva USA, and Teva Industries were necessarily aware of the patents-in-suit when they filed ANDA No. 91-583 containing the Paragraph IV certification.

32. Plaintiffs commenced this action within forty-five days of the date they received Teva Parenteral's Paragraph IV Notice of ANDA No. 91-583 containing the Paragraph IV certification.

33. Teva Parenteral has committed and will commit acts of infringement of the '925, '497, and '799 patents that create a justiciable case or controversy between Plaintiffs

and Defendants. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva Parenteral committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Teva Parenteral's generic copy of Abbott's paricalcitol injection prior to expiration of the '925, '497, and '799 patents. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the '925, '497, and '799 patents.

34. On information and belief, Teva Parenteral, Teva USA, and Teva Industries continue to collaborate in seeking approval of ANDA No. 91-583 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of a generic paricalcitol injection (including commercial marketing and sale of such products in the State of Delaware) in the event that the FDA approves ANDA No. 91-583.

COUNT 1
INFRINGEMENT OF THE '925 PATENT

35. Under 35 U.S.C. § 271 (e)(2)(A), Teva Parenteral infringed one or more claims of the '925 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '925 patent, of generic Paricalcitol Injection, USP labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, a product the use or sale of which would infringe and contribute to or induce the direct infringement of one or more claims of the '925 patent by ultimate purchasers.

36. Upon information and belief, Teva USA and Teva Industries have also infringed, induced or contributed to and will infringe, induce or contribute to infringement of one or more claims of the '925 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Teva Parenteral (1) to file ANDA No. 91-583 for "Paricalcitol Injection, 0.002 mg/mL and 0.005 mg/mL" (2) to prepare to sell such a Paricalcitol Injection product pursuant to

that ANDA, and (3) upon FDA approval, to sell such a Paricalcitol Injection product together with instructions and labeling which will result in direct infringement of one or more claims of the ’925 patent by ultimate purchasers.

37. 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 ’925 PATENT

38. Paragraphs 1-37 are incorporated herein by reference.

39. Upon information and belief, Defendants have acted in concert and made substantial preparations to sell Paricalcitol Injection, USP labeled for the same indications and the same dosage and method of use as the Zemplar® product sold by Abbott.

40. Upon further information and belief, Defendants intend to commence sales of such Paricalcitol Injection, USP immediately upon receiving approval from the FDA.

41. The manufacture, importation, sale, and offer for sale of Paricalcitol Injection, USP so labeled, once approved by the FDA, will induce and contribute to infringement of one or more claims of the ’925 patent.

42. Defendants’ actions in actively aiding, abetting, encouraging, and inducing sales of such Paricalcitol Injection, USP threaten to and will infringe and induce or contribute to infringement of one or more claims of the ’925 patent.

43. 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.

COUNT 3
INFRINGEMENT OF THE '497 PATENT

44. Under 35 U.S.C. § 271 (e)(2)(A), Teva Parenteral 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 Injection, USP labeled for the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, a product the use or sale of which would infringe, and contribute to or induce the direct infringement of one or more claims of the '497 patent by ultimate purchasers.

45. Upon information and belief, Teva USA and Teva Industries have also infringed, induced or contributed to and will infringe, induce or contribute to infringement of one or more claims of the '497 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Teva Parenteral (1) to file ANDA No. 91-583 for "Paricalcitol Injection, 0.002 mg/mL and 0.005 mg/mL" (2) to prepare to sell such a Paricalcitol Injection product pursuant to that ANDA, and (3) upon FDA approval, to sell such a Paricalcitol Injection product together with instructions and labeling which will result in direct infringement of one or more claims of the '497 patent by ultimate purchasers.

46. 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 4
DECLARATORY JUDGMENT AS TO '497 PATENT

47. Paragraphs 1-46 are incorporated herein by reference.

48. Upon information and belief, Defendants have acted in concert and made substantial preparations to sell Paricalcitol Injection, USP labeled for the same indications and the same dosage and method of use as the Zemplar® product sold by Abbott.

49. Upon further information and belief, Defendants intend to commence sales of such Paricalcitol Injection, USP immediately upon receiving approval from the FDA.

50. The manufacture, importation, sale, and offer for sale of Paricalcitol Injection, USP so labeled, once approved by the FDA, will infringe and will induce or contribute to infringement of one or more claims of the '497 patent.

51. Defendants' actions in actively aiding, abetting, encouraging, and inducing sales of such Paricalcitol Injection, USP threaten to and will infringe and induce or contribute to infringement of one or more claims of the '497 patent.

52. 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.

COUNT 5
INFRINGEMENT OF THE '799 PATENT

53. Under 35 U.S.C. § 271 (e)(2)(A), Teva Parenteral infringed one or more claims of the '799 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '799 patent, of generic Paricalcitol Injection, USP labeled for use as the prevention and treatment of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) Stage 5, a product the use or sale of which would infringe, and contribute to or induce the direct infringement of one or more claims of the '799 patent by ultimate purchasers.

54. Upon information and belief, Teva USA and Teva Industries have also infringed, induced and contributed to and will infringe, induce or contribute to infringement of one or more claims of the '799 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Teva Parenteral (1) to file ANDA No. 91-583 for "Paricalcitol Injection, 0.002 mg/mL and 0.005 mg/mL" (2) to prepare to sell such a Paricalcitol Injection product pursuant to that ANDA, and (3) upon FDA approval, to sell such a Paricalcitol Injection product together with instructions and labeling which will result in direct infringement of one or more claims of the '497 patent by ultimate purchasers.

55. 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 6
DECLARATORY JUDGMENT AS TO '799 PATENT

56. Paragraphs 1-55 are incorporated herein by reference.

57. Upon information and belief, Defendants have acted in concert and made substantial preparations to sell Paricalcitol Injection, USP labeled for the same indications and the same dosage and method of use as the Zemplar® product sold by Abbott.

58. Upon further information and belief, Defendants intend to commence sales of such Paricalcitol Injection, USP immediately upon receiving approval from the FDA.

59. The manufacture, importation, sale, and offer for sale of Paricalcitol Injection, USP so labeled, once approved by the FDA, will infringe, and will induce and contribute to infringement of one or more claims of the '799 patent.

60. Defendants' actions in actively aiding, abetting, encouraging, and inducing sales of such Paricalcitol Injection, USP threaten to and will infringe and induce or contribute to infringement of one or more claims of the '799 patent.

61. 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.

EXCEPTIONAL CASE

62. Paragraphs 1-61 are incorporated herein by reference.

63. 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 Teva Parenteral, Teva USA, and Teva Industries as follows:

(a) declaring the '497, '925, and '799 patents valid and enforceable;

(b) declaring that Teva Parenteral, Teva USA, and Teva Industries would infringe one or more claims of the '497, '925, and '799 patents by the threatened acts of using, offering to sell, or selling its paricalcitol for injection drug product prior to the expiration of said patents;

(c) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Teva Parenteral's ANDA No. 91-583 relating to paricalcitol for injection before the expiration of the six-month period of market exclusivity for the last of the '497, '925, and '799 patents granted under 21 U.S.C. § 355(a);

(d) enjoining Teva Parenteral, Teva USA, and Teva Industries from using, offering to sell, or selling its paricalcitol for injection drug product, 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Mary B. Graham (#2256)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
Attorneys for Abbott Laboratories and Wisconsin Alumni Research Foundation

OF COUNSEL:

Michael A. Morin
David P. Frazier
Robert F. Shaffer
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4000

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