IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois corporation, and WISCONSIN ALUMNI RESEARCH FOUNDATION, a Wisconsin non-profit corporation,

Plaintiffs,

vs.

TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., a foreign corporation organized under the laws of Israel,

Defendants.

Civil Action No.

COMPLAINT

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

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 5,246,925 ("the '925 Patent") and 5,587,497 ("the '497 Patent"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Abbott's highly successful Zemplar® 1 mcg, 2 mcg, and 4 mcg products prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

THE PARTIES

2. Abbott Laboratories 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 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 $915 million dollars to the University, including money to fund research, build facilities, purchase lands and equipment, and support many faculty and graduate student fellowships.

4. On information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, having a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454. On information and belief, Teva USA is engaged in the manufacture and sale of pharmaceutical products.

5. On information and belief, defendant Teva Pharmaceutical Industries Ltd. ("Teva Industries") is an Israeli corporation, having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. On information and belief, Teva Industries manufactures bulk pharmaceutical products.

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

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

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

JURISDICTION AND VENUE

9. 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).

10. Teva USA is subject to personal jurisdiction in this District under 735 ILCS 5/2-209 because it regularly and continuously transacts business within the State of Illinois.

11. On information and belief, Teva Industries regularly transacts business within this District, 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.

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

13. On information and belief, the acts of Teva USA 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 Industries.

14. On information and belief, Teva Industries directed Teva USA to perform the acts complained of herein to shield itself, in whole or in part, from liability for patent infringement based upon those acts.

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

16. Teva Industries is subject to the personal jurisdiction in this District under 735 ILCS 5/2-209 because it regularly and continuously transacts business within the State of Illinois.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

18. On September 21, 1993, the United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 5,246,925 ("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.

19. The expiration date of the '925 Patent is April 17, 2012.

20. On December 24, 1996, the PTO issued U.S. Patent No. 5,587,497 ("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.

21. The expiration date of the '497 Patent is December 24, 2013.

22. The '925 and '497 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®.

23. Zemplar® has also received pediatric exclusivity of 6 months beginning from the expiration of each of the '925 and '497 patents, during which no ANDA covering paricalcitol can be approved. Thus, no ANDA that infringes the '925 patent can be approved prior to October 17, 2012, and no ANDA that infringes the '497 patent can be approved until June 24, 2014.

24. On information and belief, through the coordinated efforts of research and development staff in Israel, Europe and North America, Teva Industries continuously seeks to expand the range of generic products it sells.

25. On information and belief, 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 an approved abbreviated new drug application) within the United States generally and the State of Illinois 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 Industries reviewed the patents-in-suit and certain commercial and economic information relating to Zemplar®, including estimates of the revenues generated by the sale of Zemplar®, and decided to file an ANDA, seeking approval to market Paricalcitol Capsules in 1 mcg, 2 mcg, and 4 mcg formulations.

28. On information and belief, Teva USA and Teva Industries collaborated in the research, development, preparation and filing of Abbreviated New Drug Application No. 90-829 for Paricalcitol Capsules in 1 mcg, 2 mcg, and 4 mcg formulations.

29. On information and belief, Teva USA submitted to FDA Abbreviated New Drug Application No. 90-829, seeking approval to engage in the commercial manufacture, use and sale of Paricalcitol Capsules in 1 mcg, 2 mcg, and 4 mcg formulations, prior to the expiration of the patents-in-suit.

30. Plaintiffs have received a letter dated October 8, 2008 from Teva USA notifying them that Teva USA's ANDA No. 90-829 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Teva USA's opinion, the patents-in-suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of Paricalcitol Capsules in 4 mcg formulation described in ANDA No. 90-829.

31. Plaintiffs have received a letter dated October 14, 2008 from Teva USA notifying them that Teva USA's ANDA No. 90-829 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Teva USA's opinion, the patents-in-

suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of Paricalcitol Capsules in 1 mcg and 2 mcg formulations described in ANDA No. 90-829.

32. On information and belief, Teva Industries made the ultimate decision to file ANDA No. 90-829 with the FDA, and encouraged and directed Teva USA to file ANDA No. 90-829 and Paragraph IV certifications, and Teva USA did so at Teva Industries' direction.

33. On information and belief, Teva Industries was necessarily aware of the patents-in-suit when it directed Teva USA to file ANDA No. 90-829 and Paragraph IV certification.

34. Plaintiffs commenced this action within 45 days of the date they received Teva USA's notices of ANDA No. 90-829 containing the Paragraph IV certification.

35. Teva USA has not offered to allow Plaintiffs to view under an agreement of confidentiality its Abbreviated New Drug Application No. 90-829 seeking approval to market Paricalcitol Capsules in 1 mcg, 2 mcg, and 4 mcg formulations.

36. On information and belief, Teva USA and Teva Industries continue to collaborate in seeking approval of ANDA No. 90-829 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Paricalcitol Capsules in 1 mcg, 2 mcg, and 4 mcg formulations (including commercial marketing and sale of such products in the State of Illinois) in the event that FDA approves ANDA No. 90-829.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '925 Patent by Teva USA)

37. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 36 hereof, as if fully set forth herein.

38. Through the conduct alleged above, Teva USA directly infringes, and continues to directly infringe, one or more claims of the '925 Patent.

39. By filing ANDA No. 90-829 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of Paricalcitol Capsules in 1 mcg, 2 mcg, and 4 mcg formulations, prior to the expiration of the '925 Patent, Teva USA infringes the '925 Patent under 35 U.S.C. § 271(e)(2).

40. Teva USA was aware of the existence of the '925 Patent prior to filing ANDA No. 90-829 but took such action knowing that it would constitute an infringement of the '925 Patent.

41. On information and belief, Teva USA acted without a reasonable basis or a good faith belief that it would not be liable for infringing the '925 Patent.

42. Teva USA's conduct renders this case "exceptional" as described in 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

43. Plaintiffs will be irreparably harmed if Teva USA is not enjoined from infringing the '925 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of and/or Contributory Infringement of the '925 Patent by Teva Industries)

44. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 43 hereof, as if fully set forth herein.

45. On information and belief, Teva Industries is contributing to the '925 Patent's infringement by supplying Teva USA with the active pharmaceutical ingredient of paricalcitol made in accordance with its FDA Drug Master File.

46. Through the conduct alleged above, Teva Industries knowingly and actively induces Teva USA to infringe, and continue to infringe, one or more claims of the '925 Patent.

47. By reason of Teva Industries' inducement of and contribution to Teva USA's direct infringement of the '925 Patent, Teva Industries will cause and continue to cause irreparable harm to Plaintiffs.

48. On information and belief, Teva Industries' inducement of and contribution to Teva USA's direct infringement of the '925 Patent before this patent expires will continue unless enjoined by this Court.

49. Plaintiffs have no adequate remedy at law for Teva Industries' inducement of and contribution to Teva USA's direct infringement of the '925 Patent.

50. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment as to Inducement of Infringement of the '925 Patent by Teva Industries and Teva USA)

51. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 50 hereof, as if fully set forth herein.

52. Through the conduct alleged above, Defendants knowingly and actively induce those members of the medical community to whom Defendants intend to market the Paricalcitol Capsules that Defendants intend to manufacture and distribute – and who encompass but are not limited to physicians, pharmacists, pharmacies, and/or pharmaceutical wholesalers (collectively, "the medical community") – to infringe, and continue to infringe, one or more claims of the '925 Patent.

53. Defendants' activities have placed Plaintiffs under a reasonable apprehension that Defendants will induce the medical community to directly infringe the '925 patent. There now exists a justiciable case and controversy for adjudication by the Court.

54. By reason of Defendants' inducement of the medical community's direct infringement of the '925 Patent, Defendants will cause and continue to cause irreparable harm to Plaintiffs.

55. On information and belief, Defendants' inducement of the medical community's direct infringement of the '925 Patent before this patent expires will continue unless enjoined by this Court.

56. Plaintiffs have no adequate remedy at law for Defendants' inducement of the medical community's direct infringement of the '925 Patent.

57. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

FOURTH CLAIM FOR RELIEF
(Declaratory Judgment as to Contributory Infringement of the '925 Patent by Teva Industries and Teva USA)

58. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 57 hereof, as if fully set forth herein.

59. Through the marketing of paricalcitol and the conduct alleged above, Defendants contribute to the medical community's infringement, and continued infringement, of one or more claims of the '925 Patent.

60. Defendants' activities have placed Plaintiffs under a reasonable apprehension that Defendants will contribute to the medical community's direct infringement of the '925 patent. There now exists a justiciable case and controversy for adjudication by the Court.

61. By reason of Defendants' contribution to the medical community's direct infringement of the '925 Patent, Defendants will cause and continue to cause irreparable harm to Plaintiffs.

62. On information and belief, Defendants' contribution to the medical community's direct infringement of the '925 Patent before this patent expires will continue unless enjoined by this Court.

63. Plaintiffs have no adequate remedy at law for Defendants' contribution to the medical community's direct infringement of the '925 Patent.

64. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

FIFTH CLAIM FOR RELIEF
(Direct Infringement of the '497 Patent by Teva USA)

65. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 36 hereof, as if fully set forth herein.

66. Through the conduct alleged above, Teva USA directly infringes, and continues to directly infringe, one or more claims of the '497 Patent.

67. By filing ANDA No. 90-829 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of Paricalcitol Capsules in 1

mcg, 2 mcg, and 4 mcg formulations, prior to the expiration of the '497 Patent, Teva USA infringes the '497 Patent under 35 U.S.C. § 271(e)(2).

68. Teva USA was aware of the existence of the '497 Patent prior to filing ANDA No. 90-829 but took such action knowing that it would constitute an infringement of the '497 Patent.

69. On information and belief, Teva USA acted without a reasonable basis or a good faith belief that it would not be liable for infringing the '497 Patent.

70. Teva USA's conduct renders this case "exceptional" as described in 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

71. Plaintiffs will be irreparably harmed if Teva USA is not enjoined from infringing the '497 Patent.

SIXTH CLAIM FOR RELIEF
(Inducement of and/or Contributory Infringement of the '497 Patent by Teva Industries)

72. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 36 and 65 through 71 hereof, as if fully set forth herein.

73. On information and belief, Teva Industries is contributing to the '497 Patent's infringement by supplying Teva USA with the active pharmaceutical ingredient of paricalcitol made in accordance with its FDA Drug Master File.

74. Through the conduct alleged above, Teva Industries knowingly and actively induces Teva USA to infringe, and continue to infringe, one or more claims of the '497 Patent.

75. By reason of Teva Industries' inducement of and contribution to Teva USA's direct infringement of the '497 Patent, Teva Industries will cause and continue to cause irreparable harm to Plaintiffs.

76. On information and belief, Teva Industries' inducement of and contribution to Teva USA's direct infringement of the '497 Patent before this patent expires will continue unless enjoined by this Court.

77. Plaintiffs have no adequate remedy at law for Teva Industries' inducement of and contribution to Teva USA's direct infringement of the '497 Patent.

78. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Teva USA directly infringes the '925 Patent;

B. An order adjudging and decreeing that Teva USA and Teva Industries induce the direct infringement of the '925 Patent;

C. An order adjudging and decreeing that Teva USA and Teva Industries contribute to the direct infringement of the '925 Patent;

D. An order adjudging and decreeing that Teva USA directly infringes the '497 Patent;

E. An order adjudging and decreeing that Teva Industries induces the direct infringement of the '497 Patent;

G. An order adjudging and decreeing that Teva Industries contributes to the direct infringement of the '497 Patent;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 90-829 be no earlier than 6 months after the expiration date of the last of the patents-in-suit, including any future additional extensions;

I. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Teva USA and Teva Industries, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Paricalcitol Capsules described in ANDA No. 90-829 or any other ANDA not colorably different from ANDA No. 90-829 until 6 months after the expiration date of the last of the patents-in-suit, including any future additional extensions;

J. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action; and

K. Such other and further relief as the Court may deem just and proper.

Dated: November 20, 2008

ABBOTT LABORATORIES and
WISCONSIN ALUMNI RESEARCH
FOUNDATION

By: /s/ Lynn H. Murray

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