

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois)
corporation, and WISCONSIN ALUMNI)
RESEARCH FOUNDATION, a Wisconsin)
non-profit corporation,)
) C.A. No. _____
Plaintiffs,)
)
v.)
)
SANDOZ, INC., a Colorado corporation, and)
SANDOZ GmbH, a foreign corporation)
organized under the laws of Austria,)
)
Defendants.)

COMPLAINT

Plaintiffs Abbott Laboratories (“Abbott”) and Wisconsin Alumni Research Foundation (“WARF”) (collectively, “Plaintiffs”), for their Complaint against defendants Sandoz, Inc., a Colorado corporation, and Sandoz GmbH, a foreign corporation organized under the laws of Austria, (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”); 5,587,497 (“the '497 Patent”); 6,136,799 (“the '799 Patent”); and 6,361,758 (“the '758 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® injectable 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 Sandoz, Inc. (“Sandoz USA”) 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.

5. On information and belief, Defendant Sandoz GmbH is an Austrian corporation having its principal place of business at Biochemiestrasse 10, A-6250 Kundl/Tirol, Austria.

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

7. On information and belief, Sandoz USA is controlled and/or dominated by Sandoz GmbH.

8. On information and belief, Sandoz GmbH conducts its North American operations, in part, through Sandoz 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. Sandoz USA is subject to personal jurisdiction in this District because 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.

11. On information and belief, Sandoz GmbH regularly transacts business within this District, including but not limited to directing the operations and management of Sandoz USA, as well as shipping pharmaceuticals to Sandoz USA from locations outside the United States for distribution by Sandoz USA within the United States generally, and within this District specifically.

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

13. On information and belief, the acts of Sandoz 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 Sandoz GmbH.

14. On information and belief, Sandoz GmbH directed Sandoz 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. Sandoz USA's acts and contacts with this District, as an agent of Sandoz GmbH, are attributable to Sandoz GmbH for jurisdictional purposes.

16. Sandoz GmbH is subject to the personal jurisdiction in this District because it regularly and continuously transacts business within the State of Delaware.

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. Prah. 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. Prah. 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. On October 24, 2000, the PTO issued U.S. Patent No. 6,136,799 ("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 expiration date of the '799 Patent is April 8, 2018.

24. On March 26, 2002, the PTO issued U.S. Patent No. 6,361,758 (“the '758 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 '758 Patent is attached hereto as Exhibit D.

25. The expiration date of the '758 Patent is April 8, 2018.

26. The '925, '497, '799, and '758 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®.

27. Zemplar® has also received pediatric exclusivity of 6 months beginning from the expiration of each of the '925, '497, '799, and '758 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; no ANDA that infringes the '497 Patent can be approved until June 24, 2014; and no ANDA that infringes the '799 or '758 Patents can be approved until October 12, 2018.

28. On information and belief, through the coordinated efforts of research and development staff in Europe and North America, Sandoz GmbH continuously seeks to expand the range of generic products it sells.

29. On information and belief, Sandoz USA and Sandoz GmbH 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 Delaware specifically.

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

31. On information and belief, Sandoz GmbH 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 a generic paricalcitol injection.

32. On information and belief, Sandoz USA and Sandoz GmbH collaborated in the research, development, preparation and filing of Abbreviated New Drug Application No. 91-108 for a generic paricalcitol injection.

33. On information and belief, Sandoz USA submitted to the FDA Abbreviated New Drug Application No. 91-108, 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.

34. Plaintiffs have received two letters dated February 19, 2008 [*sic*, 2009] and February 23, 2009 from Sandoz USA notifying them that Sandoz USA's ANDA No. 91-108 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Sandoz USA'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. 91-108. To be clear, Plaintiffs received the Sandoz USA Paragraph IV

certification letter dated February 19, 2008 on or about February 20, 2009, making it clear that Sandoz USA's Paragraph IV letter mistakenly listed 2008 as the date instead of 2009.

35. On information and belief, Sandoz GmbH made the ultimate decision to file ANDA No. 91-108 with the FDA, and encouraged and directed Sandoz USA to file ANDA No. 91-108 and Paragraph IV certifications, and Sandoz USA did so at Sandoz GmbH's direction.

36. On information and belief, Sandoz GmbH was necessarily aware of the patents-in-suit when it directed Sandoz USA to file ANDA No. 91-108 and the Paragraph IV certification.

37. Plaintiffs commenced this action within 45 days of the date they received Sandoz USA's notices of ANDA No. 91-108 containing the Paragraph IV certification.

38. Sandoz USA purported to include an "Offer of Confidential Access" to ANDA No. 91-108 along with its Paragraph IV Notice sent to Plaintiffs. The Federal Food Drug and Cosmetics Act, 21 U.S.C. § 355(j)(5)(C)(i)(III), specifies that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

39. Sandoz USA's Offer of Confidential Access to Plaintiffs restricted disclosure to two attorneys at Plaintiffs' outside law firm and certain of their support staff. Sandoz USA's Offer of Confidential Access to Plaintiffs also restricted disclosure to unspecified sections of ANDA No. 91-108 that Sandoz USA in its sole discretion would choose to make available to Plaintiffs at some point in the future.

40. The proposed terms of Sandoz USA's Offer of Confidential Access to Plaintiffs did not allow any of Plaintiffs' in-house litigation team members, who are crucial decision-makers in the process of filing any infringement action, access to the necessary information with which to decide whether Sandoz's proposed generic copy of Abbott's paricalcitol injection likely infringed Plaintiffs' patents. Furthermore, under the proposed terms of Sandoz USA's Offer of Confidential Access, Sandoz USA could have technically complied by making very minimal disclosures to Plaintiffs.

41. Soon after receipt of Sandoz USA's purported Offer of Confidential Access, Plaintiffs' outside counsel requested that Sandoz USA amend its Offer of Confidential Access to permit six lawyers at Plaintiffs' outside law firm, as well as designated in-house litigation team members at Abbott and WARF, to gain access to nine particular sections of Sandoz USA's ANDA No. 91-108 likely to bear on the composition of Sandoz USA's proposed generic copy of Abbott's paricalcitol injection. Sandoz refused to comply with almost all of Plaintiffs' requests for modifications to Sandoz USA's Offer of Confidential Access, the exception being that Sandoz USA agreed to grant access to ANDA No. 91-108 to six members of Plaintiffs' outside law firm.

42. After Sandoz USA refused almost all of Plaintiffs' requests for modifications to Sandoz USA's Offer of Confidential Access, Plaintiffs' outside counsel asked that Sandoz USA reconsider and permit access to ANDA No. 91-108 on the terms needed by Plaintiffs in order to make an informed investigation of Sandoz USA's potential infringement of Plaintiffs' patents. Sandoz USA has not responded to that request for reconsideration as of the filing of this Complaint.

43. Sandoz USA's Paragraph IV Notice does not contend that Sandoz USA's proposed generic copy of Abbott's paricalcitol injection will not infringe the '925, '497, and '799 Patents. Therefore, Plaintiffs believe that Sandoz USA's proposed generic copy of Abbott's paricalcitol injection will infringe the '925, '497, and '799 Patents.

44. No Abbott or WARF client representative has been permitted to review information concerning Sandoz USA's proposed generic copy of Abbott's paricalcitol injection beyond that which is set forth in Sandoz USA's Paragraph IV Notice itself. That Paragraph IV Notice does not specify the composition of Sandoz USA's proposed generic copy of Abbott's paricalcitol injection. Consequently, through no fault of its own, Plaintiffs have not been able to analyze the basis, if any, for Sandoz USA's assertion that its proposed generic product would not infringe the '758 Patent. Plaintiffs believe that Sandoz USA's assertion that its proposed generic product would not infringe the '758 Patent is likely without merit, in that Sandoz USA would presumably disclose any meritorious defense of non-infringement to Plaintiffs so as to avoid potential litigation.

45. Under the proposed terms of Sandoz USA's Offer of Confidential Access, Plaintiffs' outside counsel are permitted solely to advise Plaintiffs whether or not to bring an action for infringement of the patents-in-suit, without discussing any information derived from ANDA No. 91-108 that forms the basis for such advice or that would bear upon the merits of any potential action. Plaintiffs dispute the restrictions unilaterally imposed by Sandoz USA and will seek entry of a protective order permitting Plaintiffs' in-house counsel access to Defendants' proposed product composition whereby Plaintiffs may evaluate the basis, if any, for Sandoz USA's Paragraph IV Notice concerning Plaintiffs' '925, '497, '799, and '758 Patents.

46. Defendants have committed acts of infringement of the '925, '497, '799, and '758 Patents that creates a justiciable case or controversy between Plaintiffs and Defendants. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Defendants' generic copy of Abbott's paricalcitol injection prior to expiration of the '925, '497, '799, and '758 Patents. This Court has subject matter jurisdiction with respect to this action to declare Plaintiffs' rights under the '925, '497, '799, and '758 Patents.

47. On information and belief, Sandoz USA and Sandoz GmbH continue to collaborate in seeking approval of ANDA No. 91-108 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 FDA approves ANDA No. 91-108.

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

48. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

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

50. By filing ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '925 Patent, Sandoz USA infringes the '925 Patent under 35 U.S.C. § 271(e)(2).

51. Sandoz USA was aware of the existence of the '925 Patent prior to filing ANDA No. 91-108 but took such action knowing that it would constitute an infringement of the '925 Patent.

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

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

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

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

55. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 54 hereof, as if fully set forth herein.

56. On information and belief, Sandoz GmbH is contributing to the '925 Patent's infringement by conceiving of, drafting, and directing Sandoz USA to file ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '925 Patent.

57. Through the conduct alleged above, Sandoz GmbH knowingly and actively induces Sandoz USA to infringe, and continue to infringe, one or more claims of the '925 Patent.

58. By reason of Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '925 Patent, Sandoz GmbH will cause and continue to cause irreparable harm to Plaintiffs.

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

60. Plaintiffs have no adequate remedy at law for Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '925 Patent.

61. 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 Sandoz GmbH and Sandoz USA)**

62. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 61 hereof, as if fully set forth herein.

63. Through the conduct alleged above, Defendants knowingly and actively induce those members of the medical community to whom Defendants intend to market the generic paricalcitol injection 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.

64. 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.

65. 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.

66. 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.

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

68. 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 Sandoz GmbH and Sandoz USA)**

69. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 68 hereof, as if fully set forth herein.

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

71. 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.

72. 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.

73. 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.

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

75. 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 Sandoz USA)

76. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

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

78. By filing ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '497 Patent, Sandoz USA infringes the '497 Patent under 35 U.S.C. § 271(e)(2).

79. Sandoz USA was aware of the existence of the '497 Patent prior to filing ANDA No. 91-108 but took such action knowing that it would constitute an infringement of the '497 Patent.

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

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

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

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

83. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 and 76 through 82 hereof, as if fully set forth herein.

84. On information and belief, Sandoz GmbH is contributing to the '497 Patent's infringement by conceiving of, drafting, and directing Sandoz USA to file ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '497 Patent.

85. Through the conduct alleged above, Sandoz GmbH knowingly and actively induces Sandoz USA to infringe, and continue to infringe, one or more claims of the '497 Patent.

86. By reason of Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '497 Patent, Sandoz GmbH will cause and continue to cause irreparable harm to Plaintiffs.

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

88. Plaintiffs have no adequate remedy at law for Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '497 Patent.

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

SEVENTH CLAIM FOR RELIEF
(Direct Infringement of the '799 Patent by Sandoz USA)

90. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

91. Through the conduct alleged above, Sandoz USA directly infringes, and continues to directly infringe, one or more claims of the '799 Patent.

92. By filing ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '799 Patent, Sandoz USA infringes the '799 Patent under 35 U.S.C. § 271(e)(2).

93. Sandoz USA was aware of the existence of the '799 Patent prior to filing ANDA No. 91-108 but took such action knowing that it would constitute an infringement of the '799 Patent.

94. On information and belief, Sandoz USA acted without a reasonable basis or a good faith belief that it would not be liable for infringing the '799 Patent.

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

96. Plaintiffs will be irreparably harmed if Sandoz USA is not enjoined from infringing the '799 Patent.

EIGHTH CLAIM FOR RELIEF
(Inducement of and/or Contributory Infringement of the '799 Patent by Sandoz GmbH)

97. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 and 90 through 96 hereof, as if fully set forth herein.

98. On information and belief, Sandoz GmbH is contributing to the '799 Patent's infringement by conceiving of, drafting, and directing Sandoz USA to file ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '799 Patent.

99. Through the conduct alleged above, Sandoz GmbH knowingly and actively induces Sandoz USA to infringe, and continue to infringe, one or more claims of the '799 Patent.

100. By reason of Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '799 Patent, Sandoz GmbH will cause and continue to cause irreparable harm to Plaintiffs.

101. On information and belief, Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '799 Patent before this patent expires will continue unless enjoined by this Court.

102. Plaintiffs have no adequate remedy at law for Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '799 Patent.

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

NINTH CLAIM FOR RELIEF
(Direct Infringement of the '758 Patent by Sandoz USA)

104. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

105. Through the conduct alleged above, Sandoz USA directly infringes, and continues to directly infringe, one or more claims of the '758 Patent.

106. By filing ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '758 Patent, Sandoz USA infringes the '758 Patent under 35 U.S.C. § 271(e)(2).

107. Sandoz USA was aware of the existence of the '758 Patent prior to filing ANDA No. 91-108 but took such action knowing that it would constitute an infringement of the '758 Patent.

108. On information and belief, Sandoz USA acted without a reasonable basis or a good faith belief that it would not be liable for infringing the '758 Patent.

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

110. Plaintiffs will be irreparably harmed if Sandoz USA is not enjoined from infringing the '758 Patent.

TENTH CLAIM FOR RELIEF

(Inducement of and/or Contributory Infringement of the '758 Patent by Sandoz GmbH)

111. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 and 104 through 110 hereof, as if fully set forth herein.

112. On information and belief, Sandoz GmbH is contributing to the '758 Patent's infringement by conceiving of, drafting, and directing Sandoz USA to file ANDA No. 91-108 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of a generic paricalcitol injection, prior to the expiration of the '758 Patent.

113. Through the conduct alleged above, Sandoz GmbH knowingly and actively induces Sandoz USA to infringe, and continue to infringe, one or more claims of the '758 Patent.

114. By reason of Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '758 Patent, Sandoz GmbH will cause and continue to cause irreparable harm to Plaintiffs.

115. On information and belief, Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '758 Patent before this patent expires will continue unless enjoined by this Court.

116. Plaintiffs have no adequate remedy at law for Sandoz GmbH's inducement of and contribution to Sandoz USA's direct infringement of the '758 Patent.

117. 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 Sandoz USA directly infringes the '925 Patent;

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

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

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

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

F. An order adjudging and decreeing that Sandoz GmbH contributes to the direct infringement of the '497 Patent;

G. An order adjudging and decreeing that Sandoz USA directly infringes the '799 Patent;

H. An order adjudging and decreeing that Sandoz GmbH induces the direct infringement of the '799 Patent;

I. An order adjudging and decreeing that Sandoz GmbH contributes to the direct infringement of the '799 Patent;

J. An order adjudging and decreeing that Sandoz USA directly infringes the '758 Patent;

K. An order adjudging and decreeing that Sandoz GmbH induces the direct infringement of the '758 Patent;

L. An order adjudging and decreeing that Sandoz GmbH contributes to the direct infringement of the '758 Patent;

M. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 91-108 be no earlier than 6 months after the expiration date of the last of the patents-in-suit, including any future additional extensions;

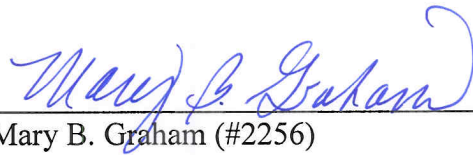
N. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Sandoz USA and Sandoz GmbH, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the

commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the generic paricalcitol injection described in ANDA No. 91-108 or any other ANDA not colorably different from ANDA No. 91-108 until 6 months after the expiration date of the last of the patents-in-suit, including any future additional extensions;

O. 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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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