

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

**UNIVERSITY OF KANSAS CENTER
FOR RESEARCH, INC.**

Plaintiff,

v.

**THE UNITED STATES OF AMERICA,
represented by the DEPARTMENT OF
HEALTH AND HUMAN SERVICES, by and
through its agents the NATIONAL
INSTITUTES OF HEALTH and the
NATIONAL CANCER INSTITUTE**

Defendant.

No.: 08-CV-2565 JAR/DJW

COMPLAINT FOR CORRECTION OF INVENTORSHIP

Plaintiff, the University of Kansas Center for Research, Inc. (“KUCR”), alleges as follows:

I. NATURE OF THE ACTION

1. This Complaint states claims for correction of inventorship of U.S. Patent Numbers 6,713,446 (“the ‘446 patent”) and 6,958,319 (“the ‘319 patent”) (collectively “the patents-in-suit”) under 35 U.S.C. § 256.

2. Each of the patents-in-suit is currently owned by the United States of America as represented by the Department of Health and Human Services.

II. JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over the United States government based on at least 28 U.S.C. §§ 1346 and 1402.

4. Venue is proper in this district under at least 28 U.S.C. § 1391.
5. This claim is commencing within six years of accruing.

III. THE PARTIES

6. Plaintiff, KUCR, is a not-for-profit corporation organized and existing under the laws of Kansas.

7. KUCR has its principal place of business at 2385 Irving Hill Road, Lawrence, Kansas 66045.

8. KUCR is related to the University of Kansas, which is an academic institution of higher learning located in Kansas.

9. The Department of Health and Human Services (“HHS”) is an agency of the United States government.

10. On information and belief, HHS is the United States government's principal agency for protecting the health of all Americans and providing essential human services.

11. The National Institutes of Health (“NIH”) is an agency of HHS.

12. On information and belief, NIH provides financial support to researchers in every state and throughout the world.

13. On information and belief, NIH is currently composed of 27 institutes and centers.

14. The National Cancer Institute (“NCI”) is an institute within NIH.

15. NIH has an Office of Technology Transfer.

16. On information and belief, the NIH Office of Technology Transfer evaluates, protects, markets, licenses, monitors, and manages the wide range of NIH discoveries, inventions, and other intellectual property as mandated by the Federal Technology Transfer Act and related legislation.

17. On information and belief, NIH's Office of Technology Transfer has overseen patent prosecution and negotiated and monitored licensing agreements for NIH since at least 1996.

IV. THE PATENTS-IN-SUIT

18. U.S. Patent Number 6,713,446 issued on March 30, 2004.

19. U.S. Patent Number 6,713,446 is assigned to the United States of America as represented by the Secretary of the Department of Health and Human Services.

20. U.S. Patent Number 6,958,319 issued on October 25, 2005.

21. U.S. Patent Number 6,958,319 is assigned to the United States of America as represented by the Secretary of the Department of Health and Human Services.

22. Claims of one or more of the patents-in-suit cover formulations or methods for formulating the drug VELCADE.

V. FACTUAL BACKGROUND

23. VELCADE is a product that is currently offered for sale and sold by Millennium Pharmaceuticals, Inc. ("Millennium").

24. On information and belief, Millennium has exclusively licensed U.S. Patent Number 6,713,446 from NIH.

25. On information and belief, Millennium has exclusively licensed U.S. Patent Number 6,958,319 from NIH.

26. In June of 1992, NCI entered into an agreement ("the 1992 Agreement") with the University of Kansas ("KU").

27. Through the 1992 Agreement, NIH asked KU to develop acceptable dosage forms for compounds to be subsequently evaluated in cancer and HIV patients and carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and/or stability.

28. The 1992 Agreement was renewed in June of 1997, to extend through June 29, 2002 (“the 1997 Agreement”), to develop acceptable dosage forms for compounds to be subsequently evaluated in cancer and HIV patients and carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and/or stability.

29. The Project Officer for NCI for at least part of the 1997 Agreement was Dr. Shanker Gupta.

30. Dr. Gupta is the only named inventor on the two patents at issue in this case.

31. The Principal Investigator for KU under the 1992 and 1997 Agreements was Dr. Valentino Stella.

32. Dr. Stella holds a tenured faculty position of Distinguished Professor in the Department of Pharmaceutical Chemistry at KU.

33. Dr. Stella first joined the faculty of KU in 1973 as an assistant professor in Pharmaceutical Chemistry.

34. Dr. Stella is a named inventor of more than 33 patents.

35. Dr. Stella is the inventor of two pharmaceutical drugs, one for the treatment of epilepsy and one for AIDS and inventor of Captisol, a solubilizer in four commercial products.

36. Ms. Wanda Waugh worked as a Research Assistant in the Department of Pharmaceutical Chemistry at KU for many years until she retired in 1999.

37. During his research under the 1992 and 1997 Agreements, Dr. Stella was assisted by Ms. Waugh.

38. By 1997, Dr. Stella had many years of product development expertise and had developed sophisticated research and analytical skills.

39. Dr. Stella's product development expertise and sophisticated research and analytical skills were essential to accomplishing the goals of the 1997 Agreement.

40. In or around early 1997, Dr. Gupta provided Dr. Stella with a certain number of compounds including peptide boronic acid compounds to be considered in his work.

41. In or around early 1997, Dr. Gupta provided Dr. Stella with the structure of many of the compounds Dr. Gupta had previously provided to Dr. Stella.

42. In or around the year 1997, the chemical stability of peptide boronic acid compounds had not been extensively reported in literature, particularly with regard to formulations of such compounds.

43. On information and belief, ProScript Inc. had independently attempted to stabilize a liquid solution of one or more of the peptide boronic acid compounds but was unable to obtain a stable solution.

44. Dr. Gupta and/or other NIH or NCI representatives asked Dr. Stella to research and develop how to make a stable liquid solution of the peptide boronic acid compounds.

45. Dr. Stella and Ms. Waugh collaborated and conducted extensive research and investigations that succeeded in determining that certain alcohols provided greater solubility of the peptide boronic acid compounds.

46. Dr. Stella and a KU research team under his direction were the first to make the significant discovery that the nature of the instability of the peptide boronic acid compound was due to an oxidative event.

47. Dr. Stella continued his research efforts to create a stable liquid formulation of the compounds as requested by Dr. Gupta, but recognized that a liquid formulation of the compounds, as suggested by Dr. Gupta, was an inadequate solution and so advised Dr. Gupta.

48. Dr. Stella conceived of the then novel idea of using a lyophilized or freeze-dried formulation of the peptide boronic acid compounds to obtain better stability and solubility.

49. Dr. Stella and Ms. Waugh then successfully developed a stable, lyophilized formulation of the peptide boronic acid compounds.

50. Dr. Stella and Ms. Waugh's inventive contributions can be found in the disclosure of United States Provisional Patent Application Number 60/264,160 (hereinafter "the '160 application"), filed on January 25, 2001.

51. The '160 application does not name Dr. Stella and Ms. Waugh as co-inventors.

52. On information and belief, Dr. Stella and Ms. Waugh were inadvertently and without deceptive intent not named as inventors on the '160 application.

53. Each of the patents-in-suit claims priority based on the '160 application.

54. Each of the patents-in-suit includes one or more claims containing significant inventive contributions of Dr. Stella and Ms. Waugh.

55. Dr. Stella and Ms. Waugh assigned their ownership rights in those inventive contributions to the University of Kansas, who in turn assigned those ownership rights to KUCR.

VI. FIRST CAUSE OF ACTION

(Correction of Inventorship under 35 U.S.C. § 256 of U.S. Patent No. 6,713,446)

56. KUCR incorporates its allegations set forth in paragraphs 1 through 55 above, as though fully set forth herein.

57. The '446 patent does not list either Dr. Stella or Ms. Waugh as co-inventors.

58. Dr. Stella and Ms. Waugh were involved in the conception and reduction to practice of and materially contributed to the conception and reduction to practice of significant features of the inventions recited in one or more claims of the '446 patent.

59. Because Dr. Stella and Ms. Waugh substantially contributed to the conception and reduction to practice of significant features of one or more of the claims of the '446 patent, they are necessarily co-inventors of the '446 patent.

60. The omission of Dr. Stella and Ms. Waugh as co-inventors of the '446 patent was done without any deceptive intent on the part of Dr. Stella and Ms. Waugh.

61. On information and belief, the omission of Dr. Stella and Ms. Waugh as co-inventors of the '446 patent was done without any deceptive intent on anyone's part.

62. Because Dr. Stella and Ms. Waugh are rightfully co-inventors of claimed features of one or more claims of the '446 patent, this Court should issue an Order directing the Commissioner of Patents to add both Dr. Stella and Ms. Waugh as co-inventors of the '446 patent.

VII. SECOND CAUSE OF ACTION

(Correction of Inventorship under 35 U.S.C. § 256 of U.S. Patent No. 6,958,319)

63. KUCR incorporates its allegations set forth in paragraphs 1 through 62, above, as though fully set forth herein.

64. The '319 patent does not list either Dr. Stella or Ms. Waugh as co-inventors.

65. Dr. Stella and Ms. Waugh were involved in the conception and reduction to practice of and materially contributed to the conception and reduction to practice of significant features of the inventions recited in one or more claims of the '319 patent.

66. Because Dr. Stella and Ms. Waugh substantially contributed to the conception and reduction to practice of significant features of one or more of the claims of the '319 patent, they are necessarily co-inventors of the '319 patent.

67. The omission of Dr. Stella and Ms. Waugh as co-inventors of the '319 patent was done without any deceptive intent on the part of Dr. Stella and Ms. Waugh.

68. On information and belief, the omission of Dr. Stella and Ms. Waugh as co-inventors of the '319 patent was done without any deceptive intent on anyone's part.

69. Because Dr. Stella and Ms. Waugh are rightfully co-inventors of claimed features of one or more claims of the '319 patent, this court should issue an Order directing the Commissioner of Patents to add both Dr. Stella and Ms. Waugh as co-inventors of the '319 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff KUCR prays for relief as follows:

1. That the Court issue an Order directing the Commissioner of Patents to add both Dr. Stella and Ms. Waugh as co-inventors of U.S. Patent No. 6,713,446.
2. That the Court issue an Order directing the Commissioner of Patents to add both Dr. Stella and Ms. Waugh as co-inventors of U.S. Patent No. 6,958,319.
3. For such other and further relief as the Court may deem just and proper.

DATED this 12th day of November, 2008.

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