

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Kozal et al.

Application No.: 07/883,327

Art Unit: Not Assigned

Filed: May 14, 1992

Examiner: Not Assigned

For: POLYMERASE CHAIN REACTION ASSAYS FOR MONITORING ANTIVIRAL THERAPY AND MAKING THERAPEUTIC DECISIONS IN THE TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME

Attorney Docket No.: 7627-002

**DECLARATION OF BARRY W. ELLEDGE, Ph.D.**

Honorable Commissioner of Patents and Trademarks  
Box AF  
Washington, D.C. 20231

Sir:

I, Barry W. Elledge, Ph.D., do hereby declare the following:

1. I am an associate attorney at the law firm of Pennie & Edmonds. In September, 1992, attorney Laura A. Coruzzi at Pennie & Edmonds requested that I investigate the inventorship issue in the above-referenced application and prepare appropriate documents for filing the correct inventorship with the PTO.
2. In September, 1992, I consulted Dr. Lisa Kole about the inventorship issue. Dr. Kole is a law clerk at the firm of Pennie & Edmonds.
3. Dr. Kole told me that she drafted the above-referenced patent application at the request of attorney Laura Coruzzi. Due to an impending presentation of portions of the subject matter of the application at a scientific meeting, the application needed to be filed by May 14, 1992. Dr. Kole told me that she drafted the application substantially over the two days immediately prior to filing, and the application was reviewed and approved by Dr. Merigan on the same day that it was filed.
4. Dr. Kole further told me that, because of the extreme time pressure under which the application was prepared, she had no opportunity to consult with Dr. Merigan about inventorship prior to filing. Dr. Kole stated that, to the best of her recollection, Dr. Merigan and Dr. Kozal were listed as inventors of the above-referenced application because they were the persons named on the Information Disclosure statement, and with whom she had discussed the invention.
5. In September and October, 1992, I consulted Dr. Merigan and Dr. Holodniy concerning the inventorship question. In November, 1992, I further consulted Dr. Kozal and Dr. Katzenstein about the same issue.
6. I have examined the Patent Application in light of the written materials supplied to Pennie & Edmonds by Dr. Merigan for preparation of the above-referenced application, including the Invention Disclosure statement by Dr. Merigan and Dr. Kozal, the unpublished manuscript by Dr. Kozal et al., the abstract by Dr. Kozal and Dr. Merigan, and the published journal article by Dr. Holodniy et al..

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7. Dr. Holodniy stated that he was until summer of 1991 a research fellow in the Division of Infectious Disease at Stanford University. His inventive contribution to the subject matter of the present application occurred during this period, and principally concerns quantitation of HIV RNA in plasma of AIDS patients.

8. Dr. Katzenstein has indicated that his inventive contribution principally concerns the relationship between the quantity of HIV RNA in plasma of AIDS patients and disease progression.

9. Dr. Kozal has been a postdoctoral research fellow in the Division of Infectious Diseases since approximately the summer of 1991, and his contribution to the present invention began at that time. He indicated that his inventive contribution principally concerns the relationship between the 215 mutation of HIV and disease progression.

10. On the basis of the above materials and conversations, I believe that both Dr. Holodniy and Dr. Katzenstein have made an inventive contribution to the subject matter of one or more claims of the above-referenced application.

11. I further believe that the error in naming the correct inventors arose principally because the extreme time pressure in preparing and filing this application did not permit an inquiry into inventorship prior to the filing date.

12. I also believe that an additional source of the error in naming the correct inventors arose because Drs. Holodniy and Katzenstein made their inventive contributions to different portions of the claimed subject matter and at different times than did Dr. Kozal. Therefore the invention disclosed and claimed in the application includes more than the subject matter of the Invention Disclosure prepared by Drs. Kozal and Merigan.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Date November 16, 1992

Barry W. Elledge, Ph.D. #31,754  
Barry W. Elledge, Ph.D. (Reg. No.)  
PENNIE & EDMONDS  
2730 Sand Hill Road  
Menlo Park, CA 94025  
(415) 854-3660

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