



**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 THOMAS C. MERIGAN, JR., M.D.**

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

Sir:

I, Thomas C. Merigan, Jr., M.D., do hereby declare the following:

1. I am the George E. and Lucy Becker Professor of Medicine in the Department of Medicine, Division of Infectious Diseases, and Director of the Center for AIDS Research at Stanford University School of Medicine. I am an originally named coinventor of the above-referenced patent application. The other originally named coinventor, Michael J. Kozal, M.D., was at the time of the invention a postdoctoral fellow in the Division of Infectious Disease and was working in my laboratory at Stanford University.

2. In March, 1992, I contacted attorney S. Leslie Misrock at the law firm of Pennie & Edmonds, and requested the firm to begin preparing the above referenced patent application. I supplied to Pennie & Edmonds a copy of an unpublished manuscript which was to be used as a source of information for the application. In that manuscript, Michael Kozal and I are listed as first and last authors, respectively. Among the three other listed co-authors is David A. Katzenstein, M.D., who is to be added as coinventor.

3. At the same time I also supplied to Pennie & Edmonds as a source of information a copy of a recently published article of which Mark Holodniy, David Kazenstein, and I are the first, second, and last authors, respectively.

4. In April, 1992, Dr. Kozal and I prepared and signed an Invention Disclosure for Stanford University, presenting recent results from our collaborative research. A copy of the Invention Disclosure and an abstract by Dr. Kozal and me were provided to Pennie & Edmonds in late April, 1992, for use in preparing the above referenced patent application.

5. In late April, 1992, I informed Pennie & Edmonds that portions of the research were to be presented by Dr. Kozal at a scientific meeting in mid-May, and that the application should be filed prior to that date. I also suggested that Dr. Kozal would be available to discuss details of the invention by phone, since I was to be away from the office until the second week in May.

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6. A final draft of the patent application was received and reviewed by me on May 14, 1992, and filed on the same date.

7. I did not discuss the issue of inventorship with the attorneys at Pennie & Edmonds prior to filing the application.

8. In mid-June, 1992, I received a letter from Pennie & Edmonds concerning a Notice to File Missing Parts, and requesting that Dr. Kozal and I sign a Supplemental Declaration naming both of us as coinventors. At that time I began to question whether Drs. Katzenstein and Holodniy also should be named as coinventors. Shortly thereafter I contacted attorney Laura Coruzzi at Pennie & Edmonds about inventorship. At her suggestion, I requested Drs. Katzenstein and Holodniy to review the patent application and determine whether in their opinions they should be included as inventors.

9. In late August, 1992, Drs. Katzenstein and Holodniy communicated to me their opinions that their contributions should entitle them to be named as coinventors. I informed attorney Laura Coruzzi of these opinions, and requested Pennie & Edmonds to pursue whatever action needed to be done to name the proper coinventors.

10. I have never attempted to mislead or deceive the law firm of Pennie & Edmonds, the PTO, Stanford University, or the scientific community concerning my role or the role of others in making the invention disclosed in the above-referenced application.

11. As an employee of Stanford University, I am required to assign my rights in the above-referenced application to the University. Therefore I will have no ownership interest in the application. Furthermore, to the best of my knowledge Dr. Kozal, Dr. Katzenstein, and Dr. Holodniy, at the time of making their contributions to the invention, were also employees of Stanford University.

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.

Date

                    05/16/92                    

Respectfully submitted,

                    Thomas C. Merigan, Jr., M.D.                    

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