Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc. et al

Case 3:05-cv-04158-MHP

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May 22, 2006

The Honorable Judge Patel
United States District Court for the Northern District of California
Courtroom 15, 18th Floor
450 Golden Gate Avenue, San Francisco 94102

Re: Stanford v. Roche Molecular Sytems (No. C-05-04158 MHP)

Dear Judge Patel:

Roche seeks documents from Stanford related to: (1) the Kozal patents; and (2) the prosecution of the patents-in-suit. Roche also offers a compromise on the number of depositions.

Roche's counterclaims seeks a declaration of ownership concerning the '128, '268, '086, and '352 patents (the "Kozal patents"). To date, Stanford has refused to produce documents concerning the Kozal patents. On March 6, the Court ordered that discovery in the first phase of this case be limited to ownership. Thus, the Kozal patents are properly the subject of discovery in this first phase. Furthermore, at a minimum, discovery concerning such patents is relevant to the patents that Stanford acknowledges are properly the subject of this first phase -- the '730 and '705 Patents. All of the patents share the same parent application, substantially similar specifications, and Dr. Merigan as a named inventor. Accordingly, Roche requests that Stanford be ordered to produce responsive documents concerning the Kozal patents.

Regarding the prosecution documents, Stanford has waived all privileges and protections concerning inventorship by virtue of its disclosures to the PTO. Accordingly, Roche seeks production of documents concerning that issue. In November 1992, during prosecution of the parent application, Stanford petitioned to correct inventorship to add Drs. Holodniy and Katzenstein as inventors. Concurrently, Drs. Merigan and Kozal and Barry Elledge, Stanford's counsel, submitted declarations detailing numerous attorney-client communications.

In particular, Dr. Merigan declared, among other things, that he discussed inventorship with counsel, had Drs. Katzenstein and Holodniy review the patent application to determine if they should be included as inventors, communicated to counsel that they believed they should be identified as co-inventors, and requested that counsel work to name the proper co-inventors. See Ex. A. Elledge declared that he consulted with Stanford's counsel and the Stanford doctors concerning inventorship; he also detailed the substance of those communications. See Ex. B. Furthermore, he offered his legal conclusion that "Dr. Holodniy and Dr. Katzenstein have made an inventive contribution to the subject matter of one or more claims of the above-referenced application." Id. Such statements waived any applicable privileges under controlling authority. See Winbond Electronics Corp. v. Int'l Trade Comm'n, 262 F.3d 1363 (Fed. Cir. 2001) (declaration by inventor disclosing communications with counsel waived applicable privileges).

Finally, in an effort to compromise, Roche proposed that each side conduct nine depositions -- 50% more than previously ordered. Stanford rejected this proposal. Although Stanford and Roche have each disclosed substantially more potential witnesses, that number should permit each side to conduct reasonable discovery in this ownership phase.

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QUINN EMANUEL URQUHART OLIVER & HEDGES, LLP

Robert W. Stone

RWS:JAB 04972/1888340.1

04972/1888340.1

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EXHIBIT A

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kozal et al.

Application No.: 07/883,327

Filed: May 14, 1992

Art Unit: Not Assigned

Examiner: Not Assigned

AYS FOR Attorney Docket No.: 7627-002

FOR POLYMERASE CHAIN RECTION SAYS FOR MONITORING ANTIVIRAL THE THE ATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME

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 tofiling 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.

Respectfully submitted,

Thomas C. Merigan, Jr.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kozal et al

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Application No.: 07/883,32

Filed: May 14, 1992

Art Unit: Not Assigned

Examiner: Not Assigned

SSAYS FOR Attorney Docket No.: 7627-002

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

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 bereby 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.
PENNIBA EDMONDS

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