

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

GALLO et al.

) Interference N° 101,574

)

) Norman G. Torchin

) Examiner in Chief

MONTAGNIER et al.

)

SUPPLEMENTAL DECLARATION OF DR JEAN-CLAUDE CHERMANN

I, Jean-Claude Chermann, hereby declare and say :

1. I am the Jean-Claude Chermann who executed a Declaration on October 9, 1986 in support of the Motion of Montagnier et al. for Judgment Pursuant to 37 C.F.R. §1.633(a).

2. LAV antigenic material from virus grown in a primary cell culture, rather than harvested from a continuously viable cell line, is not inherently incapable of detecting antibodies to the LAV virus in serum of patients with AIDS or Pre-AIDS.

3. In my opinion, carefully prepared LAV antigenic material from virus grown in primary cell culture is immunologically indistinguishable from carefully prepared HTLV-III antigenic material harvested from a continuously viable cell line.

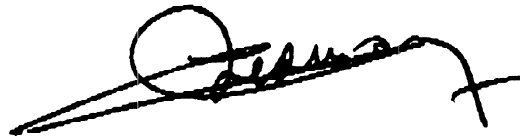
4. In the Spring of 1984, Dr. M.J. Sarngadharan of Dr. Gallo's Laboratory, a co-inventor named on the Gallo patent, came to the Pasteur Institute to do comparative testing of the proteins of LAV and HTLV-III. We prepared a manuscript describing the results of that work. A true and correct copy of this manuscript forms Exhibit 10 to the Appendix of Exhibits in Support of the Opposition of Montagnier et al. to the Motions of Gallo et al. As reported at page 5, the data we gathered and presented in the manuscript showed clearly that the major core protein of HTLV-III is antigenically identical to LAV p 25.

5. Our laboratory has made certain technical modifications of the ELISA assay, including those reported in our article appearing in the June 9, 1984 issue of The Lancet (Exhibit 13), which have increased the sensitivity of the assay. These modifications did not require the use of a continuous cell line. Instead, the increased sensitivity of the assay resulted from refinement of the purification process used to prepare antigenic material from the LAV virus. Such modification and refinement represented the application of routine skill in practicing the basic technique of the Montagnier et al. application.

6. In the Spring of 1984, a large number of serum samples were sent blind by the Center for Disease Control (CDC) for HTLV-III/LAV antibody screening by Dr. Gallo's laboratory, our laboratory, and the CDC. The samples sent to Pasteur were analyzed using antigen from LAV virus grown in primary cell culture. I visited the CDC in February of 1984. At that time, they were analyzing samples for LAV antibodies using antigen from LAV virus grown in primary cell culture. Dr Donald Francis of the CDC reported to me the results of the serum testing by all three laboratories in April of 1984. Those results indicated that similar results were obtained when either the LAV antigen from primary cell culture or the HTLV-III antigen harvested from a continuously viable cell line was used.

7. 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 issued thereon.

Date: 7 november 1986

A handwritten signature in black ink, appearing to read 'Chermann', with a long horizontal stroke extending to the right.

Jean-Claude CHERMANN