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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

ROBERT C. GALLO et al

Serial No. 602,945

Filed: April 23, 1984

Patent No. 4,520,113

Granted: May 28, 1985

For: SEROLOGICAL DETECTION OF
ANTIBODIES TO HTLV-III IN
SERA OF PATIENTS WITH AIDS
AND PRE-AIDS CONDITIONS

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

Sir:

PETITION TO CORRECT INVENTORSHIP UNDER C.F.R. §1.324

In accordance with the provisions of 37 C.F.R. §1.324 please correct the above-identified patent by adding the following twelve individuals as joint inventors:

Luc Montagnier

Jean-Claude Chermann

Françoise Barre-Sinoussi

Francoise Vezinet Brun

Christine Rouzioux

Willy Pozenbaum

Charles Dauguet

Jacqueline Gruest

Marie-Therese Nugeyre

Francoise Rey

SEP -9 1937
AND THE PROPERTY AND THE WALS

Group Art Unit: 124

Examiner: M. Moskowitz

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Claudine Ader-Elin

Solange Chamaret.

herein after "Montagnier et al".

The correct inventors were not named in the application through error without any deceptive intention on the part of the actual inventors. These circumstances are supported by the accompanying VERIFIED STATEMENT OF FACTS explaining how the error occurred and when it was discovered. The Verified Statement of Facts is summarized below.

Shortly after Acquired Immune Deficiency Syndrome ("AIDS") was first identified as a disease, scientists at Institut Pasteur (Pasteur) and the U.S. Department of Health and Human Services (HHS), through its National Cancer Institute as well as other components within HHS, undertook research relating to the cause of the disease in which they informally collaborated.

Scientists at both Pasteur and HHS succeeded in isolating a human retorvirus ("AIDS virus") known variously as HIV, LAV, or HTLV-III, which proved to be the causative agent of AIDS.

Following successful identification of this retrovirus, the scientists at HHS and Pasteur endeavored to develop a valid and reliable diagnostic assay which would indicate the presence of antibodies to the AIDS virus.

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Pasteur and HHS each filed a patent application describing a diagnostic assay and a test kit for the detection in humans of antibodies to the AIDS virus. On May 28, 1985, U.S. Patent No. 4,520,113 (the "Gallo et al Patent") was issued to HHS by the PTO.

On or about April 27, 1986, at the request of Pasteur, the PTO declared Interference No. 101,574 ("the Interference") between certain claims in Pasteur's application Serial No. 785,638, which had been filed in the names of Montagnier et al, and certain claims in the Gallo et al Patent. Between October of 1986 and February of 1987, Montagnier et al and Gallo et al (hereinafter collectively referred to as the "parties") filed their preliminary statements, motions and responses thereto.

In the course of preparation for and prosecution of the Interference, it became apparent that each party had contributed inventively to the other party's work in the development of the subject matter involved in the Interference. This is evident from discussions which occurred between the parties, correspondence and the exchange of materials relevant to the invention.

It also became apparent that the names of each party were not included in the other party's application through error and without deceptive intent.

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As a result of these circumstances, Gallo et al respectfully petition the Honorable Commissioner of Patents and Trademarks to correct this patent as indicated above.

It is respectfully requested that in correcting the inventorship as sought herein, that the Patent Office reprint the first page of the patent. Alternatively, an appropriate PTO Form-1050 is attached.

The Commissioner is hereby authorized to charge the Petition Fee of \$140.00 to the Deposit Account of the undersigned firm, Account No. 03-3975 for which purpose a <u>duplicate</u> copy of this paper is attached.

Favorable action is earnestly solicited.

Respectfully submitted,

CUSHMAN, DARBY & ÇUŞHMAN

by Moon COUN

Watson T. Scott Reg. No. 26,581

WTS:dmn

1615 L Street, N.W. 11th Floor Washington, D.C. 20036 (202)861-3067

Verified Statement of Facts

- 1. Shortly after Acquired Immune Deficiency Syndrome ("AIDS") was first identified as a disease, scientists at Institut Pasteur and the U.S. Department of Health and Human Services (HHS), through its National Cancer Institute as well as other components within HHS, undertook research relating to the cause of the disease in which they informally collaborated.
- 2. Scientists at both Pasteur and HHS succeeded in isolating a human retrovirus ("AIDS virus," known variously as H.V. LAV, or HTLV-III) which provided to be the causative agent or AIDS.
- 3. Following the successful identification of this retrovirus, the scientists at HHS and Pasteur endeavored to develop a valid and reliable diagnostic assay which would indicate the presence of antibodies to the AIDS virus.
- 4. On September 15, 1983, Pasteur, through its scientists Luc Montagnier et al., filed with the Patent Office of the United Kingdom a patent application (No. 83-24800) for a test-kit assay which would, according to the application, detect the presence in human sera of antibodies to LAV.
- 5. On December 5, 1983, Pasteur, through its scientists Luc Montagnier et al., filed in the U.S. Patent and Trademark Office (PTO) U.S. patent application Serial No. 558,109 containing the same disclosure as the United Kingdom application and claiming benefit of its September 15, 1983 filing date under 35 U.S.C. \$119. A divisional application containing the same disclosure was

filed on October 8, 1985 (Serial No. 785,638), which is involved in the pending interference.

- 6. Montagnier et al. assigned their rights in these U.S. patent applications to Pasteur.
- 7. On April 23, 1984, HHS, through its scientists Robert C. Gallo et al., filed a patent application with the PTO for an AIDS antibody test-kit assay process which would, according to the application, enable one to propagate the virus HTLV-III in a permanent cell line and which would, according to the application, detect the presence in humans of antibodies to the HTLV-III virus.
- 8. On May 28, 1985, U.S. Patent No. 4,520,113 (the "Gallo et al. Patent") was issued by the PTO on the Gallo et al. application.
- 9. Gallo et al. assigned their entire rights in the application and subsequently issued Gallo et al. Patent to HHS, which in turn assigned its rights to the National Technical Information Service (NTIS).
- 10. After the filing of the Gallo et al. application, a dispute arose between Pasteur and HHS concerning which entity was the first to conceive of and reduce to practice the AIDS virus antibody assay, and, consequently, which entity was entitled to the patent rights associated with that invention.
- 11. On or about April 27, 1986, at the request of Pasteur, the PTO declared Interference No. 101,574 ("the Interference") between certain claims in Montagnier et al.

application Serial No. 785,638 and certain claims in the Gallo et al. Patent. Between October of 1986 and February of 1987,

Montagnier et al. and Gallo et al. (hereinafter collectively referred to as the "parties") filed their preliminary statements, motions and responses thereto.

- 12. In the course of preparation for and prosecution of the Interference, it became apparent that each party had contributed inventively to the other party's work in the development of the subject matter involved in the Interference. This is evident from discussions which occurred between the parties, correspondence and the exchange of materials relevant to the invention.
- 13. It also became apparent that the names of each party were not included in the other party's application through error and without deceptive intent.
- 14. The undersigned declare that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may adversely affect the validity or enforceability of any United States patent issued as a result of such statements.

C. Axlu	4.24.87
Claudine Axler	Date
OB air	4/24/87
Francoise Barre-Sinoussi	Date