DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date August 7, 1985

From Associate Director, NCI

Subject Meeting Regarding HTLV III LAV Patents

To Chief, Laboratory of Tumor Cell Biology, DCT, NCI
Through: Director, NCI

In the past few weeks, the Institut Pasteur (IP) interacted with the Department of Health and Human Services (HHS) at its highest levels. An exchange of letters between the Pasteur Director, Dr. R. Dedonder and Secretary Heckler ensued. This led to a series of internal briefings and responses via Dr. James Mason, Acting Assistant Secretary for Health. Pertinent correspondence to which we had access is included. A major initial concern on the part of the IP was that the U.S. patent stance as adopted in the area of AIDS created a difficult climate regarding international collaboration in this pursuit.

Further input to HHS came from legal groups representing the IP and Genetics Systems. This biotechnology firm allegedly has an agreement with Institut Pasteur as the sole distributor of the ELISA test kit based on the French LAV isolate. An initial meeting was requested and scheduled between HHS and several of the parties concerned. The subject matter was to be the putative priority of the French invention and their patent, as you can see from Mr. Ferris' Memo to the Record. However, nothing was put to the HHS in writing, and the scheduled meeting was inexplicably canceled. A second contact ensued via a different legal group representing the Institut Pasteur. They requested a meeting which took place at 2:00 pm on August 6, 1985. The list of attendees is included. No written documents passed from the Institut Pasteur/Genetics Systems group to the HHS counterparts.

After an exchange of pleasantries, Dr. Dedonder initiated the presentation of formal points. He stressed the worldwide importance of AIDS and the past positive interactions between the IP and the HHS units. However, he unequivocally stated that the IP cannot accept the current U.S. Patent Policy, which allegedly led to a detrimental effect on research collaboration and other activities of the IP.

The next speaker was Dr. R. Nowinski, whose key theme was that the basis for the filing of the U.S. patents for the blood tests was incorrect. The reason was that key component of the test, i.e., the virus, was not of U.S. origin. His thesis, after citing some publications and data regarding numerous virus isolates, was that LAV and the HTLV III_B were actually one and the same, and that your laboratory somehow re-isolated the LAV and proceeded to deal with it as HTLV III from then on.

The floor was next turned over to Mr. Weisser, attorney for the IP, who intoned that after perusing hundreds of pertinent documents, he had ample evidence to support the above concern. He specifically referred to two documents:

1) Correspondence between the journal Science and Dr. Gallo, who reviewed the IP 1983 manuscript by F. Barre-Sinousse et al. This was interpreted by Mr. Weisser that Dr. Gallo had key French information one year prior to the U.S. patent application.

2) Letters between the Institut Pasteur and Dr. M. Popovic acknowledging reciept of LAV in September, 1983, which was to be used for research purposes only and was not to be disseminated.

Mr. Weisser allowed that there were two ways to proceed. One of these was to reach a settlement and the other was court action on numerous grounds.

Dr. Nowinski then clarified from their perspective what a compatible solution would entail. He cited the following four points:

1. That Dr. Montagnier be recognized by HHS as the true inventor of the virus and the basic testing methodology leading to the current test.

2. That past and future royalties be examined with a view towards redistribution because the initial licensing was inappropriate.

3. That the HHS patent be reissued properly after full examination of documents.

4. The current blood test marketing not be interfered with. He requested a final written response from HHS by September 6, 1985.

HHS personnel had a number of answering comments. The key request proffered several times was that HHS needed something in writing as to the specifics of their demands. A number of scientific points were raised as well, which answered Dr. Nowinski's allegation of HHS appropriating the French virus as a basis for the U.S. patent claim.

In the ensuing discussion among the HHS team, the following requests have a bearing on the NCI operation. NCI was to examine the events leading to the discovery of HTLV III. In that context, the documents cited by Mr. Weisser will be necessay, if available. These include all correspondence between your laboratory regarding the timing the acquisition of LAV from France and the reciprocal transmission of HTLV III and cells to the IP.

Second, the documentation of the review process of the Barre-Sinoussi Science paper with input from the editors and other reviewers will be needed.

Third, please assemble adequate documentation from your laboratory data that you have isolated an HTLV III agent(s) prior to the receipt of LAV. Standard virus differentiating criteria would be useful, such as electron micrographs, inability to immortalize T_4 cells and negativity of reactions with antibodies to p19, or p24 internal proteins which identify HTLV I or II. Additionally, cite the data which demonstrate that virus passage in culture, whether as continous production or on sequential passage to fresh cells, does not affect molecular fine structures to a substantive degree.

Your response will be useful in determining the future course of actions of HHS. Obviously, because these allegations have a significant negative bearing on your personal reputation and scientific integrity, please feel free to discuss alternative actions which would rectify the thrust of the above-cited allegations.

Peter J. Fischinger, M.D., Ph.D.

CC: Dr. Chabner