EYES ONLY

MAY 12 1987

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: General Counsel MJA

SUBJECT: Response to the Pasteur Institute's Request for a Greater Share of the Royalties Under the 1987 Settlement of the French/American Dispute Over the AIDS Blood Test Patent -- ACTION

Action Requested By: No Date Requested

**ISSUE**

How should the Department respond to the demand from the Pasteur Institute that the royalties received by the Pasteur Institute and HHS under the 1987 Settlement Agreement be reallocated to give Pasteur a greater share (HHS and Pasteur currently receive equal shares) both retroactively and prospectively?

**FACTS**

French and American interests, after several years of public disputes and litigation over their relative contributions to the discovery of the cause of AIDS and the development of a successful test kit to detect the presence of AIDS in blood, decided that the interests of science and public health would best be served by the resolution of the conflict. Therefore, in 1987 a comprehensive settlement agreement was entered into which purported to resolve not only the issue of discovery of the cause of AIDS, but also the inventorship of the diagnostic test kit and the related patent rights. The Settlement Agreement addressed all disputes regarding patent rights, as well as alleged tortious misappropriation by HHS of a specimen of LAV which had been provided by Pasteur for research purposes, gave the HHS and Pasteur inventors equal credit and joint ownership of all inventions, and provided for the allocation of royalties.

The Agreement established a research foundation, the French and American AIDS Foundation (FAAF), to which Pasteur and HHS would contribute 80 percent of the royalties they receive from licensing the patents.[1] The FAAF is managed and directed through an eight member Board of Trustees with equal representation from Pasteur and HHS. The General Counsel, Assistant Secretary for Health, Director, NIH, and Dr. Gallo are the HHS trustees. The Foundation uses the royalties to promote international cooperation and collaboration in scientific research into AIDS and other human diseases caused by retroviruses. Pursuant to a resolution of the Board of the Foundation dated December 4, 1987, Pasteur and HHS each are awarded 37.5 percent of all funds received by the Foundation, and the World AIDS Foundation (WAF) receives the remainder of such funds, less FAAF's administrative expenses, for subsequent distribution as grants to support international scientific research on AIDS. The Department has paid more than $20 million to FAAF over the past five years.

The dispute over patent rights was revived when allegations of scientific misconduct in the research underlying some of the patent applications were made against Dr. Gallo and his colleague, Dr. Popovic in 1989. In addition, as the capability to identify these retroviruses has improved, it has become increasingly apparent that the virus used in the U.S. Patent was the virus supplied by the French.[2] Finally, in a letter appearing in the May 30, 1991 issue of Nature, Dr. Gallo acknowledged that it was likely that the virus he had designated HTLV-IIIB was a virus he had received from the French (attachment). This virus was used in developing the patented blood test kit. Focusing principally on Dr. Gallo's acknowledgement and the "non-commercial use" use agreement that the Gallo laboratory executed in September 1983 upon receipt of the Pasteur virus, the French are now suggesting that there should at least be a readjustment in the distribution of the royalties. Specifically, they propose that the royalties received from FAAF be reallocated in favor of Pasteur, both prospectively and retroactively, but they have not yet formally suggested a specific dollar or percentage figure. Pasteur suggests this could be done by a vote of the French and American trustees of the foundation, which would require at least one HHS

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[1] Pasteur and HHS retain the first twenty percent of the royalties they receive. The royalties received by Dr. Gallo and the other Government inventors (equal to the statutory cap of $100,000 per person, per year) are paid from the twenty percent retained by HHS.

[2] There was apparently an error by the Pasteur Institute in identifying the source of this virus. That matter is discussed more fully later in the text.

trustee to vote for the reallocation, assuming the Pasteur trustees vote unanimously for it. While this suggestion is not totally free from legal doubt, it is likely that most of what is suggested can be accomplished by a vote of the trustees of the Foundation without amendment of the Settlement Agreement. There are a number of factors to be considered in reacting to the French proposal.

1. The Settlement Agreement

The Settlement Agreement is a formidable legal obstacle for the French to overcome. The issues they raise now were asserted by them prior to settlement and presumably were taken into account in the terms of the agreement. The major change is that Dr. Gallo now has stated that the French were probably correct in asserting that HTLV-IIIB is a virus sent to Dr. Gallo's laboratory by Pasteur. Dr. Gallo's attorney insists that the sample sent by Pasteur was contaminated by another virus in Pasteur's laboratory and subsequently that virus contaminated cultures in Dr. Gallo's laboratory. The attorneys for the Pasteur Institute recognize the legal implications of the Settlement Agreement, but emphasize the equities, and contend that the U.S. Government has obligations exceeding those of private parties, which should preclude the U.S. from hiding behind legalities in the face of the clear equities.

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[3] Reallocation in this manner would not affect royalty payments to Dr. Gallo and the other Government inventors, because those payments are made from the twenty percent (20%) of royalties that are retained by HHS, not the eighty percent (80%) of the royalties paid to FAAP.

[4] It has been alleged that Dr. Gallo knowingly misappropriated the French virus. Tests of virus samples from Dr. Gallo's laboratory done as part of the investigation by the Office of Scientific Integrity (OSI) establish contamination, but are inconclusive as to whether the contamination was accidental or deliberate. The OSI report of its investigation is being reviewed by the PHS Office of Scientific Integrity Review (OSIR). It is anticipated that the report will be submitted to Dr. Mason for final action by the first week in June, unless OSIR determines that further fact-finding is necessary or that the facts lead to a conclusion different from that reached by the NIH.

2. The "Non-Commercial Use" Provision

In September 1983, when the Gallo laboratory received the requested material from Pasteur, it executed a document pursuant to which it committed itself not to use the virus identified as LAV-1 for commercial purposes. It now seems clear that the isolate which the French sent had already been contaminated by a different strain of the virus. Accordingly, their identification of the virus contained in the isolate was also mistaken. The same virus apparently contaminated isolates in the Gallo laboratory so that the virus used by the Gallo laboratory in the development and eventual patenting of the diagnostic test kit apparently was a virus contained in the sample sent by the French. The fact that the French mislabeled the virus as LAV-1, while perhaps providing a technical response, does not seem to be a substantial defense. Thus, it appears Dr. Gallo inadvertently used the Pasteur virus for a commercial purpose; something that he said he would not do. Nevertheless, as noted above, the French claims were acknowledged in the subsequent Settlement Agreement and presumably taken into account in the give-and-take leading to the Settlement Agreement.

3. The "Rediscovery" Issue

The French, in their recent request for the reallocation of the royalties, refer to Dr. Gallo's role as being limited to the "rediscovery" of the AIDS-causing virus that had already been discovered by French. This assertion has merit if one focuses on the narrow issue of who first detected the particular virus that was subsequently shown to be the cause of AIDS. However, as you know, "discovery" of the cause of AIDS involves more than isolating a virus from the blood of an AIDS victim.[1]

For example, the ability to reproduce the retrovirus in quantity was a difficult and necessary prelude to establishing the cause of AIDS. Certainly, the Gallo laboratory played a crucial role in identifying a cell line which permitted the reproduction of the virus in adequate quantities. Thus, the issue of "discovery" is not such a simple one. Although this issue has no direct bearing on whether the U.S. violated the "non-commercial use" commitment, the matter deserves comment because the French raise their claims in this context.

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[1] In fact, the OSI report concludes that the Gallo laboratory had a number of its own retrovirus isolates at the time it was working with the French retrovirus. It is not clear, however, whether those isolates were "useable" or as "useable" as the French retrovirus.

4. Outstanding Inquiries

At the present time, there are four inquiries into matters relating to the dispute with the French, as follows.

(a) OSI Investigation. This investigation of alleged misconduct in science on the part of Dr. Gallo and Dr. Mikulas Popovic is nearing completion. The report of the Office of Scientific Integrity has been forwarded to the PHS Office of Scientific Integrity Review and will subsequently be forwarded to the Assistant Secretary for Health for final action. This investigation is limited to the validity of scientific papers on the experiments underlying the patented inventions that were published by Dr. Gallo and his colleagues in the journal Science in 1984. Some of the statements made in the papers were repeated in the patent applications and thus it is possible, albeit unlikely based on the preliminary information available to us, that the findings of the investigation might affect the validity of the patents. The OSI report does conclude that Dr. Gallo used a Pasteur virus to develop his blood test, but found no evidence of intentional misappropriation of the virus by Dr. Gallo. However, it has been reported in the media that a group of scientific consultants from the National Academy of Sciences, who advised NIH on the investigation, has criticized the NIH report of the investigation for failing to hold Dr. Gallo responsible for his failure to acknowledge in the Science papers that he had grown the Pasteur virus in his laboratory.

(b) OIG Investigation. The OIG is investigating allegations that Dr. Gallo made false statements in a declaration filed in 1986 in the patent interference proceeding with Pasteur. This investigation also encompasses charges that Department employees covered up and misrepresented the facts regarding Dr. Gallo's research on the AIDS blood test in order to gain advantage over Pasteur and retain royalties and credit for the Department.

(c) Congressional Investigation. The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce is also investigating the alleged cover up of the facts relating to Dr. Gallo's research on the AIDS blood test.

(d) Outside Patent Counsel. Under an ongoing contract for patent legal services, outside patent counsel is reviewing the validity of the Gallo patents relating to the AIDS blood test. They are particularly reviewing the question of whether Dr. Gallo's recent acknowledgement in Nature as to the origin of the virus would have any legal implications regarding the validity of the patent.

Although these investigations may generate information which could influence our decision, the French assert that Dr. Gallo's statement in Nature is tantamount to a recognition that the U.S. violated its commitment not to make commercial use of the French virus, sufficient to justify their receipt of a greater share of the royalties, and they are awaiting our response. The following options are available.[6]

A. Give the French an increased percentage of the royalties allocated by the Foundation in the future and restore to them a significant part of the royalties we have received to date from the Foundation. Our payments to the French could exceed $20 million.

Pros:

- We probably have violated our noncommercialization commitment, albeit seemingly inadvertantly.
- We could meet this demand with respect to future payments without any special appropriations or revisions of the settlement agreement.
- Refusal to make a substantial concession to the French might appear as "stone-walling."

Cons:

- The French have not yet made a demand for a specific percentage of the royalties or a dollar amount.
- Restoration of past payments would probably require a special legislative appropriation which would have to be justified to Congress.
- We have already settled this matter once and should not have to pay again.
- This might be perceived as repudiating the significant contributions made by the NIH and CDC in this area.

B. Agree to reallocate future payments only. All or some lesser amount of future payments could be reallocated to the French.

Pros:

- Same as for A, above.

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[6] Inasmuch as the Department of Justice cleared the Settlement Agreement, we would seek their advice on the legal effect of the various options.

Cons:

- Same as those in A above, but it would not require a special appropriation.

C. Reject the French proposal.

Pros:

- The Department should protect its patent rights and its researchers, because there has not been any showing of an intentional violation of the noncommercialization agreement.

- The Settlement Agreement should not, in effect, be reopened because the French have asserted from the beginning of the dispute that violation of the noncommercialization agreement was a probability and they decided to accept the Settlement instead of attempting to prove that fact in Court.

- The Settlement Agreement already favors the French disproportionately, because the Department's test kit contributes a much larger amount to the Foundation than does the French test kit.

- A distinction should be drawn between Dr. Gallo's behavior and the legitimate legal and property rights of the U.S.

Cons:

- The French might initiate legal action asserting that the Settlement Agreement was fraudulent.

- Scientific and other relations with the French government might be adversely affected.

- The Department might be perceived as stonewalling or otherwise covering up for the behavior of its employees.

D. Delay any decision until the various outstanding reviews are completed.

Pros:

- This option would ensure all facts are known before a decision is made. It would provide time for reasoned decision-making. For example, the conclusion from outside patent counsel as to the validity of our patent, in light of Dr. Gallo's recent acknowledgement, could significantly affect our deliberations.

Cons:

- We will face pressure from the French for a prompt resolution.

- This could be viewed as further evidence of stonewalling.

E. Submit the matter to a neutral body, with appropriate expertise, for a non-binding recommendation.

Pros:

- This would demonstrate our commitment to resolving the matter fairly.

Cons:

- It might be difficult to avoid following the recommendation and the recommendation could be adverse to the Department.

- It might be difficult to select an expert, objective panel that will be acceptable to the various interests.

Michael J. Astrue MJA

Decision

Option Selected: _____

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Date: _____

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Louis W. Sullivan, M.D.
Secretary, HHS