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Last Updated: 12/12/2023

19

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CO 051

PR005-01

PP005-01



May 1, 1987

Dear Mrs. Reagan,

What a lovely surprise to receive
the photographs taken the night of the State
Dinner in honor of Prime Minister Chirac!

You were very thoughtful to think of us.

We have remembered with pleasure
our return to the White House after so
many years. Thank you for so graciously
and warmly welcoming us.

With kind regards, Juli E. Eisenhower

Sg

NATIONAL SECURITY COUNCIL
WASHINGTON, D.C. 20506

431184
1110
1120
00051
FG013
FG006-12

CJ

ACTION

June 27, 1986

MEMORANDUM FOR W. ROBERT PEARSON

FROM: TYRUS W. COBB *TC*

SUBJECT: Weinberger's Attendance At Upcoming Mitterrand Events, July 3-4, 1986

Cap has requested that he attend the 3 July Mitterrand pre-brief and the 4 July bilateral in New York. Given that his counterpart, Defense Minister Giraud, will be at the bilat, we concur that the Secretary should attend.

RECOMMENDATION

That you inform Jim Lemon that the Secretary will be included in the Mitterrand events.

Approve *WRC* Disapprove _____

MC

Michael Castine concurs.

Attachment
Tab I Incoming Request

ABC ID 8604874



OFFICE OF THE SECRETARY OF DEFENSE

4874

WASHINGTON, D.C. 20301

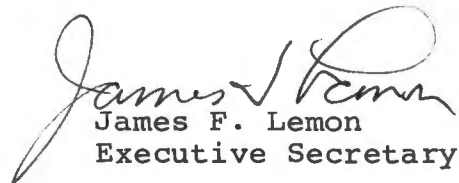
25 JUN 1966

MEMORANDUM FOR HONORABLE RODNEY McDANIEL, EXECUTIVE SECRETARY,
NATIONAL SECURITY COUNCIL

Secretary of Defense Weinberger has expressed a desire to attend the following upcoming events for the visit of French President Francois Mitterrand:

3 July - Pre-brief in the Oval Office

4 July - Meeting at Governor's Island


James F. Lemon
Executive Secretary

DM

National Security Council
The White House

86 JUN 27 10 00 AM '66 P 5: 36

System # _____
Package # 4874
DOCLOG DM A/O _____

	SEQUENCE TO	HAS SEEN	DISPOSITION
Bob Pearson	<u>1</u>	<u>P</u>	AA
Rodney McDaniel	_____	_____	_____
Don Fortier	_____	_____	_____
Paul Thompson	_____	_____	_____
Florence Gantt	_____	_____	_____
John Poindexter	_____	_____	_____
Rodney McDaniel	_____	_____	_____
NSC Secretariat	<u>2</u>	_____	<u>N</u>
Situation Room	_____	_____	_____

I = Information A = Action R = Retain D = Dispatch N = No further Action

cc: VP Regan Buchanan Other _____

COMMENTS Should be seen by: _____
(Date/Time)

NSC/S PROFILE

UNCLASSIFIED

ID 8604874

RECEIVED 26 JUN 86 14

TO MCDANIEL

FROM LEMON, J

DOCDATE 25 JUN 86

KEYWORDS: FRANCE

VISIT

WEINBERGER, C

MITTERRAND, FRANCOIS

SUBJECT: SEC WEINBERGER REQUEST TO ATTEND PRES MITTERRAND UPCOMING VISIT EVENTS
3 - 4 JUL

ACTION: ANY ACTION NECESSARY DUE: 30 JUN 86 STATUS S FILES WH

FOR ACTION

FOR CONCURRENCE

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RODMAN

COMMENTS

REF# LOG NSCIFID (HW)

ACTION OFFICER (S)	ASSIGNED	ACTION REQUIRED	DUE	COPIES TO
	<i>C 6/30</i>	<i>Pearson Approved Lemon</i>		<i>TC MRU [initials]</i>

DISPATCH _____ W/ATTCH FILE _____ (C) ✓

Ag

CJ

THE WHITE HOUSE
WASHINGTON

NOTED BY DTR

July 3, 1986

431217

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: JOHN A. SVAHN *JAS*

SUBJECT: President's Meeting with Mitterand
and an issue that might come up re.

CO051
HE006
HE001
FG022-10
PR007-01

This morning I received a call from Dr. Jonas Salk regarding an issue that Mr. Mitterand may raise with the President during their meeting. Salk said Mitterand was being briefed on it and that he (Salk) would be talking with Mitterand later today.

Issue:

There is a dispute between the French Pasteur Institute and U.S. Public Health Service over who invented the test for AIDS antibodies and therefore who is entitled to the patent and royalties.

This issue is in the courts at the present time. Our Public Health Service is also working with the French to settle the issue in an amicable way. The real fight is not over money. It is that the French want recognition and entry into the U.S. biotech market.

I have discussed this with Health and Human Services and we agree on the following talking points for the President should Mitterand bring the issue up.

- o Yes, I am aware of the dispute concerning the patent.
- o Our Public Health Service is working with the Institute Pasteur on a solution.
- o But certainly the dispute shouldn't stand in the way of our cooperative efforts on this major health threat.

TJ

THE WHITE HOUSE
WASHINGTON

FILES

July 7, 1986

431748
3200
C0051
PA002
ST032
F6006-01
PR001
M0064

Dear Ambassador de Marjerie:

With historic Liberty Weekend behind us, I wanted to express my appreciation and deep thanks for your cooperation and support over the past few months. The involvement of two governments and several branches of the armed services and cabinet agencies created a very complicated environment. With your assistance, we are pleased everything worked out so well. I look forward to working with you in the future.

All the best.

Sincerely,



FREDERICK J. RYAN, JR.
Deputy Assistant to the President

Ambassador Emmanuel de Marjerie
French Embassy
4101 Reservoir Road, NW
Washington, D.C. 20007

cc: Central Files

UNCLASSIFIED

(CLASSIFICATION)

RO* 432048
C0051

DEPARTMENT OF STATE
EXECUTIVE SECRETARIAT
TRANSMITTAL FORM

S/S 8602439

DATE MAY 01 1987

FOR: MR. FRANK C. CARLUCCI
NATIONAL SECURITY COUNCIL
THE WHITE HOUSE

REFERENCE:

TO: The President FROM: President Francois Mitterrand

DATE: January 22, 1986 SUBJECT: Greeting Card From

President Mitterrand to President Reagan in French

REFERRAL DATED: January 25, 1986 ID# 8600648

(IF ANY)

_____ THE ATTACHED ITEM WAS SENT DIRECTLY TO THE
DEPARTMENT OF STATE

ACTION TAKEN:

_____ A DRAFT REPLY IS ATTACHED.

_____ A DRAFT REPLY WILL BE FORWARDED.

_____ A TRANSLATION IS ATTACHED.

_____ AN INFORMATION COPY OF A DIRECT REPLY IS ATTACHED.

X WE BELIEVE NO RESPONSE IS NECESSARY FOR THE REASON
CITED BELOW.

_____ THE DEPARTMENT OF STATE HAS NO OBJECTION TO THE
PROPOSED TRAVEL.

_____ OTHER (SEE REMARKS).

REMARKS: "Incoming is Christmas from President Mitterrand.
President Reagan, sent Mitterrands a Christmas Card.

Melvyn A. Levitsky
Melvyn Levitsky
EXECUTIVE SECRETARY

UNCLASSIFIED

(CLASSIFICATION)

REFERRAL

8602439

DATE: 25 JAN 86

MEMORANDUM FOR: STATE SECRETARIAT

DOCUMENT DESCRIPTION:

TO: PRESIDENT

SOURCE: MITTERRAND, FRANCOIS

DATE: 22 JAN 86

KEYWORDS: FRANCE

HS

SUBJ: GREETING CARD FM PRES MITTERRAND IN FRENCH

REQUIRED ACTION: TRANSLATION

RECOMMENDATIONS

DUE DATE: 03 FEB 86

COMMENTS:



for WILLIAM F. MARTIN
Executive Secretary

*Received in S/S-I
1/27 at 10:52 AM (24)*

DEPARTMENT OF STATE
DIVISION OF LANGUAGE SERVICES

(TRANSLATION)

LS NO. 121983
JF
French

From the President of the Republic and Madame François
Mitterrand, with their thanks and best wishes.

[s] François Mitterrand
[s] Danielle Mitterrand

432048

0648 3100

0051

Ambassade de France
aux Etats-Unis FG006-12

CJ

L'Ambassadeur

Washington, January 22, 1986

JAN 24 1986

Dear Admiral Poindexter,

You will find herein a greeting card addressed by the President of the French Republic and Mrs. Francois Mitterrand to President and Mrs. Ronald Reagan, and which I was asked to forward to them.

I would be most grateful to you for remitting this to its high addressees.

With many thanks and my best regards, I am,

Yours sincerely,

x
Emmanuel de Margerie

The Honorable
Vice Admiral John M. Poindexter,
Assistant to the President
for National Security Affairs,
The White House,
Washington, D.C.

NSC # 8600648



*Le Président de la République
et Madame François Mitterrand,
avec leurs remerciements
et leurs meilleurs vœux*

François Mitterrand

Danielle Mitterrand

NSC/S PROFILE

UNCLASSIFIED

ID 8600648

RECEIVED 25 JAN 86 09

TO PRESIDENT

FROM MITTERRAND, FRANCOIS

DOCDATE 22 JAN 86

DE MARGERIE, EMMANUE

22 JAN 86

KEYWORDS: FRANCE

HS

SUBJECT: GREETING CARD FM PRES MITTERRAND IN FRENCH

ACTION: TRANSLATION / RECOMMENDATIONS DUE: 03 FEB 86 STATUS D FILES WH

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_____ *C 4/28 SBE pa Van* _____

DISPATCH 1/25 SF w/ W/ATTCH FILE *9* (C)

REFERRAL

DATE: 25 JAN 86

MEMORANDUM FOR: STATE SECRETARIAT

DOCUMENT DESCRIPTION:

TO: PRESIDENT

SOURCE: MITTERRAND, FRANCOIS

DATE: 22 JAN 86

KEYWORDS: FRANCE

HS

SUBJ: GREETING CARD FM PRES MITTERRAND IN FRENCH

REQUIRED ACTION: TRANSLATION

RECOMMENDATIONS

DUE DATE: 03 FEB 86

COMMENTS:

A handwritten signature in black ink, appearing to be 'W. F. Martin', with a long horizontal line extending to the right.

for WILLIAM F. MARTIN
Executive Secretary

THE WHITE HOUSE
WASHINGTON

August 7, 1986

434168
3200
C0051
MED06-01
FG006-01
PP005-01

Dear Mr. Ambassador:

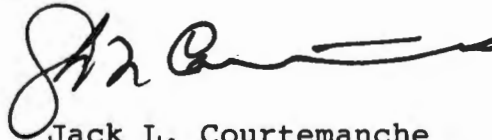
Thank you very much for your kindness in forwarding the package from Mrs. Chaban-Delmas. The programs described in the literature were most impressive, and the First Lady was very happy to have a chance to see them. It is always so exciting for her to see what is being done in other countries to fight this terrible problem.

Please convey Mrs. Reagan's sincere best wishes to Mrs. Chaban-Delmas. She was delighted to know of her hard work in the area of drug abuse prevention. You can be sure that the information enclosed will be very useful in our continued efforts to seek ways of ending this tragedy.

Again, thank you for your kind letter. I look forward to meeting you should the occasion arise.

With best wishes,

Sincerely,



Jack L. Courtemanche
Deputy Assistant to the President
and Chief of Staff to the First Lady

His Excellency
Emmanuel de Margerie
Ambassador of France

*Orig. file in Ken Barun's
office Rm 213 E. Wing*

*Ambassade de France
aux Etats-Unis*

L' Ambassadeur

Washington, July 31, 1986

Dear Mr. Courtemanche,

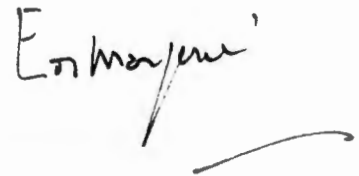
It is my pleasure to send you a set of documents compiled by the "Fondation Toxicomanie et Prévention Jeunesse", created in 1980 under the sponsorship of Mrs. Chaban-Delmas, the wife of the President of the French National Assembly and ex-Prime Minister of France. She was in Washington recently and was most interested to hear of the action undertaken by Mrs. Reagan in the fight against toxicomania. She thought the First Lady might be interested in knowing what her foundation has been trying to accomplish in this field in our country.

Madame Chaban-Delmas was struck to see how the aims of the First Lady corresponded closely with what she is herself trying to do.

I will be most appreciative if you would be so kind as to present these documents to Mrs. Reagan with the compliments of Madame Chaban-Delmas, who sent her best wishes for Mrs. Reagan's noble endeavors.

With kind regards, I am,

Yours sincerely,



Emmanuel de Margerie

Mr. Jack L. Courtemanche,
Deputy Assistant to the President
and Chief of Staff for the First Lady,
The White House,
Washington, D.C.

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Ambassade de France

aux Etats-Unis 0051

FG006-12

CJ

L' Ambassadeur

Washington, July 3, 1986

Dear Admiral Poindexter,

Please find herein the text of a message addressed to President Ronald Reagan by Mr. François Mitterrand, President of the French Republic, and which I was asked to convey to him.

With my best wishes and kind regards, I am,

Yours sincerely,

Emmanuel de Margerie

The Honorable
Vice Admiral John M. Poindexter,
Assistant to the President
for National Security Affairs,
The White House,
Washington, D.C.

Letter to President from President Francois Mitterrand

NSC # 8605038

La Fête Nationale des Etats-Unis d'Amérique m'offre l'agréable occasion d'adresser à Votre Excellence mes félicitations et les voeux très chaleureux que je forme pour son bonheur personnel et pour la prospérité du peuple américain.

Je me félicite de la qualité des relations d'amitié, d'alliance et de coopération existant entre nos deux pays et suis convaincu de leur renforcement dans l'intérêt mutuel de nos deux peuples.

Je me réjouis de vous revoir à New York à l'occasion du Centenaire de la Statue de la Liberté.

François Mitterrand

Admiral -

↑ apologise for handing this to you
directly and the hand written translation
(Alec Toumayeu did it on a tree stump) -

The French just handed it to me and

↑ thought speed was important -

Their visit is going well

Bunny Murdoch
State / Protocol

Independence Day gives me a very pleasant opportunity to present to Your Excellency my Congratulations and my warmest wishes for your personal happiness and the prosperity of the American people.

The quality of the relations of friendship, alliance and cooperation between our two countries is a cause of great gratification for me and I am convinced that their strengthening is in the mutual interest of our two people.

I look forward to seeing you again in New York on the occasion of the Centennial of the Statue of Liberty.

François Pitterrond

NSC/S PROFILE

UNCLASSIFIED

ID 8605038

RECEIVED 07 JUL 86 18

TO PRESIDENT

FROM MITTERRAND, FRANCOIS DOCDATE 03 JUL 86

KEYWORDS: FRANCE

HS

SUBJECT LTR TO PRES FM PM MITTERRAND

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FOR ACTION

FOR CONCURRENCE

FOR INFO

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Name	Date
<i>A. Higgins</i>	<i>8/29/86</i>

*Ambassade de France
aux Etats-Unis*

JUL 03 1986

5269

Washington, le July 2, 1986.

436263

3300

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FG006-12

CJ

Dear Admiral Poindexter,

Please find herein a letter addressed to you by
Mr. Jean-Bernard Raimond, Minister of Foreign Affairs, which
I was asked to forward to you.

With my best wishes, I am,

Yours sincerely,

Gaillardin

X
Alfred Siefer-Gaillardin
Minister

The Honorable
Vice Admiral John M. Poindexter,
Assistant to the President
for National Security Affairs,
The White House,
Washington, D.C.

Jean-Bernard Raimond letter to John Poindexter

République Française

Le Ministre des Affaires Etrangères

Paris, le 23 Juin 1986.

Monsieur le Conseiller,

J'ai été sensible à l'amicale attention que vous avez eue en me faisant adresser des photographies prises lors de ma venue à la Maison Blanche.

Je conserve, en effet, le meilleur souvenir de mon déplacement à Washington, à l'occasion duquel le Président REAGAN m'a fait l'honneur d'une audience.

En vous renouvelant mes vifs remerciements, je vous prie, Monsieur le Conseiller, de bien vouloir agréer l'expression de ma haute considération.

J.B. Raimond

Jean-Bernard RAIMOND

Monsieur John POINDEXTER
Conseiller pour les Affaires
de Sécurité Nationale
The White House
WASHINGTON

NSC/S PROFILE

UNCLASSIFIED

ID 8605269

RECEIVED 16 JUL 86 16

TO POINDEXTER

FROM RAIMOND, J

DOCDATE 23 JUN 86

SIEFER-GAILLARDIN, A

02 JUL 86

KEYWORDS FRANCE

SUBJECT: RAIMOND LTR TO POINDEXTER

ACTION: FOR RECORD PURPOSES

DUE:

STATUS C

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FOR ACTION

FOR CONCURRENCE

FOR INFO

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HE001
BE005
FG022
FG022-16

THE SALK INSTITUTE

15 August 1986

The Honorable Otis T. Bowen, M.D.
Secretary of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

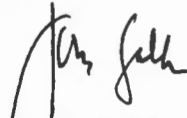
Dear Doctor Bowen:

I continue to hope that the direction may be changed to avoid litigation in the AIDS patent dispute. I enclose a copy of notes of our meeting and also a brief historical summary prepared with the help of Dr. Gallo, should a change in strategy occur and such an historical summary be needed.

I look forward to learning of any progress that is made in the course set at the time of our meeting.

If I can be of further assistance in any capacity, I shall be pleased to do so.

Respectfully,



Jonas Salk

Enc.

cc: Senator Charles McC. Mathias, Jr.
Mr. Ronald E. Robertson

bc: ✓ Mr. Jack Svahn

dispute between Institut
Pasteur (IP) in France and the
National Institutes of Health (NIH)

Notes of Meeting in Secretary Bowen's Office

Monday, 28 July 1986, 4:30 p.m.

Participants: Honorable Otis T. Bowen, M.D., Secretary of Health and Human Services

Dr. Robert Windom, Assistant Secretary for Health, Department of Health and Human Services

Ronald E. Robertson, General Counsel, Department of Health and Human Services

Donald Newman, Under Secretary of Health and Human Services

Robert Irwin, Executive Secretariat, Policy Coordinator, Department of Health and Human Services

Robert Charrow, Deputy General Counsel, Department of Health and Human Services

Senator Charles McC. Mathias, Jr.

Steven J. Metalitz, Staff Director, Senate Subcommittee on Patents, Trademarks and Copyrights

Dr. Jonas Salk

John Crawford

Joan Abrahamson

Senator Mathias thanked Secretary Bowen for holding this meeting and emphasized the importance of bringing about a resolution between the Institut Pasteur (IP) and the National Institutes of Health (NIH) regarding the AIDS research and patent controversy which is now the subject of litigation. He noted the circumstances in which Dr. Salk had been approached by both Dr. Robert Gallo and by the scientists of the IP to try his hand at facilitating an agreement between the parties. He noted that Dr. Salk had the trust and respect of both sides and therefore a unique opportunity to move the two sides toward resolution of the outstanding issues. Senator Mathias observed that the sooner the controversy is settled the sooner all scientists involved can resume unfettered efforts to develop a vaccine against the AIDS virus.

Secretary Bowen welcomed Senator Mathias, Dr. Salk and the other participants and indicated that he was interested in seeing the controversy resolved.

Dr. Salk then made a presentation of the proposal he had developed in Paris with modifications that stemmed from dialogue with the Director of the IP, the IP lawyers and with Dr. Gallo, other representatives of NIH, as well as with representatives of the Department of Justice and the Department of Health and Human Services. The model he proposed was a two-patent solution: the NIH would retain the patent it has been granted and the IP would be able to obtain a patent if both patents were held by a jointly formed Franco-American AIDS Foundation (FAAF) and if it were determined that the patented NIH serological test for AIDS was "reduced to practice" during the window of time between the September 15, 1983 date of IP patent filing in Great Britain and the December 5, 1983 date of IP filing in the United States.

Secretary Bowen asked his General Counsel what he thought of the solution proposed by Dr. Salk, and Mr. Robertson replied that the foundation approach is one that his office suggested in the past. He reported that the patent counsel retained by HHS is not as sure of the legal viability of the approach proposed by Dr. Salk, but stated that if the Secretary agreed the HSS team could proceed to examine it in greater detail. Mr. Robertson mentioned that he was surprised to learn of the French endorsement of Dr. Salk's proposal, as he thought that the French would not agree it.

Dr. Salk confirmed that the French were in agreement with his proposal. The idea of a foundation was unfamiliar to them at first, but now they understand it in its present formulation and are willing to proceed on that basis.

John Crawford, President of the American Chamber of Commerce in France, stated that it was his understanding that Professor Dedonder of the IP is in agreement in principle with Dr. Salk's proposal. He also reported that he had heard that in February 1986 a letter had been sent from the French Minister of Foreign Affairs to Secretary Shultz suggesting that the French would like to see the issue removed from the list of outstanding Franco-American issues. The United States Ambassador to France, Joe M. Rodgers, had been following this matter personally. In response to Mr. Robertson's question whether there would be one office for the foundation in this country, or if there would be one here and one in France, Mr. Crawford replied that the location of the offices was an open question. There would be an equitable number of French directors and American directors who would be above reproach from either side. He said that the French, after getting over their initial resistance and unfamiliarity with this approach, were now embracing it. As for the expenditure of funds held by the FAAF, the foundation would give one-third of the funds to the IP, one-third to the NIH/NCI, and one-third to AIDS-related research which would be administered by the foundation with special consideration to needs of developing countries.

Dr. Salk noted that the seed money for the foundation provided by the royalties from patents would be substantially increased by private sector donations. He then remarked that the scientists of France and the U.S. are not talking to each other freely and openly, and that this is inhibiting overall progress toward a vaccine. He asked what would be lost from the U.S. point

of view by allowing a patent to be granted to the French, as the patent is very important to the French and is the only point they are insisting on now, and satisfactory resolution of this point could lead to the speedy resolution of all other issues.

Mr. Robertson suggested that it is either our patent or their patent, and that in a sense the French are challenging the U.S. patent. Dr. Salk responded that by a fortunate concatenation of circumstances a window of time exists that could allow two patents to coexist, if they were owned by a single entity. This circumstance permitted him to be useful in proposing a solution to the impasse.

Senator Mathias turned to the Secretary and commented that "We need a green light" to move forward with a negotiated settlement. Mr. Robertson asked Dr. Salk for suggestions as to how to reopen negotiations assuming that Secretary Bowen were to give the green light. He also inquired who would be representing the French, and, if it was still Ira Millstein, should he contact him? Dr. Salk responded that Professor Dedonder had told him that Ira Millstein is his representative. Dr. Salk suggested that he could personally communicate the green light to Mr. Millstein and Prof. Dedonder. He also offered to be present to start off the negotiations if that were perceived as useful. He offered to send a letter and a proposal to Professor Dedonder and to Secretary Bowen to initiate discussion, and suggested that all parties could then see what changes would be necessary in the present formulation to achieve complete rapprochement.

Mr. Newman asked if this proposal was the same as before, i.e. whether it was Mr. Robertson's original formula. Mr. Robertson responded that it was a variation on the same theme and very close to the approach which HHS had initiated. The HHS position has been that the United States would contribute the royalties from the patent to a foundation and the French would in turn drop their patent application. The French, however, had wanted the royalties to be divided equally and also insisted on pursuing their patent application, so things had come to a standstill. Dr. Salk had then come up an approach regarding the patents which might advance matters. If so directed, he was prepared to bring HHS patent experts together with the IP patent experts in order to consider the validity of this approach.

Secretary Bowen remarked that the stalemate must be broken. Dr. Salk agreed, and commented that as physicians we have to try to heal this unfortunate situation. Mr. Robertson commented that that was a very important point.

Senator Mathias then introduced Steve Metalitz, Staff Director of the Senate Committee on Patents, Trademarks and Copyright, and suggested that he might be able to be of assistance in this process, particularly if any legislation were to be required. Mr. Robertson remarked that he may want to seek advice from Mr. Metalitz on the most expeditious way to proceed.

Mr. Charrow mentioned that there might be difficulty for the Commerce Department to assign the patent to a foundation, and also raised the potential problem of product liability exposure for the directors of the new foundation. Dr. Salk explained that the patents will have to be owned by a single entity, and that this is why the independent nonprofit foundation would be formed to be the recipient. He agreed that the issue of liability would have to be dealt with and resolved. Mr. Crawford agreed that those risks may exist, but suggested that the liability point could be discussed at the table along with other issues. Dr. Salk commented that ways can be found if there's a will to find them.

Secretary Bowen remarked that it sounded to him that the first step is to get together with Mr. Millstein. Mr. Robertson responded that he would be glad to do so if he receives the green light from Secretary Bowen. On receipt of the green light he would initiate discussions. Secretary Bowen noted that he goes by the theory that "as long as you're talking you're not fighting." He added that he had the responsibility to see that a fair settlement was achieved for NIH.

Secretary Bowen then asked Mr. Robertson to initiate talks, and indicated his desire to try to reach a negotiated settlement. Mr. Crawford asked Mr. Robertson if he could make arrangements for Dr. Salk to be present at the negotiations.

Secretary Bowen congratulated Dr. Salk and thanked him for his continuing assistance in this matter. Dr. Salk offered to initiate the process by sending both sides a letter the following day describing the proposed agreement in principle.

Mr. Newman commented that the centennials of both the IP and the NIH were coming up this Fall, and that it would be a good thing if resolution could be reached in time for a joint celebration, similar to the recent Statue of Liberty celebrations.

Brief Historical Summary
of the
Discovery and Demonstration of Proof
of the
Cause of AIDS
as a
Retroviral Disease

Retroviruses

- 1970-71 - H. Temin¹ hypothesized that in cells infected with RNA tumor viruses the RNA is transcribed into DNA by reverse transcriptase (RT); this enzyme, present in all animal retroviruses, was discovered by H. Temin and D. Baltimore.²
- 1970-75 - R. Gallo, S. Spiegelman and others³⁻⁵ independently developed useful sensitive specific assays for human retroviruses.
- 1976 - D. Morgan, F. Ruscetti and R. Gallo⁶ discovered T-cell growth factor, or Interleukin-2 (Il-2), necessary for long term in vitro cultivation of human T-cells, in which human retroviral infection could be detected by assay for RT.
- 1978-82 - R. Gallo and coworkers⁷ isolated and characterized human retroviruses designated HTLV-I and HTLV-II, advancing further the technology for human retrovirus cultivation.

AIDS

- 1981 - M. Gottlieb⁸ diagnosed a newly recognized disease called AIDS.
- 1982 - Epidemiological evidence suggesting that AIDS is a new infectious disease was developed by the Center for Disease Control.⁹
- R. Gallo and M. Essex^{10,11} proposed the hypothesis that AIDS was caused by a human T-cell tropic retrovirus.
- 1983 (May) - F. Barre-Sinoussi, J. C. Chermann and L. Montagnier¹² reported the isolation and identification of a new cytopathic retrovirus different from HTLV-I and HTLV-II in a patient with lymphadenopathy syndrome; the HTLV-I and II reagents and Il-2 used in these studies were provided by R. Gallo.
- M. Essex¹³ detected antibodies that are weakly cross-reactive with HTLV-I protein in 35% of AIDS patients supporting the idea that a new retrovirus may be the cause of AIDS.

- (September) - At the Cold Spring Harbor Symposium on Human T-Cell Leukemia/Lymphoma Virus, L. Montagnier and coworkers¹⁴ reported additional virus isolations from AIDS patients, and serum antibodies directed against this virus (named LAV) in 60% of patients with lymphadenopathy syndrome and in 20% of patients with AIDS. They also reported studies on virus morphology and protein composition, and demonstrated the selective affinity of the virus for T-4 helper lymphocytes.
- L. Montagnier provided to R. Gallo LAV virus in an extracellular form.
- 1984 (Spring) - M. Popovic, R. Gallo and coworkers¹⁵ reported mass production in a cell line (named H9) of retrovirus (named HTLV-III) isolated from AIDS patients; they also reported 48 isolations and the detection of antibodies in more than 90% of several hundred sera of patients with AIDS.
- R. Gallo provided to L. Montagnier HTLV-III virus in a permanently virus-producing cell line.
- 1984 (July) - A study from the Center for Disease Control and the Pasteur Institute¹⁶ revealed positive antibody tests in sera from 41% of AIDS patients.
- 1984-
early 1985 - F. Wong-Staal, M. Popovic, B. Hahn, G. Shaw, R. Gallo and coworkers¹⁷ performed molecular gene cloning of the AIDS virus; they discovered heterogeneity in the viral envelope and the presence of virus in the brain.
- 1985 - The nucleotide sequence of the AIDS virus genome was determined independently at the Pasteur Institute (S. Wayne-Hobson and coworkers¹⁸), at the NIH (L. Ratner, F. Wong-Staal, R. Gallo and coworkers¹⁹) and at Genentech, Inc.²⁰

[References to be added.]

THE SALK INSTITUTE

29 July 1986

BY HAND

The Honorable Otis Bowen
Secretary of Health and
Human Services
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Professor Raymond Dedonder
Director
Institut Pasteur
25/28 Rue du Docteur Roux
Paris 15e FRANCE

Gentlemen:

During the past several weeks, I have tried to help find a path to achieve an equitable resolution of the disputes which have arisen between the Institut Pasteur (IP) and the Department of Health and Human Services (HHS). I was moved to do so in order to permit the full attention of the scientists and scientific institutions concerned to be devoted to the urgent need to find means to protect the public against the massive threat posed by the AIDS virus.

As I became informed of the details of the controversy through conversations with the scientists, administrators and lawyers involved, I recognized two sets of issues, one scientific and the other legal, which if dealt with separately could help bring about a resolution. This, and the fact that I am known to and trusted by both parties, prompted me to develop the attached proposal (Attachment A) as a means of resolving the matter quickly through negotiations based on an agreement of principle. As a result of my discussions with all parties, it became apparent that the litigious issues concerning the patent stood in the way of agreement on all of the other proposals contained in that document. Accordingly, a number of alternatives were explored in an attempt to find an approach which might facilitate an agreement.

THE SALK INSTITUTE

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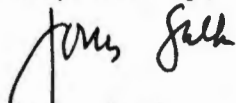
From an examination of the sequence of events that led to the dispute, it seemed to me that if separate patents could be issued to Dr. Montagnier and to Dr. Gallo, a formula could be found which would permit rapid agreement on all other matters. It became necessary, therefore, to explore whether this could be achieved within the rules governing the granting of patents by the United States Patent and Trademark Office. The results of this exploration are reflected in Attachment B. Sequential steps by which the matter might be resolved are set forth in Attachment C, and the interference might be dissolved as outlined in Attachments D and E.

My purpose is to find a way, in the public interest, to resolve the differences between IP and HHS with respect to the legal issues involved. Furthermore, my motivation is to avoid the adverse effects of a legal dispute upon the scientists whose work is the subject of a controversy which, if not settled amicably, can be resolved only through lengthy legal proceedings. I am satisfied that the scientists themselves desire a resolution, and it is for this reason that I would like to pursue the matter and make whatever contribution I can toward settlement.

I have come this far in the development of this proposal based on consultations with individuals at IP and in various departments of the U.S. Government, and with the advice of legal experts who have provided assistance to me on a pro bono publico basis.

I am prepared to meet with both of you, if you so desire, or with whomever you may designate, until sufficient rapprochement has been reached to permit settlement of the outstanding issues.

Respectfully,



Jonas Salk

Enclosures

cc: Ira M. Millstein, Esq.
Weil, Gotshal & Manges
Ronald E. Robertson, Esq.
General Counsel
Department of Health and Human Services

THE SALK INSTITUTE

29 July 1986

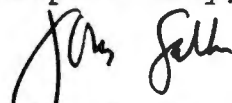
The Honorable Otis Bowen
Secretary of Health and Human
Services
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Bowen:

I want to tell you how very much I appreciated the opportunity to meet you and your colleagues and to be able to participate with you in finding a solution to an important health problem. It is clear that such problems are not solved only in the laboratory, and your wisdom in this matter will be of the greatest value in achieving a resolution.

I hope that the attached documents will serve as a basis for reaching an agreement.

Respectfully,


Jonas E. Salk

Attachments

29 July 1986

Index to Attachments

- Attachment A: AIDS - Proposal for a Franco-American Agreement
- Attachment B: Coexistence of U.S. patents to Gallo et al. and Montagnier et al.
- Attachment C: Sequential Steps
- Attachment D: Mechanisms for termination of the pending Gallo v. Montagnier interference
- Attachment E: The effect of the 1984 Amendment to 35 U.S.C. § 103 on the Proposal Settlement

AIDS
Proposal for
A Franco-American Agreement

Due to an unfortunate concatenation of circumstances, misunderstandings have arisen among teams of scientists in France and the United States as to the antecedents with respect to the discovery of the causes of AIDS. Nevertheless, the convergent efforts of these scientists have led to the development in both countries of blood tests for the diagnosis of AIDS virus infection which now permit the implementation of strategies for the avoidance of transfusion-transmitted infection. There is a continuing need for additional means to contain the viruses of AIDS.

The scientists of both countries acknowledge the important contributions that have been made in each country, and in a conciliatory spirit their respective institutions, the Institut Pasteur ("IP") and the National Institutes of Health/National Cancer Institute ("NIH/NCI"), have agreed to integrate their rights or claims to royalties from patents for sero-diagnostic kits. In the same spirit, they have agreed to place these royalties into a foundation to be established for furthering research in prevention and treatment of AIDS. This foundation will be called the Franco-American AIDS Foundation ("FAAF"), the Board of which will include equal numbers of French and American directors.

The basic principles have been agreed upon, and the details of the plans and programs will in due course be announced with respect to:

1. Satisfactory resolution of rights or claims to patents,
2. Creation of a joint fund with royalties,
3. Establishment of a foundation,
4. Utilization of foundation funds.

The principles that have been agreed upon are:

- A. The parties have recognized that under the 1883 Paris Convention for the Protection of Industrial Property and the U.S. patent laws neither the NIH nor IP patent is prior art against the other and therefore, assuming PTO agreement, both patents can issue and coexist; the FAAF will own both patents.
- B. The IP and the NIH/NCI will each receive annually from the FAAF, for continued support of research, an amount equal to one-third of the royalties received, the remaining one-third to be used for collaborative research on AIDS control and prevention, primarily directed to the specific needs of the developing countries.
- C. A scientific advisory committee will be created by the Board of FAAF to consider and suggest collaborative research strategies supplementary to efforts which are supported from other sources, as well as to advise the Board on the allocation of the remaining one-third of the royalties.
- D. This committee will also encourage the expansion of financial resources, from the private as well as the public sector, destined to encourage collaborative research toward the development of vaccines against AIDS.

Coexistence of U.S. Patents to Gallo et al. and Montagnier et al.

Currently, an interference proceeding has been initiated in the United States Patent and Trademark Office (PTO) between U.S. Patent No. 4,520,113 of Gallo et al. (the "Gallo patent") and U.S. Patent Application Serial No. 785, 638 of Montagnier et al. (the "Montagnier application") to determine priority of the invention. A settlement proposal has been proffered which provides, in part, for the continued existence of the Gallo patent and the issuance of a United States Patent to Montagnier et al. (the "Montagnier patent"). The settlement proposal includes common ownership of these patents by a foundation, the Franco-American AIDS Foundation (FAAF). The FAAF would be empowered according to this scheme to take actions necessary to obtain and maintain both patents. The legal bases for the coexistence of the Gallo patent and the Montagnier patent according to this scheme are set forth below.

As a preliminary matter, the PTO has determined that the Montagnier application was patentable over all relevant prior art except for the activities of Dr. Gallo. Dr. Gallo's activities could be prior art against the Montagnier application only under 35 U.S.C. §102(a) or §102(g).^{1/} However, the Montagnier application is entitled under the Paris Convention of 1883 to an effective U.S. filing date of September 15, 1983 (the filing date of

^{1/} See Exhibit 1 for a copy of 35 U.S.C. 102.

the British counterpart application), which, in the absence of other evidence, establishes that date as a presumptive date of invention. Since the work of Dr. Gallo was not publicly known prior to September 15, 1983, it cannot be prior art against the Montagnier application under §102(a). In re Katz, 687 F.2d 450, 215 U.S.P.Q. 14 (C.C.P.A. 1982). Additionally, if Dr. Gallo's date of invention is after September 15, 1983, the activities of Dr. Gallo are not prior art under §102(g) against the Montagnier application.

If the Montagnier application were to issue today as a patent, it would become prior art under 35 U.S.C. §102 (e) against the invention claimed in the Gallo patent. However, the Montagnier patent could be removed as a reference against the Gallo claims if Dr. Gallo were to prove a date of invention prior to the December 5, 1983 U.S. filing date of the Montagnier application. According to the U.S. Court of Customs and Patent Appeals (now the Court of Appeals for the Federal Circuit) in In re Hilmer (Hilmer I), 359 F.2d. 859, 149 U.S.P.Q. 480 (CCPA 1966), the "date of application for patent" referred to in §102(e) is the date of application in the United States. A foreign priority filing date claimed by a U.S. patent application under 35 U.S.C. §119 may not be used as the applicable date of a §102(e) reference. Hilmer I at 876-7, 149 U.S.P.Q. at 494-5.

Initially, the application which gave rise to the Gallo patent was examined and deemed presumptively patentable over the prior art cited to the PTO. 35 U.S.C. §282. This included the

May 20, 1982 Science publication by Barre et al. It is plausible that the Barre article and the presentation by Dr. Montagnier at Cold Spring Harbor on September 15, 1983 would not be patent defeating prior art against the invention claimed in the Gallo patent if they are deemed to be non-enabling. See, e.g., In re LeGrice, 301 F.2d 929, 133 U.S.P.Q. 365 (C.C.P.A. 1962) (to amount to a statutory bar, a reference must place a skilled artisan in possession of the invention). It is arguable that, in order to provide an enabling disclosure, these references required public availability of the LAV virus. See In re Argoudelis, 434 F.2d 1390, 168 U.S.P.Q. 99 (C.C.P.A. 1970). It could be contended that the LAV virus was not publicly available prior to the effective filing date of the Montagnier application.

Because the date of invention provided by Montagnier's British priority application is not based on activity in the U.S., the Montagnier invention appears not to be prior art against the Gallo patent under 35 U.S.C. §102(g). See In re Hilmer (Hilmer II), 424 F.2d 1108, 165 U.S.P.Q. 255 (C.C.P.A. 1970). Thus, if Dr. Gallo's legally cognizable date of invention is between September 15 and December 5, 1983, neither Gallo's invention nor the Montagnier application constitute prior art against the other and the only remaining impediment to the issuance of the Montagnier application as a U.S. patent is the pending interference.

Therefore, except for the interference, both the Gallo patent and the Montagnier patent could co-exist. The PTO rules

provide that, unless good cause is shown, interferences shall not be continued between applications and unexpired patents owned by a single party. 37 C.F.R. §1.602. Thus, if both the Montagnier application and the Gallo patent were commonly owned, i.e., by FAAF, the PTO should discontinue the interference.

The Manual of Patenting Examining Procedure (MPEP) in §2302 discusses the method for ending interferences when an application and a patent in an interference become commonly-owned after the interference has been declared. This discussion is intended to supplement the new interference rules which took effect on February 11, 1985. The MPEP commentary on Rule 602 (37 C.F.R. §1.602) states that interferences are to be terminated upon common ownership of the application and patent involved in the interference by judgement entered against one party or the other, citing Chillas v. Weisberg, 1928 CD 24 (Comm'r Pat. 1928).

However, these rules were promulgated prior to the decision by the Court of Appeals for the Federal Circuit in In re Longi, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). In Longi, contrary to prior PTO policy, the Court approved the coexistence of two patents in the names of different inventive entities, even though the claimed subject matter of the two patents was patently indistinct, where neither case was prior art against the other (except under 35 U.S.C. §102(g)), provided that (1) precisely the same subject matter was not claimed in each case, (2) the patents were commonly-owned, and (3) a terminal disclaimer was filed so that both patents expire on the same date. The PTO

has acquiesced in the practice sanctioned by the Federal Circuit in Lonqi in 056 OG 316 by the abandonment of its prior procedure under which it would not accept terminal disclaimers in the case of commonly-assigned applications naming different inventive entities. Because the commentary in MPEP §2302 is apparently predicated on the incorrect, prior PTO policy, which was abrogated in Lonqi and in the 1985 changes in 37 C.F.R. §1.78(d) necessitated by the Patent Law Amendments Act of 1985 (Pub. L. 97-247), it should be possible to dissolve an interference when (1) the interfering cases become commonly-owned and (2) the interfering subject matter of the parties is patentably indistinct but not identical,^{2/} by abandoning the interference and filing a terminal disclaimer, thus obtaining issuance of both patents in spite of the difference in inventive entities.

^{2/} In this regard, it should be noted that the subject matter claimed in the Montagnier application is not identical to that claimed in the Gallo. For example, the subject matter differs at least in the scope of the descriptions of the immuno diagnostic assays which are used.

INVENTIONS AND GRANT OF

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TY OF INVENTIONS

and loss of right to patent.
ous subject matter.

text otherwise indicates —
vention or discovery.
rocess, art or method, and
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"this country" mean the
and possessions.
only the patentee to whom
successors in title to the

and useful process, machine,
or any new and useful
t therefor, subject to the

§ 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other (Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; November 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691.)

§ 103. Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this ti-

ATTACHMENT C

SEQUENTIAL STEPS

1. Set up Franco-American AIDS Foundation (FAAF).
2. (a) Transfer the NIH patent and the IP patent application to FAAF with a statement that September 15, 1983 - December 5, 1983 was the legal date of invention, i.e., patentable stage (see Case No. 5 in Gallo letter to Nature attached) and with the agreement by FAAF to apply for IP patent which will go to FAAF upon granting.
- (b) IP will file a terminal disclaimer that Montagnier patent will not extend beyond the 17 year limit of the Gallo patent.
- (c) NIH will transfer application or patent or license for cell line to FAAF.

First isolation of HTLV-III

SIR—We wish to address several points raised in a recent commentary in *Nature*¹ regarding HTLV-III/LAV (human T-lymphotropic virus type III/lymphadenopathy-associated virus), the aetiological agent of acquired immune deficiency syndrome (AIDS). It was mentioned that the CEM cell line infected with HTLV-III/LAV may be a better source of antigen for testing HTLV-III/LAV in patients with AIDS and AIDS-related complex (ARC).

The transmission of HTLV-III isolates in several T4⁺ permanent cell lines, including CCRF-CEM, was reported first by our laboratory²⁻⁴. The transmission of HTLV-III isolates into those T4⁺ cell lines, including CEM, was the subject of a patent application made in early 1984 and now pending.

The fact that we had in our possession electron microscopic pictures of transiently transmitted LAV in Hut-78 and Ti7.4 cell lines should not be surprising. The LAV sample was obtained as a tissue culture supernatant from Dr Montagnier with the express understanding that it could be used for biomedical, biological and molecular biological studies. In accordance with this understanding, we had transiently transmitted LAV into the Hut-78 and Ti7.4 cell lines. Prior to the development of specific reagents for the detection of HTLV-III, the presence of retroviruses other than HTLV-I and HTLV-II could be detected in cultures from AIDS or ARC patients only by re-

verse transcriptase assay and electron microscopic examination.

At the time we obtained LAV it was the contention of several experts on virus morphology that the particles shown in the electron micrograph published in *Science*⁵ by Barre-Sinoussi *et al.* was an arena virus. Naturally we wanted to check the material received from Dr Montagnier by electron microscopy to check this contention. Before receipt of LAV, we had detected reverse transcriptase activity in a number of cultures from AIDS and ARC patients which showed no cross-reaction with HTLV-I or HTLV-II reagents, thus indicating the presence of a new retrovirus. In a number of cases electron microscopic examination showed the presence of virus particles with a cylindrical core, characteristic of HTLV-III (Table 1, Fig. 1). A chronological identification of some of these virus particles from cultures obtained from AIDS and ARC patients by our laboratory beginning in December 1982 is summarized in Table 1 and Fig. 1.

The experimental results shown were obtained shortly after receipt of the samples, usually a matter of weeks. We had evidence for the presence of a new retrovirus in AIDS and ARC patients long before the LAV particles were sent to us and even before the publication of the results by Barre-Sinoussi *et al.* in 1983. Since we considered the mere detection of virus particles in cultures from AIDS and ARC patients to be insufficient to confirm scientifically our hypothesis that such particles were implicated in the aetiology of the disease, we decided first to obtain specific reagents against the new virus in order to publish definitive results concerning AIDS aetiology. The results presented in our four papers provided clearcut evidence that the aetiology of AIDS and ARC was the new lymphotropic retrovirus, HTLV-III^{2,3,6,7}. In addition, for the first time the virus was produced in large

quantities, specific reagents to the virus were made, and a reliable blood test to protect the blood supply and prevent blood transfusion-associated AIDS was now available.

ROBERT C. GALLO
PREM S. SARIN
BERNARD KRAMARSKY*
ZAKI SALAHUDDIN
PHILIP MARKHAM†
MIKULAS POPOVIC

Laboratory of Tumor Cell Biology,
National Cancer Institute,
Bethesda, Maryland 20892, USA

*Electronucleonics, Inc.,
Silver Spring, Maryland 20904, USA

†Bionetics Research, Inc.,
1330-A Piccard Drive,
Rockville, Maryland 20850-4373, USA

1. Beardsley, T. *Nature* 320, 563 (1986).
2. Gallo, R.C. *et al. Science* 224, 500-503 (1984).
3. Popovic, M. *et al. Science* 224, 497-500 (1984).
4. Popovic, M., Read-Connoe, E. & Gallo, R.C. *Lancet* ii, 1472-1473 (1984).
5. Barre-Sinoussi, F. *et al. Science* 220, 868-870 (1983).
6. Shüpbach, J. *et al. Science* 224, 503-505 (1984).
7. Sarngadharan, M.G. *et al. Science* 224, 506-508 (1984).

Table 1 Summary of the chronological isolation of HTLV-III from patients with AIDS and ARC

No.	Patient samples	Date rec'd	Source	RT	EM	Immunological reactivities				
						HTLV-I p19	p24	AIDS sera	HTLV-III p19 p24	
1	G.W./AIDS	12/23/82	Gutterman, Houston, Texas	+	ND	-	-	ND	ND	ND
2	C.C./AIDS*	2/15/83	Leibowitch, Paris	+	+	±	±	ND	ND	ND
3	M.A./AIDS	2/15/83	Leibowitch, Paris	+	ND	-	-	ND	ND	ND
4	B.U./AIDS	2/15/83	Leibowitch, Paris	+	ND	-	-	ND	ND	ND
5	S.N./AIDS	9/23/83	Haynes, N. Carolina	+	ND	-	-	+	ND	ND
6	R.F./AIDS	10/18/83	Hoxie, Philadelphia	+	+	-	-	+	ND	ND
7	R.R./AIDS	2/4/84	Redfield, WRAIR, Washington, DC	+	+	-	-	+	+	+
8	S.S./ARC	2/4/84	Redfield, WRAIR, Washington, DC	+	+	-	-	+	+	+
9	K.E./ARC	2/4/84	Redfield, WRAIR, Washington, DC	+	+	-	-	+	+	+
10	S.B./ARC	2/4/84	Redfield, WRAIR, Washington, DC	+	+	-	-	+	+	+

Abbreviations used: G.W., C.C., M.A., etc., patients' initials; RT, reverse transcriptase; EM, electron microscopy; ND, not done.

*Patient C.C. was infected with both HTLV-III and HTLV-I.

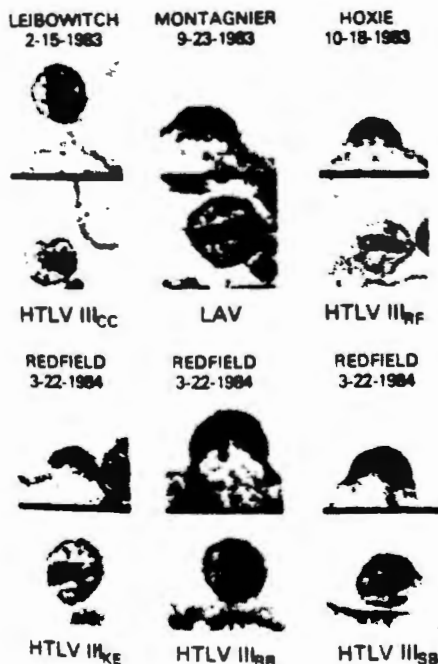


Fig. 1

Several mechanisms for termination of the pending Gallo v. Montagnier interference are possible if (1) Dr. Gallo were to allege a date of invention between September 15, 1983 and December 5, 1983 and (2) the Montagnier application and the Gallo patent are commonly-owned. The simplest of these mechanisms is described below.

The Manual of Patent Examining Procedure (M.P.E.P.) provides in § 1105.02 that:

It should be noted that if all parties agree upon the same ground for dissolution, which ground will subsequently be the basis for rejection of the interference count to one or more parties, the interference should be dissolved pro forma upon that ground, without regard to the merits of the matter.

See also Pearson v. Wolfe, 210 U.S.P.Q. 686 (Com'r Pat 1979).

As noted previously, pursuant to 37 C.F.R. § 1.602(a), an interference should not be continued if the interfering subject matter becomes commonly-owned. Thus, upon common ownership by FAAF of the Montagnier application and the Gallo patent, the pending interference should be discontinued. Such discontinuance could be by dissolution. To terminate the interference in this manner, a Motion to Dissolve would be filed, based upon the parties' agreement that (1) neither is prior art against the other, an averment supported by Dr. Gallo's showing that his date of invention falls between September 15, 1983 and December 5, 1983, and (2) the count is unpatentable to Montagnier et al. on the ground of obviousness-type double patenting.

This agreement would result in the interference being terminated, the Montagnier application being returned to ex parte prosecution and the claims rejected under the obviousness-type double patenting doctrine. The obviousness-type double patenting rejection of the claims of the Montagnier application then would be overcome through the filing by the FAAF of a Terminal Disclaimer, resulting in the issuance of the Montagnier patent.

ATTACHMENT E

THE EFFECT OF THE 1984 AMENDMENT TO
35 U.S.C. § 103 ON THE PROPOSED SETTLEMENT

It has previously been suggested that the Gallo v. Montagnier interference could be resolved following assignment of the Gallo patent and the Montagnier application to a common owner by dissolution of the interference. While the Montagnier application would then be rejected on the ground of obviousness-type double patenting, the common owner could obtain issuance of both the Gallo and Montagnier patents by filing a terminal disclaimer in the Montagnier patent so that the two patents would expire concurrently. The feasibility of this settlement mechanism depends on Dr. Gallo's date of invention in the United States falling between Dr. Montagnier's foreign priority date of September 15, 1983 (arising from filing of an application in Great Britain) and Dr. Montagnier's actual U.S. filing date of December 5, 1983. Under such circumstances, neither the Gallo nor the Montagnier inventions would be prior art against the other under any section of 35 U.S.C. § 102.

A question has now been raised as to the impact, if any, of the amendment to 35 U.S.C. § 103 contained in the Patent Law Amendments Act of 1984 on the proposed settlement. For reasons set forth more fully below, that amendment does not alter the ability to consummate the proposed settlement.

Legal Background

Section 102 of Title 35 of the United States Code (Attachment A) defines the prior art against which the patentability of an invention is to be measured. That section

requires the invention sought to be patented to be "novel," i.e., not to be identically described in the prior art defined in § 102. Section 103 (Attachment B) goes on to provide that an invention which is not identically described in the prior art may nonetheless be unpatentable if it would have been obvious to a person of ordinary skill in the art based on the state of the prior art. For purposes of the obviousness determination under 35 U.S.C. § 103, the prior art includes those items defined by 35 U.S.C. § 102.

Among the provisions of § 102 are two sections which deal with information which may not be publically known. These are 35 U.S.C. §§ 102(f) and 102(g), which read:

§ 102. Conditions for patentability;
novelty and loss of right to patent

A person shall be entitled to a patent
unless--

. . . .

(f) he did not himself invent the
subject matter sought to be patented, or

(g) before the applicant's invention
thereof the invention was made in this
country by another who had not abandoned,
suppressed, or concealed it

Subsection (f) is basically a requirement for originality and prohibits an applicant from applying for a patent on material which he derived from another. Subsection (g) sets forth the policy of the United States that the first person to make an invention in the United States is entitled to the patent even if he was not the first to file an application.

Prior case law had suggested that information derived from others prior to the applicant's date of invention cognizable only under 35 U.S.C. § 102(f) could be used as evidence of the state of the prior art in determining obviousness under 35 U.S.C. § 103. See, e.g., Ex parte Andresen, 212 U.S.P.Q. 100 (PTO Bd. App. 1981). Prior cases had also suggested that prior inventions of others in the United States cognizable only under 35 U.S.C. § 102(g) could also be used as prior art in determining obviousness under 35 U.S.C. § 103. See, e.g., In re Bass, 474 F.2d 1276, 177 U.S.P.Q. 178 (C.C.P.A. 1973).

The Patent Law Amendments Act of 1984 amended 35 U.S.C. § 103 by adding the following sentence:

Subject matter developed by another person, which qualifies as prior art only under the subsection (f) or (g) of § 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The purpose of the amendment was to remove from the prior art available in determining obviousness under 35 U.S.C. § 103 information which was prior art only under 35 U.S.C. §§ 102(f) and (g). The amendment was intended to ameliorate the impact of the above-cited cases on the patentability of the fruits of intracorporate research. It did so, however, only in cases where the information which would otherwise have been prior art under 35 U.S.C. § 102(f) or (g) and the invention sought to be patented were owned by the same entity at the time the second invention

was made. See Cong. Record (H10522-32), October 1, 1984 (Attachment C).

Analysis

It is clear from the foregoing that the amendment to 35 U.S.C. § 103 in the Patent Law Amendments Act of 1984 simply removed certain information from the prior art which would have been recognized as prior art under previously existing law. The amendment did not add anything to the prior art which was not already cognizable as prior art under previously existing law. Accordingly, the amendment had no effect on prior case law holding that certain types of information were not in the prior art. Moreover, since it appears to be unnecessary to rely on the exclusion of prior art now set forth in amended 35 U.S.C. § 103 in order to sustain the validity of the Gallo and Montagnier patents under the proposed settlement, any conditions imposed by the statute on the availability of that exception are irrelevant.

Specifically, it had previously been held that an invention described in a patent first filed in a foreign country was not prior art under 35 U.S.C. § 102(g) as of the date of the foreign patent application. According to such holdings, such an invention did not meet the requirement of 35 U.S.C. § 102(g) that the prior invention have been made in the United States. In re Hilmer, 424 F.2d 1108, 165 U.S.P.Q. 255 (C.C.P.A. 1970). Thus, Dr. Montagnier's September 15, 1983 filing of an application in Great Britain does not constitute prior art under 35 U.S.C. § 102(g) against the Gallo patent under previously existing law.

That result remains unaffected by the 1984 amendment to 35 U.S.C. § 103.

Moreover, the Government contends that Dr. Montagnier's work was not the point of departure for Dr. Gallo's invention. If this is true, then Dr. Montagnier's work would not have been prior art under 35 U.S.C. § 102(f) under previously existing law, and this conclusion remains unaltered by the 1984 amendment to 35 U.S.C. § 103.

The need for the Gallo and Montagnier patents to be commonly assigned does not arise from any provision of 35 U.S.C. § 103. This need arises instead from 35 U.S.C. § 135 and PTO practice regarding the conduct of interferences. The only way two patents claiming obvious variants of the same invention can validly coexist is if an interference proceeding between the two can be avoided through common ownership of the two patents and if double patenting can be avoided through a terminal disclaimer. The PTO practice regarding termination of interferences between commonly owned applications has never been predicated on common ownership of the two inventions at the time they were made. Instead, § 2302 of the Manual Of Patent Examining Procedure spoke of termination of the interference when the involved application and patent "became" commonly assigned. Similarly, the ability to file a terminal disclaimer in order to obviate double patenting rejections in commonly assigned applications involving different inventive entities, as embodied in current PTO policy, does not depend on common ownership at the time the inventions were made. The PTO's guidelines on the point state (Attachment D):

Double patenting rejections may now be made in applications based on commonly owned patents of different inventive entities and double patenting rejections of the obviousness type can be overcome by terminal disclaimer.

Conclusion

For reasons noted above, the 1984 amendment to 35 U.S.C. § 103 does not preclude consummation of the previously proposed settlement.

OF

§ 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other (Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; November 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691.)

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ATTACHMENT A

§ 103. Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this ti-

tle, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (Added November 8, 1984, Public Law 98-622, sec. 103, 98 Stat. 3384.)

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(More history published at 28 BNA PTCJ 645-656 on October 4, 1984)

Cong. Record (H10522-32)
October 1, 1984

**PATENT LAW AMENDMENTS ACT
OF 1984**

Mr. EASTENMEIER. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6286), as amended.

The Clerk read as follows:

H.R. 6286

As it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

* * * * *

PRIOR ART

Sec. 104. Section 103 of title 35, United States Code, is amended by adding at the end thereof the following:

"Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

JOINT INVENTORS

Sec. 105. (a) Section 116 of title 35, United States Code, is amended by amending the first paragraph to read as follows:

"When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."

(b) Section 120 of title 35, United States Code, is amended by striking out "by the same inventor" and inserting in lieu thereof "which is filed by an inventor or inventors named in the previously filed application".

* * * * *

Prior art

Section 104 of the bill changes a complex body of case law which discourages communication among members of research teams working in corporations, universities or other organizations. See Remarks of Robert W. Eastenmeier, 129 Cong. Rec. E3777 (daily ed. Nov. 13, 1983).

Section 104 amends section 103 of the patent law by adding a new sentence providing that subject matter developed by another person which qualifies as "prior art" only under subsections 103 (f) or (g) of the patent law is not to be considered when determining whether an invention sought to be patented is obvious under section 102, provided the subject matter and the claimed invention were commonly owned at the time the invention was made.

"Prior art" is the existing technical information against which the patentability of an invention is judged. Publicly known information is always considered in determining whether an invention is obvious. However, under *In re Saxe*, 474 F.2d 1376, 177 USPQ 178, (C.C.P.A. 1973), and *In re Clemens*, 623 F.2d 1028, 306 USPQ 288 (C.C.P.A. 1980), an earlier invention which is not public may be treated under section 102(g), and possibly under 102(f), as prior art with respect to a later invention made by another employee of the same organization.

New technology often is developed by using background scientific or technical information known within an organization but unknown to the public. The bill, by disqualifying such background information from prior art, will encourage communication among members of research teams, and patenting, and consequently public dissemination, of the results of "team research."

The subject matter which is disqualified as prior art under section 103 is strictly limited to subject matter which qualifies as prior art only under sections 102 (f) or (g). If the subject matter qualifies as prior art under any other subsection—e.g., subsection 102 (a), (b) or (c)—it would not be disqualified as prior art under the amendment to section 103.

The amendment applies only to consideration of prior art for purposes of section 103. It does not apply to or affect subject matter which qualifies as prior art under section 102. A patent applicant urging that subject matter was disqualified has the burden of establishing that it was commonly owned at the time the claimed invention was made.

Section 104 is not intended to permit anyone other than the inventor to be named in a patent application or patent. Also, the amendment is not intended to enable appropriation of the invention of another.

The Committee expects that the Patent and Trademark Office will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter. In accordance with established patent law doctrines, double patenting rejections can be overcome in certain circumstances by disclaiming the terminal portion of the term of the later patent, thereby eliminating the problem of extending patent life.

The language in section 104 is parallel to but also is more precise than the language of H.R. 4528. For example, section 104 makes clearer that information learned from or transmitted to persons outside the inventor's immediate organization is not disqualified as prior art.

The term "subject matter" as used in section 104 is intended to be construed broadly in the same manner as the term is construed in the remainder of section 103. The term "another" as used in this amendment means any inventive entity other than the inventor. The term "developed" is to be read broadly and is not limited by the manner in which the development occurred.

Joint inventors

Section 105 complements section 104 of the bill. It recognizes the realities of modern team research. A research project may include many inventions. Some inventions may have contributions made by individuals who are not involved in other, related inventions.

Subsection (a) of section 105 amends section 116 of the patent law to allow inventors to apply for a patent jointly even though (i) they did not physically work together or at the same time, (ii) each did not make the same type or amount of contribution, or (iii) each did not make a contribution to the subject matter of every claim of the patent. Items (i) and (ii) adopt the rationale of decisions such as *Monsanto v. Kama*, 269 F. Supp. 818, 154 USPQ 288 (D.D.C. 1967). Item (iii) adopts the rationale of cases such

as *SAB Industri AB v. Bendix Corp.*, 199 USPQ 95 (E.D. Va. 1978).

Like other patent applications, jointly-filed applications will continue to be subject to the requirement of 35 U.S.C. § 121 that an application be directed to only a single invention. If more than one invention is included in the application, the Patent and Trademark Office may require the application to be restricted to one of the inventions. In such a case, a "divisional" application would be entitled to the benefit of the earlier filing date of the original application.

Subsection (a) of section 105 increases the likelihood that different claims of a patent may have different dates of invention, even though the patent covers only one independent and distinct invention within the meaning of 35 U.S.C. § 121. When necessary, the Patent and Trademark Office of a court may inquire of the patent applicant or owner concerning the inventors and the invention dates for the subject matter of the various claims.

Subsection (b) of section 105 amends section 120 of the patent law to provide that an application can obtain the benefit of the filing date of an earlier application when not all inventors named in the joint application are the same as named in the earlier application. This permits greater latitude in filing "divisional" applications. For example, if the previously filed application named inventors A and B as the inventors, a later application by either A or B could be filed during the pendency of the previously filed application and claim benefit of the previously filed application. In order to be entitled to the benefit of an earlier pending application, of course, the subject matter of the claims of the later application would have to be disclosed in the earlier application.

Section 105 is taken from H.R. 4527 and includes changes recommended during testimony before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice.

* * * * *

Section 104 provides that unpublished information known to the inventor does not constitute prior art in the field of the invention, and therefore cannot serve to defeat the patentability of that invention. This latter change will be of material benefit to university and corporate research laboratories where the free exchange of ideas and concepts may have been hampered by the current state of the law with respect to what constitutes "prior art."

Section 105 of the bill provides that two or more inventors may obtain a patent jointly even though each inventor has not contributed to each and every claim found in the patent application. This technical amendment should also be of benefit to universities and corporations which rely on team research.

Attachment D

Initial Guidelines As To Implementation Of 35 U.S.C. 103

Public Law 98-622 added a new sentence to 35 U.S.C. 103 which reads as follows:

"Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

The significant features resulting from this amendment to §103 are the following:

- (1) The only prior art which is disqualified is prior art under §102(f) or (g) where the subject matter, i.e., the prior art, and the invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." (Person includes organization)
- (2) If the subject matter (prior art) qualifies as prior art under any other section, e.g., §102(a), (b), or (e), it is still prior art and can be used.
- (3) Amendment applies only to subject matter which qualifies as prior art under §103; it does not affect subject matter which qualifies as prior art under §102, i.e., anticipatory prior art.
- (4) Term "another person" means any inventive entity other than the inventor and includes the inventor and any other person.
- (5) Term "developed" is to be read broadly and is not limited to any particular manner of development.
- (6) Subject matter derived from another under §102(f) is prior art under §103 unless the derived subject matter and the claimed invention are owned by, or subject to an obligation of assignment to, the same person at the time the claimed invention was made.
- (7) The disclosure of an earlier filed patent application which issues as a patent continues to be prior art under §102(e) against a later invented and filed application of another inventor even though the patent and the later application are owned by, or subject to an obligation of assignment to, the same person.

- (8) Commonly owned applications, i.e., applications owned by the same person, may be refiled as a single application to avoid one or more of them becoming prior art against another under §§102(e) and 103.
- (9) The phrase "owned by the same person" requires that the same person, persons, or organization own 100% of the subject matter (prior art) and 100% of the claimed invention.
- (10) The phrase "subject to an obligation of assignment to the same person" requires that a legal obligation of assignment exist and not merely a moral or unenforceable obligation.
- (11) As long as the same person owns the subject matter and the invention at the time the claimed invention was made, a license to another may be made without the subject matter becoming prior art.
- (12) Amended §103 requires actual ownership (or obligation to assign) be in existence at the time the claimed invention is made for the subject matter to be disqualified as prior art; acquiring one or the other later is not sufficient.
- (13) Burden of establishing that subject matter is disqualified as prior art is placed on patent applicant and not on the patent examiner once the examiner establishes a prima facie case of obviousness based on the prior art.
- (14) Double patenting rejections may now be made in applications based on commonly owned patents of different inventive entities and double patenting rejections of the obviousness type can be overcome by terminal disclaimers.
- (15) A double patenting rejection may also be made in a later filed application where the application/patent on which the rejection is based and the later filed application are not commonly owned as long as one of the inventors is common between the later filed application and the application/patent; such a rejection cannot be overcome by terminal disclaimer in view of the lack of common ownership.
- (16) The Commissioner's Notice of January 9, 1967, "Double Patenting", 834 O.G. 1615 (Jan. 31, 1967) is withdrawn to the extent that it does not authorize a double patenting rejection where different inventive entities are present.
- (17) Inventors of subject matter not commonly owned at the time of the invention may file as joint inventors in a single application. However, the claims in such an application are not protected from a §102(f)/103 or §102(g)/103 rejection.

WHO SIGNS?