DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

NJL
File
w/ Nelson

PATENT BRANCH, OGC
DHEW

JUL 14 1978

The Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
and Anticompetitive Activities
Select Committee on Small Business
United States Senate
Washington, D,C. 20510

See Justice + Bureau letters on IPA's application to DNA.

Dear Senator Nelson:

Thank you for the opportunity to testify before your Subcommittee on June 26 concerning NIH patent policies.

I have reviewed the transcript of the hearing, and an edited version is attached. At the time of the hearing, I left two items with the Subcommittee for the record:

1. A list of inventions involving recombinant DNA techniques made with the help of HEW funds; and

2. The DNA Patent Decision Document, the supporting analysis, and all of the comments received from the public.

During the hearing, you asked for copies of the comments of the various Federal agencies on the DNA Patent Decision Document. All of the written comments received from other Federal agencies, including those of the Department of Justice, are attached. Also during the hearing, your staff assistant, Mr. Gerald Sturges, asked if the University of California (UC) has any patent related petitions pending review in DHEW. UC has one petition on file under the deferred determination policy, asking the Department to grant UC rights in an invention made with HEW financial assistance. This invention is not related to recombinant DNA but is for Azetomycins, a new drug. UC also has on file a petition to enter into an Institutional Patent Agreement (IPA) with the Department.

After the hearing, Mr. Sturges asked my staff to provide for the record a clarification of the number of institutions having IPA's with HEW. We have double checked the list and, as stated in my testimony, 72 institutions have IPA's with HEW. A copy of the list is enclosed.

Sincerely yours,

Donald Fredrickson

Donald S. Fredrickson, M.D.
Director

Enclosures

cc: Mr. William B. Cherkasky

INSTITUTIONS HAVING INSTITUTIONAL PATENT AGREEMENTS
WITH
THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
DECEMBER 7, 1977

1.	11/13/70	Alabama, University of
2.	4/18/75	American Dental Assn. Health Foundation
3.	12/31/69	Alton Ochsner Medical Foundation
4.	11/ 5/76	Boston University, The Trustees of
5.	12/ 1/68	California Institute of Technology
6.	8/16/73	Cancer Research, Institute for
7.	4/25/70	Case Western Reserve University
8.	2/20/74	Children's Hospital and Research Foundation
9.	12/ 7/77	Colorado, Board of Regents of the University of
10.	10/14/70	Colorado State University
11.	2/20/74	Community Blood Council of Greater New York, Inc.
12.	12/ 1/68	Cornell University
13.	9/24/71	Deleware, University of
14.	12/ 1/68	Florida State University
15.	7/ 5/72	Forsyth Dental Center
16.	3/26/70	George Wasghington University
17.	2/20/74	Georgia, University of
18.	1/12/73	Harbor General Hospital, Attending Staff Association of
19.	6/ 6/77	Harvard University
20.	12/ 1/68	Illinois, University of
21.	5/15/74	IIT Research Institute
22.	7/23/76	Indianapolis Center for Advanced Research, Inc.
23.	1/12/73	Indiana University - Indiana University Foundation
24.	10/14/70	Iowa, University of
25.	12/ 1/68	Iowa State University
26.	12/ 3/71	Jackson Laboratory
27.	2/28/73	Joslin Diabetes Foundation, Inc.
28.	11/26/73	Kaiser Foundation Research Institute Division of Kaiser Foundation Hospitals
29.	12/ 1/68	Kansas, University of and University of Kansas Medical Center
30.	4/21/70	Maryland, University of
31.	12/ 1/68	Massachusetts Institute of Technology
32.	11/15/74	Medical Sciences, Institutes of
33.	7/25/74	Miami, University of
34.	5/15/70	Michigan, The Regents of the University of
35.	12/ 1/68	Michigan State University
36.	11/26/73	Michigan Technological University
37.	12/ 1/68	Minnesota, University of
38.	2/10/71	Mississippi, University of (Oxford Campus)
39.	1/ 4/77	Missouri, University of
40.	12/ 1/68	Mount Sinai Hospital, and Mount Sinai School of Medicine of the City University of New York
41.	6/18/69	New Hampshire, University of
42.	3/ 4/75	New York, City University of
43.	1/ 2/69	New York, State University of and The Research Foundation of State University of New York
44.	4/ 7/76	New York State Department of Health

45.	11/13/70	Northwestern University
46.	12/ 1/68	Ohio State University, and The Ohio State University Research Foundation
47.	11/26/73	Oregon Research Institute
48.	5/28/69	Pennsylvania, University of
49.	10/15/70	Pennsylvania State University,
50.	12/ 1/68	Princeton University
51.	3/26/75	Providence Medical Center
52.	12/ 1/68	Purdue University and Purdue Research Foundation
53.	6/24/77	Research Triangle Institute
54.	7/23/76	Rochester, University of
55.	6/15/73	Rockefeller University
56.	11/ 5/76	Rush-Presbyterian-St. Luke's Medical Center
57.	1/ 9/70	Rutgers University
58.	11/15/74	Salk Institute
59.	12/ 7/71	Southern California, University of
60.	8/26/69	Sloan-Kettering Institute for Cancer Research
61.	6/ 6/69	SRI International
62.	4/ 5/72	Stanford University
63.	12/10/68	Utah, University of
64.	8/ 9/71	Vanderbilt University
65.	4/ 5/74	Virginia, University of
66.	10/26/77	Virginia Commonwealth University
67.	12/ 1/68	Washington, University of
68.	12/ 1/68	Washington State University
69.	3/26/75	Washington University (St. Louis)
70.	12/ 1/68	Wisconsin, The Regents of the University of
71.	6/ 6/69	Wistar Institute
72.	8/ 9/73	Worcester Foundation for Experimental Biology

DJ-150
(4-26-65)

Insert for page 16

UNITED STATES GOVERNMENT

DEPARTMENT OF JUSTICE

Memorandum

TO : Mr. Anthony C. Liotta
Acting Deputy Assistant
Attorney General
Land and Natural Resources Division

DATE: May 5, 1977

FROM : Joseph A. Hill
Chief, Patent Section
Civil Division

SUBJECT: The Patenting of Recombinant DNA Research Inventions

In your Memorandum of April 29, 1977 you ask for comments on two enclosed documents pertaining to patent policy in regard to recombinant DNA research. The two documents are:

(1) a 13-page paper entitled "Analysis of the Patenting of Recombinant DNA Research Inventions Developed Under DHEW Support, By the Director, National Institutes of Health," and

(2) copies of Sections 1821-1824 of a bill being worked on by the Senate Health Subcommittee.

You request comments in time for the May 6, 1977 meeting of the Interagency Committee on Recombinant DNA Research.

The NIH paper reviews some of the solicited comments from several groups on DHEW-NIH patent policy with respect to recombinant DNA research (R-DNA research). Most of the NIH comments are related in some way to the issue of ownership (as between the United States and its contractors, grantees, etc.) of inventions stemming from DHEW-sponsored R-DNA research.

The thrust of the current DHEW regulations is that ownership of inventions growing out of DHEW-supported research with universities is left with the universities. The ownership of such inventions is subject to certain conditions, such as a free license for the use of the Government. In many cases there exists an agreement between the university and DHEW known as an IPA (Institutional Patent Agreement) which contains all the conditions. The essence of the matter is, however, that under an IPA the university will own the inventions and, of course, any patents that result.

Intradepartmental Memo--not necessarily the official views of the Department of Justice.

There is considerable discussion in the NIH paper about whether R-DNA inventions should be excluded from the IPA's, whether the IPA's should be modified with respect to R-DNA research, etc. We believe that such problems will fall into place once the fundamental issue of ownership is resolved. The bill of the Senate Health Subcommittee is drafted around the concept of Government-ownership of such inventions. We would like to comment on that bill next and then return to the NIH paper.

The bill of the Senate Health Subcommittee is modeled after the patent provisions of the Atomic Energy Acts of 1946 and 1954 (See 42 U.S.C. 2181-2185). The overall approach is the same and much of the language is identical. The bill

(a) puts ownership of all inventions "useful in recombinant DNA research" that stem from Government contracts or arrangements, in the United States, subject to specified waiver provisions, and

(b) prohibits the patenting of all inventions "useful solely in recombinant DNA research."

We believe that the approach of the bill is correct, particularly in view of the great public interest in R-DNA research. We point out a provision in the bill which may cause difficulty, but we have not had time to become sufficiently familiar with the NIH guidelines and the technical field to propose a solution. In subpar. (b)(1) of section 1821 the inventions referred to are those "useful in recombinant DNA research." The quoted language may so limit the category of inventions embraced as to be almost useless. The comparable language in the AEC acts is with respect to those inventions "useful in the production or utilization of special nuclear materials or atomic energy. . .". Our fear is that the word "research" in the term R-DNA research may unduly restrict the category of inventions intended to be covered. There are also two errors in citations in the bill. In subpars. (a)(4) and (a)(5) of Sect. 1821, subsection (c) should be subsection (a)(3).

From our limited knowledge of the NIH guidelines it appears that Government ownership of DHEW-sponsored inventions in the relevant field supports the purpose of the guidelines. Furthermore if the basic concepts of the bill being worked on by the Senate Health Subcommittee are carried forward into legislation, questions concerning the applicability of the IPA's would be moot.

It may be that no one knows whether inventions pertaining to R-DNA activities should be affected with a public interest to the degree that atomic energy inventions were in 1946 and 1954. In any event the patent provisions of the AEC acts are a precedent which worked very well there. On the other hand it may well be that the R-DNA field is so important that certain of the inventions should be owned by the Government, thus affording greater control of the subject matter. Accordingly, we recommend that ownership of inventions stemming from Government-sponsored research in the R-DNA field, be in the United States subject to the waiver provision (See Section 1821(b) of the bill).

UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Science and Technology
Washington, D.C. 20230

JUL 6 1977

Joseph G. Perpich, M.D., J.D.
Associate Director for Program
Planning and Evaluation
Department of Health, Education, and Welfare
Public Health Service
National Institute of Health
Bethesda, Maryland 20014

Dear Dr. Perpich:

This is in response to your letter of May 27, 1977 requesting the views of the Department of Commerce on how it might handle its patent agreements with universities and nonprofit organizations with respect to recombinant DNA inventions.

Under our present practice, since there is no patent policy guidance imposed upon the programs of the Department by statute, the Department follows the policy set forth in the Presidential Memorandum and Statement of Government Patent Policy issued in 1971.

Generally, with regard to government-sponsored research performed by universities and nonprofit organizations, I believe the federal agencies should follow the recommendations in the Report of the University Patent Policy Ad Hoc Subcommittee of the Executive Subcommittee of the Committee on Government Patent Policy, Federal Counsel for Science and Technology. This report recommended that the executive agencies adopt policies and regulations recognizing that the public interest will normally best be served by allowing the institutions with an approved technology transfer program to retain title to inventions made in the course of or under any government research grant or contract. The report further recommended that these policies and regulations should require the use of Institutional Patent Agreements (IPA's) with universities and nonprofit organizations that are found to have an established technology transfer program that is administered consistently with the stated objectives of the President's Memorandum and Statement of Government Patent Policy. The report noted, however, that the agency should reserve the right to exempt specific grants and contracts at the time they are awarded from the operation of the Agreement, since there may be instances where exclusions from the normal policy are warranted as being in the public interest.

I understand that the principal concerns in this area of DNA research are that there be rapid exchange of information in this important new field, and that there be some degree of control over the type of experiments carried on to avoid possible hazards to humans. Presumably, there is also the desire to make available to the participating institutions the incentives for exploitation which patents provide, so long as this does not interfere unduly with an appropriate resolution of the other concerns.

It would appear to me that the Institutional Patent Agreement approach for DNA research performed by universities and non-profit organizations would represent a balanced resolution of these concerns. In order to insure adequate control, the institutions could be required to comply with certain guide-lines when licensing patented DNA inventions.

I chair an interagency committee - the Committee on Intellectual Property and Information - of the Federal Coordination Council for Science, Engineering and Technology, which is charged with the responsibility of evaluating and coordinating Federal patent policy. The Committee is comprised of policy-level officials in the R&D sponsoring agencies, in addition to representatives from the Departments of State and Justice. I would be pleased to have the Committee consider the issue of patent agreements with universities and nonprofit organizations with respect to recombinant DNA inventions if the Committee's advice would be helpful to you.

Sincerely,

Jordan J. Baruch

Environmental Protection Agency
Washington, DC 20460

JUN 29 1977

Dr. Joseph G. Perpich
Associate Director for Program
Planning and Evaluation
Public Health Service
National Institutes of Health
Bethesda, Maryland 20014

Dear Dr. Perpich:

The enclosed information was solicited from EPA's patent counsel regarding patenting of Recombinant DNA Research Inventions as requested by Dr. Fredrickson in your letter dated May 27, 1977.

I apologize for the delay in providing you this information.

Sincerely yours,

H McElroy

Delbert S. Barth, Ph.D.
Deputy Assistant Administrator
for Health and Ecological Effects

Enclosure-1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 10 1977

OFFICE OF
GENERAL COUNSEL

MEMORANDUM

SUBJECT: Recombinant DNA Research - Invention Rights to Universities

FROM: Benjamin H. Bochenek
Patent Counsel (A-134)

TO: Dr. Delbert Barth, Deputy Assistant Administrator
Office of Health & Ecological Effects, ORD (RD-683)

A copy of the enclosed letter of May 27, 1977 from Dr. Joseph Perpich to Dr. Herman Lewis was made available to me on June 9, 1977, at a meeting involving a number of patent attorneys from various agencies. I hope you will not mind my taking the liberty to provide some input to the matter in the first paragraph regarding patenting of recombinant DNA by universities operating under EPA grants and contracts.

The patent clause used by EPA in grants and contracts with universities gives the Government the option to take title to any invention made thereunder. However, there is a provision in both the grant and contract clause that permits the Agency to allow the university to retain rights greater than a nonexclusive license in any such invention if the administrator or his designee determines that such a disposition of rights is in the public interest. It is emphasized that, under present EPA patent right clauses, and under present policy, an invention in the area of recombinant DNA would be treated in the same manner as any other invention. This would be true in the case of both universities and profit making organizations. If you have any thoughts regarding this matter, please contact me at 50794.

Enclosed is a copy of relevant grant regulations (40 CFR section 30.500 et seq.) and relevant contract regulations. In connection with the letter a copy of the clause entitled "Patent Rights-Acquisition by the Government," which is used in our contracts, is enclosed.

Enclosures

[Editor's note: For enclosures, see Federal Register, May 8, 1975, pp. 20053, 20083, and 20232-20253; May 14, 1975, pp. 20952-20953; and EPA Form 1900-28 (Rev. 11-76).]

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

May 18, 1977

Dr. Donald S. Fredrickson
Director, National Institutes of Health
Department of Health, Education, and
Welfare
Bethesda, Maryland 20014

Dear Dr. Fredrickson:

This is in response to your request for the U.S. Department of Agriculture to comment on the "Analysis of the Patenting of Recombinant DNA Research Inventions Developed under DHEW Support". We understand this response is for your use as Chairman of the Federal Interagency Committee on Recombinant DNA Research.

The analysis has been reviewed by our Office of General Counsel and representatives of the USDA agencies involved in recombinant DNA policy.

In our view, the analysis raises three basic issues.

(1) Whether recombinant DNA inventions resulting from HEW-sponsored research should be patented:

Such inventions should be patented to help insure the availability of the technology to the public. In many instances, the technology may require the incentive of exclusive patent rights in order to bring the benefits to the public.

The suggestion to expedite processing of patent applications at the Patent Office has merit because such a program would advance the date of dissemination of valuable information.

(2) Whether HEW's Institutional Patent Agreement (IPA) program should also apply to recombinant DNA research:

Since the IPA program apparently has effectively worked for HEW to bring the benefits of technological discoveries to the public, there does not appear to

be any logical reason to deviate from this successful program as to recombinant DNA technology.

(3) Whether the IPA program should be modified to require institutions to insure that their patent licensees comply with the NIH guidelines:

In view of proposed legislation, which would extend Federal guidelines to everyone, this issue would no longer be relevant.

If clarification is needed, please contact us.

Sincerely,

James Nielson
Deputy Assistant Secretary for
Conservation, Research & Education

UNITED STATES GOVERNMEN

memorandum

DATE: June 9, 1977

REPLY TO ATTN OF: Assistant to the General Counsel

SUBJECT: NSF Patent Policy Regarding Recombinant DNA Patents

TO: Dr. Herman W. Lewis

This memorandum has been prepared in response to your memorandum of May 31, 1977. We would have no objection to your forwarding a copy directly to Dr. Frederickson.

NSF patent policies as established by the National Science Board and set forth at 45 CFR 650 and 41 CFR 25-9 do not provide for any special treatment of inventions pertaining to recombinant DNA. Most NSF grants contain a "deferred determination" type patent clause allowing NSF to determine the disposition of rights in inventions made under NSF grants. However, some universities have received Institutional Patent Agreements authorizing them to retain principal rights at their option subject to various terms and conditions. These agreements, with some minor exceptions, are substantially the same as the Institutional Patent Agreements used by DHEW.

We are aware of no reason why recombinant DNA inventions should be treated differently than any others. Thus we see no reason to use more stringent patent clauses in grants involving research with recombinant DNA. Similarly, we see no reason to be more restrictive in allowing a university to retain principal rights in inventions that are reported to NSF under a deferred determination clause.

Indeed, we would note that a principal objective of NSF patent policy is to encourage further development and utilization of inventions. In most instances, this requires further development by commercial concerns under license from the grantee institution. In the area of drugs and medical instrumentation, to which we believe most recombinant DNA inventions will relate, retention of patent rights by the inventing university is especially important to successful licensing efforts. Hence, we would regard as a step in the wrong direction any effort to bar the patenting of such inventions or to require that title to such inventions be transferred to the Government.

Jesse E. Lasken