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ROCHESTER, NEW YORK 14642

OFFICE OF RESEARCH & PROJECT ADMINISTRATION
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File

31 August 1976

PATENT BRANCH, GSA

SEP 9 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read: Re: FPR, Subpart 1-9.1 Amendments

Your letter of 5 August 1976 regarding the above patent provisions and the Institutional Patent Agreement with educational and other nonprofit institutions has been received.

We are pleased to note the general trend toward a more reasonable and realistic approach in bringing inventions to the public sector quickly by means of such agreements.

However, some concern exists in the language which appears to speak of individual agreements negotiated with each of the various agencies. See for example proposed Subsection(6) to 1-9.107-4(a) line 9 referring to "...an..." agreement and also proposed Subsection (c) to 1-9.107-6 line 2 "...an..." agency, and line 3 "...an..." duplicated. This would appear to mean that it is intended that no single agency-wide agreement is contemplated, which we believe to be a mistake resulting in costly and needless duplication of work. It would seem more reasonable to expect that the information required to satisfy one agency in this regard should generally suffice for all others.

Finally, we are in agreement with the deletion of a prescribed award scheme and the resulting proposed Section (7)p.3 providing for incentive awards and utilization for educational and research purposes. The agency imposition by means of a previously determined royalty amount to be awarded to an inventor appears to be an unwarranted intrusion into the relationship between the grantee institution and its employees.

We are pleased to have had this opportunity to offer the above comments.

Very truly yours,

David A. McBride,
Director

DAM:ccm
cc: Norman Latker, Esq.

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

RESEARCH AND SPONSORED PROGRAMS • 116 COLLEGE AVENUE • NEW BRUNSWICK • NEW JERSEY 08903 • 201/932-7118

August 10, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

This is to acknowledge receipt of your memo concerning the amendment on patents proposed for the Federal Procurement Regulations. I have no questions to pose or views to express that are contrary to the content of the document in its present form.

Sincerely yours,

David Pramer
Associate Vice President for Research

DP:bd

cc: Mr. E. Isaacs

WISCONSIN ALUMNI RESEARCH FOUNDATION

POST OFFICE BOX 7365 • MADISON, WIS. 53707 • TELEPHONE (608) 263-2500

September 17, 1976 263-2831

Mr. Philip G. Read
Director of Federal Procurement Relations
General Services Administration
Federal Supply Service
Washington, D. C. 20406

Dear Mr. Read:

Re: Federal Procurement Regulations - Proposed Institutional Patent Agreement

We appreciate having the opportunity to comment upon the proposed Institutional Patent Agreement with educational and non-profit institutions which accompanied your letter of August 5, 1976. We are pleased to see that consideration to this approach to the transfer of technology from such organizations has progressed to this point. Our comments on the terms and provisions of the proposed Institutional Patent Agreement follow:

1. Scope of Agreement

The comments here can also be readily tied to and should be considered along with the comments to Article IV (b) (B).

We do not understand the need for any exclusion of certain contracts from the Institutional Patent Agreement. To our knowledge there has been no history of abuses leading to the need for such exclusion. More importantly, no criteria have been established upon which the decision to exclude is to be based. Hence, the decision at the outset to exclude a contract from the scope of the Institutional Patent Agreement can be completely arbitrary in nature. The inclusion of such a provision also seems redundant in view of the march-in rights reserved to the Government in Article IV (b) (B).

In addition, for every exclusion from the Institutional Patent Agreement, the only alternative presented to the Institution is to abandon administration of an invention arising under the

excluded contract or to again go back to a case-by-case determination. Experience with this latter approach has established that it is unsatisfactory. I can introduce what can be critical time delays in the transfer of the technology to the private sector with the result that the public may in reality be deprived of that technology. It will certainly serve to significantly increase the burden of administering the invention.

Further in relation to Article I of the proposed Institutional Patent Agreement, we do not understand why the Institutional Patent Agreement should not apply to subject Inventions where the Institution is a contractor under a prime contract of the Agency. By parity of reasoning if the Institutional Patent Agreement is available to an Institution where it is the prime contractor it should also apply when the Institution is a subcontractor.

IV (b) Minimum Rights Acquired by the Government

The general emphasis in the application of Section (b) appears to be the reverse of that in existing like provisions of the Institutional Patent Agreements with both the Department of Health, Education, and Welfare and the National Science Foundation. The format in which this Section has been couched would appear at the outset to shift the burden of proof in the administration of an invention. In other words, it would appear that under the literal language of the proposed provision the Government can request the Institution to grant a license to a third party at any time before the running of the 3-year period after the patent issues. The burden of proof then appears to shift to the Institution to show that effective steps have been taken to bring the invention to the point of practical application, or that the invention has been licensed on reasonable terms or that principle or exclusive rights should be retained - the 3-year "incubation" period being available to the Institution by implication.

It would seem more appropriate that the 3-year "incubation" time should be more specifically set out so that there is no misunderstanding of the intent of the whole of paragraph (b). We believe the language of Article XII (a) of the Institutional Patent Agreement with the Department of Health, Education, and Welfare would be more appropriate.

With regard to paragraph (b) (B) of Article IV the decision (see comments under Scope of Agreement above) can be an arbitrary one. No guidelines or criteria are established upon which such a decision can be based. Moreover, the decision to license others can be made under this provision without even giving the Institution an opportunity to be heard. That opportunity, at the very least, should be included in the provision. The format of the corresponding provisions from the Institutional Patent Agreement with the Department of Health, Education, and Welfare, Section XII (b), which is reproduced below for your convenience, would be more appropriate and equitable:

> "The Grantor reserves the right to license or to require the licensing of other persons under any U. S. patent or U. S. patent application filed by the Grantee on a subject invention on a royalty-free basis or on terms that are reasonable in the circumstances, upon a determination by the Assistant Secretary (Health and Scientific Affairs) that the invention is required for public use by governmental regulations, that the public health, safety, or welfare requires the issuance of such license(s), or that the public interest would otherwise suffer unless such license(s) were granted. The Grantee and its licensees shall be given written notice of any proposed determination pursuant to this subparagraph not less than thirty (30) days prior to the effective date of such determination, and that if requested, shall be granted a hearing before the determination is issued and otherwise made effective."

It is submitted that the Institution should at least have the right to be heard and adoption of the above language from the Department of Health, Education, and Welfare Institutional Patent Agreement is urged in place of Article IV (b) (B).

V. Invention Identification, Disclosures and Reports

The implication of Section (d) is that where no patent application is filed the Institution can bar or prohibit publication without limitation.

upon a determination by the Assistant Secretary

VII. Filing of Foreign Patent Applications (This Article is mislabelled at VIII in the proposed Institutional Patent Agreement.)

The time frames established by Subsection (a) (i) are in fact arbitrary in nature and have no relationship to the practices which normally govern the filing of patent applications in foreign countries in a patent-license situation. Traditionally, once the convention date has been established, as by filing in the U. S. before publication, it is the usual practice to delay as long as possible the filing of foreign applications. This is done for a number of reasons, among which are:

(1) to establish a commercial interest or perhaps even enter into an actual license so that a more reasoned decision can be made on where to file corresponding foreign applications;

(2) to determine the effect of publications if and when made since certain countries do have grace periods after publication which do not absolutely bar the filing of a patent application;

(3) administrative considerations such as the obtaining of export licenses under certain conditions; and

(4) the increase in the administrative burden which the establishment of artificial time periods, over and above the normally considered and controlling statutory time periods, which now goven foreign filing considerations, will cause.

In view of the above we would suggest that the portion of Article VII (a) following "regulations" in line 5 be deleted.

Some of the reasoning applied above would also apply to Article VI (a) relating to the filing of domestic patent applications, with, of course, provisions which would protect the agency in the event the Institution decided to file no patent application.

IX. Administration of Inventions in Which the Institution Elects to Retain Rights

Section (b)

In relation to the time provisions of Section (b) of this Article, it has been our experience that development of inventions arising in a University environment, and particularly those in the pharmaceutical field, can take an exceedingly long time. Consequently, the finite period of 8 years from the date of granting an exclusive license for the maximum life of such license may, in many situations, be completely inadequate for the licensee to even introduce an invention into the market, let alone recoupt his expenses from the sale or use of such invention. It is well understood that many of the major delays in reaching the marketplace with an invention relating to the pharmaceutical filed are occasioned by the control exercised by various Federal regulatory agencies. Since these practical considerations do pertain, we would suggest that the running of the 8-year period be tolled for that period of time that the permission to sell or use the invention in the marketplace, up to the receipt of approval for such marketing or use, is in the hands of the regulatory Agency in control. The inclusion of such a provision would be equitable to the licensee without affecting the protection afforded the public by the march-in provisions of the agreement and could be a significant factor to a favorable determination by a company in the private sector to invest the necessary funds to commercially develop a University generated invention.

IX Section (f)

We would suggest the deletion of Section (f) of Article IX.

On the one hand, the effect of Sections (a) and (b) of Article IX is to leave the decision concerning licensing with the Institution and then through the operation of Section IX (f) promptly take away a portion of that prerogative.

regulatory agencies. Since these practical considerations do

The provisions of this Section could have a decidedly adverse affect upon the transfer of technology from the University to the private sector. Thus, who can more quickly transfer the technology of a Subject Invention than one who participated in the research leading to its conception and/or actual reduction to practice? Who is most knowledgeable about the subject matter of the invention? Who has more of the "know-how" which may be an ancillary but unwritten and undefinable part of the invention? In the event the investigator is willing to assume or participate in the high risk involved in transferring technology from the University to the private sector, where there is little doubt that the odds are extremely long in achieving success, why is his investment so different from that of a third party as to become the subject of a specific prohibition? If such a person, or an organization of which such a person is a part, meets all the criteria to qualify for a license, it seems abundantly clear that transfer of technology involved to the public would occur more expeditiously than if third party, which has first to be taught the technology before such transfer can be made, attempts to make such transfer. We firmly believe that there is little danger of "unjust enrichment", which appears to be the thrust of Section (f), when there is so little capability to adequately forecast of the commercial success of any given invention and where the investment risks have not been changed. It is well recognized that each invention has its moment in time and if an Institution is under compulsion to first try to find organizations other than those specified in Subsections (i) (ii) (iii), the time delay could be fatal to the transfer of technology to the private sector. Also, the time delay occasioned by obtaining special permission from the agency involved, could also mitigate against the timely transfer of the technology and would, without doubt, significantly increase the administrative burden for the Institution as well as the Agency.

A further point with regard to Section IX (f) is that Institutions for the most part have had a great deal of experience with and have had been most cognizant of

technology involved by the public would occur more ex-

potential conflict of interest situations which arise because of their operations and because of the various interrelations between funding arising from private and public sources (the latter including Federal Agency funding) and consulting arrangements entered into by University investigators. We believe that the Institutions' ability to police these problems is well established and that in the great majority of situations such policing is adequate without imposing specific restrictions such as are imposed by this Section.

As a last point, some of the terms used within Section (f) tend to defy definition. For example, in the context of the Section what in fact does "promoter", "organizer" or "financier" mean? These words can have very different connotations depending upon the kind of institution to which they are being applied.

If you or any of your colleagues have any specific questions on the foregoing remarks or would like additional information regarding our experiences with extant Institutional Patent Agreements we will be pleased to give you our complete cooperation.

Very truly yours,

Howard W. Bremer

Howard W. Bremer
Patent Counsel

HWB:rw

CALIFORNIA INSTITUTE OF TECHNOLOGY

PASADENA, CALIFORNIA 91125

PATENT OFFICE

17 August 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
U. S. General Services Administration
Washington, D. C. 20406

Dear Mr. Read:

This is in response to your August 5 letter announcing the proposed amendment to Chapter 1, Title 41 of the Code of Federal Regulations specfically involving a proposed subpart 1-9.1 dealing with patents and Institutional Patent Agreements.

This is to express our enthusiastic approval for this type of approach to standardization of government patent policy as it affects educational and other nonprofit institutions. However, I do have some suggestions for possible amendment.

First, I would propose that the words ---the reason, including--- be inserted before "any written reports" in the third from the bottom line of Section III(a) of the proposed IPA. This proposal is made because the last sentence of this subsection, at least inferentially, implies a requirement for formal and possibly expensive inquiry as the basis for each negative decision. Under the reporting requirement of Section V(a), and the definition of "subject invention" in Section II(a), many items will be reported which will obviously be of a noncommercial nature. In practice, decisions as to many such items are made informally, and institutions such as ours would be much more comfortable if the language were altered as suggested above.

I would further suggest that a new subsection be added to Section VIII of the proposed IPA to take care of a situation which has troubled us in connection with the existing agreements with HEW and NSF. The problem arises from the fact that some educational institutions (as in our case) have policies which prevent granting of rights in inventions to sponsors other than government. Accordingly, when we are the subcontractor to another educational institution which has an IPA, the requirement that title vest in the prime contractor forces either a deviation from our own policy or negotiation of some sort. We would suggest a new subsection be added to provide that when the subcontractor has an IPA with the agency involved -

(1) the subcontractor inventions be subject to the IPA of the subcontractor;
(2) the reporting responsibility of the subcontractor be directly to the agency; and
(3) information copies be required to be sent to the prime contractor.

It is my feeling the above proposals would improve the proposed Institutional Patent Agreements, and I hope they will receive serious consideration.

Sincerely,

T. L. Stam

T. L. Stam
Patent Officer

S/r

cc: Mr. Norman Latker

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : Mr. Latker

DATE: 17 August 1976

FROM : Mr. Ferris

SUBJECT: Telecon with Mr. Stam, Cal Tech (213-795-6811) re proposed GSA Institutional Patent Agreements.

Mr. Stam called and advised that he had received a letter from Philip G. Reed at GSA requesting comments regarding the proposed GSA IPAs. He has two suggestions based upon difficulties that he has experienced with IPA's from us and from NSF which he wishes to bring to your attention.

1. Section IIIa provides that if the grantee elects not to administer an invention under the IPA it must provide the documentation upon which the decision was based. This appears to require that they document every turn down. Some inventions reported are so obviously lacking in commercial potential, etc. that a decision is made not to administer under the IPA without further evaluation, surveys, etc. He suggests that this clause be clarified to eliminate the implication that documentation is required in every case, but that it be provided only in those cases in which it has been established.

No change necessary

2. Section VIIIa requires that an IPA holder retain title to inventions made by a contractor of the grantee. This is fine except when the IPA holder is the contracor. Cal Tech's policies preclude granting title to inventions to anyone other than the Government. He suggests that this section be amended by adding a provision that where the contractor has an IPA its responsibility to report is to the agency sponsoring the research and that the disposition be in accordance with the IPA.

Agree change necessary

Mr. Stam would like to discuss these two points with you when you have had a chance to think about them.

UNIVERSITY OF CALIFORNIA SYSTEMWIDE ADMINISTRATION

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Vice President--
Business and Finance

BERKELEY, CALIFORNIA 94720

August 16, 1976

Mr. Phillip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

Mr. Norman Latker has transmitted to me a copy of the proposed amendment to Sub-part 1-9.1 of the Federal Procurement Regulations. Although I feel that the information which is required to be filed by institutions seeking Institutional Patent Agreements is somewhat detailed any may be onerous for an educational institution to readily gather together, I nonetheless feel that the overall approach is one that is most commendable and therefore, on balance, I feel that the proposed amendments are satisfactory and would be of benefit to educational institutions.

Very truly yours,

Mark Owens, Jr.

AMERICAN SOCIETY OF CIVIL ENGINEERS
FOUNDED 1852

# AMERICAN SOCIETY OF CIVIL ENGINEERS

## CONSTRUCTION DIVISION

**Committee on Contract Administration**

4099 Derry Street
Harrisburg, Pennsylvania 17111

August 18, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D. C. 20406

Re: Federal Procurement Regulations
Subpart 1-9.1 - Patents

Dear Mr. Read:

Receipt is acknowledged of your letter of August 3rd requesting a review of the proposed subject revision.

Our Committee, at present, has no expertise or experience in the area of patents and, therefore, we will not be able to make a contribution on this particular subject. During and prior to 1971, our Committee had reviewed and offered comments on various proposed revisions to the FPR. Our last contact with your office was on the same subject matter, Patents, in 1972. I suspect that your reference to our organization may have us mis-identified as being interested in patents. Our Committee is involved with the broad field of Construction Contract Administration, and we would be pleased to submit comments in other areas of the FPR's.

Sincerely,

Robert D. Rowland

Robert D. Rowland, P. E.

RDR/hg

cc: Robert A. Rubin w/Proposed FPR Revision
: George A. Fox

Dear Mr. Read:

WASHINGTON UNIVERSITY

ST. LOUIS, MISSOURI 63130

OFFICE OF ASSOCIATE VICE CHANCELLOR FOR RESEARCH

August 17, 1976

Mr. Philip G. Read
Director of Federal
Federal Supply Serv
General Services Ac
Washington, D.C.

To be

Scanned

Dear Mr. Read:

I am responding to forwarded the proposed FPR amendm greements.

It is my understand nt by the ad hoc subcommittee of Policy has been a long and thoughtf amendment draft is workable and rep ring for the American public the nsored research not previously obta should be anticipated this proposal provides the sound procedures, long term commitments and essential incentive mechanisms, the lack of which has produced the poor results achieved to date. I whole heartedly endorse its acceptance.

There is always room for change in the draft of such a new regulation much of which may represent personal preferences. I would hope that the earliest adoption of this proposed amendment will not be hampered by a deluge of conflicting personal changes. Rather, I would hope that the well thought out product of the ad hoc subcommittee be accepted, placed in practice and then, after a reasonable period of use by the various agencies, improvements based on experience should be sought.

Again let me express my hope that this progressive and innovative amendment be adopted as soon as possible. For the first time the basis for a cooperative relationship among Government research sponsors, institutional research scientists and the production sector of our economy is being estabiished for public benefit. Without the enthusiastic involvement of all three parties the delivery of new and improved products and services stemming from Government research programs will not prosper in the future any more than it has in the past.

Sincerely,

E. L. MacCordy

E. L. MacCordy
Associate Vice Chancellor for Research

cc: Norm Latker

ELM/sbe

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
77 MASSACHUSETTS AVENUE ROOM E19-702
CAMBRIDGE, MASS. 02139

OFFICE OF SPONSORED PROGRAMS
General Counsel
Room E19-722

TELEPHONE (617) 253- 6966

September 13, 1976

Mr. Philip G. Read
Director of Federal Procurement
Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

Thank you for your thoughtfulness in providing M.I.T. with a copy of the proposed amendment to the Federal Procurement Regulations concerning patents. M.I.T. supports the addition of provisions dealing with institutional patent agreements for qualified educational and other non-profit institutions.

We would propose that the issuance of IPAs to qualified institutions be made mandatory for all government agencies rather than leaving same to the discretion of each agency. We would assume that if the criteria for the award of an IPA is satisfactory to one government agency, it should normally be satisfactory to other agencies. We would also propose a provision within the IPA that states for the record that the agency granting the IPA recognizes that the 8-year time period for a limited-term exclusive shall automatically be told in those instances where regulatory agency approvals (such as FDA) are required to enable a licensee to market the invention. With these few comments, however, we are in accord with the proposed regulations. Thank you.

Very truly yours,

Arthur A. Smith, Jr.

Arthur A. Smith, Jr.
General Counsel
Office of Sponsored Programs

AAS:LB

UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE
22901

UNIVERSITY PATENTS PROGRAM
OFFICE OF ASSOCIATE PROVOST FOR RESEARCH
THORNTON HALL
(804) 924-7356

September 22, 1976

Philip G. Read, Director
Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Reference: Proposed Amendment to FPR Subpart 1-9.1, Patents

Dear Mr. Read:

This is in response to your letter of August 5, 1976 soliciting comments on the proposed FPR changes regarding Institutional Patent Agreements. Needless to say, we are in full agreement with the intent of this legislation and, except for some minor changes, feel that it will be effective and workable.

A few specific comments and proposed changes would be as follows:

1. Subsection (6) to 1-9.107-4 (A):

The language in line 3 indicates that agencies may enter into Institutional Patent Agreements. In our opinion, this should be changed to should or must enter into such agreements with those institutions having an approved technology transfer program. The rationale behind this change is that, those agencies which do not already have Institutional Patent Agreements, particularly ERDA, will certainly not be in any rush to change their system of handling patents without some strong impetus such as a regulation change. Additionally, from the University's end, it would significantly reduce the already demanding paperwork load if such things as annual reports, initial invention reports, request for waivers, etc. could all be handled on an identical basis, no matter which agency is involved.

2. Subsection (C) to 1-9.107-6:

(D) indicates a limiting period for the exclusive license necessary to provide incentive to the commercial firm. In order to prevent continual requests for extensions, some allowance should be made for an exempt period before the period of exclusivity starts running for those inventions which require government agency approval.

For example, a new drug invention may very well take five to six years of intensive effort before it is ready for the marketplace. Under the present terms of the recommended IPA, this would only leave three years of exclusivity remaining, and would effectively prevent a company from licensing such an invention. Another example would be the new regulations on pre-market clearance for medical instrumentation. Again, an exempt period must be allowed before the exclusive license limitation starts so that the licensee can obtain the necessary government clearances.

3. Items under the sample Institutional Patent Agreement IX. (f)

This paragraph should be deleted in its entirety. Although the rationale for this section is certainly laudatory, conflict of interest questions should not be handled at the government agency level, and in fact, are probably impossible to handle at that level. Universities are, by their very nature, highly sensitive to conflict of interest problems, and are already effectively solving this problem. Therefore, this is an area that should be left to the discretion of the University in the Institutional Patent Agreement.

Once again, we appreciate your thoughtfullness in allowing us to comment on this most important subject, and if you need any clarification or further information, please do not hesitate to contact me.

Very truly yours,

C. B. Wootten
Director

CBW:mtk

cc: G. A. McAlpine
Raymond J. Woodrow, President
Society of University Patent Administrators
Norman J. Latker

MICHIGAN STATE UNIVERSITY

OFFICE FOR RESEARCH DEVELOPMENT
238 ADMINISTRATION BUILDING

EAST LANSING · MICHIGAN · 48824

September 17, 1976

Mr. Philip G. Read
Director, Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

Receipt is acknowledged of your letter of August 5 forwarding the proposed Federal Procurement Regulations Revision prepared by the Ad Hoc Subcommittee on University Patent Policy.

We appreciate the opportunity to respond to the proposed revision and respectfully submit the following suggestions.

1. Consideration should be given to the proposed Institutional Patent Agreement (IPA) being mandatory for all federal agencies rather than an item to be employed at an individual agency's discretion (paragraph 1, proposed Federal Procurement Regulations Revision). We believe that in general the university community is supportive of the IPA's developed by the National Science Foundation and the Department of Health, Education, and Welfare (DHEW) and recommend, therefore, that the proposed revision be brought into as close agreement as possible with those agreements. The uniform application of a single IPA by all government agencies would greatly simplify this area of federal grant and contract negotiations and reduce enormously the administrative expense currently associated with such activities.

2. Page 7, Section IV, Minimum Rights Acquired by the Government.

   It is our understanding that this section deals with what is generally referred to as "March-In Rights" of the Government. It is suggested that this section be modified to include a provision whereby the institution can request a hearing prior to the Government exercising these rights. This would bring the proposed agreement more closely in line with the DHEW's Institutional Patent Agreement, which we find very acceptable.

3. Page 13, Section IX (b).

   The limitation of an exclusive license to eight years from the date of issue can be very inadequate and such a restriction could work a particular hardship in those cases of biomedical research where

pre-clinical testing may be required before the product can be brought to market. Such testing can consume years of effort even with the most diligent prosecution. It is suggested that language be introduced to exclude from the eight years of exclusivity allowed, that time which elapses between the submission of a request for clearance from a federal agency and the granting of that request.

4. Page 14, (f).

We recommend that this entire section be deleted. The requirement that clearance or approval must be obtained from the federal agency prior to licensing employees of the institution, etc., is an excessive intrusion on the management prerogatives of the institution.

Thank you again for the opportunity to respond to the proposed amendment. We will follow future developments with interest.

Sincerely,

Henry E. Bredeck
Associate Director

HEB/jms

cc: Cantlon
Latker
Woodrow

THE UNIVERSITY OF ROCHESTER
MEDICAL CENTER P.O. BOX 649
ROCHESTER, NEW YORK 14642

OFFICE OF RESEARCH & PROJECT ADMINISTRATION
Telephone (716) 275-4031

31 August 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read: Re: FPR, Subpart 1-9.1 Amendments

Your letter of 5 August 1976 regarding the above patent provisions and the Institutional Patent Agreement with educational and other nonprofit institutions has been received.

We are pleased to note the general trend toward a more reasonable and realistic approach in bringing inventions to the public sector quickly by means of such agreements.

However, some concern exists in the language which appears to speak of individual agreements negotiated with each of the various agencies. See for example proposed Subsection(6) to 1-9.107-4(a) line 9 referring to "...an..." agreement and also proposed Subsection (c) to 1-9.107-6 line 2 "...an..." agency, and line 3 "...an..." duplicated. This would appear to mean that it is intended that no single agency-wide agreement is contemplated, which we believe to be a mistake resulting in costly and needless duplication of work. It would seem more reasonable to expect that the information required to satisfy one agency in this regard should generally suffice for all others.

Finally, we are in agreement with the deletion of a proscribed award scheme and the resulting proposed Section (F)p.3 providing for incentive awards and utilization for educational and research purposes. The agency imposition by means of a previously determined royalty amount to be awarded to an inventor appears to be an unwarranted intrusion into the relationship between the grantee institution and its employees.

We are pleased to have had this opportunity to offer the above comments.

Very truly yours,

David A. McBride,
Director

DAM:acm
cc: Norman Latker, Esq.

Battelle
Memorial Institute
505 King Avenue
Columbus, Ohio 43201
Telephone (614) 424-6424
Telex 24-5454

October 4, 1976

Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Washington, D.C. 20406

Dear Mr. Read:

We would like to take this opportunity to comment favorably on a proposed amendment to the Federal Procurement Regulations, Subpart 1-9.1, "Patents", which recently came to our attention. The proposed amendment involves the addition of provisions dealing with Institutional Patent Agreements with educational and other nonprofit institutions which have a satisfactory technology transfer program.

It is our belief that this proposed amendment will significantly further the stated objectives of the President's Memorandum and Statement of Government Patent Policy, dated August 23, 1971, by encouraging development and commercialization of inventions arising out of activities supported by the Federal Government. We feel that this proposed amendment quite properly recognizes that the public interest in the availability of inventions arising under Federally-sponsored programs will normally best be served by allowing educational and other nonprofit institutions a first option to take title to such inventions, provided the institution has an effective technology transfer program.

The efforts of the ad hoc subcommittee of the Committee on Government Patent Policy, Federal Council for Science and Technology in developing this proposal are to be commended, and we are pleased to have this opportunity to express our support.

Sincerely,

Paul T. Santilli
Vice President and
General Counsel

PTS:jm

stated objectives of the President's Memorandum and Statement of Government

N5L

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

OFFICE OF GENERAL COUNSEL

B-187066

November 12, 1976

PATENT BRANCH, OGC

NOV [illegible] 1976

Mr. Philip G. Read
Director of Federal Procurement
Regulations
Federal Supply Service
General Services Administration

Dear Mr. Read:

By letter dated July 23, 1976, with enclosure, you transmitted for our comment a proposed revision to Federal Procurement Regulations (FPR) Subpart 1-9.1 dealing with Institutional Patent Agreements (IPA).

The present patents section of the FPR (subpart 1-9.1) begins with the assertion that the Government normally acquires principal rights to any invention resulting from federally funded R&D. The contractor is normally granted a nonexclusive license for the invention. On an exceptional basis, the administrator of the funding agency may grant greater rights to the contractor either at the time the contract is granted or on a case-by-case basis after a specific invention is reported. Nonprofit institutions and profitmaking firms are essentially treated alike under the present patent regulations.

The proposed amendment to this patent section concerns IPAs to be entered into by Government agencies with appropriate educational and nonprofit institutions. Under such an agreement with a Government agency, an institution would automatically acquire principal rights to inventions under all of its contracts with the Government agency, subject to various criteria. Prior to entering into this agreement, the agency must assess the institution's patent management capabilities and the ability of the institution to promote rapid commercialization of the invention by the use of a formal technology transfer program. This proposed amendment would extend the licensing authority of Government agencies to nonprofit institutions entering into IPAs. These institutions would be required to aggressively pursue commercial utilization of their inventions by granting licenses to private firms.

We endorse this effort to cast some uniformity over the present confusing jumble of different agency patent policies and we favor the granting of exclusive rights (with appropriate Government protection) to provide incentive for private investment for commercialization. However, there may be some question as to whether it is necessary or advisable for the Government to grant title (as opposed to an exclusive license) to the contractor. Granting of exclusive licenses subject to march-in rights with the Government retaining title, is consistent with the statement on Government Patent Policy by the Comptroller General before the Subcommittee on Domestic and International Scientific Planning and Analysis, House Committee on Science and Technology, on May 5, 1976.

This preference for an exclusive license should also pertain to the relationship between the institution and profit-making firms. The proposed IPAs would require the institution to normally grant nonexclusive licenses, granting exclusive licenses only on an exceptional basis. We feel that the dismal record of commercialization of federally sponsored inventions indicates that a policy which prefers the granting of nonexclusive licenses doesn't provide enough incentive for industrial investment toward commercialization.

Sincerely yours,

Paul G. Dembling
General Counsel

RESEARCH CORPORATION
405 LEXINGTON AVENUE, NEW YORK, NEW YORK 10017

WILLARD MARCY
VICE PRESIDENT-PATENTS

(212) 986-6622

September 24, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
Federal Supply Service
General Services Administration
Washington, D.C. 20406

Re : Proposed FPR Revision relating to Educational and Nonprofit Institutions

Dear Mr. Read:

Copies of the above proposed FPR revision were circulated by your office under the date of August 3, 1976, to a selected mailing list for comment and suggestions. These were to be sent in by October 8, 1976.

While Research Corporation was not on this mailing list, we have received copies from a variety of sources with the request that we formulate our comments and suggestions on the proposed revision for guidance in responding. Specifically, we have received copies from:

Mr. Norman J. Latker, Patent Officer, National Institutes of Health

Mr. Raymond J. Woodrow, President, Society of University Patent Administrators

Dr. Stephen Quigley, American Chemical Society

Several universities with which we have Patent Assistance Agreement.

This letter encloses our considered reply to these requests, entitled " Comments and Suggestions on Proposed FPR Revision". I thought you might like to have a copy for your information and use. We hope you will find this information constructive and useful in making further revisions to the FPR.

Basically, we feel that a revision of this type is long overdue and is a major step in the direction of developing a uniform, rational Government patent policy. The revisions proposed, for the most part, provide administratively workable procedures, even though some specific items could be improved as noted in the attached "Comments and Suggestions".

As you will note we have carefully studied the proposed revision and suggest substantive changes only in these sections of the proposed Institutional Patent Agreement:

Section II(a) and (c) - 2 suggested changes
Section II(e)
Section IV(a)
Section V(c)
Section VI(b) - 4 suggested changes
Section VII(a)
Section IX(c)
Section IX(f)

Other comments in these remarks expand somewhat on our opinions as to the need or advisability of several other sections. A list of typographical errors is also appended for your information as these are frequently difficult to detect.

I am sending copies of these comments and suggestions to the individuals named previously in this letter for their information and use.

I would be pleased to expand on any of these points at your convenience, if you wish.

Sincerely yours,

Willard Marcy

Willard Marcy

WM:kp
Attachment

Comments and Suggestions on Proposed FPR Revision - January 1976

Page 1 - Addition to Present FPR Paragraph 1-9.107-4(a)

No comments. We favor the use of institutional patent agreements wherever feasible. It should be noted, however, that we do not expect that administrative costs or complexities under such agreements will be substantially less than under a case-by-case determination procedure. Nevertheless, these agreements are a major step in the direction of establishing a uniform Government patent policy and providing known criteria and administrative procedures for expediting the transfer of technology developed under Government funding.

Page 1 - Retitled Paragraph 1-9.107-6

No comments.

Page 1 - Addition to Paragraph 1-9.107-6(c)

No comments.

Page 4 - Proposed Standard Institutional Patent Agreement

Second Whereas Clause

Second line - the first "and" should be replaced by "the".

Third line - either a phrase has been unintentionally omitted or the word "in" should be deleted.

Section I - Scope of Agreement

Line 4 - Reference (3) should specifically state: "Insert a date of approximately 3 years [after date of this agreement]." (Phrase in brackets to be added.) As it stands and reads in connection with line 4, Section I, this reference is unclear.

Section II - Definitions

Definition (a) - This definition, as stated, applies to inventions conceived before award of a contract or grant on which patent applications may have been filed prior to the date of the award. Some recognition of such a situation should be made in this paragraph. In all fairness to the inventor and any previous sponsors he may have had, in the case of prior-filed patent applications, only the use discovered in the "reduction to practice" under the Government grant or contract should be subject to the terms of the IPA.

A second point - this definition as regards plant varieties is limited to patentable varieties. Does this exclude Plant Protection Certification provided by the U.S. Department of Agriculture? Such certification should come within the scope of the IPA, in our opinion.

Definition (c) - Same comment as under Definition (a) regarding prior filed patent applications.

Definition (e) - We suggest that the extension of Federal government rights to States and domestic municipal governments be placed on a case-by-case discretionary basis. The rationale for such an extension is believed to be an assurance that inventions in the public health area, such as certain drugs, pharmaceuticals and safety devices, would be made widely available at minimum costs through state or municipal sponsorship. This is a reasonable requirement. However, by making the extension mandatory many inventions not having such urgent public health benefits would also be included and would seriously impinge on a just return to the contractor and inventor and reduce the incentive to make improvements or further inventions.

Section III - Allocation of Principal Rights

No comments.

Section IV - Minimum Rights Acquired by Government

Subsection (a) - This subparagraph states that the Government has the right to make, use and sell on behalf of the Government of the United States, etc. By including the right to "sell" this considerably broadens the concepts embodied in previous institutional patent agreements, and enables the Federal Government to enter into competition in the general market with commercial enterprises. In our view, this would be undesirable. Our suggestion is that the right to sell be deleted and that a modifying phrase - "for governmental purposes" - be inserted after the word "Invention" on line 4, page 7.

We would also suggest that the phrase in this subsection be ended at the end of the parenthesis on line 6, thus omitting States and domestic municipal governments from this part of the sentence.

The matter of state and municipal government rights should be set forth in a separate subsection for both clarity and more specific definition of these rights. As mentioned previously such rights should not be mandatory, but decided on a case-by-case basis. The basis for any decision on these rights should be set forth in positive language rather than in the negative sense used in this proposed agreement. For example, the statement might read:

"The Agency may determine after the invention has been identified that it is useful in the area of public health and safety, and, therefore, acquisition of a license for States and domestic municipal governments is required."

A corresponding change will need to be made in Exhibit A, Confirmatory Instrument.

Section V - Invention Identification, Disclosures, Reports

Subsection (a) - In practice this requirement may be difficult to comply with within the time limit imposed. Partial or incomplete disclosures may be necessary and may have to be accepted by the agency. The reason for this is that inventions practically never spring into existence full-blown and most often require considerable trial and testing before the technical details are fully known to the extent that a working model or well-defined products are available; such testing frequently takes months and even years from conception or even the first crude reduction to practive.

Subsection (c) - Care must be taken by the Government that the right to duplicate and disclose invention disclosures is not carelessly or thoughtlessly misused in such a way as to jeopardize foreign patent rights or to inadvertently set an unnecessarily early deadline for filing patent applications in the United States. Patent statutes in the U.S. and foreign countries govern these matters and should be observed. Our suggestion would be to add language limiting duplication and disclosure rights only to those rights required to conform to the Freedom of Information Act. Privileged and confidential information as noted in Section XI (to which this subsection refers) with respect to license information applies equally well to information in disclosures and it should be so noted in this Subsection.

Section VI - Filing of Domestic Patent Applications

Subsection (b) - The time schedule for reporting filing date and serial number prescribed in this subsection is not under the control of the contractor or grantee, but depends on Patent Office administrators. It should be recognized that some flexibility in the times stated must be allowed. Our suggestion is that in VI(b)(i) the application should be submitted within two months after the filing but that the filing date and serial number should be submitted within 30 days after their receipt from the Patent Office. Similarly, in VI(b)(ii), if a copy of the recorded assignment is desired, the date of its submission to the Agency should be set at 30 days after its receipt from the Patent Office. Simple unrecorded copies of the assignment could be submitted within two months of the filing date, however. Likewise, in VI(b)(v), the date for submission of a copy of the issued patent to the Agency should be set at 30 days after printed copies are made available by the Patent Office to the contractor or grantee (as this date frequently follows the date of issue by several weeks).

foreign countries govern these matters and should be observed.

Subsection (vi) - While we agree that timely notification of discontinuance of prosecution is necessary, we suggest that powers of attorney be issued only on request by the Agency. In the majority of cases, discontinuance of prosecution by the institution is based on the discovery of overwhelming prior art, unlikely prospects for commercial or public use, or other obvious fatal flaws which would preclude obtaining patent coverage. Under these circumstances it would be unlikely that the Agency would find it advisable to continue prosecution. In addition such continuance would involve a waste of public funds. Thus, it would be the exception rather than the rule that powers of attorney would be required.

Section VII - Filing of Foreign Patent Applications

Subsection (a)(i) - The time limit of 8 months from the date of filing a corresponding United States application for filing in foreign countries is unrealistic for two reasons. The primary reason has to do with the practical need to include as much new material as possible, which has been developed after filing in the United States but before the end of the one year of grace under the international Patent Convention. This makes for the strongest patent claims in foreign countries. The second reason is that the mechanics of preparing adequate patent applications for filing in foreign countries, including translation, frequently is difficult to accomplish within 8 months, especially when complex technology is involved. We suggest that the time limit in this subsection for foreign filing be increased to 11 months.

The second part of this subsection is not clear as to its purpose or meaning. This phrase should be eliminated or restated.

Subsection (a)(iii) - If subsection VII(a)(i) is modified as suggested above, subsection VII(a)(iii) would apply only to subsection VII(a)(ii).

Section VIII - Subcontracts

This section will rarely be used since most contracts and grants to educational and nonprofit institutions do not involve subcontracting.

Section IX - Administration of Inventions in which the Institution Elects to Retain Rights

Subsection (b) - The provision for exclusivity of 5 years from date of first commercial sale or 8 years from date of the license, whichever occurs first, is a reasonable restriction. In our experience most exclusive licensees have been able to operate under this provision without difficulty or financial loss. There will be a rare case where an extension of exclusivity can be justified, so it is important to have the opportunity to request such an extension from the Agency, as provided in the proposed agreement.

Subsection (c) - The second sentence in this subsection will put an intolerable burden on the institution and will set up a requirement which will be impossible to administer. To determine what refunds are necessary would require the institution to have complete access to all sales records of every licensee and to determine in many gray area cases whether sales had been made for or on behalf of the Government. The burden of collecting or not collecting royalties on sales must rest with the licensee and this should be so stipulated in the original license agreement. In practice, at present, licensees are generally obligated contractually to report all sales by product (not by customer) listing separately by totals those sales on which royalties are collected and those sales on which royalties are not collected. In this way the sales price originally quoted by contractors in grant and contract proposals to the Government already include a lower price because they are quoted royalty-free. This system is workable administratively and is currently common practice in industry. Our suggestion is to continue this known and workable system rather than to impose a new and administratively complex and difficult system. The language in this subsection should be rewritten accordingly.

Subsection (f) - This subsection is unduly restrictive. Inventors or their co-workers are frequently the very best people to exploit their inventions since they have a dedication and enthusiasm for seeing the fruits of their inventiveness used in the public interest far greater than others who have to be indoctrinated with these attributes before they can become product champions. If the inventors and their co-workers can show they have the requisite abilities in financial, legal, management, production and marketing matters, or can show they can attract people with such abilities, in our opinion, they should be allowed to become personally involved in carrying through to the marketplace the inventions they have given birth to on the same basis and with the same restrictions as third parties. To do otherwise flies in the face of human nature and the competitive spirit on which this country is based. The undue restriction in this subsection can be removed by deletion in its entirety of the last sentence, and we so suggest. The requirement to have Agency approval should be retained and such approval should not unreasonably be withheld.

Section X - Patent Management Organizations

No comments. We feel institutions should have the choice of using such organizations, if they so desire.

Section XI - Reports on Development and Commercial Use

No comments. While the requirements in this section will require a substantial administrative effort by the institution and/or its designated patent management organization, the type and scope of information requested is not unreasonable and will be made available by licensees without any major resistance.

Section XII - Inventions by Federal Employees

No comments.

Section XIII - Termination

No comments.

Section XIV - Communications

No comments.

Page 18 - Reference 6

We feel that it is desirable that institutional patent agreements cover both grants and contracts as noted in this reference.

Page 20 - New Section Paragraph 1-9.109-7(a)(9)

Responses to information requested in this subparagraph relative to past activities of educational and nonprofit institutions should be used as historical data only, and should not be weighed very heavily in deciding whether an adequate capability for patent management exists at a given institution. Such data are fairly meaningless as most institutions have only recently begun to undertake this type of activity and their past record is either non-existent or reflects a very low level. This would have little or no bearing on future activities, provided the other aspects of the institution's policies, administrative procedures and staffing are deemed adequate, as outlined in Paragraph 1-9.109-7(b).

Willard Marcy:kp
24 September 1976

Attachment

to undertake this type of activity and their past record is either

Typographical Errors in Proposed Institutional Patent Agreement

Page 1, Line 2 - "America" is misspelled

Page 5, Line 15 - "is" should be "its"

Page 5, Line 19 - "Agencies" is misspelled

Page 5, Line 28 - "to" is misspelled

Page 8, Line 7 - delete "on" before "sale"

Page 8, Line 22 - delete "on" before "sale"

Page 8, Line 31 - add comma after "contract"

Page 9, Line 32 - delete "personnel"

Page 10, Line 19 - "VIII" should be "VII"

Page 10, Line 27 - "it" should be "if"

W. Marcy:kp
24 September 1976

WASHINGTON STATE UNIVERSITY
PULLMAN, WASHINGTON 99163

ASSISTANT VICE PRESIDENT—FINANCE

October 5, 1976

PATENT BRANCH, USDA

OCT 13 1976

Mr. Norman Latker
Patent Council
Westwood Building, Room 5A03
C/o National Institutes of Health
Bethesda, Maryland 20014

Dear Mr. Latker:

I have made a brief review of the proposed federal procurement regulation revision prepared by the Ad Hoc Committee on University Patent Policy. I have also asked for comments from some fellow administrators and faculty members here at Washington State University.

I would like to make some comment and suggestions based on our review.