an employee who solely conceived or made the invention, and shall be paid in shares to two or more employees who jointly made the invention in such respective proportions as the board may determine. The board in its discretion may increase the amount by which any employee or employees may participate in such net proceeds. (1949 Rev., S. 3281.)

Sec. 10-128. Disagreements; procedure. Disagreements as to the allocation of any invention to one of said categories, or as to the obligations of any employee or due performance thereof, or as to participation of any employee in net proceeds, or as to rights or obligations with reference to inventions in any category, shall be disposed of as follows: (a) By voluntary arbitration of all relevant issues, if the disagreeing parties approve and agree to be bound by the decision upon such arbitration; (b) by compulsory arbitration if that is provided for in any applicable contract between the disagreeing parties; (c) by recourse to courts of appropriate jurisdiction within the state if arbitration cannot be resorted to under either subsection (a) or (b) of this section. (1949 Rev., S. 3282.)

Sec. 10-129. Regulations for arbitration. The board is authorized to establish and regulate, equitably in the public interest, such measures as the board deems necessary for the purposes of such arbitration, and to make contracts for compulsory arbitration, in the name of the university or of the foundation. (1949 Rev., S. 3283.)

Sec. 10-130. Enforcement of regulations. The board is authorized to make and enforce regulations to govern the operations of the university and the foundation in accordance with the provisions of sections 10-124 to 10-131, inclusive. (1949 Rev., S. 3284.)

Sec. 10-131. Rights as to products of authorship. The provisions of sections 10-124 to 10-131, inclusive, shall not entitle the university or the foundation to claim any literary, artistic, musical or other product of authorship covered by actual or potential copyright under the laws of the United States; but the university and the foundation shall each be authorized to make and enforce any contract, express or implied, which it may make with reference to any such subject matter. (1949 Rev., S. 3285.)

AMERICAN PATENT LAW ASSOCIATION

SUITE 203 - 2001 JEFFERSON DAVIS HIGHWAY, ARLINGTON, VA. 22202

Telephone (703) 521-1680

August 4, 1976

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

Dear Mr. Read:

We indeed are appreciative of the opportunity to review the Proposed FPR Revision. It immediately will be referred to our Committee on Government Patent Policy for study and review. The committee will be asked to report any recommendation which it believes should be made with respect to this proposed revision to the Board of Managers of the Association. It is the Board that takes action on and adopts a position on behalf of the Association.

Our Annual meeting is scheduled for October 7 and 8, 1976. Thus, it would be on October 8 that the Board of Managers would consider any recommendation which may be made to it by the aforementioned committee. Promptly thereafter we will send you our views on the proposal. Realizing, of course, that these views will not reach you by October 8 but necessarily a few days later, we trust that you will allow us those few additional days in order that a proper and thorough review of the proposal may be undertaken by our committee.

Sincerely yours, Charlotte) E. Gauer

Executive Director

314



American Patent. Law Association

SUITE 203 · 2001 JEFFERSON DAVIS HIGHWAY, ARLINGTON, VA. 22202

Telephone (703) 521-1680

October 21, 1976

Reply to: 800 N. Lindbergh Blvd. St. Louis, Missouri 63166

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Executive Director CHARLOTTE E. GAUER

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LOANTE I

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

Re: Institutional Patent Agreements

Dear Mr. Read:

Thank you for submitting to the American Patent Law Association (APLA) by your letter of August 3, 1976, the proposed amendments to the Federal Procurement Regulations which would add Institutional Patent Agreement provisions to Chapter 1, Title 41, CFR, Subpart 1-9.1.

The American Patent Law Association membership, over 4,000, is made up of judges, law professors, and over one-half of the patent lawyers in the United States, engaged in private, corporate and government practice.

After study and recommendation by our Government Patent Policy Committee, the Board of Managers of APLA has adopted the following resolutions on this matter:

> I. Whereas, a proposed amendment to the Federal Procurement Regulations dealing with Institutional Patent Agreements has been developed by an Ad Hoc Subcommittee of the United States Government's Committee on Government Patent Policy; and

-2-

Whereas, on page 7, Paragraph IV(a), with respect to Subject Inventions, a paid-up license is given to State and Domestic municipal governments, unless the Agency determines after the invention has been identified that it would not be in the public interest to acquire the license for State and Domestic municipal governments;

Now Therefore, it is resolved by the American Patent Law Association that the license to and for State and Domestic municipal governments should be only on an exception basis where special circumstances justify the exception; and not automatic, subject to exclusion.

II.

Whereas, Federal Procurement Regulations provide Patent Rights clauses for use and guidance for selection of such clauses in subcontracts for Research and Development work;

Now Therefore, it is resolved by the American Patent Law Association that subcontracts for Research and Development work under Institutional Patent Agreement grants or contracts should not require patent title to be assigned to the University or the Government in all cases; rather the Federal Procurement Regulations guidance should be followed in selection of the proper patent rights clauses.

Our concern in both resolutions is that the proposed regulations in question would rémove the incentive for competent organizations to accept Philip G. Read

-3-

Research and Development grants or contracts or subcontracts, and that as a result the government will be hampered in carrying out its purposes. Inventions are unlikely to be developed and actually made available to the public without reasonable incentives. Institutional Patent Agreements such as utilized by the Department of Health, Education and Welfare provide adequate safeguards of the public interest, including marchin rights if the patent owner or licensee is not commercializing.

We hope our views will be of assistance to you in formulating policy.

Very truly yours,

Bizzon

John D. Upham President

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DEPARTMENT OF STATE AGENCY FOR INTERNATIONAL DEVELOPMENT WASHINGTON, D.C. 20523

September 17, 1976

Mr. Philip G. Read Crystal Square Building 5 Room 1107 Washington, D.C. 20406

Dear Mr. Read:

This is in response to your letter of July 23, proposing an amendment to FPR 1-9.1, Patents, and related to Institutional Patent Agreements and certain institutions having technology transfer programs.

General circulation was provided to procuremnt, legal and other offices that would be involved, and the following comments were received:

- On page 4, "Institutional Patent Agreement", the first "and" in the second line of the second "whereas" does not seem to be the right word. Perhaps "an" was intended.
- The pertinent contract office has expressed concern about Clause XIII. Termination (page 15,), and does not agree with giving the right to terminate for convenience to both parties.

Subject proposal was otherwise regarded favorably overall, and approval was recommended.

Sincerely,

Joseph C. Watkins Chief Support Division Office of Contract Management



United States Department of the Interior

OFFICE OF THE SECRETARY WASHINGTON, D.C. 20240

Mr. Philip G. Read Director of Federal Procurement Regulations Federal Supply Service General Services Administration Crystal Square #5, Room 1107 Washington, D.C. 20406

Dear Phil:

Enclosed herein are comments in reply to your letter request of July 23, 1976, with respect to a proposed amendment to Subpart 1-9.1, of the Federal Procurement Regulations. The comments have been prepared by patent counsel within our Office of the Solicitor, as requested in your letter.

Sincerely,

S. Onleik liff. A. Acting Assistant Director for Procureme

Enclosure

cc: SOL



Save Energy and You Serve America!



UNITED STATES DEPARTMENT OF THE INTERIOR OFFICE OF THE SOLICITOR WASHINGTON. D.C. 20240

SEP 3 1976

Memorandum

To: Assistant Director for Procurement Office of Management Services

From: Assistant Solicitor-Procurement Division of General Law

Subject: Proposed Amendment to the Federal Procurement Regulations (FPR)--Institutional Patent Agreement

This is in response to your request for comments regarding the above referenced proposed FPR revisions.

A major concern about the proposed provisions would be that the Government should be assured to the greatest extent possible that inventions are promptly and effectively put into production and marketed if the Government is to allow the retention of principal or exclusive rights by educational or nonprofit institutions. Because such institutions do not typically have production and marketing facilities or established commercial channels, the risk that inventions developed under the proposed institutional patent agreements would not be successfully marketed is considerably greater than in the case of a commercial contractor. To minimize this risk under the proposed revision, we suggest the following changes and additions:

- Proposed section 1-9.107-6(c)(1)(D) should set a definite time limit on the exclusive licenses, but with provisions for allowing the contracting officer to extend the period for an individual contract if he makes a well supported determination that an extension is warranted. The length of the allowable extension should likewise be limited.
- Proposed section 1-9.107-6(c)(1)(G) should give the Government more discretion in excepting individual contracts or grants from the operation of the agreement. The Government should not have to make an affirmative



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showing regarding the "public interest" in order to except a contract, but should have discretionary authority to review each contract on its merits and elect whether or not to place the contract under the agreement.

- 3. Sections III(b)(ii) and III(c)(iii) of the "standard institutional patent agreement" set out under section 1-9.107-6(c)(2) should define what constitutes a "decision" not to continue prosecution of a patent application. Inaction for a specified length of time without adequate explanation should be deemed to constitute such a decision.
- 4. Section VI(a) of the "standard institutional patent agreement" should provide that when the agency prescribes a period shorter than 6 months for the filing of a patent application, this shorter period shall end no <u>later</u> than 30 days prior to the running of the statutory period. As presently worded, the section might be construed as providing that the shorter period could end no <u>earlier</u> than 30 days before the end of the statutory period.
- 5. Section III(a) of the "standard institutional patent agreement" should provide that in deciding whether to grant an extension on the institution's time for making its election, the Government shall consider whether the statutory 1 year period is running. If the period is running, no extension should be granted which would delay the election to within 60 days of the end of the statutory period.

We also note that the "exceptional circumstances" and "special situations" language of current FPR provisions are being used as justifications for the use of institutional patent agreements. We find this questionable, since such language has previously been used only in specific cases where it was determined to be in the <u>Government's</u> interest to make an exception in order to obtain research which otherwise would not be done. It is not clear that the proposed arrangement for institutional patent agreements fits this category, since the proposal appears to be of more benefit to the institutions than to the Government.

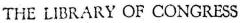
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Giving institutions an advantage not enjoyed by private concerns, which are generally in a better position to assure successful development and marketing, cannot be justified unless it is shown to be of special benefit to the Government in advancing the development of the technology. At present, no such benefit is apparent, and use of the "exceptional circumstances" and "special situations" language appears to be unjustified.

Our patent section has reviewed and condupred in thas response.

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stin P. erson





WASHINGTON, D. C. 20540

Administrative Department Procurement and Supply Division

September 13, 1976

Dear Mr. Read:

Your proposed amendment to the FPR's, covering additional provisions for Institutional Patent Agreements with educational and other nonprofit institutions, has been reviewed. No objections are noted.

Sincerely,

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Floyd . Hedrick

cc: John J. Kominski, General Counsel Office of the General Counsel

General Services Administration Mr. Fhilip G. Read Director of Federal Procurement Regulations Federal Supply Service Washington, D.C. 20406 The University of Georgia / Office of the Vice President for Research / Boyd Graduate Studies Research Center / Athens, Georgia \$

October 5, 1976

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

Dear Mr. Read:

The opportunity to present our views on the proposed Federal Procurement Regulations Amendment concerning patents growing out of federallysupported university research is appreciated. We are in total agreement with the principle of using an Institutional Patent Agreement to administer this important activity. In fact, we strongly recommend going a step further than your proposal in requiring all federal agencies to operate under one Institutional Patent Agreement. Where necessary additional legislation should be passed to permit this. Administrative costs for the universities and the Government would be greatly reduced.

The Institutional Patent Agreement form you propose has many positive features. We would, however, offer the following comments:

(1) It is a great waste of effort to have to renew IPA's periodically. The 30-day notice of cancellation provided is entirely sufficient, and we see no reason whatever to limit the life to three years or any other specific period of time. The cost of maintaining files for governmental and other documents and correspondence is already prohibitive, and IPA's for successive increments of time would undoubtedly add to this burden. This is especially true since it is highly probable that successive agreements will differ, making it necessary to administer each one separately for the life of any patents related to them. Therefore, we recommend that the agreement have no expiration date and that it be changed only for compelling reasons.

(2) In Paragraphs II(a) and (c) these definitions should be restated to include <u>only</u> those applications or uses of inventions which are developed under Government funding in those cases where inventions have been conceived and/or applied prior to such funding involvement.

(3) Paragraphs III(a) and V(a) require the University to report and make an election whether it will retain right and title to an invention within six months after its conception or first reduction to practice, whichever occurs first in the course of or under the contract. Paragraph VI(a) requires the University to file a patent application within six months after such election. It is our opinion that in a university situation it is unreasonable to expect that in all cases a patent application can be filed within 12 months after the conception of the invention. Reduction to practice can be very time-consuming because of the possible lengthy delays in funding and because university priorities are different from those in private industry. These provisions should be changed to allow the <u>election</u> and the <u>filing of patent applications</u> within six months following the conception or reduction to practice, whichever occurs last.

(4) In Paragraph IV(a), the Government's license to a subject invention should be for governmental purposes only rather than to "make, use, and sell."

(5) It is understandable that the Government should have the right to disclose, eventually, invention disclosures under the IPA (Paragraph V(c), Page 8). However, provision should be made to allow the filing of a U.S. Patent Application prior to any such governmental disclosure.

(6) We recommend the changing of wording on Page 9 in Paragraph VII(b) to specify that the Grantee shall furnish <u>promptly</u> a copy of each U. S. Paten Application with data filing and serial number, and shall <u>promptly</u> obtain and deliver a copy to the Agency an assignment form, etc. The information required here can be obtained only from the Patent Office and the University' reporting is subject to the timing of that office.

(7) Provision for the extension of the period of exclusivity in rare cases should be made.

(8) Paragraph IX(c) should specify that royalty-free sales to the Government shall be provided for in licenses, to be handled by licensees. It would be completely unthinkable to try and have universities administer royalties by licensee and by consumer and rebate to the Government those royalties on sales to governmental agencies.

(9) The IPA should provide in Paragraph IX(e) that licenses be made subject to the conditions of the royalty-free license to the Government and not subject to the conditions of the IPA itself. Any specific conditions which need to be provided for in licenses in order to meet the terms of the IPA should be stated briefly and concisely in the IPA for inclusion in licenses. Thus, the necessity of making the IPA a part of every license would be avoided, along with a great deal of paper work.

(10) The provisions of Paragraph IX(f) are contrary to public policy as applied in the Small Business Administration and other agencies of the Federal Government and the states. Individuals are encouraged to benefit from the application of Federal funds in innumerable cases when the public benefits in the long run. Government-supported inventions should not be an exception to this established public policy. Many thanks, again, for this opportunity to respond to the proposed GSA Institutional Agreement.

rdially J

Robert C. Anderson

BRA:ev

PURDUE RESEARCH FOUNDATION

WEST LAFAYETTE, INDIANA 47907

FICE OF PATENT MANAGEMENT

October 6, 1976

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

Subject: Proposed Institutional Patent Agreement

Dear Mr. Read:

Comments on the proposed Agreement follow:

- 1. Paragraph I stipulates that "This Agreement shall not apply to Subject Inventions in cases where the Institution is a subcontractor under a prime contract." We are unable to reconcile this statement with paragraph II(b) which states that "Contract" means any contract (agreement, grant, or other arrangement) or <u>subcontract</u>---" The Agreement should permit the Institution to retain rights to inventions under subcontracts. Such a change would encourage interinstitutional research.
- Paragraph V(c) stipulates that "The Institution agrees 2. that the Government may duplicate and disclose Subject Invention disclosures and subject to Section XI, all other reports and papers furnished or required to be furnished pursuant to this Agreement." At times it is not possible to license and/or evaluate the foreign market potential within the one-year requirement to file a foreign counterpart to a U.S. application. Such publication of the disclosure as stipulated in paragraph V(c) would prohibit filing in most foreign countries after the one-year period. A similar situation could result with respect to paragraph V(d). It is a policy of our Institution to encourage publication but at times such is not feasible until a complete analysis of the commercial opportunities is made in foreign countries.

P. G. Read October 6, 1976 Page 2

- 3. With respect to paragraph IX(b) stipulating that the period of exclusivity shall not exceed five (5) years from first commercial sale or eight (8) years from the date of the exclusive license, whichever occurs first, the eight-year limitation will be a problem when extensive premarket clearance of a product or device is required by the government. This paragraph should be modified to exclude from the eight-year limitation that time required by the government for premarket government clearance.
- 4. Paragraph IX(f). Some inventions have a very limited specialized market although they could make significant contributions. The public could best be served by licensing the technology to the inventor. Universities are probably more concerned than the government about conflict of interest. Prudent management dictates that the Universities be able to license where the use of the technology will be maximized. If this is the inventor, then such should be permitted without first having to contact a number of companies. For most inventions, the inventor would not have the capital to develop the technology.

Paragraph IX(f) should be modified to permit licensing the technology to the inventor without having to obtain permission from the agency when good management dictates licensing to the inventor.

The Institutional Agreement is the best approach to enhance technology transfer. The principle ingredient in technology transfer is the inventor. Without his dedicated effort, the invention is seldom successfully commercialized. By leaving title with the Institution, the inventor retains a vital interest.

Very truly yours,

R. E. Davis, Patent Manager

RLD/tp cc: Norman Latker

SOCIETY OF UNIVERSITY PATENT ADMINISTRATORS



PATENT BRANCH, OGC

DHEW

NCT 1 3 1976

October 5, 1976

PRESIDENT Mr. Ray Woodrow Princeton University P. O. Box 36 Princeton, N. J. 08540

PAST PRESIDENT Dr. George H. Pickar Patents & Lincensing University of Miami P. O. Box 249133 University Branch Coral Gables, Fla. 33124

VICE PRESIDENT EASTERN REGION Mr. Lawrence Gilbert Patent Administrator Boston University 881 Commonwealth Avenue Boston, Ma. 02215

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VICE PRESIDENT WESTERN REGION Mr. Clarence W. Martin Director Patent & Product Dev. University of Utah Salt Lake City, Utah 84112

SECRETARY-TREASURER Dr. Earl J. Freise Assistant Director Office of Research & Sponsored Programs Northwestern Univ. Evanston, Ill. 60201 Philip G. Read Director of Federal Procurement Regulations United States of America General Services Administration Federal Supply Service Washington, D.C. 20406

Dear Mr. Read:

Your letter of August 3, 1976 asked for our comments on the proposed FPR Revision covering University Patent Policy prepared by the Ad Hoc Subcommittee of the Committee on Government Patent Policy. Because of the exigencies of time and communication problems, I am not able to give you an official position endorsed by the members of the Society of University Patent Administrators. However, I have received copies of the comments submitted by a number of those members, and they have been used in preparing what I have to say in the following.

Enclosed herewith is a copy of my recent testimony before the House Subcommittee on Domestic and International Planning and Analysis. Towards the latter part of that testimony you will note that I have endorsed the concept of an Institutional Patent Agreement with reasonable and minimum requirements. The following comments on the proposed FPR Revision are, I believe, consistent with my prepared testimony and also with later comments during the hearing.

1. to add subsection (6) to 1-9.107-4 (a) During the hearing after the testimony discussed above, I took vigorous exception to making the IPA permissive and not mandatory (except of course where agency statutes do not permit it). Other FPR's are mandatory, why not the IPA? We need to go in the direction of one government, not a multiplicity of governments. Exactly the same invention can be made under a contract or grant from any agency, so it should be in the public interest that it be handled the same way.

Exactly the same comments apply to the provision that individual contracts can be excluded from the IPA. There are no guidelines given except the "public interest" later under 3 (G). Consistent with what I said in my testimony, that IPAs should have reasonable and <u>minimum</u> provisions, let the university administer the inventions, and then crack down if something particularly unfortunate happens. It is impossible to tell in advance of a contract what kind of inventions will be made, if any, so it is impossible to judge whether the IPA should or should not be applied.

3 (D)

I recommend deletion of the word "normally". Because of the fact that most inventions when they come out of a university are far from the point of commercial production and marketing, most inventions must be licensed exclusively, albeit for a limited period and even for a limited application, if the necessary investment is to be attracted.

I Scope of Agreement

It is not clear why the Agreement must expire after three years. There seems to be little gained, and a considerable amount of renegotiation and change of references will be added. Termination on 30 days notice is provided in XIII.

The last part of the first sentence would be deleted if comments under 1 above are accepted.

I object vigorously to the second sentence and the pertinent part of VIII with regard to subcontractor rights. These provisions completely overlook the equity of the inventors who are subcontractor employees as well as the equity of the subcontractor itself. The prime contractor has little or no equity. If the subcontractor has a valid IPA, it should get the same treatment as in a prime contract.

IV Minimum Rights Acquired by the Government

(a) In place of the phrase "make, use, and sell" in the fourth line, a phrase "practice and have practiced" as contained in ASPR 7-302.23 would be much preferable. For some inventions, potential licensees could be greatly turned off by having to compete with the Government in the marketing and sale of a product.

(a) With regard to the extension of the license to state and local governments, see my testimony. They have no equity. Administratively, the problem is an impenetrable maze.

(b) B In the hearing after my testimony I also referred to the very serious concern, to the extent of refusal, of potential licensee's to agree to license others if an "invention is required for use by governmental regulations or as may be necessary to fulfill public health or safety needs, or for other public purposes stipulated in the applicable contract". The problem is not so much that these are not worthy reasons, but rather that the decision may be made at a low level and without full consideration of all the facts and circumstances. Some assurances should be given that the decision will be made at a high level, with an opportunity for a hearing. V Invention Identification, Disclosures and Reports

Research Corporation comments are pertinent here.

VI Filing of Domestic Patent Applications

Again see Research Corporation comments.

VII Filing of Foreign Patent Applications

The time periods need to be flexible.

VIII Subcontracts

See last paragraph under I above. Subcontractor should have the same rights as it would have were it the prime contractor.

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

(c) As indicated in the Research Corporation letter, the royalty refund requirement would put a great burden on the universities. A much preferable procedure in my way of thinking would be to incorporate in any license a requirement that no royalty is to be included in the price of an item sold to the Government or for the Government's account.

(f) Stanford and Research Corporation have both written thoughtful comments on this section. The Government's concern is understandable. One solution that occurs to me is:

(1.) To have the section applicable <u>only</u> if the person or organization is the <u>sole</u> or exclusive licensee, since more than one licensee should be protection enough.

(2,) To delete the last sentence entirely. It is impossible to prejudge what the circumstances should be for Agency approval.

(3.) The word "financer" under (iii) needs better definition. Obviously it can't mean stockholder.

4 - new 9.109-7 Negotiation of Institutional Patent Agreements

(a) (9) It would seem that a description of institutional patent activities during the past five years would suffice, and even that will not prove a great deal for many institutions. A ten year history as called for can be a very big job.

(b) (2) A requirement that employees must assign to the institution or its designee or the Government is too inflexible. It does not allow for the unusual but occasional case where neither the institution nor the designee nor the Government wants to

Mr. Philip G. Read

prosecute a patent application, but the inventor does (many university patent policies permit this). Exactly the same protection would be provided by a clause stating "Agreements with employees requiring them to assign or license as directed by the institution any invention conceived....."

I hope that the above comments will receive your consideration. If we can provide any further information, or if discussion appears desirable, please let me know.

Sincerely yours,

red Raymond J. Woodrow

Raymond J. Woodrow President

RJW/dh

Enclosure

cc: Norman J. Latker David Eden SUPA members (w/e)

STATEMENT OF

RAYMOND J. WOODROW, PRESIDENT

OF THE SOCIETY OF UNIVERSITY PATENT ADMINISTRATORS

BEFORE THE

SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING

AND ANALYSIS

OF THE

HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

WITH REGARD TO

UNIVERSITY PATENTS AND FEDERAL GRANTS AND CONTRACTS

SEPTEMBER 23, 1976

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity of appearing before the Subcommittee today. My purpose in appearing is to discuss with you the treatment of inventions and patents in grants and contracts from the Federal Government to colleges and universities. The primary matters of concern in what I have to say are the public interest, inventors' equities and university equities.

I should say at this point that a significant portion of my statement has been based upon a 1968 paper issued by the Subcommittee on Patents and Copyrights of the NACUBO* Committee on Governmental Relations. My remarks can be considered to be those of a member of that Sub-Committee in addition to my speaking as President of the Society of University Patent Administrators. We are gratified that your Subcommittee is

*NACUBO stands for National Association of College and University Business Officers. examining the ownership of inventions resulting from Federally funded research and development, and especially gratified that the unique position of colleges and universities should be taken into consideration.

Universities by their very nature and by their charters have an obligation to serve the public interest. They do this in a variety of ways in a variety of endeavors. In order to do it effectively in the patent area, universities need to have a patent program which will make patentable inventions arising in the course of university research available in the public interest under conditions that will promote effective development and utilization.

It is said that the reason why many organizations apply for at least some patents is as a defensive measure to protect a commercial position. Universities do not apply for patents for defensive reasons, since they have no commercial position to defend. Their motivation is in the direction of seeking objectively the best qualified sources for delivery to the public on the broadest possible scale the results of their research.

Few university inventions are commercially practicable in the form in which they are conceived or reduced to practice in the University. Many, if not most, are in fact unanticipated byproducts of the research effort. Universities do not have the funds, the incentive or the expertise to develop patentable inventions to the point where they can be produced and marketed. Almost always, therefore, further investment is necessary in order to have an invention publicly available. What organization will be willing to make the necessary investment to bring an invention to the market without the kind of protection that a patent gives, protection from others who would pick the fruits without planting the tree?

As a result of what I have said, universities need to retain rights

-2-

to inventions whether made in the course of Federally funded research or otherwise. Patent applications can then be filed promptly and negotiations immediately commenced with prospective licenses, with the active assistance of the inventor, so that an invention can be developed to the point of public use. In some fields, such as drugs, agreements can be entered into for the testing of compounds with some protection for the testing firm's expenditures before it is even clear whether there is a patentable invention. By these means patentable inventions can be put into use widely and effectively. As a result, the public will benefit.

Where does the university inventor stand? University personnel, as compared with those in a commerical research organization, are employed and promoted with salaries which give <u>no</u> recognition to the value of any inventions they make. Their interests and in many ways their futures lie primarily in the publication of research results in the open literature. As a matter of equity, therefore, universities, without any exceptions that I know of, provide for a share of royalties from patented inventions to be paid to the inventor. This provides an incentive for him or her to spend the time and effort necessary to disclose an invention properly, to participate in invention evaluation, to work with patent attorneys, and to provide information and assistance to potential or eventual licensees. Without this incentive, and it must be an adequate incentive, experience shows that few inventions are disclosed, for the amount of persuasion which a university can effect with members of the faculty for disclosure is very limited.

In addition to the inventors, the university has an equity in inventions made using its funds or facilities. No matter who pays for the research performed, the payments are invariably for less than the full true

-3-

costs. With some exceptions the university has paid for the facilities needed. And it has a huge investment in accumulating and providing a highly competent cadre of personnel without which no Federally funded research would be possible. Should perchance lightning strike and a bonanza invention come forth, the university's share of any funds realized would by the terms of its charter be used for the public interest purposes of education, research and public service.

It is our firm and strong belief that the conditions of Federally funded research grants and contracts with colleges and universities should be consistent with and adapted to the factors I have discussed above. We have seen little evidence that Government ownership of university inventions will promote the public interest in the sense of development and production for public use, since the investment necessary to convert the professor's brainchild to a marketable product is not forthcoming. Government ownership gives the university inventor no incentive to disclose his invention and to divert time and effort to working with patent attorneys and potential users. The university has little incentive to obtain adequate invention disclosures and its equity in inventions is not recognized.

How about the Government's equity in inventions resulting from Government funded research in universities? This ought to be satisfied by a royaltyfree nonexclusive license for Governmental use. The Government thus receives the right to use royalty-free the results of the research which it paid for. Greater rights, such as title to inventions, are, for reasons I have already discussed, against the public interest because of the problems of development and marketing, and they vitiate the inventors' equity as well as the university's equity. The Government when it gives a contract or a grant for research is not buying an invention or inventions. One cannot contract for a patentable invention to be made which is as yet

-4-

unborn and even unconceived.

I have spoken about a royalty free license for Governmental use. In recent times Governmental use has been extended to use by state and local governments as well as by the Federal Government. This seems unfortunate and undesirable. State and local governments do not have an equity. Licensees balk at tracing the payment or nonpayment of royalties through the almost impenetrable maze of manufacturers, wholesalers, distributors and outlets in order to insure the some fractional royalty hidden in various markups is not being paid by a local township.

A provision for title in the Government with the opportunity for waivers is practiced by some agencies. Sometimes the waiver is granted in advance for a particular grant or contract for all inventions that may be made. Sometimes the waiver is granted after an invention is identified. My experience and that of my colleagues are not favorable in either situation. Waiver applications are complicated and costly. The agency criteria for granting waivers are difficult to satisfy and their administration demonstrates the typical bureaucratic tendency of being more stringent than necessary in order to avoid criticism. Waivers also often carry with them march-in requirements and other strings. Waivers on individual inventions after identification generally make it impossible to enter into drug testing agreements or other cooperative undertakings. Waivers put the shoe on the wrong foot. If what I have said earlier is true, there should be a very strong presumption that the country's interests are best served by vesting title to inventions in university contractors and grantees unless there is good and sufficient reason to do otherwise.

The question can be asked whether leaving title with universities for all inventions resulting from Federally funded research, with only

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a royalty free nonexclusive license to the Government, will adequately protect the public interest. If what I have said earlier is true, and I firmly believe it is, the probability should be very high that the public interest will be served. However, there may be the need for even greater assurances. In this case probably the best mechanism that has yet been devised is the Institutional Patent Agreement. The IPA as it is termed was first developed as far as I know by the Department of Health, Education, and Welfare and was more recently adopted by the National Science Foundation. The General Services Administration now has out for comment--and we are in the process of preparing comments--a proposed amendment to the Federal Procurement Regulations which would provide for Institutional Patent Agreements. If this FPR amendment is adopted, IPA's might then be available from all agencies except where the statutes prevent it.

Briefly the Institutional Patent Agreement is an agreement between an agency and a college or university covering the management of all inventions arising from agency grants or contracts to the institution, unless specifically excepted. As an advance condition the institution's patent policy and program must meet certain criteria. There are limitations on how patentable inventions can be handled, and the Government may require licenses or additional licenses if adequate progress is not made towards practical application, or for purposes such as fulfillment of public health or safety needs.

In place of the widely varying and often inequitable patent arrangement: now prevalent, we would greatly prefer that the Institutional Patent Agreement principle be applied to all Federal agencies in funding research and development at colleges and universities. This will mean a change in the statutes for some agencies, and a change in attitude in others. There will undoubtedly be some exceptions taken to the

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detailed requirements contained in IPA's since nothing is ever perfect, but we would hope that these requirements could be held to a bare minimum, with a termination of the agreement in the unlikely instance of a violation of the spirit of the arrangement, instead of the imposition of onerous conditions on everyone.

To summarize, I urge that the title to inventions arising from Federally funded research at colleges and universities be left with the institutions, that this be done with the Government receiving a royalty-free nonexclusive license for Federal Government purposes, and that the Institutional Patent Agreement with reasonable and minimum requirements, as the best method so far encountered, be the method for implementation. If these objectives can be accomplished, the public interest will be advanced and the equities of university inventors and of universities themselves will be satisfied.

RJW/dh

September 16, 1976

Dupliet

THE PENNSYLVANIA STATE UNIVERSITY

207 OLD MAIN BUILDING

UNIVERSITY PARK, PENNSYLVANIA 16802

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Vice President for Rescarch and Graduate Studies		ť	PATENT BRANCH, OGC		Area Code 814 865-6332
Federal Sup Washington,	vices Administration ply Service DC 20406 Mr. Philip G. Read Director of Federal Prov	curen	OCT 4 1976		1 Oct. 1976
Subject:	Proposed Amendment to F Institutional Patent Ag		· · · · · · · · · · · · · · · · · · ·		

Reference: (a) GSA 1tr to PSU, dtd August 5, 1976

Dear Mr. Read:

In response to your invitation for submission of my views on the proposed revision concerning Institutional Patent Agreements, the following is set forth:

The Pennsylvania State University has had a formal Patent Policy for over 50 years which is directed to the maximum utilization of inventions for the public good. The University has an Institutional Patent Agreement with HEW, negotiated in 1970 and recently reviewed and renewed in view of a new University Patent Policy. The University Patent Policy was approved under the DOD "list of approved patent policies" during the period that DOD used such a list. The above is set forth to document that the University is willing to cooperate with governmental procedures to enhance the transfer of University-generated technology to industry.

The "proposed FPR revision" is the third detailed patent procedure we have received recently which is considered to be moving in a direction counterproductive to meaningful university/industry technology transfer. The other two documents are the EPRI Patent Provisions and the latest ERDA Patent Procedures. The reasons these three documents may produce negative results are set forth below:

The three parties of vital interest must cooperate if University-generated technology is to reach the maximum utilization -- (1) the Federal agencies; (2) the University, including both faculty inventors and contract and patent administrators; and (3) industrial licensees to accept, develop, and market appropriate technology. The terminology and tenor of the proposed FPR revision is too strongly in favor of the Federal agencies without sufficient consideration and input from the university research community and potential industrial licensees. The general objectives of this proposed revision to the FPR can be achieved with a document that will be clearer and simpler, written in terminology which can be understandable to the average faculty researcher, i.e. simplicity and clarity overall is so desirable that an occasional loss of invention by publication and resulting "dedication to the public" by Statutory Bar may be preferable to a rigidized system without substantial inventor incentives. Specified comments are indicated below: Mr. Philip G. Read General Services Administration

The University considers that the provisions set forth in the present HEW Institutional Patent Agreement and their administration in the cooperative and sensitive manner are both desirable and effective. Any further encroachment on the inventors incentives and additional procedural complications by Institutional Patent Agreements will reduce the inventors incentive for making inventions and reporting them, and will reduce industry predisposition to invest capital in technology developed under these agreements.

Specific comments are:

Section V(a)(i) This section appears to make an absolute requirement for disclosure submission prior to any publicity. Many inventions, especially in the chemical and pharmaceutical arts, are developed in fragments and a valid patent application cannot be filed at a time prior to publication, since the necessary human physiological and toxicity testing has not yet been achieved. Many of our invention disclosures are triggered by a presentation at a national or international technical meeting and only obtained at that time. Additionally, many inventions are achieved in a manner that the inventors cannot be sure at what stage conception is achieved, especially with respect to chemical, pharmaceutical, and process inventions.

Section V(a)(ii) The words "authorized by or known to" the institution could be construed to require detailed administrative supervision of all presentations, seminars, and meetings; and all publications -- which are presently the responsibility of the principal investigator or research director.

Section V(b) It is not clear whether the "patent agreements" which are required will have to be in the same detail as the Institutional Patent Agreement itself. If so, and the Institutional Patent Agreement must, in effect, be incorporated by reference into the patent agreements to be executed by university employees, then it is critically important that these agreements be as simple, clear and concise as possible.

Section V(c) It is not clear whether this provision would permit the Government to publish an invention disclosure covering a pharmaceutical which was "conceived" but not yet actually reduced-to-practice, and upon which a valid patent application could not be filed because of a lack of human effectiveness testing.

Section VI(b)(i) and (ii) The period of two months set forth in each of these sections is too short in view of the delays in the Patent Office, and the fact that there should be no urgency in these submissions, i.e., six months would be better.

Section IX It is not clear what percentage of royalty income can be paid to the inventors, and it would appear from subsection (c) to 1-9.107-6"feature (F)" that only "incentive awards" could be paid to inventors, rather than a share of gross royalties which may be essential to obtain the inventors continuing cooperation necessary during the licensing and development effort needed to transfer technology to industry. Section IX(f)(i) and (ii) These two restrictions on licenses to organizations in which the inventor may be the catalyst for further development are considered to be negative, since they may eliminate the best mode of technology transfer -- the entrepreneurial enthusiasm of the inventive group. Further, the term "substantial financial interest" is vague.

Section 1-9.109-7(b)(3) The administration of this "identification" of inventions could be construed to require administrative surveillance of research, rather than placing the responsibility upon the principal investigator.

In summary, it is considered that more consideration should be given to the fragile nature of inventions and inventors -- which are the indispensable prerequisites of both invention administration and technology transfer. Without the enthusiastic acceptance and support of faculty inventors, the perfectly worded Institutional Patent Agreement will still produce a negative result. In the event GSA would be willing to have a committee of user organizations propose alternative terminology to that set forth in the referenced FPR revision, the University will make available the services of Dr. Robert F. Custard, our full time University Patent Counsel, to serve on such a committee or task force. A useful relationship could be created by a working committee in which the interests of the university and inventors and the industrial licensee/developer were represented in the selection of the terminology rather than the submission for "views" after drafting.

The University has utilized both Battelle and Research Corporation in the past and presently utilizes Research Corporation for our primary evaluation, marketing and licensing activity. It is suggested that Research Corporation should be invited to participate in the drafting of any final Institutional Patent Agreement regulations, since many universities without other resources have no other realistic alternative than to utilize the services of Research Corporation. We have found the services of Research Corporation to be a significant and valuable contribution to the national public interest with respect to University/industry technology transfer. GSA should recognize this "pioneering" contribution and invite their cooperation in developing a master Institutional Patent Agreement which would be acceptable to the U. S. Government and Research Corporation.

Please let me know how the University can be of assistance in this general area.

Very truly yours,

Richard G. Cunningham Vice President for Research and Graduate Studies

RGC-RFC:hw

cc: N. Latker W. Marcy

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EXECUTIVE DIRECTOR

Reagan A. Scurlock

Mr. Philip G. Read Director of Federal Procurement Regulations Federal Supply Service General Services Administration Crystal Square, Bldg. 5, Room 1107 Washington, D.C. 20406

Dear Mr. Read:

The one hundred participating institutions of the Committee on Governmental Relations, National Association of College and University Business Officers, welcome the opportunity to comment on the proposed Federal Procurement Regulations prepared by the Ad Hoc Subcommittee on University Patent Policy, concerning Subpart 1-9.1 Patents.

The COGR believes that university ownership of inventions arising out of government sponsored research is a necessary ingredient in the effective transfer of technology to the market place, since it:

- enables the university to grant to the private sector rights that, while limited, are commensurate with product introduction risks;
- (2) insures inventor participation in the development of the invention or product; and
- (3) encourages the university to bring together industry and inventors, thereby enhancing the probability of successful commercialization of the invention.

Moreover, vesting title to those universities that can qualify under the proposed regulations, represents a giant step forward toward fostering a technology transfer capability among universities that as yet have not been so inclined.

September 28, 1976

The comments below relate to the proposed Institutional Patent Agreement.

1. I. Scope of the Agreement.

Request deletion of the last sentence of the paragraph and substitute therefor:

"In cases where the Institution is a subcontractor under a prime contract of the Agency, the Agreement of the Institution shall govern."

Comments.

It sometimes is the case that an educational or nonprofit institution will grant a subcontract to the Institution. Under such circumstances, the inability of the Institution to acquire rights will tend to discourage interuniversity research and unfairly treat the university inventor who may well lose his equity interest in his invention. COGR institutions typically do not have patent policies that cover inventions that arise outside of the university. Moreover, the COGR institutions favor retention of rights by a sister institution as a matter of equity and fairness.

Finally, as a matter of law, the requirement to grant back rights to the prime contractor could, under certain facts and circumstances, be in violation of the anti-trust laws or construed as a patent misuse.

2. VIIZ. Filing of Foreign Patent Applications.

Section VIII should be changed to read Section VII.

Request Paragraph VII (a) (i) be changed to read as follows:

"ten (10) months from the date of the corresponding United States patent application filed by or on behalf of the Institution, or if such an application is not filed, six (6) months from the date a license is granted by the Commissioner of Patents to file foreign applications providing an election has been made pursuant to section III (a) of this Agreement."

Comments.

Good patent practice dictates that a foreign filing be made just prior to the end of the convention period. Especially in the case of university inventions, additional material is made available subsequent to the U.S. filing which becomes incorporated in a continuation-in-part. It is advantageous to base the foreign filing on the most complete disclosure available.

If no application has been filed, an export license would be required to foreign file. The time granted to foreign file should be the same as that granted in section VII (a) (ii).

3. VIII. Subcontracts.

Request deletion of (a) in entirety and substitute therefor:

"(a) Except as provided in (b) below, the Institution shall include in any subcontract where a purpose of that subcontract is the conduct of experimental, developmental or research work the "Patent Rights-Acquisition by the Government" clause, found at 41 CFR 1-9.107-5, or the "Patent Rights Retention by the Contractor" clause, found in ASPR 7-322.23 (b)."

Comments.

The above changes are required to conform to the changes proposed in paragraph 1 herein concerning Section I, Scope of the Agreement.

4. <u>IX. Administration of Inventions in which the Institution Elects to</u> <u>Retain Rights</u>.

Request deletion of Section IX9 (f) in its entirety.

Comments.

Universities, due to their special character, continually must exert their best efforts to protect their good name and the good name of their professors and researchers. The interleaving of interests of government, state, non-profit, and private sponsors dictates that the university exercise due care in its relations with the aforesaid parties. Frequent consultant arrangements between university professors and the private sector make it necessary for the university to inform its professors of their duties and obligations to the U.S. government, the university, and the consulting company with respect to patent rights that might arise out of work performed for the consulting company that also relates to sponsored work done by them at the University. Consequently, the university is well experienced in policing its own affairs that are sensitive in nature. Adverse or unfavorable reports by the media in this regard would be far more costly by way of loss of alumni funds and gift giving than any potential return from a highrisk, high-gain patent license venture. Accordingly, it is submitted that Section IX as drafted, is unnecessary in view of the university's sensitivity to the potential problems that might arise in this area.

Section IX requires efforts to license others first. Any such license will be time-limited, and the public interest will be protected thereby. A university should not be required to demonstrate that an invention has no takers before directly assisting in the transfer of technology to the marketplace. Moreover, the university is faced with a very real problem if it elects not to make an invention widely available, since it is quite likely that one or more of the trustees or alumni will want to know why his company was precluded from having an opportunity to license the invention. Hence, the university, when it decides to support an invention, must take this fact into consideration.

Therefore, the relationship of the university to those outside of the university community, by its very nature, is such that patent abuses are highly unlikely.

The university community believes that the proposed IPA presents an opportunity for a major improvement in the management of inventions developed under government sponsored research.

If you require additional information, please let me know.

Sincerely yours,

Reagan Scurlock

RS:dk

PHARMACEUTICAL MANUFACTURERS

1155 FIFTEENTH STREET, N.W. WASHINGTON, D. C. 20005 AREA CODE 202-295-2440

September 29, 1976

PATENT BRANCH, OGC DHEW

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

Dear Mr. Read:

C. JOSEPH STETLER

PRESIDENT

We appreciate the opportunity to present comments on the proposal to amend the Federal Procurement Regulations, at Title 41, Subpart 1-9.1, to include provisions for the Government entering into Institutional Patent Agreements with educational or other nonprofit institutions conducting research with Government funds. As requested, our comments are submitted in duplicate.

The Pharmaceutical Manufacturers Association is a voluntary nonprofit association comprised of 130 member companies engaged in the development and manufacture of prescription drugs and medical devices. PMA and its member companies advocate a strong United States patent system as an effective incentive for developing results of innovative research to commercial applications. Many PMA member companies have negotiated for patent rights with nonprofit institutions who operate under the Institutional Patent Agreement concept fostered by the Department of Health, Education, and Welfare and have entered into patent license arrangements with respect to patentable inventions made by these institutions in the performance of DHEW grants.

The Standard Institutional Patent Agreement, developed over the past several years within the Department of Health, Education, and Welfare, therefore, has facilitated the commercialization of the results of DHEW funded research through nonprofit institutions. The pharmaceutical company experience to date has been favorable. The DHEW IPA concept is consistent with the PMA position that the United States patent system should encourage as fully as possible the commercialization of the innovative results of both Government and privately-funded research.

> Representing manufacturers of prescription pharmaceuticals, medical devices and diagnostic products

We further endorse the extension of the Institutional Patent Agreement procedures to those civilian executive agencies subject to the Federal Procurement Regulations. Appropriate amendment of these regulations would allow a Government agency to enter into Institutional Patent Agreements with educational and other nonprofit institutions which have acceptable technology transfer programs. In our view, the use of such agreements would recognize and retain the incentives of the United States patent system to obtain prompt commercialization of the results of Government-sponsored research, with appropriate safeguards to the public interest.

If we can be of additional assistance to you in consideration of this subject, we will be happy to provide whatever additional information is needed.

Respectfully submitted,

C. Joseph Stetler

- 2 --

AEROSPACE INDUSTRIES ASSOCIATION OF AMERICA. INC.

1725 DE SALES STREET. N.W., WASHINGTON, D. C., 20036 TEL, 347-2315

September 27, 1976

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

Dear Mr. Read:

This is in reference to the proposed amendments to the Federal Procurement Regulations dealing with patents, transmitted by your letter of August 3, 1976 to Mr. Karl G. Harr, Jr., President of this Association.

In view of the subject matter of the proposed amendments, this Association has not formulated a position thereon. However, comments received from a member company, copy attached, were thought to be of such significance as to warrant being forwarded informally for your consideration.

Very truly yours,

Thing Olhhan

Franz O. Ohlson, Jr. Vice President Aerospace Procurement Service

FOO:ph

Attachment

Proposed Amendments to Federal

Procurement Regulations on Patents

The idea of leaving title to subject inventions with the Institution where the inventions are made is good, but some of the conditions for qualifying under the program are highly objectionable. Section VIII of the proposed agreement, for example, requires R&D subcontractors to assign their subject inventions to the Institution or to the Government; Section IX, subsection (f) prevents the Institution from granting license rights to employee inventors or to organizations with which the inventor(s) is connected; and Section X prohibits assignment of subject inventions to anyone other than a patent management organization approved by the contracting agency. These conditions are counterproductive and discourage the making of subject inventions and the utilization of the inventions.

Qualifying subcontractors should be allowed to retain at least a defeasible title to their subject inventions, and inventors and their associates should be allowed to participate in achieving utilization of their inventions through licensing or otherwise.

As you well know, there is generally no one more dedicated to achieving utilization of an invention than the inventor, particularly when he stands to share in the profits of a successful venture. Why then tie the hands of these people and their business associates and principals by limiting their participation?

The restriction against assigning rights to anyone other than an approved patent management organization is likewise objectionable as discriminatory and void of any useful purpose in achieving utilization of subject inventions. While reasonable conditions such as granting only a title which is defeasible for failure to achieve utilization might be appropriate, there is no apparent reason why such an assignment should not be available to any qualified applicant willing to accept the same conditions.

The Government procurement patent policy pendulum is showing signs of swinging back from a title-taking position to a license position. Industry should encourage this movement and help guide the return so that the patent system will be able to better serve the public interest in Government funded R&D.

Conditions in regulations which prevent the inventor and those closest to the invention from participating in its commercialization should be opposed. At the same time, however, reasonable conditions aimed at protecting the public against unbridled or unwarranted private economic gain from Government funded research should be recognized as proper. In this regard, the requirements in the proposed amendment to the regulations that the Institution use its royalty receipts, after payment of administrative costs and incentive awards to inventors, for educational or research purposes should not be objectionable.

UNIVERSITY OF WASHINGTON SEATTLE, WASHINGTON 98195

Government Fiscal Relations and Patent Office 275 Administration Building AG-70

September 23, 1976

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

Dear Mr. Read:

Thank you for your letter of August 5, 1976 inviting comments on a proposal to extend the Institutional Patent Agreement (IPA) concept to all Federal granting and contracting agencies.

The University of Washington has had such an agreement with DHEW for nearly eight years, and we are pleased to note that action is moving forward towards a fuller implementation of the concept. We believe that the Committee on Government Patent Policy has adequately identified the several benefits of using an IPA at approved institutions. In our view, the most beneficial aspect of the IPA is that it establishes a <u>certainty factor</u> that enables the University to move forward promptly with technology transfer arrangements.

In general, we are satisfied with most of the provisions in the proposal you sent to us for review. We are also pleased to note the absence of any clause limiting the maximum amount of royalty income that the grantee-contractor may pay to faculty or staff inventors. Such restrictions are difficult to state in relationship to the various institutional policies, and we feel that the royalty arrangements should be one of the factors, among others, in the total institutional proposal, i.e., on a case-by-case basis.

The remainder of our comments are keyed to the proposal you sent to us:

I. Scope of Agreement

This section suggests piecemeal application of the IPA to the institution's grants and contracts by providing for a cut-off date beyond which contracts would not be affected by the IPA. We think that a complete cut-over would be simple and preferable for all inventions identified after the date of the IPA, irrespective of how long the specific contract had been in effect.

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Mr. Read (cont) 9/23/76 Page Two

V. Invention Identification, Disclosures, and Reports

Since grantee or contractor's proposals may contain information of patent significance, we recommend that an additional sentence be added to Clause V(d): "The Government agency will take reasonable steps to insure that data or information furnished by the Institution is not released to the public before the agency obtains confirmation from the Institution that the proposed release will not adversely affect the patent interests of the Institution and the Government."

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

We do not agree with the provisions of subparagraph (c) under this section. The Government, rather than the Institution, should have the responsibility to monitor its procurements and claim royalty exemptions at the time of purchase. Moreover, it is not reasonable for the Government to look to the Institution and/or the inventor for royalty refunds (perhaps applicable to transactions occuring several years in the past) if the Government mistakenly pays the full price to a licensee rather than the royaltyfree price.

Notes for Completion of IPA

Item 6 suggests that an agency may restrict the IPA to contracts (and exclude grants, for example). We cannot foresee any logical circumstances justifying the exclusion of grants. To the contrary, such exclusion would be counter-productive towards achieving effective technology transfers. We recommend that Item 6 be deleted.

Information to be Submitted by Institution

Sub-clause (a) requires the applicant to furnish detailed data regarding invention and patent administration experience covering the past 10 years. In our opinion, it will be burdensome for most applicants to develop the required statistics for so many years back. We believe that data covering the most recent five years would be adequate to demonstrate the applicants' experience, and would not require as much research of past records in order to summarize the requested information. Mr. Read (cont) 9/23/76 Page Three

The above-stated comments are intended as constructive suggestions to hopefully improve an otherwise excellent proposal. The efforts of the Committee on Government Patent Policy and your office are commendable.

Sincerely yours,

Wallace C. Treibel Government Fiscal Relations and Patent Officer

WCT:mb

cc: Mr. Adkisson Dr. Geballe Mr. Latker Mr. McCartney Mr. Ryan Mr. Scurlock

RESEARCH TRIANGLE INSTITUTE

RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709

September 10, 1976

Mr. 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 Sir:

Thank you for giving me the opportunity to comment on the proposed amendment.

I have a few comments but first I want to say that it takes a big step in an important direction. I fervently hope it is accepted by all agencies that support university and non-profit research and development because I believe it will go a long way toward introducing technology to the market place where consumers can benefit therefrom.

My comments pertain to the criteria set forth for the institution's technology transfer program. The wording in subparagraph (5) of 1-9.107-7(b) is quite satisfactory. To quote, the institution must have "an active and effective promotional program for the licensing and marketing of inventions." However, in other sections of the Revision and in the sample IPA, there are strong implications that the government has in mind certain currently existing patent management organizations. See for example the emphasis in Section X of the sample IPA on "organizations" rather than "capability." Indeed, the Report of the Interagency Patent Policy Committee went so far as to name two organizations.

There are disadvantages, as well as advantages, to the current nationally known patent management organizations. One prominent disadvantage is that they are self-serving, i.e., they seek patents that will bring them the most income and those that will have a short-term pay-off. There are many inventions which are useful to industry, and through industry useful to the consumer, in which the potential pay-off is below the interest threshold of these companies but is still economically valuable. One accusation that has been made is that they skim the cream off the top.

A further criticism is that they are too far from many universities to provide the personal touch that most inventors need. I would like to see universities encouraged to establish their own technology transfer function or to use local institutions (The University of North Carolina at Chapel Hill and North Carolina State University in Raleigh have arranged with the Research Triangle Institute to undertake their patent management activities). This

(919) 549 - 8311

FROM RALEIGH,

IGH. DURHAM

Mr. Philip G. Read September 10, 1976 Page Two

also creates the environment whereby a greater patent awareness can be brought to the university research staff. I am not encouraged by the results of the Patent Awareness program of the Research Corporation at the three universities I have observed. Inventors have a strong suspicion of the "traveling salesman" or the "big-city slicker." An effective local capability gets around these problems. I do agree that a demonstrated patent management or technology transfer capability must exist before an IPA is made. Therefore, universities starting their own program must accept case-by-case negotiations of inventions until they have demonstrated their capability or use an existing organization while they develop such capability.

In order to accomplish what I would like to see, I suggest that in Section X of the sample IPA the word "organization(s)" be changed to "agent(s)" including the section title. This should not cause confusion with the word "Agency" if agent is always modified by the words "patent management." In the present version, six of the eight times "organization(s)" is used it is so modified. It would cause no problem to properly modify the word "agent" the other two times it is used.

To make the Revision consistent with this suggestion, the words "patent management organization(s)" appearing elsewhere should be changed to read "patent management agent(s)":

Paragraph (I) of subsection (c) of 1-9.107-6 (Page 3) Item <u>9</u>/ of Notes for Completion of IPA (Page 18) Paragraph (7) of the new section 1-9.109-7(a) (Page 20)

Further, the information requested in subparagraphs (9)(ii) through (9)(vi) of section 1-9.109-7(a) should be broken down by the patent management agent used. This will give the Agency an opportunity to evaluate the effectiveness of the current patent management agent in those cases where a change may have been made recently.

Gentlemen, I applaud your efforts and the results of those efforts. I look forward to seeing this policy widely used by government agencies. Thank you again for the opportunity to comment.

Sincerely,

alph L.

Ralph L. Ely, Jr., Director Office of University Relations

RLEjr:cd

cc: Norman J. Latker

STANFORD UNIVERSITY STANFORD, CALIFORNIA 94305 Area Code 415 497-3567

OFFICE OF TECHNOLOGY LICENSING ENCINA 6-930

September 8, 1976

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

Subject: Proposed Federal Procurement Regulations dealing with Institutional Patent Agreements with Educational and other Non-Profit Institutions

Dear Mr. Read:

This letter will comment on the proposed standard Government Institutional Patent Agreement with educational and other non-profit institutions, which document was provided with your letter dated August 5, 1976. As a general comment, we wish to observe that the proposed uniform regulations are a substantial improvement from the varying regulations of the various agencies and should enhance the flow of technology to the public from research conducted at the country's educational and other non-profit institutions. The following are directed to revisions which we believe will enhance the utility of the Institutional Patent Agreement (IPA) and its administration both by the universities and other non-profit institutions as well as by the government agencies.

Exclusion of certain contracts from the IPA. 1. An intent of the IPA is to reduce the administrative burden on both the agencies and the universities. However, the clauses which pertain to excluding certain contracts from the IPA will add to the administrative burden. It is noted that the very successful HEW IPA does not have such a provision. With such a provision for exclusion of certain contracts, there is then a requirement on the part of the agency grant and contract administration personnel to have grants and contracts reviewed by the agency patent personnel to determine, using unspecified criteria, whether or not a . particular grant or contract should be excluded from the IPA. From the contractor's point of view, the contractor must then deal with exceptions to a standard operating procedure which is administratively cumbersome. It can

Mr. Philip G. Read September 8, 1976

> be observed exceptions to normal rules in administrative requirements are similar to exceptions in the English language in terms of complicating something simple.

It is not clear why the ad hoc subcommittee of the Committee on Government Patent Policy of the Federal Council for Science and Technology saw fit to include this requirement. If there isn't any documented history of abuses leading to the need to have such a provision, we strongly recommend that the clauses pertaining to exclusion of contracts from the IPA's be deleted. (Depending on the motivations of the subcommittee for including this requirement, the reasoning of paragraph 6 below may also call for deletion.)

2. Requirement to normally license non-exclusively. Paragraph (C) of the proposed new subsection (C) to 1-9.107-6 specifies: "A requirement that licensing by the institution will normally be non-exclusive except...". In actual practice, because of the undeveloped nature of university technology, a first license will "normally" be exclusive, not non-exclusive. We recognize the intent of this paragraph is to insure that, where possible, first licensing will be done on a nonexclusive basis, and we have no objection to the intent. However, the subparagraph wording is somewhat misleading, particularly to institutions beginning a licensing program. We thus recommend revised wording such as: "A requirement that the institution make subject inventions available on a non-exclusive basis except...".

3. The inapplicability of the IPA where the institution is a subcontractor (last sentence of Article I of the IPA). It is not clear why the IPA does not apply where the institution is a subcontractor. It would appear the logic of using an IPA applies equally well to subcontracts as well as prime contracts.

4. <u>March-in rights for public health or safety needs</u> or for other public purposes. Subparagraph IV.(b)(B) covers march-in rights for the government to require granting licenses to the extent that the invention is required for public use by government regulations

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> or as may be necessary to fulfill public health or safety needs, or for other public purposes stipulated in the applicable contract. The need to include this subparagraph is well understood. However, on its surface, it is a potential danger to an exclusive licensee that may be planning to invest substantial risk capital in the development of an invention. This is particularly appropriate in inventions in the health field, where very large sums are expended at risk before first public marketing. It will be helpful if the IPA can include an assurance for potential licensees that this subparagraph is only invoked in rare situations when certain specified conditions occur.

5. Filing of foreign patent applications. Article VII a. specifies certain time periods for filing foreign patent applications (note Article VII is mislabeled as Article VIII). This article also provides that the specified periods can be extended if approved in writing by the agency.

While we can comply with paragraph VII(a), it appears to be an unnecessary and possibly counterproductive "overcontrol." It is readily observed that additional administrative effort is required both on the part of the agency and the institution to follow both the arbitrary periods of VII(a) and actual bar The requirements, intended to administratively dates. insure foreign filing dates are not missed, may possibly be self-defeating of that goal because an institution's licensing officer may be lulled into overlooking the need to take into account many other timing considerations with respect to a foreign filing program than indicated in these paragraphs. For example, if publication has occurred, and the U.S. patent application is not filed until after such publication, an institution still can obtain patent protection in West Germany and Japan if they file within six months of the publication. Other factors also come into play such as the need to obtain an export control license before filing abroad in certain cases, such as filing in Japan after publication but less than six months after the U.S. filing.

As a further observation, in a dynamic licensing program of undeveloped technology of uncertain value, more often than not corresponding foreign patent applications are filed <u>after 8 months from the date</u> of the U.S. application. VII(a) then requires both the agency and the institution to set up procedures to follow artificial dates, to request and issue approvals for variations from those artificial dates. Economic forces and practical considerations will drive filing before bars, not arbitrary time periods. We recommend that subparagraph VII(a) end after the word "regulations" in line 5. (It is observed Article VI which covers filing of domestic patent applications could similarly be shortened for similar reasons.)

In regard to subparagraph VII(b), we recommend, to reduce administrative burdens upon both the agency and the institution, that rather than notify the agency after filing of each foreign patent application, that data regarding foreign applications filed be included in the annual report.

6. Approval to license. Subparagraph IX(f) prohibits the granting of licenses to certain persons or organizations who have been involved with research leading to the invention, even on a non-exclusive basis, except after organizations which have no involvement decline to license. Rather than having the three criteria indicated in that paragraph treated as prohibitions, the IPA should encourage institutions to make arrangements meeting one or more of the criteria, and on an exclusive basis.

The critical ingredient to any transaction which will transfer a research advance to a product available to the public, in our free enterprise system, is economic incentive. It is apparently perceived a conflict of interest will exist if an individual or organization associated with an invention conceived under government sponsored research becomes motivated by economic factors, and this result will be contrary to the public interest. Clearly, if government funds are diverted from a grant or contract to private pockets, this economic motivation is both corrupt and contrary to the public interest. But being motivated to make money by investing effort and capital at considerable risk in development of a research advance to a product, and then succeeding in making that money (in spite of well known odds against such success) appears both appropriate to our economic system and very much in the public interest.

We also note IX(f) will prohibit licensing by Stanford to Hewlett Packard, Varian and many

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more companies because of our clear role as "promoter, organizer, or financier" in those companies (unless other companies in their markets all decline to license). In addition, it is not clear if the definition of "financier" extends to companies represented by investments of our endowment.

The challenge to the ad hoc subcommittee is to develop mechanisms to achieve the goal of early and broad transfer of research findings under government financed research to public use and benefit. The subcommittee has chosen the free enterprise system in lieu of the option of government development or the option to do nothing. Subparagraph IX(f) is in direct contradiction to the correct decision of the subcommittee and to the achievement of its goal. It is ironically also in direct contradiction to programs of the National Science Foundation-Research Applied to National Needs and the Small Business Administration. We strongly recommend that subparagraph IX(f) be deleted in its entirety.

The key to successful implementation of the IPA will be both the process of selection of institutions eligible for the IPA and the provision for termination on 30 days notice for convenience. Thus, if an institution performs incompetently (habitually missing bar dates, for example) or abrogates IPA provisions in letter or spirit, the IPA can be promptly terminated. The funds saved by reducing government administration could beneficially be utilized to improve licensing programs of the institutions--but not the point of removing the risk from their risk/reward equation.

We appreciate the opportunity to have been able to comment on the proposed IPA with educational and non-profit institutions. If amplification of the foregoing comments will be helpful, or if there are any questions, we will be pleased to cooperate.

Very truly yours,

Niels J. Beimers

Manager, Technology Licensing

Norman Latker, DHEW David Eden, Dept. of Commerce Urban Faubion, Stanford Research Institute Howard Bremer, Wisconsin Alumni Research Foundation Philip Sperber, Cavitron Corp. Norman Jacobs, Amicon Corp. Clive Liston, Stanford University

cc:

COUNCIL OF DEFENSE AND SPACE INDUSTRY ASSOCIATIONS (CODSIA)

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14 September 1976

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

Dear Mr. Read:

The member associations of the Council of Defense and Space Industry Associations (CODSIA) appreciated the opportunity provided in your letter of 3 August 1976 to comment on a proposed amendment to the FPR dealing with Institutional Patent Agreements with educational and other non-profit institutions having a technology transfer program meeting specified criteria. However, in this instance, the member associations of CODSIA will not be submitting coordinated comments through CODSIA.

It may be that one or more of the member associations might submit separate comments directly to you.

Sincerely,

George E. Young Hood

Administrative Officer

GEY/m