manpower and other costs as well as provide desirable visibility." [Emphasis added.]

The report indicates that of the $17 billion spent during Fiscal Year 1973 on Federally-supported Research and Development, $935 million went into the collection, organization, and dissemination of technical and descriptive information. Only $43 million of that amount -- or .25% of the total $17 billion -- was authorized to encourage technology utilization.

More specifically, the report continues:

"Moreover, there is a lack of personnel slots and no specific Civil Service Commission job descriptions exist for those engaged in technology transfer-utilization activities. This is a factor inhibiting the implementation of programs and the recruitment of expert personnel. Without a Federal policy designed to overcome these constraints, there will continue to be a poor environment in which to accomplish the objectives."

"Therefore, (the report continues) the Committee recommends that the Federal Government:

- Empower appropriate Federal agencies to set up explicit programs as an added part of their missions with specific charter and guidelines for embarking on these secondary or horizontal applications programs.

- Make technology utilization a line item in the budgets of Federal agencies in order to provide appropriate funding.
- Create new Civil Service designations and job descriptions to cover personnel with program skills and expertise. The Civil Service Commission should recognize the profession of technology utilization agent and establish a separate classification series within the General Schedule system from beginning positions to senior executive levels."

Without agreeing entirely with all these recommendations, I believe we can all agree that there has not been adequate attention paid to properly organizing and funding technology transfer functions either within the Government or at universities and non-profit research centers. But most disturbing is the fact that notwithstanding the identification of the problem, the ERDIP program, which appeared responsible for implementing possible worthy recommendations, has been abolished. Without such an organization, it appears that the burden of voicing the needs of technology transfer will be returned to the existing, but fractionalized, technology transfer groups. Successfully arguing such needs may be quite difficult in light of the fact that so many who work on transfer do so on a volunteer basis along with other regularly assigned duties. However, I believe that

these problems are intrinsically tied to the patent rights problem in which you are, by necessity, involved. Accepting involvement in voicing the organization and funding problem should enhance the possibility of early resolution of the patent rights problem.

In conclusion, I think it can be said that at this point in time, technology transfer functions, with some noteworthy exceptions, fall within the "approved but not funded" category. Because of the important service they afford in delivering technology to the public, I believe they are deserving of a higher priority among those seeking available Federal funds.

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8. The Committee on Appropriations Report No. 93-1146, accompanying DHEW Appropriation Bill H.R. 15580
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   National Academy of Engineering, 1974
10. "Legal Incentives and Barriers to Utilizing Technological Innovation" -
    Harbridge House, Inc., 1974

11. President's Message to Congress -

March 16, 1972, on "Science and Technology"

12. Conference Report on S. 1283, Federal Energy Research and

Development Program -

December 11, 1974, Congressional Record, P. H-11653

13. "The Organization Man" -

William H. Whyte, 1956

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CURRENT TRENDS IN TECHNOLOGY TRANSFER

Address by Norman J. Latker, Patent Counsel, Department of Health, Education, and Welfare, at Third Annual University/Industry Forum - Technology Exchange - The Pick Congress Hotel, Chicago, Illinois - February 3 - 7, 1975 - Sponsored by Dr. Dvorkovitz & Associates

I would like to call attention to the fact that the views expressed here are my own, and do not necessarily represent those of the Administration or the Department of Health, Education, and Welfare.

With the increase in our economic problems, there is naturally an increase in the media of suggestions on how we might resolve our difficulties. Of course, I, like you, read and listen in the hope that someone really can provide a quick solution.

Henry Kissinger, probably noting our frustrating search, recently said, "America's problem is that it tends to direct its attention to dealing with and solving immediate problems, while the necessity is for discipline and foresight to carry out necessary measures that cannot in advance be proven to be necessary." He went on to say that current problems demand that industrial nations enter "a new era of creativity and cooperation." Now, I am sure Dr. Kissinger meant creativity in its broadest sense, but I'm also certain he did not mean to exclude the kind of creativity that this audience is concerned with. In fact, his theme of "creativity" is clearly identifiable in a number of statements that can be generically described as calls for increased technological investment for the purpose of increasing productivity and defusing inflation. In fact, by definition, inflation is a condition where money exceeds the goods available for purchase. Thus, it seems that each new process, material, or device delivered to the market which satisfies a need not previously filled, or at a cheaper price than previously offered, aids in overcoming inflation.

Dr. Simon Ramo of TRW, echoing Dr. Kissinger, indicated recently that "Technological development is a basic, but not a short-term solution to inflation. To realize the benefits a few years ahead, we should lose no time in creating new conditions favorable for maximum research and development." Nearly invariably, along with statements like Dr. Ramo's, comes a call for Government policies which encourage technological development. Some of the specific policy recommendations, among others, include increased subsidization of research.

Subsidization of research of a more fundamental nature may be especially important in light of evidence that the economic climate has speeded an already existing preference in the industrial sector toward small improvements in existing products. This, of course, is a movement in an opposite direction to that which seems entirely desirable.

If, in fact, the above is correct, then we are led to the conclusion that, more than ever, the most likely source of fundamental innovations would be universities, non-profit, and Government research centers, or independent inventors. Twenty years ago William H. Whyte stated in his popular book, The Organization Man, "It is to be expected that industry should spend far less of its time on fundamental research than the universities, and for the same reason, it is to be expected that the most outstanding men would tend to stay in universities."

Thus, it would appear most likely that the initial work in new fields as dramatically innovative as Xerox, radar, computer memory cores,

lasers, Polaroid, antibiotics, and, more recently, holography, will continue to emerge from sources other than the industrial sector. Whyte explains this by pointing out that every study he had noted indicated that the most dominant characteristic of the outstanding scientist was fierce independence. Noting some of the scars on my colleagues in the audience, I doubt if we're going to get much argument on that. Now, fierce independence is a characteristic that one would not expect to be appreciated by an industrial organization interested in sharpening up existing products, but is still a trait which, whether appreciated or not, has been unsuppressible at our universities.

Leaving, for a moment, the discussion of likely sources of fundamental innovations, I would like to pass on to another group of reports less publicized than the media items mentioned above, but no less important. During the past year there has been an increasing number of reports, both public and private, similar to those we've seen in the past, suggesting the need for increasing the effectiveness of transferring technology from those generating it to those who could make best use of it, or at least the establishment of means to document the flow of research funds into practical results. Probably the most pointed was the following comment made in the Senate Conference Report on DHEW's Appropriation Bill:

> "Throughout this entire report the Committee through its increased funds and report language has shown its strong

support for both basic and applied research programs. The Committee should note however that neither of these research approaches is valid unless the information received from them is properly utilized. . . . . The hearings have been held and the Committee is registering its complete disappointment with the NIH and the Institutes' efforts in disseminating information. In testimony after testimony, the Institute Directors talked of how many new pamphlets had been printed or possibly how many conferences had been attended. This is clearly a very weak effort and the Committee instructs the Director of NIH to develop a specific course of action in helping to improve the situation as it presently exists. All programs within the NIH are to be consulted and a complete action report with recommendations and a plan for implementation is to be given the Committee no later than 4 months following the enactment of this bill.

"Information dissemination is a very high priority of this Committee because it directly affects just how quickly the research findings accomplished by the NIH are actually put into practice. The Committee notes that all of the research supported by NIH is undertaken in the expectation that it will ultimately contribute to the development of better prevention, diagnostic or therapeutic measures. That is and should be the mission of each of the Institutes.

> Until citizens actually receive some type of assistance from the many facets of research carried out by the NIH the total tax dollar has not been effectively utilized."

Though not explicit, little doubt is left as to whether Congress is concerned about technology utilization.

At this point, I think it very important to emphasize the obvious. The groups most in need of making transfers are the same parties that I previously identified as the most likely sources of fundamental innovations -- universities, non-profit, and Government research centers, or independent inventors. It is these sources that must obtain the cooperative aid of industry, the most likely transferee, since they ordinarily do not have the means of delivery to the market. It is true that industry does involve itself in licensing other industrial concerns in order to create a new market for an invention, if outside its field of interest. But this is not the area where the reports perceive problems. The area of concern involves transfers from fundamental innovators to sophisticated industrial developers.

Most of these reports implicitly indicate that inherent to the transfer process is a decision on the part of the industrial entrepreneur on whether the intellectual property rights in the innovation being offered for development are sufficient to protect its interests. Now, we all know that not all transfers include an exchange of intellectual property rights, but it is unpredictable as to which transfers the entrepreneur will consider to require such an exchange. We do

know, however, from experience, that where substantial risk capital is involved, there is a likelihood that transfer will not occur if the entrepreneur isn't afforded some property protection. This was discussed in the context of DHEW research in the 1968 GAO Report, Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry.

Now, this leads to the obvious, but not yet substantially implemented, conclusion that in order to afford the correct property exchange from the fundamental innovator to the industrial developer at the right time, the innovating group must identify, disclose, and establish rights in more intellectual property than it will exchange through the timely management and intelligent intellectual property policies. Because of this necessary property protection, investigators must be taught to think ahead, since the patent laws are written against those who delay protection. [Cite Mayo case.] This type of management can only be afforded by personnel willing to acquaint themselves with the basic principles of intellectual property protection and the ability to communicate to investigators its importance in the transfer mechanism. Stated another way, it may be said that patent licensing and technology transfer are substantially overlapping mechanisms or near-synonymous terms.

It is axiomatic that if you want to hasten technological solutions to current problems, you not only increase funding of research and

development, but, to my mind, first (and maybe instead), do something to close the identified gap between fundamental innovators and industrial developers. I believe the closing of the gap where further Government development funds are unavailable requires the solution to two not entirely separate problems:

(1) Assurance that the innovating group has the right to convey whatever intellectual property rights are necessary to accomplish a transfer; and

(2) A management focal point in the innovating organization trained to elicit and establish rights in intellectual property on a timely basis.

It would seem that the second problem cannot be finally resolved without the incentive of a solution to the first problem. However, the larger the number of sophisticated patent management groups, the more likely the solution to the rights problem.

In the last year, it is apparent that you have made unprecedented strides toward solution of the rights question. At the beginning of the year, you were faced with a set of patent clauses attached to the Energy Bill reported out of the Interior and Insular Affairs Committee which were entirely inimical to technology transfer. Even after a number of attempts by some of you to explain the problems of transfer, the Committee agreed only to an amendment which recognized some differences between the universities and industry, but

which did not provide the guarantee of rights necessary to accomplish successful technology transfer. It was only after this group was instrumental in precipitating a House floor fight which led to the deletion of the initial patent clauses with its amendments that the Administration gained the bargaining power which enabled negotiation of the finally enacted energy patent clauses. As you know, these clauses, although indicating that the Government will normally retain title to all patentable inventions, do provide in the Administrator the right to waive title to any invention or class of inventions, either at the time of contracting or upon identification, provided he makes certain considerations, as well as including specified march-in rights and conditions deemed necessary in the public interest. In the case of non-profit educational institutions, the Administrator is directed to consider before waiver the extent to which such institution has a technology transfer capability and program approved by the Administrator. Now, the guarantee of rights in the universities and non-profit organizations hoped for has not been provided by the legislation, but more importantly, it also has not been denied, as originally suggested. You are basically left in the position of explaining your needs to the Administrator, who, in my opinion, has all the authority necessary to resolve in ERDA the technology transfer problem as it is affected by patent rights.

Also on the bright side, keep in mind that this legislation, for the first time, weighs the significance of a technology transfer

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capability at universities. This carries with it the understanding that the disposition of patent rights generated with Government funds may be different, depending on whether the innovating group is a university or a profit-making organization.

In addition, you should also note that within 12 months after the date of enactment, the Administrator, with the participation of the Attorney General, the Secretary of Commerce, and others designated by the President, is to submit to the President and the appropriate Congressional committees a report on the administration of the patent clauses. If administration of these clauses does not meet the needs of technology transfer, the legislation and the Conference Report invite you to make your feelings known.

You may wish to consider this under any circumstance, since review of the original hearings before the Interior and Insular Subcommittee indicates no explicit attempt to set out the university position, with the exception of some generic coverage by Dr. Ancker-Johnson. Of possible importance is the fact that the required report will not go to the Interior and Insular Committee of the House, but to the Science and Astronautics Committee, which is perceived to have a greater understanding of technology transfer problems on the basis of past experience than Interior and Insular. Further, to the extent that this legislation may serve as the basis for, or the catalyst of, Government-wide patent legislation, it demands your continued attention. (Note availability of Dr. Ancker-Johnson's December 16, 1974, comments.)

Returning to the second problem of closing the gap between the fundamental innovator and the industrial developer, I would point to a National Academy of Engineering report, which recommends the establishment of management focal points for technology transfer, and an NSF grant to Research Corporation for the purpose of crystalizing such activity at eight selected universities. I must, on the negative side, advise that the National Science Foundation's Experimental Research and Development Incentive Program (ERDIP), which funded both the N.A.E. report and the Research Corporation grant, has been abolished.

Returning to the N.A.E. report as it related to technology transfer management, I should first indicate that it appears to have limited its review to transfer from Government laboratories to industry. To the extent that universities and non-profit research centers are similarly isolated from the industrial developer, I believe the following quote from the report is clearly applicable to substantially all universities and non-profit research centers receiving Federal support for research and development:

> "At present there is no overall policy guidance or direction for the transfer and utilization of technology from either the executive or legislative branches of Government to Federal agencies. <u>The single omission commonly noted is the legislative authority and/or budget line item which would support the required</u>

manpower and other costs as well as provide desirable visibility." [Emphasis added.]

The report indicates that of the $17 billion spent during Fiscal Year 1973 on Federally-supported Research and Development, $935/went million into the collection, organization, and dissemination of technical and descriptive information. Only $43 million of that amount -- or .25% of the total $17 billion -- was authorized to encourage technology utilization.

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Current Trends in Government Patent Policy
September 18, 1975 Presentation by Norman J. Latker
Patent Counsel, Department of Health, Education, and Welfare
before the New Jersey Patent Bar Association

Of course, these are my own views and are not necessarily consistent with those of my Department or the Administration.

In 1971 the controversy regarding the appropriate policy for disposing of inventions resulting from Government funded research surfaced again as a public issue after being relatively dormant since the 1965 attempts by Senator Long to amend the NASA and Public Health Service appropriation bills to assure ownership of such inventions in the Government. There is little evidence, after four years of various confrontations between the protagonists, of any abatement. However, as I will explain later, there are now serious discussions occurring in the Executive toward bringing the matter to some conclusion. In order for you to participate in the public debate that may be precipated by any possible recommendation from the Executive, I thought it might be useful to briefly comment on the most significant events affecting Government Patent Policy since 1971.

The first apparent catalyst of the controversy appears to have been the reissued President's Statement of Patent Policy of 1971. The '71 Statement differed from the previous '63 Statement in the main by providing to the Executive Agencies, not otherwise precluded by statute, greater flexibility in (1) permitting Government contractors to retain exclusive rights in inventions after they have been identified and (2) granting exclusive rights in inventions owned by Government to selected licensees. These changes were made to correct identified problems in Agencies such as HEW in bringing the results of their research to the marketplace.

Let me stress that the '71 Statement made no changes in the criteria governing disposition of invention rights at the time of contracting.

To implement the licensing amendment, the Statement required the GSA to issue Government-wide licensing regulations. Soon after the issuance of these regulations, Public Citizens, Inc., a Ralph-Nader organization, joined by eleven Congressmen, sued the GSA to enjoin their implementation on the primary basis that any grant of an exclusive license under the regulations without statutory authority was an unconstitutional disposition of property.

Also, shortly after the issuance of the '71 Statement, the Commission on Government Procurement, formed at the direction of Congress, began its review of Government Patent Policy. This study culminated in a December 1972 report containing 16 recommendations on Intellectual Property Matters. The first and second of these recommendations were:

1) Implement the revised Presidential State of Government Patent Policy promptly and uniformly, and

2) Enact legislation to make clear the authority of all agencies to issue exclusive licenses under patents held by them.

The first recommendation did not in fact follow the recommendation of the Commission's Task Force on disposition of invention rights. That Task Force, made up of representatives from the private and public sectors, clearly indicated in its report a dissatisfaction with the

'63 and '71 Statements. Their unhappiness centered on indications that the Executive Agencies were not uniformly utilizing the discretion provided to them by the Statements in recognizing the equities of contractors in resulting inventions in appropriate cases. The Task Force felt the lack of uniform treatment most likely adversely affected contractor participation in Government Research Programs or, more important, ultimate delivery to the public of inventive results of completed research. The Task Force recommended ending the discretion left to the Agencies by requiring use of a single invention rights clause in all research and development contracts providing for first option to all resulting inventions in the contractor subject to strengthened march-in provisions.

I believe that the primary reason for the recommendation was the realization that a substantial majority of inventive ideas require "advocates" in order to reach the marketplace and that experience indicates that the inventing organization, if interested, is more a likely "advocate" than a distant, unmotivated Government staff. Other factors were the recognition that the contractor had an equitable position in future invention rights on the mere basis that its selection as a contractor was indicative of its prior background position. Further, in the case of the University contractor the ownership of its ideas was deemed imperative to the University's continued involvement in obtaining industry collaboration in delivery to the market. A good example of the need for committed

"advocates" is Xerox, one of the generation's most successful inventions. It is said that the inventor of Xerox, Chester Carlson, contacted over 100 concerns before he was able to obtain a financial commitment to development. There is no evidence that a Government organization would be willing to duplicate that kind of effort nor is it apparent that many organizations or persons would absent a property interest.

The Commission though ultimately rejecting the advice of its Task Force did go on to say:

> "If evaluation of experience under the revised Presidential policy indicates a need for futher policy revisions, we urge consideration of an alternative approach generally allowing contractors to obtain commercial rights but subjecting these rights to a strengthened "march-in" procedure.

In partial response to the Commission's first recommendation to implement the President's Statement uniformly and, partially on its own initiative, the GSA acting for the Executive Agencies issued patent Procurement Regulations. These regulations include standard contract language to be used by all the Agencies when implementing an Agency decision to either (1) take title to resulting inventions, (2) leave title with the contractor in such inventions, or (3) defer determination until the invention is identified.

I would emphasize again that these regulations in no way provide any new direction not found in the '63 or '71 Statement on when an Agency is to use a title, license or deferred patent clause. In other words these regulations make no attempt to guarantee uniform treatment of contractors dealing with different Agencies under similar fact situations.

Prior to the issuance of the GSA regulations the Justice Department along with the other Agencies of the Executive furnished comments and recommended changes to the drafting committee. In their comments the Justice Department for the first time raised the question of whether the disposition of future or contingent invention rights to contractors without statutory authority was an unconstitutional disposition of property. This concept was summarily dismissed by all the research and development agencies on the basis that even if the possibility of making an invention could be deemed property the ultimate invention was the property of the inventor absent a chain of assignment to the Government.

Soon after the issuance of the regulations, Public Citizens joined by seven congressmen, again brought suit against GSA to enjoin their implementation on the basis that they provided for contract clauses, which permit contractors to retain the exclusive right to future inventions. The plaintiff, citing Justice as its primary authority, contended that such clauses amount to a disposition of property without statutory authority.

to contractors without statutory authority was an unconstitutional

In retrospect, although the two sets of regulations under attack in the Public Citizens cases were admirable attempts to bring about greater uniformity of language on patent matters within the Executive, it was unanticipated (though probably healthy) that they would provide a target enabling a protagonist to attack all Agency policies through only two actions. As you probably know, the Justice Department later publicly disavowed that its comments had any support in law. Further, both cases have now been dismissed on the basis of plaintiff's lack of standing to sue (no doubt due to the absence of a case or controversy affecting the plaintiffs). The plaintiff is seeking review of the decision, and are now more concerned over their loss of standing in similar situations than the issues they sued on.

Notwithstanding, the Executive's apparent victory in these two cases, the failure of the court to refute the plaintiff's contentions has had serious ramifications. Notwithstanding, the Justice Department's disavowal it is apparent that alleged patent infringers have adopted the Justice's initial position as evidenced by its use as a defense in two recent patent infringement cases brought on a patent obtained by the plaintiff through a positive Government decision. The defense that the invention in question was generated in whole or even in part with Government funds may well come to be utilized as often as anti-trust or fraud on the Patent Office defenses until Congressional or Supreme Court clarification is forthcoming.

While the reissued statement of 1971 catalyzed the Court challenges discussed above the energy crisis of 1973 has catalyzed the Congressional challenge to the '71 Statement.

At the beginning of 1974 the proposed patent clauses attached to the Federal Non-Nuclear Energy Research and Development Act of 1974

by the Interior and Insular Affairs Committee made no provisions for patent ownership by prospective contractors. Even after a number of attempts by the Executive, Industry, and Universities to explain the need for a policy which would create an atmosphere encouraging contractor participation in this important program and ultimate utilization of results, the Committee agreed only to insignificant amendments. It was only after industry and university groups precipitated a fight on the floor of the House which led to the deletion of the initial patent clauses did the Executive gain the bargaining power which enabled negotiation of the finally enacted energy patent clauses. As you know, these clauses, although indicating that the Government will normally retain title to all patentable inventions, do provide in the Administrator the right to waive title to any invention, either at the time of contracting or upon identification provided he make certain considerations, as well as including specified march-in rights and conditions deemed necessary in the public interest.

At the time these clauses were negotiated the Executive was relatively pleased in being able to redeem the patent policy of a major research and development program from the brink of an inflexible title policy. After all - the ERDA clauses parallel and in some respects are superior to the equivalent provisions of the '71 Statement especially since they are in legislative form. Notwithstanding, these provisions pose a substantial new threat since they have now been adopted by the Congress as its choice of Government Patent Policy. Since enact-

ment of the Non-Nuclear Energy Research and Development Act, Congress has routinely attached the ERDA patent provisions to each new research program before it. This piecemeal approach has created an apprehension in some that the Executive may lose the initiative in formulating patent policy, especially in light of its apparent inability to respond to this Congressional approach.

Of course, continued inaction on the part of the Executive could eventually result in an ERDA type policy applied to all the agencies. It is agreed this would merely place in legislative form the same kind of policy that the Commission's Task Force found wanting, since it requires an Agency to utilize its discretion in granting a waiver of rights. Current statistics clearly indicate that most Agencies are not utilizing this discretion. This is not too surprising since all the visible political opinion and administrative pressures are in the direction of avoiding waivers especially at the time of contracting even though such waivers may be clearly justified as being equitable and in the public interest. Examination of Agency attitudes also clearly evidences the belief that waivers serve the contractor's interest only and the burden of justifying such waivers, should, therefore, be carried entirely by the contractor. Of course, if a waiver can be in fact considered to be in the public interest the Agencies should be assuming a quasi-judicial attitude in evaluating waiver requests and itself weighing the prospect of Agency "advocacy" of the invention against the prospect of contractor "advocacy". Certainly if a waiver can be considered to be in the public interest failure to grant a waiver may well be against the public interest. Yet most of the

major civilian research and development agencies have no identified waiver procedures and no or negligible waiver statistics.

Early this month the Executive Subcommittee of the Committee on Government Patent Policy met to discuss the dilemma generated by the events discussed above. (The Executive Subcommittee is made up primarily of the Patent Counsels of all the major research and development agencies of the Executive Branch). The Subcommittee indeed did agree that the Congress's apparent abandonment of the President's Statements and the cloud created by the court cases challenging the constitutionality of agency disposition of patent rights are serious matters and have, accordingly, recommended to the Committee on Government Patent Policy the need to seek repeal of all existing legislation covering Agency disposition of patent rights in favor of Government-wide legislation covering this subject. In addition to recommending legislation, the Executive Subcommittee has presented in general terms the parameters of two approaches within which a uniform Government Patent Policy might be formulated.

The first of these approaches involves revision of the patent provisions attached to the Federal Non-Nuclear Energy Research and Development Act of 1974, discussed above, to accommodate all the Executive Agencies. It should be noted that these provisions provide for Agency licensing of those inventions to which it has retained title. If the provisions were amended to more clearly provide for HEW's Institutional Patent Agreement policy, which provides a FIRST option to future inventions to Universities with an identified technology transfer function, the provisions would parallel HEW's present patent practices.

The second approach adopts the alternate patent policy proposed by the Commission on Government Procurement also discussed above. (I would note that the alternate approach parallels the HEW Institutional Patent Agreement policy but is broadened to include not only the non-profit sector, but also commercial concerns.) It is envisioned that legislation encompassing the alternate approach would also contain a provision authorizing Agency licensing of those inventions that an inventing contractor did not wish to exploit.

Of the two approaches debated by the Subcommittee, a substantial majority favored the alternate approach which was deemed to be more likely to maximize utilization of inventive results.

Now to indicate that we are well on the way to a uniform Government-wide patent policy would have to be considered the most optimistic statement of the year. To presume that these few comments could convey all the important ramifications of the events of these last years is equally optimistic. However, I would like very much to convey to you my strong feeling that the issue of Government Patent Policy has much broader impact than a narrow controversy of who should own a specific invention.

I understand that Government funded research is approximately 50% of the total research conducted in this country and is still growing as a percentage of the total. It seems clear to me that continuation of a patent policy which permits the Agencies to utilize their discretion to determine whether or not the normal incentives of the patent system should be applicable to Government Research cannot help, but to eventually undermine the integrity of

our Patent System if substantially all decisions result in Government ownership without further effort toward commercialization. If the Government itself cannot find reason to support the applicability of the patent system to nearly 50% of the country's research, can it really be expected that the patent system will be honored in the private sector?

It is axiomatic that the existence of the free enterprise system and the delivery of goods to the marketplace has been dependent on the private ownership and advocacy of inventive ideas. If our supply of privately owned ideas is reduced due to a larger percentage of the national research budget going into public research and resulting inventions being dedicated to the public without assurance of an advocate, I wonder whether our system will be able to continue to compete in the international market with countries who are taking advantage of the world's patent systems?

Presentation of Norman J. Latker, Patent Counsel, DHEW
Before the Academy of Pharmaceutical Sciences
Atlanta, Georgia - November 19, 1975

"THE PROTECTION OF INTELLECTUAL PROPERTY UNDER THE FOURTH EXEMPTION OF THE FREEDOM OF INFORMATION ACT"

(Oral disclaimer on representing Department view)

Since the departure of President Nixon, it appears to many that much of Congress's effort to restore itself, as it deems necessary, as an equal partner to the Executive and Judicial Branches in the "checks and balance" system has been directed to earlier involvement in the development of policy. Unfortunately, accompanying Congress's undeniable right to pursue such a course, a great many indiscriminate statements such as: "We've had it to the teeth with secrets" or "Anything the Executive refuses to make public amounts to lying to the American people" have served to create an atmosphere in which even the most obvious of the Executive's discretionary powers have become suspect. It is against this tidal wave of indignation and demands for openness that Federal Agencies must attempt to protect intellectual property placed in their hands by persons presuming that such property has nothing to do with the development of policy. Some such Agencies have already been swept away with this current passion while others are frustrated by the added administrative burden of protection which they view diverting their energy from primary assignments. Thus, some have moved to presumptions that no excuse for protection is available.

While I hold no particular brief for policy-making behind closed doors, I believe the fervor to promulgate "sunshine laws" to

guarantee to all citizens the absolute right to access to all aspects of the Executive's business, subject to some narrow exceptions, underestimates or chooses to ignore the vastness of the Executive's interface with private industry, universities, and nonprofit organizations in the area of product and service regulation, and the seeding of research and development to solve social problems.

This interface as we all know requires submission of documentation within which are included disclosures of ideas, inventions, technical and clinical data, novel business and accounting methods, trade secrets, computer programs, etc. which represent the end result of a significant private investment and do now, or could in the future, confer the competitive advantages which justify the owners' past and continued investment and/or advocacy in delivering the service or item disclosed to the marketplace. This array of intellectual property is truly a substantial portion of the present and future building blocks and cornerstones of our free enterprise system.

Now, presuming that such submissions must continue in order to obtain the Government action sought, whether it be seed money to encourage initial research and development in areas of public concern or clearance of an item of service for public use, it follows that full "openness" could result in the total loss of the property value in such intellectual property which has not already been covered by patent protection. In other words, the entire area of legal protection of intellectual property available since the founding of this republic,

which exists due to the ability of the owner to control its accessibility, will have no relevance when dealing with the Executive Branch. (I would add inferentially at this point that as far as I can determine none of the "sunshine laws," including FOIA, distinguishes between the U.S. public and foreign interests. Thus, where a U.S. citizen can gain access, so can a foreign competitor or government.

When one of Congressman John E. Moss's constitutents wrote to set forth his opinion that the present FOIA did not provide sufficient protection against premature disclosure of inventive ideas that were not yet patentable, the Congressman responded by indicating that:

> "While I am sorry that the Act imposes a certain hardship on inventors, I feel strongly that the public has a right to know how Government funds are spent. As you realize, the FOIA only applies to Government information and if anyone is willing to accept Government funding for a project he must also be willing to accept the added responsibility of public scrutiny."

Of course, to construe, as I believe Congressman Moss had done, that a research proposal submitted for some type of funding support is government property is tantamount to a declaration that one forfeits all past and future personal proprietary rights and private equities in such dealings with the Government. I would note that the Congressman's position even denies to the Government the right to protect any

intellectual property within the research proposal in the interest of the public since the Government in turn must disclose to any third party under FOIA.

When one explores the present FOIA and the excessive burden it places on the Government administrator in protecting intellectual property against premature disclosure, it is clear that Congressman Moss's view had substantially prevailed in the drafting of the Act.

The FOIA generally requires disclosure of all Government records upon request. There are a number of exemptions to the required disclosure. Of these exemptions, we are primarily interested today in number 4 which appears to exempt "trade secrets and commercial or financial information which is privileged or confidential." The leading case on the fourth exemption, National Parks and Conservation Association v. Morton, 498 Fed. 765 (1974), D.C. Circuit Court, states that the fourth exemption applies if it could be shown that disclosure was either likely, first, to impair the Government's ability to obtain necessary information or second, to cause substantial harm to a competitive position of a person providing the information. The Court toughened the qualification in Petkas v. Staats, 501 F. 2d 887 (1974) by refusing to accept a government assurance of nondisclosure in a regulation requiring information where filing the information was conditioned on confidentiality. The Cost Accounting Standards Board regulation in the case required defense contractors to submit disclosure statements setting forth their accounting procedures, and the suit was to obtain public disclosure of the statements filed by Lockheed,

IIT, and General Motors. The court held that the Government assurance and the Corporations' respective filings conditioned on confidentiality were not determinative, and remanded the case for disposition in accordance with the test of the National Parks case noted above. Thus, a promise of confidentiality by the Government in and of itself may not prevent disclosure.

The Office of Legal Counsel of the Justice Department has advised that as a result of the above cases, government protection of intellectual property and its withholding under the fourth exemption under a FOIA suit is very unpredictable, at best.

Further, 18 U.S.C. 1905 does not appear to have any effect in a FOIA suit. This statute, if applicable, would impose criminal penalties on Government officials who disclose proprietary information in the possession of the Government. At best, then, it is a deterrent to unauthorized disclosure, but it only takes effect after the disclosure and the damage to the owner. 18 U.S.C. 1905 has been virtually ignored by the courts in FOIA suits because of a general exemption contained in the statute, "unless otherwise provided by law." Courts generally have interpreted the quoted passage as exempting disclosure under the FOIA. Section 1905's penalties, therefore, would not be applied to an official who disclosed proprietary information in response to a freedom of information suit.

Even though commercial concerns might with predictable difficulty meet the "substantial harm to a competitive position" test of the National Parks case, universities and nonprofit organizations wishing

to deny access to their research proposals appear to have little hope of meeting this test in light of Washington Research Project v. Weinberger. In that case, Washington Research Project sought access to a number of research proposals from different universities and nonprofit organizations in order to investigate the ethics of the experiments in question, most of which dealt with the treatment of hyperactive children. Washington Research supported its claim to access with indications that "it is essential for researchers to be held accountable, and the research process has to be something other than the closed society which it is now." The court indicated, in denying the use of the fourth exemption, that:

> "It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a perference for or an interest in nondisclosure of this research design, only that it is not a trade or commercial interest . . ."

Now, if it is not already clear that the FOIA and present court interpretation is severely imbalanced toward prompting Federal Administrators to release intellectual property whether arguable within the fourth exemption or not, consider the Act's requirement

that the Federal Administrator provide a "yes" or "no" answer to a requester within 10 days of the request or be subject to severe personal financial penalties. The 10-day rule, as noted by Deputy Assistant Attorney General Mary Lawton, is "absolutely irrational. In some case you can't even get through the material required in 10 days."

Let me illustrate, in the case of a request for access to a research proposal. To say "no" basically requires that a Federal Administrator handling the request apply the National Parks test to the situation and provide a written prima facie case to the Department Public Information Officer recommending denial. If the information the Federal Administrator believes should be denied involves a disclosure of an idea, invention, trade secret, etc., a prior art search which indicates that such idea, invention, trade secret, etc., is in fact novel in comparison to the prior art must be conducted before a prima facie case could be made. If novelty cannot be shown it seems clear that the Governemnt could not prevail in a suit to show that there will be "substantial harm to the owners' competitive position." I would ask inferentially at this point, how can a Federal Administrator, yet alone the owner, show that a computer program or a business method is novel compared to the prior art? Where would you look for the prior art? Should the owner be penalized

because the Administrator doesn't know how to make a case? In those few situations where "novel" information can be decisively identified and a denial considered justifiable, the Act further requires that the information to be denied be excised from the documents requested and the resulting "swiss cheese" document forwarded to the requester. Now multiply this procedure by the 200 research proposals Washington Research Projects requested shortly after prevailing in their first suit for access or the number of requests for similar information FDA receives.

Can it really be suggested that many Federal Agencies will travel the denial route in other than situations where the equities of the owner are immediately and dramatically apparent, when release merely requires a xerox copy to the requester with no threat of penalty under 18 U.S.C. 1905?

I note on the bright side that NIH has voluntarily adopted a policy of contacting our research investigators immediately after a request for release of research proposals to determine whether there is any intellectual property which he believes will be destroyed through premature disclosure. Of course, as already noted, the investigator's request to deny access is not determinative of the action which the Government will take under the National Parks case test, but it is certainly helpful in identifying those situations where access may be particularly damaging.

As suggested in the wake of the Washington Research Project case there has been a large surge of requests for release of research proposals. Although requesters need not identify the purpose of their requests, volunteered information in addition to their organizational identification seems to place requesters in two broad but identifiable categories;

1) Public interest groups pursuing the possibility that research investigators are in some way abusing the public interest in the course of their research, or
2) Commercial concerns and other research investigators wishing to capitalize on the work product disclosed.

The requester in the second category can ordinarily be identified as having an investment in the same field of research as the research proposal he is seeking. It has been ascertained through volunteered information from these requesters that they wish the information sought generally to either 1) determine the degree to which the investigator is moving the state of the art ahead or 2) use as a format for the requesters own grant or contract application.

At this time, it appears that public interest groups are requesting access to more research proposals than commercial concerns and research investigators. Notwithstanding the large number of research proposals requested by public interest groups, to my knowledge substantially all of the requests have

been made by only two groups. The large number of requests made by public interest groups seems easy enough to explain since the search for or the discovery of possible abuse appears to be the only way such groups can justify continued existence.

The requests from the commercial concerns and other research investigators cover a much smaller number of grants coming from a larger number of sources, since its appears that these requesters have a preconceived idea of exactly what they want.

Based on this preliminary and rather sketchy data, I am of the opinion that the primary beneficiaries of the Act gaining access to research proposals have been parties interested in enhancing their own financial or organizational positions at the expense of the work product of NIH-funded investigators, rather than the public on the basis of any identified evidence of redirection of policy development due to the action of public interest groups.

It is my understanding that the imbalance between the number of requests for intellectual property from commercial concerns and public interest groups is even more pronounced in the direction of commercial concerns at FDA.

At a September 24 meeting, the Inter-Assembly Council of the Assemblies of Scientists of NIH and NIMH voted to send every NIH and NIMH scientist and to Science magazine a notice of their concern, a part of which is as follows:

"The Inter-Assembly Council of the Assemblies of Scientists of the National Institutes of Health and National Institutes of Mental Health, while fully recognizing the legal right of scientists to make such a request, strongly urges NIH and NIMH Intramural scientists voluntarily continue to act according to past practice and not request copies of Grant Applications. We advocate this policy because we fear the effectiveness of the peer review system may be diminished and biomedical research impeded if applicants believe their Grant Applications will be widely circulated.

This recommendation is subject to revision should professional scientific societies adopt appropriate guidelines."

(I would suggest that when any group of scientists can agree to make a positive recommendation on anything, the situation has probably reached the point where other elements of society need also be concerned.)

Now the real issue in the controversy over release of research proposals is not whether the information therein will be released but when it will be released. It is perfectly clear that investigators are anxious to publish the results of their research for the scrutiny and critique of the entire profession when they believe it has moved to some reportable conclusion. The above statement by NIH and NIMH scientists clearly indicates that investigators in general, are not ready to relinquish the timing of publication to an unidentified third party.

The public interest groups insist that the timing of access should be in the hands of the public. The public in practice turns out to be self-designated surveillance groups whose opinions cannot be identified as representing any kind of public consensus and who are not subject to the "checks and balance" system.

In support of their position, public interest groups point to a very small number of research projects which they believe involve abuse of human subjects which they claim would not have been funded if they were involved in the clearance procedure. Now it is well known that NIH-funding procedure already includes means to devote special attention to the risk y. benefit problem when human subjects are to be involved. It seems entirely speculative that the addition of another echelon of review by public interest groups will enhance the quality of the existing review. In fact, the opposite may be the effect, since it seems that the groups now functioning outside the official surveillance procedure tend to equate the public interest to funding only those research projects with identified benefits and no risks. A number of investigators have noted that the atmosphere created by these groups is already resulting in replacing the remote possibility of any error of commission by many errors of omission. Dr. Dwight Harken of Boston, one of the Nation's pioneer heart surgeons, recently warned, "The fact that any failure of a device or procedure may be penalized has stifled innovation, restricted industry and