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THE MONOPOLY AND ANTICOMPETITIVE ACTIVITIES SUBCOMMITTEE SENATE SMALL BUSINESS COMMITTEE

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INSTITUTIONAL PATENT AGREEMENTS FOR UNIVERSITIES -

COMMENTS AND OBSERVATIONS BY

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INTRODUCTION

I appreciate the invitation and opportunity to participate in the hearings being conducted by this Subcommittee relating to the history, legal basis and implications of Institutional Patent Agreements as an implement of Government patent policy.

In an earlier session of these hearings, on May 23, 1978, Dr. Thomas Jones, Vice President for Research at the Massachusetts Institute of Technology, presented a case for the desirability of Institutional Patent Agreements for universities on behalf of the Association of American Universities and sister organizations. On behalf of the Wisconsin Alumni Research Foundation and the University of Wisconsin as well as the Society of University Patent Administrators, I fully and heartily endorse the views and comments as expressed by Dr. Jones in the written statement which he submitted to this Subcommittee. In fact, Dr. Jones' statement was so complete and so effectively presented the case for the universities that it has made my task more difficult and I can give you my views today only at the risk of repeating some of Dr. Jones' testimony.

HISTORICAL

In considering Institutional Patent Agreements as an implement of Government patent policy we must first concern ourselves with inventions and patents since their ownership is fundamental to the concept of such Agreements. This compels us to look at the special treatment given intellectual property by the framers of our Constitution in an effort to stimulate the talent of invention, which is an expression of intellectual originality. James Madison, chief architect of the Constitution wrote in the Federalist:

Then later, in a letter to Thomas Jefferson recognizing the value of permitting artificial monopolies to be granted as encouragements

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to literary works and ingenious discoveries:

"Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be

dreaded that the few will be unnecessarily sacrified to the many. " The key words in these quotations are "The public good fully coincides in both cases with the claims of individuals." and "It is much more to be feared that the few will be unnecessarily sacrificed to the many." Thus, in recognition that there should be no indefinite monopolization of valuable intellectual property, where the public good would not fully coincide with the claims of individuals, and that the rights of the creative few would be in danger of being sacrificed to the many without clarification a compromise was struck under which intellectual property was to be owned for only a limited term during which the creator had the right to exclude others.

There it is, the recognition of the necessity for stimuli to inventive activity and innovation - <u>the incentive</u> - the basis for the patent system and the key to the conversion of scientific knowledge into production benefitting human welfare.

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We can certainly all agree that we can rely upon man's self interest to motivate his actions. Therefore, if society wishes to benefit from its research dollars, regardless of the source of those dollars, it must supply the necessary incentives to translate research results into consumer goods and services.

It is on and about that all important word and concept, incentive, that my further remarks will be addressed to today.

At this point it would probably be well to consider the situation that pertains when the Government does take ownership of a patent. The idea of the Government owning a patent is in a sense an anomaly. The patent system was created as an incentive to invent, develop and exploit new technology - to promote science and useful arts for the public benefit. When the Government holds the patent under the aegis that the inventions of the patent should be freely available to all, much the same as if the disclosure of the invention had been merely published, the patent system cannot operate in the manner in which it was intended. The incentives inherent in the right to exclude conferred upon the private owner of a patent, and which are the inducement to development efforts, are simply not available.

NATURE OF UNIVERSITY RESEARCH

During the prevalence of the "Ivory Tower" concept of universities, and the research function which was carried out in them, little thought or impetus was given to the transfer of the results of that research to the

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public other than through the accepted and acceptable route of publication. In fact, under that "Ivory Tower" concept a researcher who accepted a corporation subsidy aroused the suspicion that he had been diverted from his basic research and had, in effect become a tool of the vested interests. He had accepted "tainted" money!

The purists, at the University of Wisconsin and elsewhere, applied this same sort of reasoning when it was suggested that a plan be developed to make use of patentable ideas of various faculty members that would protect the individual taking out the patent, insure its proper use, and at the same time bring financial help to the institution to further the University's research. There were those who then feared that any such arrangement would divert the scientist from his basic research and induce him to work on only those ideas which had commercial potential. In other words, it would convert the research function at the University from its basic character, i.e. the seeking of new knowledge, to an applied character, i. e., the assessing of concepts discovered in basic research to determine whether they can be utilized in solving problems in the real world, or even to actual development, i. e. the preparation of products or processes to a market-ready condition.

The fears propounded by the purists did not materialize. There was no great rush to patents; there was no evident movement to product orientation by the scientists at the University; and there was no observable change in the research scientist's attitude. In fact, and except for the

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more specific contractual arrangements with Government agencies in more recent years, the nature of university research has remained essentially basic. The generation of inventions is almost never the main objective of such research. If inventions do flow from the research activity it is a largely fortuitous happening that takes place because the scientist-inventor has the ability to see some special relationship between his scholarly work product and the public need. It is the recognition of this connection which can convert a discovery or invention into patentable invention.

It is also important to note that the university invention, unlike those of larger industrial firms, normally stand alone. A study by Harbridge House in 1974 entitled "Legal Incentives and Barriers to Utilizing Technological Innovation" addresses this point in the following language:

> "Their isolation is a major obstacle to utilization since most inventions are not marketable products in themselves. The industrial product is often protected by a cordon of patents, as illustrated by the list of patents on a packet of Polaroid film. A university invention, on the other hand, is a one-shot patent. Even if the patent specification discloses an ingenious invention, the patent claims which define the scope of monopoly are likely to be narrowly drawn. Whereas industry will add

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to its patent arsenal as a product is improved, a university patent, if it is to be licensed at all, must be licensed on the initial effort."

THE CHARACTER OF THE UNIVERSITY INVENTION

Inasmuch as university research is primarily basic in nature, the inventions which are recognized during the course of such research are generally embryonic or, at best, tend to be in the very early stages of development. Thus, they require the investment of substantial private risk capital before the invention can be introduced into the market.

Educational institutions are, of course, not organized to either manufacture or to produce and market patentable inventions. Consequently, if university generated inventions are to be of use to the public, the institutions will have to interest someone in the industrial sector who has the commercial capability and willingness to take the embryonic invention through applied research and development and, beyond that, through market development.

In addition, the products of basic research will often require regulatory agency clearance, e.g. FDA, EPA or USDA, before marketing. These are hurdles which must be surmounted in addition to the two major steps of product and market development. I am sure that your collective experience will confirm that these additional hurdles consume tremendous quantities of time and seemingly endless amounts of money.

Tie these technical hurdles to the not-invented-here syndrome so

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often encountered in industry and the unpredictability of a large market or high return on investment in an embryonic invention and one can readily see the difficulties involved in the technology transfer process. There is little truth in the old saw "Build a better mouse trap and the world will beat a path to your door."

TECHNOLOGY TRANSFER

We can certainly all agree that we are interested in a common purpose - protecting the interest of the public by insuring that every effort will be made to effectively translate the tax dollars which are invested in research at universities into new products, processes and services available in the marketplace.

What are the necessary ingredients in a given situation to achieve such purpose? What are the sequential steps involved?

- We must first have invention, which can be defined as the creation of a new or useful product, process, machine or design that was not obvious from what existed before.
- 2. We must have patentable invention if the incentive for innovation is to be present.
- 3. We must have a middleman, either the university itself or a patent management organization, to timely recognize patentable invention, to canvass appropriate industry for potential licensees, and to "sell" the desirability for developing the invention to one or more potential licensees.

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We must have innovation which includes:

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- (a) recognition of the invention and its potential;
- (b) acceptance of the challenge to develop the invention;
- (c) engaging in the technical task of understanding,developing and improving the invention;
- (d) engaging in the development of a market for the invention through informational, selling and service programs; and , OF COURSE,
- (e) assuming the financial obligations attendant upon all of the above.

In sum, the foregoing steps can be considered to comprise the technology transfer function.

Universities that have established technology transfer capabilities also have established patent policies since a sound patent base is the heart of a technology transfer function. Although, a patent position does permit one to establish a prospective market position for a relatively small financial investment, that position is only prospective, and highly speculative as well. The mere fact that an institution has a patent policy, or even the means to invest in patent applications holds out no hope that inventions, as assets, will represent a readily available source of funds that can be applied to solve acute financial problems. Rather, such policies permit each institution, without excessive expenditures, to place itself in a

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position that if a commercially valuable discovery is made in its laboratories, it will have the capability to cause the discovery to be brought into public use, and perhaps recover its costs.

Despite all of the difficulties attendant upon technology transfer, universities are in a unique position to objectively seek the best qualified industrial developer and, under appropriate licensing arrangements, to monitor the diligence of development efforts by such developer. Such arrangements can, of course, be made only if the university can furnish some incentive to the industrial developer, the innovator. This is best provided in the form of a limited exclusive license under appropriate patent coverage.

The certainty of the university having ownership of any patents is essential to the transfer of the technology. Without that certainty, timely patenting activities cannot be engaged in and the inventions are less likely to be developed to the point of marketability. This is equally true whether federal or other funds are involved in the research effort leading to the conception or reduction to practice of an invention, and is the principal reason why the IPA is so important to the universities. Most universities though they rarely make any sizeable income from inventions, would largely lose the incentive to seek licensees if they did not hold the patent rights. Because of the "publish or perish" ethic and the wide availability of the results of federally supported research, the university normally neither would nor could consider it appropriate to deal in "trade secrets."

Ownership of the invention by the university brings another asset

into the technology transfer picture, namely, the active participation of the inventor. It is the inventor who has the best current knowledge of his own invention and who also has the interest in seeing his research endeavors bear fruit in the form of a commercial product or in commercial use. The active participation of the university inventor is a prime ingredient in the successful transfer of an invention to the market and generally, a workable and successful technology transfer function at a university will involve the inventor on either a formal or informal basis.

Although the odds are heavily against a university-generated invention surviving the critical assessment imposed upon it during development by an industrial concern, it is self-evident that the possibility of sharing from the successful commercialization of an invention will be an inducement to the inventor to actively participate with the university and its licensees in the invention development effort.

Even in circumstances, as at the University of Wisconsin, where the individual can dispose of his invention as he wishes, absent obligations resulting from Government funding, the inventor has overwhelmingly elected to assign his invention to WARF for the benefit of the University and more often than not has worked diligently to promote transfer of his technology. There is often an expressed moral obligation or desire by the inventors to benefit the institution which has provided the scholarly atmosphere and other benefits for which they feel indebted. Moreover, most inventors recognize that if they turn entrepeneur they will be faced with time-consuming

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business and technical commitments which will result in their being unable to keep current in their chosen fields. Then too, every inventor wants to see his invention in the marketplace.

THE INSTITUTIONAL PATENT AGREEMENT (IPA)

In earlier testimony before this Subcommittee, Mr. Norman Latker, Patent Counsel for the Department of Health, Education, and Welfare (DHEW), summarized the history of the IPA program and its legal basis, but nowhere in his written testimony or in the testimony of others which was given earlier has anything been said about the chaotic condition which existed prior to the issuance of the current IPAs beginning in 1968.

In the early 1960's when I first became involved with the questions raised by Government funding of research at universities, the Department of Health, Education, and Welfare was functioning basically with a title with waiver policy, even though a number of IPAs were outstanding. In that period we encountered circumstances where requests for determinations of waiver and reminders of the running of statutory bars against patenting would go unanswered until after the bar had run. Then too, on the very few occasions where a waiver was granted it was so fraught with restrictive provisions that it presented an unworkable basis for transferring technology. No commercial firm would accept the conditions which were imposed by the waiver.

The effect of such circumstances was to completely discourage the inventor from seeking to commercialize his inventions and, in fact, of even recognizing the presence of invention - the burdens attached because of the posture and attitudes of that Department toward the transfer of

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technology were simply too overwhelming.

The issuance of an IPA to the University of Wisconsin by the DHEW, with the Wisconsin Alumni Research Foundation (WARF) as its designee under that Agreement, simplified the handling of inventions at the University By giving the University the first option of ownership of the invention it provided the certainty which permitted earlier patent actions to be taken and, therefore, earlier contacts with industry. Moreover, and very importantly, it appears that the attitude of commercial organizations has changed toward research where an IPA is controlling. We have been encountering more instances where companies have made contributions, in cash or in kind, to otherwise Government funded research projects where only the prospective rights to inventions, yet unmade, is involved. The certainty that the university will have first option to any invention apparently being the prime motivation. Also, mounting evidence since 1968 with Institutional Patent Agreements indicates that more and more technology developed at universities is being transferred into public use under such agreements.

As was pointed out earlier, there must be incentives supplied to all those who are essential to the technology transfer process.

There must be an incentive for the university inventor whose research is funded by taxes, not to do research, nor even to invent, but to actively engage in the technology transfer function including the patenting process;

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There must be an incentive for the institution, or patent management organization, to engage in invention evaluation, in patenting and in seeking out and convincing potential licensees of the merits of an invention;

There must be an incentive for the innovator, the commercial company - licensee, to risk capital in developing and marketing the invention offered under license in lieu of its own internally developed products or process.

What does the IPA offer in this regard?

- 1. For the inventor the incentive is the right to obtain a small percentage of income derived from the invention.
- For the middleman (the university and/or patent management organization) - the incentive is university ownership and thus potential benefit through royalty income.
- 3. For the innovator the incentive is the certainty that the university will have the first option to any inventions generated under an IPA and the possibility that a short term exclusive license could be negotiated to permit recovery of high risk investment.

More importantly, these incentives are provided with appropriate safeguards for the public. For example,

1. the inventor retains his right to publish his findings;

2. the Government is given a confirmatory license permitting

it to practice the invention for Governmental purposes;

3. the Government may exercise the right to require additional licenses to be granted if effective steps have not been taken within three years to bring the invention to the point of practical application or to the extent the invention may be necessary to fill public health or safety needs.

IPA EXPERIENCE AT WISCONSIN

Under the IPA effective December 1, 1968 between the Department of Health, Education, and Welfare and the University of Wisconsin a total of 64 invention disclosures have been processed. On 14 of these no patent applications were filed. On the remaining 50 a total of 78 patent applications were ultimately filed (including divisional applications) and to date 46 patents have issued.

A total of 17 licenses are extant under one or more of these patents and applications. Negotiations are currently underway with five potential licensees while a number of licenses, earlier granted, have been terminated at the request of the licensee or because of its inactivity.

Under the IPA effective July 1, 1973 between the National Science Foundation and the University of Wisconsin, again with WARF as the designee of the University, a total of 21 invention disclosures have been processed. On six of these no patent applications were filed while on the remaining 15 a total of 16 patent applications were filed, from which eight patents have issued to date. Currently two licensees are extant, each under one of the issued patents, while several licenses have been terminated. In taking the necessary patent and licensing actions on the invention disclosures evaluated under both IPAs, WARF has conservatively spent \$500,000. Income generated by the licensing of these inventions has thus far been approximately \$125,000.

Obviously, WARF is contributing dollars earned from other sources as well as substantial time and effort to transfer technology generated under the IPAs to the public with the hope that a few inventions will ultimately be successful and return sufficient income to more than offset the costs of those that never reach the market or fail to generate a positive dollar return.

Much more important is the fact that technology generated in part with Government funding has been transferred under license to the private sector and that, with the active participation of the inventors, the licensees are spending millions of dollars to modify that technology to the optimum acceptance level with potential far-reaching benefits for the public health and benefit. We are firmly convinced that in the absence of an IPA the expeditious transfer of the technology which has occurred would not have been possible and that, had the Government taken title to the inventions involved, would probably never have occurred.

OBSERVATION AND COMMENT

With the indicated experience to date with inventions generated under the IPAs as a background, it is suggested that this or some other committee of Congress should address itself not to what happens to the very few inventions which seem to flow from tax-supported research but to what can be done to secure greater public benefit from that research.

The University of Wisconsin is widely recognized as being a great research school and, through the cooperation of university staff and WARF, of having a reasonably effective technology transfer capability. Yet \$100,000,000 spent yearly at the University results in an average of about 60 invention disclosures and 18 filed patent applications. Even discounting research funded in the social sciences, where patentable invention is a rarity, the cost per invention disclosure appears inordinately high and the cost per patent application, obviously, even higher.

We are convinced that, not only at Wisconsin, but at other universities, discoveries are made daily but go unrecognized as invention. It would appear, therefore, that some incentive is needed to get more research discoveries reported so that they can be evaluated for possible transfer to the public through our free enterprise system.

We suggest that a Government-wide IPA arrangement is a good start in that direction and further suggest and urge that you not only lend your support to the amendment to the Federal Procurement Regulations permitting such arrangements but that, except where prohibited by law, you seek to make such arrangement mandatory.

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THANK YOU FOR YOUR ATTENTION! IF YOU HOVEANLY QUESTIONS I WILL DO MY BEST TO BASSUER THEM

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