AFTTE
The Association of Federal Technology Transfer Executives

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Clifford E. Lanham
Manager, Army Domestic Technology Transfer Program
Army Research Laboratory
Department of the Army

Bruce Mattson
Chief, Technology Development Technology Development Program
National Institute of Standards and Technology

Nick Montanarelli
Director, Technology Applications
Ballistic Missile Defense Organization

Richard Rein
Director, Office of Technology Transfer
Naval Research Laboratory
Department of Navy

Lee W. Rivers
Executive Director
National Technology Transfer Center

Theodore T. Saito
Program Leader
Precision Engineering Program
Lawrence Livermore National Laboratory

June 10, 1994

Norman J. Latker, Esq.
Browdie and Neimark
419 7th Street, N.W.
Washington, D.C. 20004

Dear Norm:

It is a real pleasure to inform you that you have been unanimously chosen by the Board of Directors of the Association of Federal Technology Transfer Executives (AFTTE) as the first recipient of the *Vannevar Bush Award for Outstanding Contributions to the United States of America in Technology Management.* The Bush Award is given to an individual who has increased U.S. competitiveness through successful public technology management. It is certainly fitting that you are our first honoree.

To say that you are the father of modern technology management in the public sector is not an exaggeration. Your vision in creating the Institutional Patent Agreements while at the National Institutes of Health was the first instance of effective decentralized technology management in our public sector. Your later work in helping to shape the Bayh-Dole Act, drafting its implementing regulations while at the Office of Management and Budget and the Commerce Department laid a solid foundation that we are still building upon.

You were a pioneer in seeing the contribution that the federal laboratories could make to the U.S. economy based on the success of universities in managing their R&D through collaboration with U.S. industry.

You drafted the prototype of the Federal Technology Transfer Act in 1983 and continued to struggle for its passage despite overwhelming obstacles resisting this historic change in policy. You were a central figure in extending Bayh-Dole coverage to university-operated federal laboratories in 1984. The final passage of the Federal Technology Transfer Act in 1986 was based upon the work that you led in building a consensus that the time had come to re-examine the relationship between the laboratories and the private sector. To say that you faced an up-hill struggle is no small exaggeration.

NORMAN J. LATKER RECEIVES FIRST VANNEVAR BUSH AWARD
WASHINGTON, July 11 /PRNewswire/ -- Norman J. Latker, a recognized expert in the field of federal technology transfer, has been named the first winner of the Vannevar Bush Award for significant contributions to the U.S. in technology management aimed at furthering America's economic competitiveness, the Association of Federal Technology Transfer Executives (AFTTE) announced today.

The award will be presented during ceremonies at 9:00 a.m., Wednesday, July 13, The Grand Hotel, 2350 M Street, NW, Washington, D.C., by AFTTE. AFTTE was formed in 1992 to bolster the professional development, training and education of technology transfer personnel within the federal government.

Department of Commerce's Deputy Under Secretary, Gary R. Bachula, will present the award on behalf of AFTTE.

Increasing American global competitiveness through the use of technologies developed in federal research facilities is a key federal government activity and priority of the 1990s.

President Bill Clinton said, "The private sector must maintain the initiative to keep our technological edge, but government has an indispensable role. The extraordinary talent at our national laboratories must be utilized to keep the U.S. at the forefront of civilian and military technology."

Latker helped create the mechanisms for fostering U.S. public and private sector economic cooperation that is becoming a keystone of U.S. economic policy.

While almost every other budget segment was cut, the administration asked for more than $71 billion in spending for

federally funded R&D in fiscal year '95, roughly a 4.1 percent increase over current levels. The civilian R&D budget would climb $1 billion to $32 billion.

AFTTE President Joseph P. Allen, director of Training and Economic Development with the National Technology Transfer Center (NTTC), said the Vannevar Bush Award is presented to an individual who has furthered U.S. economic competitiveness through significant contributions to the field of technology management.

Allen said the award honors the memory of Vannevar Bush, who had a long and productive career as a scientist, inventor and government official.

"In essence, Bush became the father of government support for research and development activity that we know today," Allen said. "It is fitting that the award recognizing significant contributions to technology management carry his name."

Bush suggested how to re-direct World War II's research and development (R&D) effort into civilian uses to President Franklin D. Roosevelt. Latker spearheaded public technology management by helping craft laws and their implementation allowing R&D to benefit U.S. private companies.

Bush pointed out to President Roosevelt in "Science: The Endless Frontier," that for the U.S. to get ahead in international trade, there must be a stream of new scientific knowledge to turn the wheels of private and public enterprise.

Bush's recommendations are being realized because Latker's later work allows universities and federal laboratories to

manage their research and partner with U.S. industry to pursue commercial markets. Latker was instrumental in the Bayh-Dole Act of 1980, which opened universities to collaborative R&D, and the Federal Technology Transfer Act of 1986, which opened federal laboratories.

Latker is a pioneer in seeing the contribution that the federal laboratories could make to the U.S. economy based on the success of the universities' collaboration with U.S. industry.

Latker, managing attorney with the Washington, D.C., firm of Browdy and Neimark, has a long history of contribution to the field of federal technology commercialization through his work allowing universities and federal laboratories to team with U.S. industry to commercialize new products.

Latker was the first director of the U.S. Department of Commerce's Office of Federal Technology Commercialization. Prior to that he served as patent counsel of the National Institutes of Health.

As a result of Bayh-Dole, the amount of industry funds invested in university R&D increased 160 percent since 1980. Meanwhile, the number of patents being produced by universities increased 500 percent since 1980.

The National Science Board's 1993 Science & Engineering Indicators notes that the university sector is performing a larger share of research in the U.S. than in the past. In 1985, universities performed 9 percent of the total R&D, but by the end of 1993 that figure has risen to 13 percent. In contrast, the amount of R&D performed by industry fell from 72 percent to 68 percent. However, some decline is attributed to growing university/industry teaming set forth in the Bayh-Dole Act. The

entire nation has entered a new phase of partnership between the public and private sectors because of the tools Latker created.

The 1993 direct economic returns from academic technology transfer include: $9 billion of products sold, 53,000 new jobs, $1.8 billion in tax revenues to all levels of government and an economic impact growth rate of 25-30 percent per year.

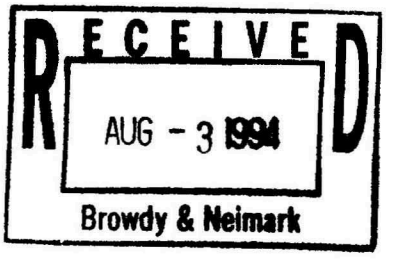
Federal laboratories are now beginning to make similar progress. -0- 7/11/94 /CONTACT: Gerrill Griffith or Diane Hedinger of NTTC, 800-678-6882/
CO: Association of Federal Technology Transfer Executives; National

Technology Transfer Center ST: District of Columbia IN: SU:

Transmitted: 94-07-11 16:06:31 EDT

MELVIN C. GARBOW
1200 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, D.C. 20036-6885

August 2, 1994



Norman J. Latker, Esq.
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419 7th Street, N.W.
Suite 300
Washington, D.C. 20004

Dear Norman:

Les Weinstein called me to advise of your recent receipt of the Vannevar Bush Award. That is a wonderful achievement and I offer you my warmest congratulations. I look forward to buying you a celebratory lunch in the near future when you can tell me what you did to deserve the award.

Best regards to Carol.

Sincerely,

Mel

Melvin C. Garbow

DRAFT

July 22, 1994

Mr. Joseph Allen
President - elect
The Association of Federal
Technology Transfer Executives
316 Washington Ave.
Wheeling, WV 26003

Dear ~~Mr. Allen;~~ Joe

I would like to again express my thanks to you, Jon Soderstrom and the Board of Directors for chosing me as the first recipient of the Vannevar Bush Award. It was the most welcome recognition I have ever received and made clear that our work was well worth the effort.

I hope you and AFT^{2}E continue your good work and the I can provide you with some assistance.

Best Regards.

Sincerely,

Norman J. Latker

NJL:ekd
cc: Jon Soderstrom

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You drafted the prototype of the Federal Technology Transfer Act in 1983 and continued to struggle for its passage despite overwhelming obstacles resisting this historic change in policy. You were a central figure in extending Bayh-Dole coverage to university-operated federal laboratories in 1984. The final passage of the Federal Technology Transfer Act in 1986 was based upon the work that you led in building a consensus that the time had come to re-examine the relationship between the laboratories and the private sector. To say that you faced an up-hill struggle is no small exaggeration.

Institute

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You were instrumental in the issuance of Executive Order 12591 making this law the centerpiece of Administration technology management policy. You created the Interagency Committee on Federal Technology Transfer so that the various agencies could work together to successfully meet the new challenges of the law.

You designed the Department of Commerce's implementation of that Act. Your system has allowed the National Institute of Standards and Technology to be hailed by the Council on Competitiveness as a model in processing cooperative research and development agreements with a minimum of red-tape.

Finally, you also were a key figure in forcing a re-examination of government science and technology policy agreements to bring them into line with the new technology management policies of the U.S. so that they would no longer be instruments for giving away taxpayer-supported research and development.

Like most pioneers you were frequently misunderstood and feverishly fought by those who feared change. You willingly paid the price required of those who dare to move beyond the bounds of conventional thinking. Not only have public technology managers benefitted by your actions, but the entire nation has entered a new phase of partnerships between the public and private sectors because of the tools you created.

AFTTE would be honored if you could join us on July 13, 1994 at our Third Annual Meeting which will be held at the Grand Hotel, 24th and M Streets, N.W. Washington, D.C. We would like to present your award at the plenary session at 9:00 a.m. Please let us know if you have any questions.

Again, congratulations. The members of AFTTE are looking forward to personally thanking you for your tremendous achievements in public technology management.

Sincerely,

Jon Soderstrom
President

Joseph P. Allen
President-Elect

cc: Board of Directors

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Jon Soderstrom
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A Win-Win Philosophy for Technology Management

Norman Latker*

In 1690, John Locke asserted that constitutional government could only be effective and legitimate if it recognized and preserved the natural rights of man including the right to life, liberty, and property. This was crystallized by his belief that "a man has a right to what he hath mixed his labor with." Locke's proposition is widely understood to be the underpinning of our Constitution. Locke's writings further made clear that he broadly construed property to mean virtually the entire personal sphere of what is a man's own, *including his ideas*. This principle was specifically manifested in our constitution by the grant of power to the Congress to secure for limited times to authors and inventors the exclusive right to their respective writings and discoveries. Congress' enactment of the patent and copyright laws demonstrated its belief that the right to own intellectual property is a right of man and a necessary element for successful constitutional government and the promise of prosperity envisioned for such governments. Similarly, all state laws protect the right of individuals to maintain trade secrets.

Neither the Constitution nor the respective implementing laws guarantees any right to the employers of such authors or

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Norman Latker is Vice President, Legal and Technology Affairs, University Science, Engineering and Technology, McLean, VA 22102; he was formerly Director, Office of Federal Technology Management, Department of Commerce and Patent Counsel, Department of Health, Education & Welfare.

inventors. The failure to address the rights of employers is not surprising because in 1787 writers and inventors were in most part self-employed. But as that fact changed, the common law addressed the relationship between employers and employees by upholding the assignment of a person's ideas as a condition of employment. This evidently was based on the belief that employers and their prospective employees were on an equal footing at the time of hiring, and there were no overriding national issues which need interfere with their freedom to contract. This seemingly logical rule of law eliminated any future need on the part of employers to examine whether it was equitable or desirable company or social policy to require the assignment of ideas solely as a condition of being employed. No further consideration was given to the fact that such ideas were not yet made and could not be evaluated to determine their future value to society. It does seem clear, however, that given a possibility of equal footing, the law intended that employees would negotiate for a value "in what he hath mixed his labor with." But as time passed, it became evident that employees would not achieve such footing.

It was in the context of this right in employers (including its acceptance and application by the federal government) coupled with the growth of large private and public organizations and the concentration of research funding in these organizations that the rights of authors and inventors faded into obscurity in the 1950's and 60's. Interestingly, at the same time the public perception of these organizations became increasingly critical. It seems appropriate to suggest that as latter day Edisons and Westinghouses became obscure within these organizations, the public lost its ability to relate to the organizations' achievements and began focusing on their problems.

Indeed, Congress later refused to join business (other than small business) to Bayh-Dole because of the near universal requirement for assignment of ideas of employees without additional remuneration as a condition of employment.

It was within this environment that the leadership of the Society of University Patent Administrators (SUPA) began a long struggle to gain control of ownership of inventions made with public research funding. This undertaking was driven by the understanding that successful application of university technology by industry must be a win-win situation aimed at mutual respect in which all participants, including industry and the inventor must benefit equitably from the result. From the beginning it was understood that any return from industrial licensing must be shared with the inventors that produced it based on predetermined agreement.

Victories in the executive branch came in the late 60's at the Department of Health, Education and Welfare, then in the early 70's at the National Science Foundation, but impending reversal at HEW in 1977 and intransigent bureaucratic resistance made it clear that strong university technology management offices could not be built on the shifting sands of executive policy.

Perseverance of the SUPA leadership finally delivered the Bayh-Dole Act of 1980 and through it later a coherent government policy aimed at further decentralizing technology management by permitting all federally funded creating organizations and their investigators, first at universities and then at federal laboratories, to own and benefit from the application of their technology.

Well . . . principles are fine, but there will always be people who legitimately question whether they work in practice. There are a number of items that lead to the conclusion that the principles embodied in Bayh-Dole are working better than even its advocates expected.

In their last report on Bayh-Dole, the GAO indicated that in addition to increased university invention reporting and licensing, the funding of cooperative arrangements between universities receiving federal R&D funds and industry has grown 74 percent from $227 million in FY 1980 to $482 million in FY 1985 (in constant dollars). Average private funding of universities has risen to between 6 to 8 percent.

The University of Minnesota study, "University Patents Issued in 1987," verifies that invention reporting has dramatically increased: Over 900 patents issued to universities in 1987. That is four times the 230 patents that issued in 1976!

Nineteen seventy-six was the last year in which the Department of Commerce collected statistics on patents issued to federally funded research performers. In that year, the total number of patents issued for all federally funded research performers regardless of their ownership was approximately 1800 and was headed down on the basis of the trend set by the prior five years. There is no evidence that, for performers other than the universities, the statistics reversed after 1976. In fact, a report by the Patent and Trademark Office in February 1988 suggests that they still may be declining.

But presuming that since 1976 they remained flat for other performers, the total number of patents issued in 1987 for all federally funded performers would be approximately 2500, including the 900 attributed to universities. That makes the university portion 36 percent of the total, which means that university research, with approximately 10 percent of the federal R&D budget, is producing over a third of the resulting

patents. Even more fantastic is the fact that unlike the other performers this is being done at virtually no cost to the taxpayer. Further, the fact that the patents are being paid for by the universities or its licensees also suggests that they are patents that were filed after careful consideration. Can there be much question that the incentives of Bayh-Dole have worked?

Although we can be genuinely encouraged by these statistics, the report from the Patent and Trademark Office is not bright. Of the 90,000 patents issued in 1987, 47 percent went to foreign nationals, up from 45 percent in 1986. This marks a continuation of a trend that has seen the overseas share of American patents double over the past 20 years while the number of patents going to American nationals has remained static. Patents received by U.S. citizens have been steadily falling from a high of over 50,000 in 1972 to below 40,000 in 1985. At the same time scientific papers published by industrial employees slipped from 12,200 in 1973 to 10,400 in 1980. Yet R&D budgets grew 80 percent to about $52 billion from 1975 to 1985. With increasing expenditures and decreasing output, the OTA concludes that American R&D is exhibiting all the classic signs of declining productivity.

But in the midst of this industrial gloom a glimmer of hope comes from the current trend to restructure corporate America. One of the principal lessons of restructuring, just about everyone agrees, is that an experienced operating manager given the right guidance, liberal incentives, and enough freedom, can almost invariably do a better job generating value from a business than someone from corporate headquarters. So the lessons of decentralizing are also being undertaken by business. If these liberal incentives lead to better policies on remunerating their employed inventors, Bayh-Dole suggests their statistics on patents will surely improve. I think start-up companies already understand the need to take care of their inventors.

Washington still has a significant number of people hoping to manage the next big science project. Each project is supported as the answer to our competitiveness problem. "Mr. President, fund this one and we promise you that the by-products that will result will vault us ahead of foreign competition in any area of technology touched by the project." But the past has shown that those who gain control of the funding demand control of resulting technology on grounds that inability to direct the actions of the creator will impact on the funder's targeted result.

The members of SUPA have learned that it is possible and probably imperative to address both the directed and the serendipitous results of science. Indeed, the serendipitous result

could be the initial step to a technology of greater importance to society than the directed or funded result. The most common problem of large research programs has been the lack of understanding at the funding level on how to manage serendipitous results. Bayh-Dole responds directly to that problem. In fact, the state of the art in technology management has advanced to the point where it is legitimate to challenge the funding of science projects that will not be managed by agencies under Bayh-Dole principles. The projects that immediately come to mind are the Superconducting Supercollider and Mapping the Human Genome, both of which are advocated by the Department of Energy.

If I have not made my point, I believe this last story demonstrates it. A few weeks ago a friend called at the request of his son, who is a computer scientist at one of the major universities. My friend's son wanted me to know that with the assistance of his university he had just concluded the licensing of a software program he designed for a significant return and on the basis of this he has decided to reject a job offer from a major company. He felt that the opportunity to pursue his own research to completion and still share in the value created was something that could not be met by the offer.

Louis Pasteur probably said it best:

> There is no greater charm for the investigator than to make new discoveries, but his pleasure is heightened when he sees that they have a direct application to practical life.

It seems to me that when all our creative people are treated with respect through sharing with them the return on what they have created, we will have switched on a power that no foreign competitor can equal. But, in the meantime, John Locke clearly lives here.

NORMAN LATKER
VICE PRESIDENT, LEGAL AND TECHNOLOGY AFFAIRS
UNIVERSITY SCIENCE, ENGINEERING AND TECHNOLOGY
FEBRUARY 29, 1988 PRESENTATION
SOCIETY OF UNIVERSITY PATENT ADMINISTRATORS ANNUAL MEETING
SAN DIEGO, CALIFORNIA

My assignment "Washington in Review" gives some license to spend a few moments in the distant past.

Lincoln once said, "I was told that I'm on the way to Hell -- I didn't know that it was only one mile away and under a dome." My friends here know that I've left the government to do something I believe in. Whether I'm going to Hell is not yet clear. But when in a new environment, it's probably normal to dwell on where you've been as well as where you're going. Where I've been with the founder's of this association is someplace that those of you who were not there unfortunately cannot easily revisit. But I think that it's important from time to time to remind you of the legacy that your founder's have left.

In 1984, Ed MacCordy made a masterful presentation which I cannot do justice to today, about the formative years of the association which lead to the passage of Bayh-Dole. But I would like to briefly address what I believe in hindsight were the underlying principles that motivated those extraordinary years.

In 1690, John Locke asserted that constitutional government could only be effective and legitimate if it recognized and preserved

the natural rights of man including the right to life, liberty and property. This was crystalized by his belief that "a man has a right to what he hath mixed his labor with." Locke's proposition is widely understood to be the underpinning of the our constitution. Locke's writings further made clear that he broadly construed property to mean virtually the entire personal sphere of what is a man's own, <u>including his ideas</u>. This principle was specifically manifested in our constitution by the grant of power to the Congress to secure for limited times to authors and inventors the exclusive right to their respective writings and discoveries. Congress' enactment of the patent and copyright laws demonstrated their belief that the right to own intellectual property is a right of man and a necessary element for successful constitutional government and the promise of prosperity envisioned for such governments. Similarly, all state laws protect the right of individuals to maintain trade secrets.

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requirement for assignment of ideas of their employees as a condition of employment without additional remuneration.

It was within this environment that the leadership of this association began a long struggle to gain control to ownership of inventions made with public research funding. This undertaking was driven by a clear understanding that successful application of university technology by industry must be a win-win situation aimed at mutual respect in which all participants including industry and the inventor must equitably benefit from the result. From the beginning it was understood that any return from industry licensing must be shared with the inventors that produced it based on predetermined agreement.

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50,000 in 1972 to below 40,000 in 1985. At the same time scientific papers published by industrial employees slipped from 12,200 in 1973 to 10,400 in 1980. Yet R&D budgets grew 80 percent to about $52 billion from 1975 to 1985. With increasing expenditures and decreasing output, the OTA concludes that American R&D is exhibiting all the classic signs of declining productivity.

But in the midst of this industrial gloom a glimmer of hope comes from the current trend to restructure corporate America. One of the principal lessons of restructuring, just about everyone agrees, is that an experienced operating manager given the right guidance, liberal incentives, and enough freedom, can almost invariably do a better job generating value from a business than someone from corporate headquarters. So the lessons of decentralizing are also being undertaken by business. If these liberal incentives lead to better policies on remunerating their employed inventors, Bayh-Dole suggests their statistics on patents will surely improve. I think start-up companies already understand the need to take care of their inventors.

Notwithstanding, Washington still has a significant number of people hoping to manage the next big science project. Each project is supported as the answer to our competitiveness problem. "Mr. President, fund this one and we promise you that the by-products that will result will vault us ahead of foreign competition in any area of technology touched by the project."

But the past has shown that those that gain control of the funding, demand control of resulting technology on grounds that inability to direct the actions of the creator will impact on the funder's targeted result.

But this association has learned that it is possible and probably imperative to address both the directed and the serendipitous results of science. Indeed, the serendipitious result could be the initial step to a technology of greater importance to society than the directed or funded result. The most common problem of large research programs has been the lack of management understanding at the funding level on how to manage serendipitious results. Bayh-Dole responds directly to that problem. In fact, the state of the art in technology management has advanced to the point where it is legitimate to challenge the funding of science projects that will not be managed by agencies under Bayh-Dole principles. The most immediate projects that come to mind is the super conducting-super collider and mapping the human genome, both of which are advocated by the Department of Energy.

If I have not made my point, I believe this last story demonstrates it. A few weeks ago a friend called at the request of his son who is a computer scientist at one of the major universities here today. My friend's son wanted me to know that with the assistance of his university he had just concluded the licensing of a software program he designed for a significant

return and on the basis of this he has decided to reject a job offer from a major company. He felt that the opportunity to pursue his own research to completion and still share in the value created was something that could not be met by the offer.

Louis Pasteur probably said it best:

> "There is no greater charm for the investigator than to make new discoveries, but his pleasure is heightened when he sees that they have a direct application to practical life."

It seems to me that when all our creative people are treated with respect through sharing with them the return on what they have created, we will have switched on a power that no foreign competitor can equal. But in the meantime, John Locke clearly lives here.

I thank you for your indulgence both today and in the past.

the marketplace for public consumption, it must travel a long road, usually measured in years, from discovery to complete development. This road includes the actual discovery of the potential therapeutic agent, the preliminary screening to determine if the agent has possible therapeutic usefulness, different stages of animal testing, preliminary tests in humans and, finally, full-scale clinical testing of the agent. The newly discovered agent may be a completely new chemical entity or an old chemical either of which is shown to be useful as a therapeutic. The developmental process in either case is governed by the Federal food and drug laws which require evidence of careful testing before the agent can be cleared for the market.

In most instances the NIH or its grantees do not participate in the full development of a therapeutic agent up to the point where it is made available commercially. We view our role in the Nation's medical research effort as complementary to the activities of the other elements within our society, both public and private, that also support research and development related to health. It seems to us that the interests of the American people are best served when the various elements of this medical research structure can interact. The most effective interrelationship results when the particular capabilities of the various elements, Federal and nonfederal, can be utilized to the fullest extent.

Generally speaking an NIH scientist or grantee will be involved, if at all, at one of four points in the developmental process:

[redacted]

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Testimony by
Dr. James A. Shannon,
Director, National Institutes of Health,
before the
Subcommittee on Patents, Trademarks, and Copyrights
of the Senate Committee on the Judiciary
August 17, 1965

Mr. Chairman and Members of the Committee:

I appreciate the opportunity afforded by your invitation to appear before this Committee and discuss the relationships of patent policies to NIH programs, especially as it concerns research financed by multiple sources or situations where additional private funds are necessary for the full development of an invention. At the outset, I would emphasize that the NIH, as one of the bureaus of the Public Health Service, is a component of the Department of Health, Education, and Welfare, and functions within the patent regulations set forth by the Department.

I understand that the Department's patent policies and its position on the legislation before this Committee have already been presented. For this reason, I will limit my statements to the two areas of concern mentioned in your invitation.

I would first like to address myself to situations where additional private funds are necessary for the development of an invention made under Federal support, since I believe the policy problems attending these situations are a major public concern.

The NIH supports research activities through grants, contracts, and within its own laboratories which may result in the discovery of

[illegible] under the patent regulations see letter

potential therapeutic agents. Before one of these agents can reach the marketplace for public consumption, it must travel a long road, usually measured in years, from discovery to complete development. This road includes the actual discovery of the potential therapeutic agent, the preliminary screening to determine if the agent has possible therapeutic usefulness, different stages of animal testing, preliminary tests in humans and, finally, full-scale clinical testing of the agent. The newly discovered agent may be a completely new chemical entity or an old chemical either of which is shown to be useful as a therapeutic.

The developmental process in either case is governed by the Federal food and drug laws which require evidence of careful testing before [illegible] be cleared for the market.

... an NIH scientist or grantee will be involved, ... at all, at one of four points in the developmental process:

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definitive conclusion.

More generally the chemist, given freedom of action, would approach the pharmaceutical industry which has extensive capability to undertake the entire development and testing process and is able to accumulate all the data from different stages of development necessary for FDA acceptance.

b. NIH funds may also be involved in support of research which involves the probing of biological mechanisms with chemical agents. Out of such investigation may well come new knowledge on novel uses for a compound, but in general such an investigator will rarely have the capability of follow-through as with a wholly new therapeutic agent.

c. NIH funds more recently support broad clinical investigation and such work has a heavy commitment to the assessment of therapeutic activity either in absolute or comparative terms. Out of this type of work in the past has come wholly new therapeutic uses that have had broad impact on clinical medicine. I have in mind in this respect the discovery of tranquilizing properties of reserpine when this drug was in use as a blood pressure lowering agent and the discovery of energizing properties of isoniazide when the drug was being explored as an antitubercular agent.

...ABILITY OF FOLLOW-THROUGH AS WITH ...

d. Finally, NIH has, in the past, supported and/or participated in the extensive type of field trial which firmly establishes the net benefit to be derived from a given compound under well-defined clinical conditions, and will no doubt do so in the future.

The first three of these types of studies can be expected to yield patentable discoveries and consequently the rate of evolution to an effective therapeutic agent generally available to the public will be determined by the terms and conditions which facilitate the interplay of the resources of the Federal Government, the university scientists and the pharmaceutical industry.

Although NIH support of an investigator may stop at an early stage of development or cover only a part of the complicated sequence of drug development, our Departmental patent policy requires that his invention be reported to the Surgeon General for his disposition since the invention in most instances is complete within the definition of the U.S. Patent Office. The Surgeon General's disposition generally results in title to the Government in accordance with the provisions of the Department's regulations, the title provisions of the President's Memorandum and the Executive Order governing disposition of employee inventions.

The uncertainties involved in after-the-fact determinations have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application. The industrial firms want some guarantee of

exclusive patent rights as compensation for and protection of their possible investment, which may be considerable before FDA clearance can be obtained. Because, as I understand it, there is some question as to whether we can or should extend such a guarantee, it is often difficult to motivate industry to undertake the perfection and marketing of the NIH-supported inventions.

We, of course, support the basic policy that title to health and welfare inventions generated primarily with Federal support should reside in the Government. It does seem to us as persons responsible for the largest Federal medical research program that there does need to be clarification of the situation with regard to the issuance of licenses to inventions held by the Government. One possible solution might be the granting of short periods of exclusivity in such situations as I have discussed--that is, where it is found to be necessary to develop an invention to the point of practical application and there is no other way to obtain the needed industry cooperation. Compounds which show some promise in early stages of investigation may be of no benefit to the public and may not serve the public interest unless clinical testing is undertaken and the resulting drug is cleared by the FDA and marketed. We also believe that it seems sensible to be able to involve industry in the testing and marketing phases of drug development since these firms already possess capabilities in these areas that would have to be duplicated elsewhere to accomplish these necessary purposes.

The Department is in the process of reviewing its entire patent policy and practices.

Passing on now to the second area on which you wished my comments, I would note that one of the common characteristics of scientific research activities performed in universities is receipt of joint and simultaneous support from Government and nonprofit organizations, and not infrequently from industry. In the biomedical sciences, the Government support is most frequently provided in the form of a grant from the NIH. Funds from these different sources of support are often commingled with the result that a given research project may be financed and dependent upon several different sources of income at the same time. Where the private sources of support impose no conditions upon their grant relating to inventions, the DHEW regulations requirement that the NIH grantees report all their inventions to the Surgeon General for his disposition poses no problem. However, where, as in the case of the American Cancer Society and the American Heart Association, co-sponsors maintain patent policies requiring their grantees to agree to assign all invention rights to them, the grantee who accepts support for the same research activity from both the NIH and such other sponsors has undertaken conflicting obligations he cannot fulfill. It is difficult to solve problems of conflict after the fact on the basis of priority as between the co-sponsors. Neither is it a satisfactory solution to suggest that the grantee be limited to acceptance of support from only a single source which imposes such an obligation.

I believe it is in the public interest to encourage support of research from the private sector of our economy and to discourage exclusive reliance upon Government-financed support. In order to further this objective, it may be necessary to relieve universities and their researchers from the dilemma created by conflicting obligations to assign patent rights.

At the present time, it is my understanding that the patent regulations of our Department do not take into consideration the equities of co-sponsors in making disposition of inventions arising from research financed by multiple sources, and the Surgeon General must make his determination solely on the basis of our support. As I have mentioned, I do understand that these regulations have been under review for some time with this matter being given consideration by the Department.

Thank you very much for this opportunity to appear before you. I would like to emphasize that I am obviously not a patent expert, but I would be glad to answer any questions from my perspective as the director of a large Federal research activity.

User Group Meeting

Federal laboratory technology transfer offices are now eligible for subsidized access to the Knowledge Express Core Contents℠ online service for technology transfer under the Technology Reinvestment Project (TRP). Existing and future users of the service are encouraged to attend this User Group Meeting to learn how they can get the greatest benefit from the service.

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Time: **4:15pm to 5:15pm**

Date: **Thursday, July 14, 1994**

Location: **Grand Ballroom, The Grand Hotel**

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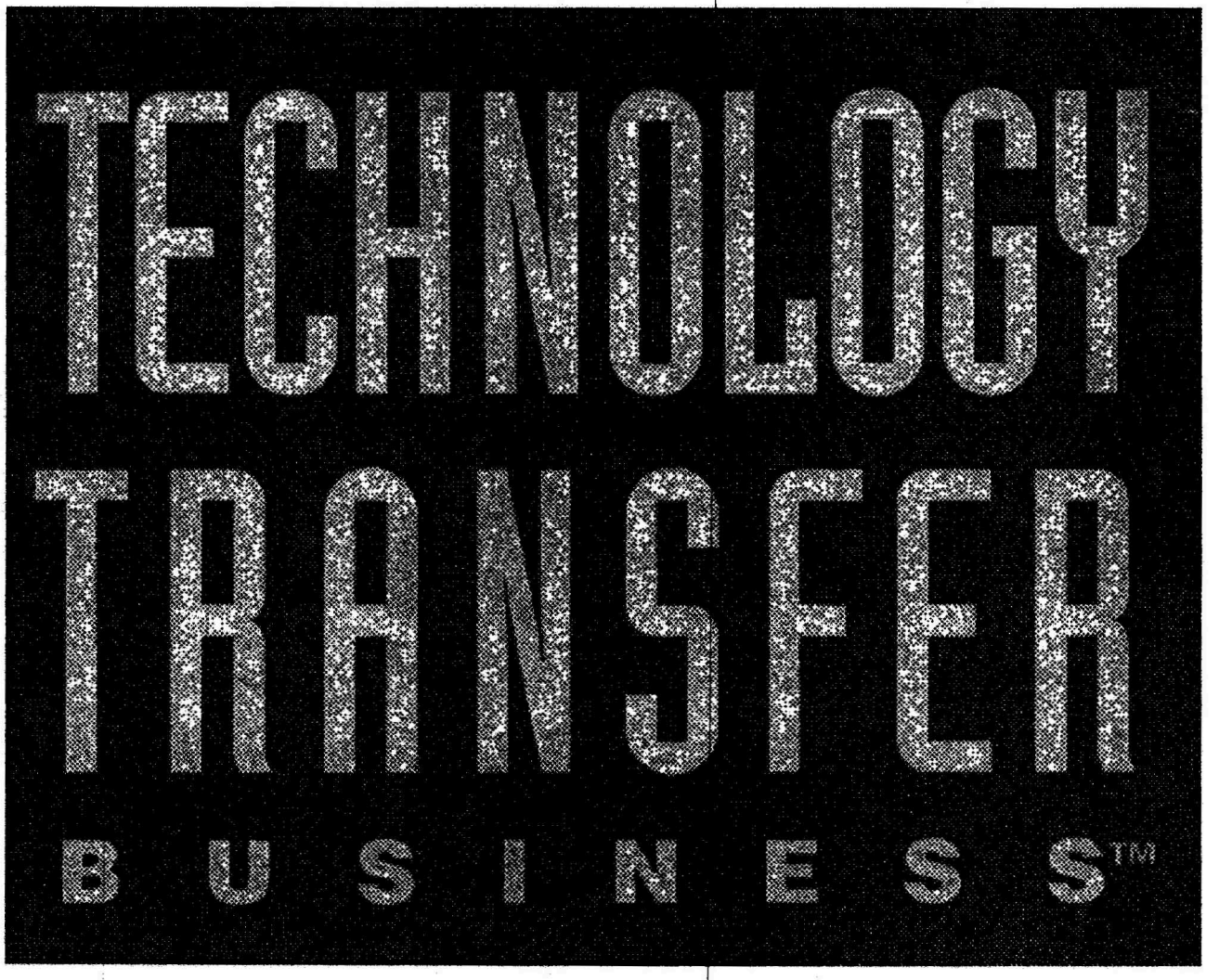

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