

**Statement of
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U.S. Department of Commerce**

Before the

**Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs**

**U.S. House of Representatives
107th Congress, 2nd Session**

**Hearing on the Department of Veterans Affairs Medical
Research Programs**

September 19, 2002

**TESTIMONY OF
BENJAMIN H. WU
DEPUTY UNDER SECRETARY FOR TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE**

**BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE COMMITTEE ON VETERANS' AFFAIRS
SEPTEMBER 19, 2002**

Good morning, Chairman Buyer, Ranking Member Carson, and Members of the Subcommittee. I am Ben Wu, Deputy Under Secretary for Technology at the Department of Commerce. I have been asked to participate at today's hearing on the Department of Veterans Affairs (VA) research activities and to comment on the VA's technology transfer efforts. In addition, I will broadly review the Federal technology transfer enterprise of transferring government technology to the private sector for commercialization.

The Department of Veterans Affairs deserves commendation for its efforts in developing an active technology transfer program. In February 2000, VA appointed the first director of its technology transfer program and its first patent attorney last year. Additionally, VA has entered into an arrangement with the National Technology Transfer Center at Wheeling Jesuit University in West Virginia to assist it with its technology transfer program.

These developments, coupled with the April 2001 announcement by Secretary Anthony Principi that the VA would take the lead in aggressively disseminating new discoveries and inventions made by VA researchers, indicate a new and growing recognition of the importance of technology transfer to the vitality of the Department's research activities. Thus, it is expected that the number of VA inventions, patents, and licenses will substantially increase over time.

The Department of Commerce is pleased to play a significant role in Federal technology transfer because of the benefits received by the public from the billions of dollars spent on research and development by the Federal government. By statute, Commerce coordinates Federal technology transfer policies.

In my testimony, I will review the Department of Commerce coordination leadership roles and responsibilities in technology transfer, the importance of intellectual property rights in creating greater innovation partnerships with the Federal government, provide a statutory review of Congressionally enacted technology transfer laws, and offer some thoughts regarding VA and its technology transfer efforts.

The Department of Commerce Roles and Responsibilities in Technology Transfer

The Department of Commerce, through our Technology Administration (TA), has specific roles and responsibilities in the area of technology transfer – particularly through our Office of Technology Policy and the National Institute of Standards and Technology. These functions are detailed below.

Technology Administration, Office of Technology Policy (OTP)

The Office of Technology Policy plays a significant role in the development, implementation, and analysis of technology transfer policies and practices, in close consultation with Congress and other agencies. As the Administration's focal point for discussion of technology transfer issues, OTP also coordinates and works closely with the Inter-Agency Working Group on Technology Transfer (IWG). The IWG discusses a wide range of agency activities and issues relating to technology transfer, recommends policies for technology transfer, and coordinates the submission by agencies of data on inventions and technology transfer for congressional reports.

OTP's statutory responsibilities include:

- Assisting agencies in the implementation of relevant laws, including the Bayh-Dole Act and the Stevenson-Wydler Act;
- Developing policies and issuing regulations governing the ownership of patents arising from Federally funded research and the licensing of Federally owned inventions (see implementing arrangements in 37 CFR Parts 401 and 404); and
- Compiling and analyzing information and reporting on agency implementation of technology transfer mechanisms such as Cooperative Research and Development Agreements (CRADA) and patent licenses.

Through FY 2000, the Office of Technology Policy was responsible for producing a biennial report to Congress on the technology transfer activities of all Federal agencies. Requirements in the Technology Transfer Commercialization Act of 2000 (TTCA) shifted this reporting responsibility to an annual basis. Beginning in the current fiscal year, the TTCA requires each agency with a Federal laboratory to produce with its budget submission, an annual report on its technology transfer activities and outcomes. In addition, the Secretary of Commerce is required to prepare a government-wide summary report based on these submissions. The Office of Technology Policy is responsible for coordinating agency submissions and producing the Secretary's summary report.

In the role of coordinator and leader of the IWG, OTP has crafted administration support for a number of technology transfer-related provisions and legislation, including the recently passed Technology Transfer Commercialization Act of 2000. As the Administration considers ways to improve the efficiency and speed of technology transfer, it is important to

consult the technology transfer practitioners throughout the government, as well as their counterparts in industry and universities.

The Department of Commerce's experience and relationship with the IWG has been, and will no doubt continue to be, a strong asset in organizing such consultations, identifying recommendations, and prioritizing appropriate administrative or regulatory action.

Technology Administration, NIST

NIST's mission is to develop and promote measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life. The NIST laboratories develop and disseminate measurement techniques, reference data, test methods, standards, and other infrastructural technologies and service that support U.S. industry, scientific research, and the activities of many Federal agencies. NIST works directly with industry partners (and consortia), universities, associations, and other government agencies, and utilizes diverse mechanisms to transfer the knowledge and technologies that result from its laboratory research.

In keeping with its mission, NIST's technology transfer activities are focused on pursuing the most efficient and effective path to utilization and commercialization, which often necessitates the broad dissemination of research results, rather than the creation of intellectual property and associated licenses.

Activities carried out by NIST related to technology transfer include:

- NIST's Office of Technology Partnerships manages NIST's formal technology transfer activities, such as CRADA participation and the protection and licensing of intellectual property.
- Pursuant to the Technology Transfer Commercialization Act of 2000, NIST has reported on its technology transfer activities annually to the Technology Administration's Office of Technology Policy. This information will be incorporated into a report submitted with the Department's annual budget documents.
- NIST works closely with the Office of Technology Policy on other technology transfer-related issues, through participation in the IWG, the Federal Laboratory Consortium for Technology Transfer (FLC), and informal consultation.

The Importance of Intellectual Property Rights in Creating Greater Innovation Partnerships with the Federal Government through Technology Transfer

Technology transfer tools such as Cooperative Research and Development Agreements (CRADA) and patent licensing are relatively simple ways for U.S. businesses to develop Federally funded innovations into commercially useful products and processes. Congress created these tools in the 1980s at a time of unprecedented technological challenge to U.S. industry, but they are useful even in today's dynamic technology markets.

The manner in which the Federal government works with the private sector in developing and diffusing technologies changed fundamentally with the passage of the Bayh-Dole, Stevenson-Wydler, and Federal Technology Transfer Acts. The agencies and the private sector began to find ways to partner in the development of technologies that both furthered agency missions and advanced the competitiveness of industry and the strength of our economy.

Federal technology transfer has helped develop everyday products such as stronger and lighter materials for more fuel efficient cars, the Global Positioning System (GPS) that offers pinpoint precise locations for navigation on the seas or on the highways, and the HIV home kit that allows people to collect samples in the privacy of their own home and send them to a laboratory for analysis. These are just a few of the many hundreds of examples of technologies to which the Federal government originally held intellectual property title, and either licensed the technology or collaborated with industry to commercialize. These examples demonstrate the extent to which effective Federal technology transfer serves to stimulate the economy.

Successful technology transfer is a constantly evolving effort. In its biennial technology transfer report entitled *Tech Transfer 2000*, the Department of Commerce's Office of Technology Policy found the following:

- Managing intellectual property must become more of an agency priority;
- More help is needed to make it easier for industry partners to find the right laboratory;
- A CRADA can be used effectively in many different circumstances and is an extremely flexible instrument; and
- Measures of success in technology transfer must be developed by agencies in partnership with the business community.

Recent Technology Transfer Laws and Intellectual Property Rights Distribution

Congress has a rich and long history of promoting technology transfer. Federal technology transfer began with the Stevenson-Wydler Technology Innovation Act in 1980 (P.L. 96-480). The Stevenson-Wydler Act required Federal laboratories to take an active role in partnering with industry and established technology transfer offices at all major Federal laboratories.

That landmark legislation was expanded considerably with the Federal Technology Transfer Act of 1986 (P.L. 99-502) and the National Competitiveness Technology Transfer Act of 1989 (P.L. 101-189). The Federal Technology Transfer Act of 1986

allowed a government-owned, government-operated laboratory, which we know as a GOGO, to enter into a CRADA with industry, universities, and others. A CRADA allows a laboratory and an industrial partner to negotiate patent rights and royalties before they conduct joint research. This gives the company patent protection for any inventions and products that result from the collaboration. This patent protection provides an incentive for the companies to invest in turning laboratory ideas into commercial products.

A CRADA also provides a Federal laboratory, in fulfilling its mission, with valuable insights into the needs and priorities of industry, and with the expertise available only in industry. The National Competitiveness Technology Transfer Act of 1989 extended the CRADA authority to a government-owned, contractor-operated (GOCO) laboratory such as the Department of Energy labs. It also protected information and innovations, brought into and created through a CRADA, from disclosure.

Since 1986, thousands of CRADA's have been signed, resulting in the transfer of technology, knowledge, and expertise back and forth between our Federal laboratories and the private sector. Under current law, the work done under a CRADA must not detract from the mission responsibilities of a Federal laboratory.

Yet despite the success of the CRADA legislation, there were existing impediments for companies that Congress felt needed to be addressed. The law was originally designed to provide a great deal of flexibility in the negotiation of intellectual property rights to both the private sector partner and the Federal laboratory. However, it provided little guidance to either party on the adequacy of the rights that a private sector partner should receive in a CRADA.

Agencies were given broad discretion in the determination of intellectual property rights under CRADA legislation. This often resulted in laborious negotiations of patent rights for certain laboratories and their partners each time they discussed a new CRADA. With options ranging from assigning the company full patent title to providing the company with only a nonexclusive license for a narrow field of use, both sides had to undergo this negotiation on the range of intellectual property rights for each CRADA.

This uncertainty of intellectual property rights coupled with the time and effort required in negotiation, hindered collaboration by the private sector with Federal laboratories. Some agencies have found that companies are reluctant to enter into CRADAs, or equally important, to commit substantial investments to commercialize CRADA inventions, unless they have some assurance they will control important intellectual property rights.

The enactment of the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113) enhanced the possibility of commercialization of technology and industrial innovation, by providing assurances that sufficient rights to intellectual property will be granted to the private sector partner with a Federal laboratory. The Act

guarantees to the private sector partner the option, at minimum, of selecting an exclusive license in a field of use for a new invention created in a CRADA. The company would then have the right to use the new invention in exchange for reasonable compensation to the laboratory.

In addition, the Act addresses concerns about government rights to an invention created in a CRADA. It provides that the Federal government will retain minimum statutory rights to use the technology for its own purposes.

Another one of the most successful legislative frameworks for advancing Federal technology transfer has been the Bayh-Dole Act of 1980 (P.L. 96-517, Patent and Trademark Act Amendments of 1980). The Bayh-Dole Act permits universities, not-for-profit organizations, and small businesses to obtain title to inventions developed with Federal support. The Bayh-Dole Act also allows Federal agencies to license Government-owned patented scientific inventions nonexclusively, partially exclusively, or exclusively, depending upon which license is determined to be the most effective means for achieving commercialization.

Critical pressures originally prompted the passage of the Bayh-Dole Act. Prior to its enactment, many discoveries resulting from Federally funded scientific research were not commercialized for the benefit of the public. Since the Federal Government lacked the resources to market new inventions, and private industry was reluctant to make high-risk investments without the protection of patent rights, many valuable innovations were left unused on the shelf of Federal laboratories.

With its success in licensing Federally funded inventions, the Bayh-Dole Act is widely viewed as an effective framework for Federal technology transfer. For example, the Association of University Technology Managers (AUTM) conducted a study on the effect of the Bayh-Dole Act. AUTM said that the Bayh-Dole Act not only encourages the commercialization of inventions by universities that would otherwise gather dust on the shelf, but it also brings in revenues to the Federal Government through licensing fees on Government-owned patents. The private sector has already demonstrated a strong interest in the strategic advantages of partnering with a Federal laboratory through a CRADA or through the licensing of Government-owned technology.

Nevertheless, both past and prospective private industry partners voiced their concerns regarding the Federal technology licensing process. Companies were deterred by the delays and uncertainty often associated with the lengthy Federal technology transfer process. These procedural barriers and delays could increase transaction costs and are often incompatible with the private sector's need for a swift commercialization calendar. The regulations governing Federal technology transfer also made it difficult for a Government-owned, Government-operated laboratory (GOGO) to bring existing scientific inventions into a CRADA even when its inclusion would create a more complete technology package.

A GOGO did not have the flexibility that small business and non-profits had in

managing their inventions under the Bayh-Dole Act. Also, a GOGO, unlike a GOCO, faced statutory notification provisions when granting exclusive licenses, and more importantly, it could not include existing inventions in a CRADA.

By reducing the delay and uncertainty created by existing procedural barriers, and by lowering the transactional costs associated with licensing Federal technologies from the Government, Congress believed it could greatly increase participation by the private sector in its technology transfer programs. This approach would expedite the commercialization of Government-owned inventions, and through royalties, could reduce the cost to the American taxpayer for the production of new technology-based products created in our Nation's Federal laboratories.

As a result, the Technology Transfer Commercialization Act of 2000 (P.L. 106-404) was enacted. The law sought to remove the procedural obstacles and, to the greatest extent possible, the uncertainty involved in the licensing of Federally patented inventions created in a Government-owned, Government-operated (GOGO) laboratory. This was achieved by applying the successful Bayh-Dole Act provisions to a GOGO. With the enactment of this law, the ability of the United States to compete has been strengthened and a new paradigm for greater collaboration among the scientific enterprises that conduct our nation's research and development – Government, industry, and universities – has been created.

Implementation of the Technology Transfer Laws by the VA

According to the May 17, 2001 Department of Veterans Affairs Intellectual Property Handbook, retention of ownership and protection of intellectual property developed by VA investigators are key issues. It is also important to acknowledge cases where co-ownership issues exist with VA academic affiliates. To address this issue, a model inter-institutional agreement (IIA) was developed by the VA. This legal agreement outlines relevant definitions, terms, and conditions for handling intellectual property between both organizations.

The VA believes that using the IIA allows VA a co-ownership interest while providing the academic affiliate unimpeded access and authority to patent and market the intellectual property in question. This makes the invention attractive to manufacturers to ensure that if they develop the product for the marketplace, they will have exclusive rights to produce and market the invention. Additionally, the VA believes that the overall benefit to the Federal government and the taxpayers is that a patent will protect an invention resulting from Federally-funded research.

Successful patents licensed to manufacturers would provide a royalty stream. As a result, VA inventors would benefit from royalties for their personal use, as well as a return of royalties to their research laboratories and facility. The taxpayer gains by the return of funds to the laboratories to further medical research. The VA believes that using IIAs provides a win-win situation for the VA and academic affiliates, while maintaining, strengthening, and/or expanding existing partnerships to the mutual benefit

of both organizations. Consequently, these agreements are used with academic affiliates whenever possible.

Regarding patents, the VA patent process begins when intellectual property has been disclosed and reviewed by the VA General Counsel and a determination has been made to retain ownership of an invention. An invention owned by the Federal government needs to be protected by an application for a domestic patent.

The VA may elect to use outside counsel if it is determined appropriate. All VA-owned inventions not covered by IIAs will receive centralized patenting support. This support includes handling patent applications, provisional patents, patent filings, follow-up requests for information concerning pending patent applications, international filings where applicable and other necessary actions.

Regarding a CRADA, in exchange for what VA receives from a collaborating party, the VA may provide personnel, services, facilities, equipment, or other resources, but not funding toward the conduct of specific research and development efforts which are consistent with VA's mission. The laboratory director may grant licenses or, in exceptional circumstances, assignments or options thereto, for reasonable compensation when appropriate, to collaborating parties for any inventions made by a Federal employee under such agreements. However, a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world, by or on behalf of the Government, must be retained. In such cases where it is determined to grant any of the rights in advance, they shall be granted directly to the collaborating party. The VA prefers to use a CRADA only when no other appropriate option is available.

VA Technology Transfer Issues

Although VA does not have an external research program, it has significant interaction with universities because many of the researchers also hold appointments at universities. For those receiving money from their universities under grants and contracts from other agencies, the Bayh-Dole Act may determine the rights to their inventions.

The facts surrounding the making of those inventions determine what type of recognition and return is appropriate. For example, under Bayh-Dole, the inventing university must acknowledge the rights of the Federal government in the patent with the name of the funding agency. The university is required to share royalties with the inventors but not with the funding agency although the university must use the remainder of the royalties for education or scientific purposes.

With the VA's new emphasis on technology transfer over the past two years, the agency has entered into more than 40 Cooperative Technology Administration Agreements (CTAA) with universities. These agreements usually cover the patenting and licensing of inventions made by individuals who have joint appointments at the VA

and a university. By clarifying the rights and responsibilities of the parties, these agreements are intended to facilitate the commercialization of joint inventions.

The issues associated with joint appointments in R&D collaborations, however, are not limited to the VA and so we believe should be addressed more broadly. This VA issue was recently discussed in the IWG on technology transfer and it was discovered that VA is not the only agency that has joint appointments. In addition, the treatment of inventions by university employees who work in Federal laboratories as visiting scientists seems to vary among the agencies. Accordingly, the Department of Commerce is planning to continue the discussion with the interagency group to develop some uniform principles in dealing with inventions by university visiting scientists and "joint" employees without impacting negatively the very successful technology transfer programs at universities under the Bayh-Dole Act. We are planning to ask the IWG to assist in developing a model agreement to cover the administration of such inventions and intend to use VA's CTAA as a point of departure.

Thank you, Mr. Chairman. I appreciate the opportunity to present the views of the Department of Commerce today on intellectual property rights from a technology transfer viewpoint. I will be pleased to answer any questions that you and the other members of the Committee may have.

DEPUTY UNDER SECRETARY FOR TECHNOLOGY**U.S. DEPARTMENT OF COMMERCE****TECHNOLOGY ADMINISTRATION****BENJAMIN H. WU**

Benjamin H. Wu was sworn in as Deputy Under Secretary for Technology at the U.S. Department of Commerce on November 6, 2001. In this capacity, he works along side Under Secretary Phillip J. Bond in advising Commerce Secretary Don Evans in science and technology policies to maximize technology's contribution to America's economic growth.

The Office of the Under Secretary for Technology supervises policy development and direction among the Office of Technology Policy (OTP), the National Institute of Standards and Technology (NIST), the National Technical Information Service (NTIS), the Office of Space Commercialization (OSC), and other areas.

Prior to joining Commerce, Mr. Wu held senior staff positions in the U.S. Congress for thirteen years. Most recently, from 1995 until his current appointment, Ben led on technology issues with the Technology Subcommittee of the House Science Committee. He began his Congressional service in 1988, having served as Counsel to Congresswoman Constance A. Morella of Maryland and on the Science Committee, first serving on the Investigations and Oversight Subcommittee staff in 1993.

Ben has extensive experience working on issues affecting United States technology and competitiveness policy. Specifically, he focused on information technology, biomedical technology, and technology transfer policy. He was the primary congressional staff member for legislation affecting Federal intellectual property and Federal technology transfer. Additionally, Ben worked on Technology Administration issues since TA's inception in 1989, with particular emphasis on the National Institute of Standards and Technology. Ben was also the most senior member and the lead Committee staff of the House Y2K Task Force that directed congressional efforts to correct the Year 2000 computer problem.

Ben received a Bachelor of Arts from New York University in 1985 and a Juris Doctor from the University of Pittsburgh in 1988.