Statement of Dr. Mark Allen
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Testimony to the House Committee on Science and Technology
Subcommittee on Technology and Innovation

July 17, 2007

Mr. Chairman, Ranking Member Gingrey and members of the Subcommittee, my name is Dr. Mark Allen and I am pleased to be able to present testimony to the Subcommittee on the topic of Bayh-Dole – The Next 25 Years. I received the SM and Ph.D. degrees from the Massachusetts Institute of Technology (M.I.T.) in l986 and 1989 respectively, and joined the faculty of the Georgia Institute of Technology[1] (Georgia Tech) after a postdoctoral appointment at M.I.T. Currently I am Regents' Professor of Electrical and Computer Engineering at Georgia Tech, with a joint appointment in the School of Chemical and Biomolecular Engineering, and hold the J.M. Pettit Professorship in Microelectronics. Georgia Tech was founded in 1885 and is one of the nation's top research universities, distinguished by its commitment to improving the human condition through advanced science and technology. Georgia Tech's campus occupies 400 acres in the heart of the city of Atlanta, where more than 17,000 undergraduate and graduate students receive a focused, technologically-based education. Georgia Tech also has satellite campuses worldwide. Georgia Tech's vision and mission is to define the technological research university of the 21st century, and educate the leaders of a technologically-driven world.

This hearing is focused on the next 25 years of technology transfer governed by the Bayh-Dole Act. In order to comment on the next quarter century, I will rely upon my past experience as a researcher and transferor of technology. This experience also reflects upon the questions the Subcommittee has asked of me.

In the mid to late 1990s and in my capacity as a Georgia Tech professor I was involved with a Multidisciplinary University Research Initiative (MURI) program on Intelligent Turbine Engines. As defined by the Department of Defense, "The MURI program is a multi-agency DoD program that supports research teams whose efforts intersect more than one traditional science and engineering discipline. Multidisciplinary team effort can accelerate research progress in areas particularly suited to this approach by cross-fertilization of ideas, can hasten the transition of basic research findings to practical applications, and can help to train students in science and/or engineering in areas of importance to DoD."[2]

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[1] http://www.gatech.edu
[2] http://www.acq.osd.mil/ddre/research/muri/muri.htm

The particular program was sponsored by the Army Research Office and was on the topic of "Intelligent Turbine Engines." My portion of the project was to develop a pressure sensor that could be used in particular locations in the engine to provide control signals to ensure optimal engine performance. Working with a Ph.D. student, we designed, fabricated, and tested a new type of pressure sensor that was (1) small in size; (2) capable of operating in harsh environments, such as high temperature; and (3) capable of wireless interrogation.

The results of my research were provided to the Army. In addition, the research results were patented by Georgia Tech[3] in accordance with the provisions of the Bayh-Dole Act. Conference publications[4], journal publications[5], and a Ph.D. thesis[6] were written and disseminated as an ongoing part of this academic research.

In the 2000-2001 timeframe, I began discussions with a medical doctor who was interested in exploiting microelectromechanical systems (MEMS)-based manufacturing technologies to create a new generation of medical devices. Wireless sensors, that could sense disease states from within the body, were a particular interest area of both of us; from his perspective as a clinician and from mine as an engineer. After several discussions, we noted that the turbine engine sensor developed for harsh environments under the MURI research program might also be applicable in another harsh environment, the human body. We formed a company, Cardiomems[7], dedicated to the commercialization of this technology. Cardiomems licensed key patents, including the two cited from the MURI project, exclusively in the field of medical devices. Based on these patents, Cardiomems engineers developed wireless sensors as monitors of endovascularly-repaired abdominal aortic aneurysms. The sensors are integrated with an external measurement antenna. A real-time waveform of the pressure environment of the excluded aneurysm is extracted and provided to the physician to diagnose the state of the aneurysm repair.

The government funding provided by the Army Research Office that was directed to the development of this sensor was approximately $500,000. To date, Cardiomems has received approximately $50 million in private equity investment, a ratio of approximately $100 of private investment for each $1 of government investment. Cardiomems currently employs over 100 people. Its wireless pressure sensors for aneurysm sensing were cleared for sale in the United States by the FDA in late 2005 and to date thousands of people have received them.

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[3] U.S. Patents 6,111,520 and 6,278,379

[4] English, J.M.; Allen, M.G., "Wireless micromachined ceramic pressure sensors," *Technical Digest, Twelfth IEEE International Conference on Micro Electro Mechanical Systems*, p.511-16 (1999)

[5] Fonseca, M.A.; English, J.M.; von Arx, M.; Allen, M.G., "Wireless Micromachined Ceramic Pressure Sensor for High Temperature Applications*," IEEE/ASME J. Microelectromechanical Systems*, v. 11, no. 4, pp. 337-43 (2002)

[6] English, J.M., "*Wireless micromachined ceramic pressure sensors for high temperature environments*", Ph.D. Thesis, Georgia Institute of Technology (2000)

[7] http://www.cardiomems.com

One of the key due diligence reviews prior to any private equity investment is a thorough review of the intellectual property licensed by the company, and it was clearly stated by investors that a strong intellectual property position would be a prerequisite for any investment. Without this strong position, enabled by licensing the critical technologies from Georgia Tech, in my opinion it would have been impossible for the company to have raised funding for this product. Due in part to the strong IP position the company holds as enabled by the Bayh-Dole Act, the medical community now has available a commercial device that has helped thousands of people, won multiple awards, and was cited in the 2005 annual report of the Food and Drug Administration as a device "that we believe will have a particular impact on patient care.[8]".

To summarize this portion of my testimony, what these experiences have taught me is that the commercialization process has many challenges. By far the largest challenge is the development effort required to transform academic discoveries into useful, commercial, salable products (as I mentioned above, this effort at least for Cardiomems was in dollar terms approximately a 100:1 ratio), and includes not only further technical development, but also legal issues, raising funds, liability protection, and securing regulatory approval. However, before embarking on any of these additional challenges, and before raising the first dollar from private investments, Cardiomems negotiated for licenses to the intellectual property with the university holders. Having clear access to the intellectual property developed in the academic laboratory through the mechanisms of the Bayh-Dole Act was the prerequisite for Cardiomems' success.

Although I have spoken previously from my viewpoint as an academic researcher and given a single example of Bayh-Dole-enabled success, it is clear that the Bayh-Dole Act has had a broad and profound effect on academic technology transfer more generally. In the first twenty-five years after its passage, there was a ten-fold increase in academic patent portfolios according to statistics maintained by the Association of University Technology Managers. If, as some have said, innovation is the intersection of invention and opportunity, this wave of innovation created 5000 new businesses, 3,641 new products, and generated 300,000 jobs[9]. Annually, U.S. research universities and institutions receive about sixty-seven percent of their research funding from the federal government[10]. Inevitably, simply because the vast majority of inventions in universities arise in the course of federally-funded projects, universities' obligations under Bayh-Dole will shape administrative systems for handling intellectual property, irrespective of the funding source.

In the State of Georgia the economic impact of technology transfer activities at universities is profound. Georgia Tech ranked 9th on the US Patent and Trademark Office's List of Top 10 Universities Receiving the Most Patents in 2005 (April 6, 2006). In announcing the list, Jon Dudas, Undersecretary of Commerce for Intellectual Property

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[8] Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration, *2005 Annual Report*, pp.1-4

[9] Data from the Association of University Technology Managers: www.autm.net

[10] Association of University Technology Managers' 2005 U.S. Licensing Survey

noted that "America's economic strength and global leadership depend on continued technological advances. Groundbreaking discoveries and patented inventions generated by innovative minds at academic institutions have paid enormous dividends, improving the lives and livelihoods of generations of Americans." That certainly seems to be the case in Georgia. In our most recent fiscal year, Georgia Tech executed 42 licenses and options, most for more than one patent. In fiscal year 2006, ten new companies were formed based Georgia Tech technologies; between 2001 and 2006, that list includes 53 companies. Since 1999, companies from the Advanced Technology Development Center (ATDC)[11], a business incubator that is part of Georgia Tech's Enterprise Innovation Institute, have raised over one billion dollars in venture capital. In 2006, 10 of the top 25 largest venture capital deals in Georgia – including the two largest – went to ATDC companies, representing 21% of investments in Georgia.

The most significant contribution of the Act may be that it ensures non-discriminatory access to and benefit from the technologies that result from the public investment in university research. Small businesses receive preference under Bayh-Dole but the marketplace establishes the consideration for the license. As a condition of federal awards, universities are obligated to take steps to make nascent technologies available to the public by licensing them to entities that have the ability to bring them to the marketplace. Universities must ensure that licensees meet milestones for development of the technologies or products. Universities provide the government with a royalty-free right to use the technology for government purposes. Finally, in the relatively rare event that the university receives royalties under a license, its share of the funds may only be used to further research and the education of students. This reinvestment in research and education benefits both industry and the public through building research capacity in the public space and expanding the high tech workforce.

The impact of the Bayh-Dole Act varies across industry sectors. Biotechnology, medical device, and pharmaceutical companies typically must have the ability to obtain exclusive licenses to intellectual property. In this sector, new products tend to have fewer components. They also must meet expensive, time-consuming, but necessary regulatory requirements to bring a product to market. By comparison, in the electronics sector, where the long-term value of specific intellectual property is variable, access to a wide portfolio of patents may be necessary to develop a product. Product realization tends to be more rapid. Similarly, different licensing strategies may apply in dealing with small companies, in particular start-ups, than with larger companies. And, in a number of circumstances, the competitive advantage afforded through exclusivity may be absolutely critical to justify the risk undertaken by a company in developing a product from a promising early-stage university technology, as it was in the case of Cardiomems. As technology transfer within U.S. universities has matured over the past twenty-five years, this need for different licensing strategies across and within industry sectors has become widely recognized. Fortunately, the authors of the Act anticipated this need and provided universities with the flexibility to pursue exclusive or non-exclusive licensing strategies.

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[11] http://www.atdc.org/overview.asp

Challenges do exist in the relationship between American companies and universities. The primary cultural differences between them stem from their divergent missions and result from differences in their research agendas and positions on the dissemination of knowledge. In 2004, the National Academies of Sciences' Government University Industry Research Roundtable served as the neutral convener for a collaborative effort of the National Council of University Research Administrators and the Industrial Research Institute that would lead to an open dialogue about these cultural differences. It was hoped that the conversation would lead to new approaches that could respect the missions of higher education and private industry and their respective contributions to innovation. In April 2006, this group published *Guiding Principles for University-Industry Endeavors*[12] which examines the perspectives of universities and industries and identifies the common ground and the symbiotic relationship between American companies and universities. These *Guiding Principles* can serve as a roadmap for building collaboration and have the potential to foster stronger ties among those with common interests. However, an examination of this document reveals that the treatment of inventions that arise from federally-funded research at universities is not a factor in the relationship between industry and universities.

The Subcommittee asks about the possible effects of the globalization of research.

Universities in the United States have traditionally welcomed students from around the world. Faculty members have for many decades engaged in open collaborations in research and educational programs with colleagues in other countries. Universities have, therefore, had long experience in competing globally for talented students and faculty and competing globally in scholarship and intellectual output. For the last half of the twentieth century, the United States was undoubtedly the world's leader in science and technology. Even as European universities rebuilt following World War II, other nations' research institutions have emerged and grown along with R&D investment in those countries. Scientific and technological research as a global phenomenon has been studied intensively in recent years by a number of organizations including the National Academies of Sciences, The President's Council of Advisors on Science and Technology (PCAST), and the National Science Board.

The Committee on Science, Engineering and Public Policy of the National Academies stated in 2006[13], "Many international comparisons put the United States as a leader in applying research and innovation to improve economic performance". However, both this report and the PCAST report, *Sustaining the Nation's Innovation Ecosystems: A Report on Information Technology Manufacturing and Competitiveness*[14], noted that other nations are catching up to U.S. leadership in information technology research and development. In its *Science and Engineering Indicators 2006*[15]*,* the National Science

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[12] National Council of University Research Administrators (NCURA) 2006

[13] *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Future.* National Academies Press, 2007

[14] *Sustaining the Nation's Innovation Ecosystems: A Report on Information Technology Manufacturing and Competitiveness,* January 2004

[15] *Science and Engineering Indicators 2006, Volume 1, Chapter 4*

Board characterized the link between innovation and economic competitiveness by asserting that,

> *Increasingly, the international competitiveness of a modern economy is defined by its ability to generate, absorb, and commercialize knowledge. Although it is no panacea, scientific and technological knowledge has proven valuable in addressing the challenges countries face in a variety of areas such as sustainable development, economic growth, health care, and agricultural production. Nations benefit from R&D performed abroad, but domestic R&D performance is an important indicator of a nation's innovative capacity and its prospects for future growth, productivity, and S&T competitiveness.*

This report also found that the majority of research and development in the world is still performed by a small number of wealthy nations but that, as in many sectors, emerging economies are investing increased resources in research. The National Science Board identified the following factors in assessing a country's R&D performance and innovation capabilities:

- The culture of cooperation between R&D performing sectors
- The ability of a country to train and retain its highly skilled scientists and engineers
- Strong intellectual property laws and a strong patent system
- Governmental, legal, and cultural restrictions
- The presence of a sophisticated, demanding, and wealthy domestic market for innovation
- The quality of research institutions (universities and government facilities) as quantitatively assessed by objective measures of research output and peer rankings
- Research infrastructure including facilities and instrumentation

The Bayh-Dole Act is a key element in several of these factors. The Act is part of strong protections for intellectual property that arises from federally-funded research and helps ensure that entrepreneurs can find the sophisticated, wealthy, demanding investors and, ultimately, markets for new technologies. Bayh-Dole also contributes to the strength and quality of U.S. research universities. In 2003, PCAST affirmed the success of the Bayh-Dole Act and noted that other nations are attempting to replicate this model. As Senator Birch Bayh commented in a speech last year to the Licensing Executives Society, "It is no accident the rest of the world is copying the Bayh-Dole model. The European Union, Japan, China, India and many others hope to tap their own cutting edge university research to win the future economic race. We in the United States cannot afford to rest on our laurels." For example, Japan, clearly recognized as a world economic leader with a focus on technology markets, began implementing laws in the 1990's that contained provisions similar to the U.S. Bayh-Dole Act. Other countries throughout the world now recognize the importance of protecting intellectual property, having laws that allow their universities to assert rights in employee created intellectual property, and of benchmarking the system that resulted from the passage of Bayh-Dole. As Senator Bayh further noted, "When India decided that it wanted to start being a creator of technology and not an exporter of scientists to the West, it began protecting intellectual property."

Finally, the Subcommittee has asked what changes might be appropriate as we look forward to the next 25 years of Bayh-Dole.

The President's Council of Advisors on Science and Technology undertook a year-long study of the results of the federal investment in research and development. Their *Report on Technology Transfer of Federally Funded R&D: Findings and Proposed Actions*[16] was submitted to the Office of Science and Technology Policy on May 13, 2003. I commend this report, which offers a thorough analysis of technology transfer by a panel representing both higher education and industry, to the Subcommittee and have included it as an appendix to this written testimony. While PCAST made a number of recommendations to the Department of Commerce and others regarding education and implementation, their conclusion is:

> *"Existing technology transfer legislation works and should not be altered."*

By almost any objective standard, the Bayh-Dole Act has been an exceptional success. More compelling than the 4,932 new licenses signed, the 527 new products introduced into the market or the 628 new companies formed in 2005 according to the AUTM's U.S. Licensing Survey are the individual technology realization stories captured in their The Better World Report first published last year. This report takes an in-depth look at twenty-five innovations derived from academic research that has had a dramatic impact on the world. Whether it is the story of Taxol® and the more than 2 million women worldwide who have taken the drug to fight ovarian and breast cancer, the SpeechEasy® device that has helped thousands of individuals affected with stuttering, Google™ and its more than 10,000 employees, or countless others, including the Cardiomems story, the success of academic technology realization is clear. This is a significant improvement from when intellectual property resulting from federally funded research was available to all non-exclusively and nearly 30,000 patents laid dormant.

Over twenty-five years ago, Senator Birch Bayh opened the hearings on the legislation with the following statement:

> *"The United States has built its prosperity on innovation. That tradition of unsurpassed innovation remains our heritage, but without continued effort it is not necessarily our destiny. There is no engraving in stone from on high that we shall remain No. 1 in international economic competition. In a number of industries we are no longer even No. 2. New incentives and policies are needed to reverse this trend."*

Today, U.S industry continues to face competitive pressures globally. The need for basic research as the foundation of innovation still exists. And, while, cultural differences

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[16] *Report on Technology Transfer of Federally Funded R&D: Findings and Proposed Actions*

sometimes strain collaboration between industry and academia, the Bayh-Dole Act has helped foster a new and highly successful era of collaboration by establishing a uniform federal invention policy, encouraging universities to develop relationships with industry through commercialization of inventions, and establishing preference for manufacturing of products in the United States.

Based on the objective, numerical successes of the Act as well as my personal experiences with Cardiomems, I feel strongly we should not alter in any significant way the legislation that has been so successful, and that the rest of the world is using as the model of innovation.

Thank you again for this opportunity to comment on my experiences and the topic of Bayh-Dole. I am pleased to respond to any requests the Subcommittee may have for additional information regarding my testimony.

Attachment: *Technology Transfer of Federally-Funded R&D,* PCAST 2003

EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

May 15, 2003

President George W. Bush
The White House
Washington, D.C. 20502

Dear Mr. President:

We are pleased to transmit to you a copy of the report, *Technology Transfer of Federally Funded R&D*, prepared by your Council of Advisors on Science and Technology (PCAST).

This report completes PCAST's two-part review of the federal government's research and development (R&D) portfolio. The first component examined the basic balance and direction of federal R&D spending, and this second report examines the government's effectiveness in transferring the results of federal R&D to the private sector.

Federal legislation enacted in the early 1980s allowed universities and businesses to retain intellectual property rights to the results of federally funded R&D. PCAST found this model has not only dramatically improved the Nation's ability to move ideas from R&D into commerce, but also helped enhance the return on this substantial taxpayer investment. The recent past demonstrates a record of commercial successes, including the creation of entirely new technology-based industries that are the envy of the world. Indeed, other nations are striving to replicate our model. As a result, we are not recommending any fundamental changes to our technology transfer mechanisms.

PCAST does, however, suggest several areas where improvements can be made. In particular, a teamwork approach among the federal agencies and the private and university sectors will help achieve improved success. The development of "best practices" and more centralized reporting will help streamline the transfer process.

The full PCAST discussed and approved this report at a public meeting. Please let us know if you have any questions concerning the enclosed report.

Sincerely,

John H. Marburger, III
Co-Chair

E. Floyd Kvamme
Co-Chair

Enclosure

EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

May 12, 2003

The Honorable John H. Marburger III
Director, Office of Science and Technology Policy
The Executive Office of the President
Washington, DC 20502

Mr. E. Floyd Kvamme
Co-Chair
President's Council of Advisors on Science
and Technology (PCAST)
Washington, DC 20502

Dear Floyd and Jack:

On behalf of the PCAST panel on Federal Investment on Science and Technology and its National Benefit, I am pleased to submit to you our final report with recommendations for improving technology transfer at the federal level. As you will recollect, PCAST reviewed the panel's report at our last meeting and we have incorporated comments provided at that meeting as well as those from agencies like the Department of Commerce. While the report represents the work of many people, I would like to especially call your attention to the efforts of Kathy Behrens, who led the panel in drafting the report and accommodating the many comments. Kathy was assisted considerably in this process by our fellow panelist, Luis Proenza.

The report was developed based on a series of meetings and hearings held over the course of the past fourteen months. Representatives of industry associations, government agencies, national laboratories and universities participated in our hearings and provided us with advice and insight. We also sought comment via a series of mailings and offered the opportunity for interested individuals to express their opinions. In addition, the RAND Corporation provided an excellent background study and review of the process of technology transfer. The RAND report from this study is available and was distributed at the March 3, 2003, PCAST meeting.

In the course of our work, we found that the process of technology transfer is not simple and can be challenging. Our report provides background information which attempts to impart an appreciation for the components that go together to make up the technology transfer enterprise.

The gist of the results we assembled shows that the federal legislation which was put into place in the early 1980s has dramatically improved the nation's ability for moving ideas from research and development to the marketplace and into commerce. However, as with any good idea, time has shown there are a number of areas where improvements can be made and we provide recommendations to this effect in the report. To achieve the impact desired, it will take a teamwork approach among the federal agencies responsible for research and development as well as those in the private and university sectors.

We are grateful to Drs. Amy Flatten and Stan Sokul of the Office of Science and Technology Policy for their considerable assistance in our work. Many others contributed by participating in our hearings and providing information, but we especially acknowledge the help and advice of Bruce Mehlman of the Department of Commerce, Jilda Garton and Marie Thursby of the Georgia Institute of Technology, Jerry Thursby of Emory University, and David Mowery of the University of California at Berkeley.

If you have any questions about the report, please feel free to contact me or a member of the panel. I commend all of the members of the panel for their diligence and hard work on this project.

Sincerely,

Wayne Clough
Chair, PCAST Panel on Federal Investment in
Science and Technology and Its National Benefit

/ch

Enclosure

cc: Kathy Behrens
Erich Bloch
Raul Fernandez
Martha Gilliland
Walter Massey
Gordon Moore
Luis Proenza
George Scalise
Charles Vest
Bruce Mehlman
Amy Flatten
Stan Sokul

THE PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY

Report on

Technology Transfer of Federally Funded R&D

Findings and Proposed Actions

THE PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY

Report on Technology Transfer of Federally Funded R&D

Executive Summary

Overview

This Report completes a two-part review conducted by the President's Council of Advisors on Science and Technology (PCAST) on two specific aspects of the government's investment in research and development (R&D). The first part of this review reported on the federal government's research portfolio, as summarized in PCAST's October 2002 Report: *Assessing the U.S. R&D Investment*. The second part of the review focused on the value of federal research in maintaining the United States' economic leadership as it relates to the commercial use of technology developed with federal funding.

Specifically, through the PCAST Panel on Federal Investment in Science and Technology and its Economic Benefits, a study was conducted of the technology transfer mechanisms that encourage commercial developments, as well as the state of development of the research. The PCAST Panel held a series of industry and government hearings, as well as solicited written comment, looking at various aspects of the transfer of government-funded technology and its subsequent commercialization.

Overall, PCAST found that the process of technology transfer is not simple and can be challenging. The federal legislation which was put into place in the early 1980s has dramatically improved the nation's ability to move ideas from R&D into the marketplace and into commerce. Equally important, the transfer of publicly funded technology is a critical mechanism to optimizing the return for this substantial taxpayer investment. Nonetheless, this Report suggests a number of areas where improvements can be made. A teamwork approach among the federal agencies and the private and university sectors will help achieve improved success.

The key for the federal government is to find a course that can be followed routinely to serve the best interests of the nation for commercialization of research, but one that allows flexibility to accommodate "extremes" when appropriate, regardless of the nature of those engaged. Although the present system is not perfect, the recent past demonstrates a record of reproducible commercial successes and creation of entirely new technology-based industries that are the envy of the world. The role the government plays in this process has been and will continue to be vitally important to the future success of many technology-based industries, where basic research, technology transfer and the coordination of these activities are key factors.

Recommendations

The PCAST review of technology transfer policies led to the following recommendations:

1. Existing technology-transfer legislation works and should not be altered.

2. Federal agencies, government laboratories and the Department of Commerce need to formalize their oversight of and accountability for technology transfer.

3. Industry differences need to be recognized and practiced by institutions licensing government-sponsored technology, but made consistent within individual disciplines.

4. The Department of Commerce should document "Best Practices" for technology transfer, as well as refine a set of metrics to better quantify practices and their effectiveness.

5. The Department of Commerce should include "education" as a part of its technology transfer mission and task the individual agencies to disseminate related materials specific to their R&D programs.

6. Individual agencies and government laboratories need to provide regular transaction "process reviews" to reduce the complexity of, and time required to complete, technology transfer transactions.

7. The Office of Science and Technology Policy should assist the new Department of Homeland Security in rapidly developing technology transfer policies and capabilities that meet the immediate and long-term agency needs.

8. The Government should centralize information on technology transfer into a single, accessible location.

9. The Department of Commerce should study and assess the implications for technology development and transfer in a global environment, as well as the possible effects of emerging technologies.

10. Recent discussions about the availability of research tools that result from federally-funded research need to be monitored to insure that there is a balance in the protection of the commercial value of such inventions and assurance of access to these tools for further research and exploration.

THE PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY

Report on Technology Transfer of Federally Funded R&D

Findings and Proposed Actions

Overview

The President's Council of Advisors on Science and Technology (PCAST), through its Panel on Federal Investment in Science and Technology and its Economic Benefits, has reviewed two specific aspects of the government's investment in research and development (R&D). The first part of this review reported on the federal government's research portfolio, and can be found in PCAST's October 2002 Report: *Assessing the U.S. R&D Investment*.

This Report completes the second part of the R&D review, which focused on the value of federal research in maintaining the United States' economic leadership as it relates to the commercial use of technology developed with federal funding. Specifically, a study was conducted of the technology transfer mechanisms that encourage commercial developments, as well as the state of development of the research.

This review looks at technology licensing practices that have a very long and established history in the United States. Technology transfer practices are embedded in the earliest national defense research, activities of the Extension Services, especially the Agricultural Extension Services, and the preparation of scientific publications that date back nearly 100 years. The nation evolved rapidly during and after World War II[1] from one with very little technical development work or interest in intellectual property, to one leading a revolution in several technological disciplines.

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[1] Howard W. Bremer. November 11, 2001. "The First Two Decades of the Bayh-Dole Act as Public Policy". Presentation to National Association of State Universities and Land Grant Colleges, Washington, D.C.

The increasingly sophisticated military demands of this era caused a dramatic increase in technological research, as it quickly became apparent that the government alone was not able to conduct the range and number of scientific projects needed to win a war. These priorities gave rise to a rapid evolution of government funded R&D contracts, which further proliferated with the commencement of substantial federal funding for disease related medical research in 1950.

However, in these early years there was only limited commercial interest by industry in federally funded inventions due to several factors. Most important, the government retained title to and ownership of most inventions, relinquishing title to the inventing organization only in unusual circumstances and making the inventions available to industry on a non-exclusive basis. These issues were compounded by the government's failure to develop a uniform patent policy, as well as the absence of any statutory authority giving agencies the ability to patent or license their inventions. Significant inconsistencies in the practices by a large number of agencies gave companies little incentive to invest in and develop products that were not properly protected and could be readily licensed and sold by competitors. As a result, the government accumulated an enormous backlog of unused federally funded and patented inventions, which numbered 25-30,000, only about 5% of which had been licensed to the private sector for commercialization.[2]

Although several incremental legislative initiatives were introduced over a number of years to facilitate the commercialization of taxpayer-financed research, the Bayh-Dole and Stevenson-Wydler Acts of 1980 and related follow-on legislation are credited as the first impetuses for a dramatic change in technology transfer practices in the United States. A recent study[3] provides evidence that additional factors, such as the increasing industrial commitment to technological R&D and a judicial trend to strengthening intellectual property rights, were also important contributors to the rapid rise in licensing activities commencing in 1980. Nevertheless, Bayh-Dole was in itself successful because it gave businesses and non-profit organizations, including universities, the right to retain title to federally funded inventions thereby providing an effective

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[2] *Ibid.*

[3] David C. Mowrey, Richard R. Nelson, Bhaven N. Sampat and Arvids A. Ziedonis. 1999. "The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980" in *Research Policy* 30 (2001) 99-119.

conduit for the timely and broad distribution of government funded technology to the private sector. (The latter requires a *quid pro quo* set of obligations from universities to retain and administer such rights.) Provisions of Bayh-Dole are extended to the federal laboratories, large businesses conducting federally funded R&D, intramural federally funded R&D, the National Aeronautics and Space Administration, and the Department of Energy through a series of additional federal actions.[4]

The Bayh-Dole Act

The Bayh-Dole Act* is legislation that changed several practices to create a favorable environment for the transfer of government-funded inventions to the private sector for commercialization. The Act provided a uniform patent policy among the various governmental agencies that funded research and, most importantly, enabled businesses and not-for-profit organizations, including universities, to retain title to inventions made under federally funded research programs. The major provisions of the Act include:

- Non-profit institutions, including universities, and small businesses may elect to retain title to innovations developed under federally funded research programs;
- Universities are encouraged to collaborate with commercial enterprises to promote the utilization of inventions arising from federal funding;
- Universities are expected to file patents on inventions they elect to own;
- Universities are expected to give licensing preference to small businesses;
- The government retains a non-exclusive license to practice the patent throughout the world; and
- The government retains march-in rights.

*The legislation was enacted on December 12, 1980, as P.L. 96-517 (35 U.S.C. §§ 200-12) under the co-sponsorship of Senators Birch Bayh of Indiana and Robert Dole of Kansas.

The PCAST Panel held a series of industry and government hearings, as well as solicited written comment, looking at various aspects of the transfer of government-funded technology and its subsequent commercialization.[5] Testimony was heard in three separate briefings from experts

[4] The Trademark Clarification Act (1984), Executive Order 12591(1987), Stevenson-Wydler Technology Innovation Act (1980), National Aeronautics and Space Act (1958) and the Atomic Energy Act (1954) and Non-Nuclear Energy Research Act (1974).

[5] April 11, 2002, PCAST conducted hearings involving the Pharmaceutical Research and Manufacturers Association of America, Biotechnology Industry Organization and the Semiconductor Research Corporation. May 9, 2002, PCAST heard from the Association of University Technology Managers, Battelle Memorial Institute, the U.S. Department of Commerce and the NIH Technology Transfer Office. December 12, 2002, PCAST conducted a public hearing through the sponsorship of the Rand Science & Technology Policy Institute with presentations by the

representing industry and academic trade associations, research consortia, universities, government contracting research organizations, national laboratories and government agencies involved in the oversight of technology transfer, as well as its practice. The first two sessions gathered information on technology transfer resulting from the Bayh-Dole Act of 1980 and related legislation. The Panel looked more broadly at general technology transfer mechanisms in its third forum, a public session, on December 12, 2002. Plans for this meeting were published in advance in the Federal Register to encourage public discussion and comment from anyone who was interested. Written comment on the subject was also solicited from the venture capital community, which provides early stage capital to entrepreneurial technology companies largely involved in health care, biotechnology and information technology.

The Science and Technology Policy Institute[6] at RAND Corporation was asked to document technology transfer mechanisms resulting from federal legislation in order to provide a frame of reference for the hearings and a basis for PCAST's recommendations. The report, "Facilitating Technology Transfer of Federally Funded R&D,"[7] discusses five specific areas:

- An overview of the purpose and complex process of technology transfer;
- Legislation that governs technology transfer;
- Measuring the effectiveness of technology transfer activities;
- A summary of presentation and discussion themes from the December 12, 2002, public forum; and
- A process for identifying and documenting the best technology transfer practices.

Council on Government Relations, Massachusetts Institute of Technology, Hogan and Hartson, Sandia National Labs, General Electric and the Semiconductor Research Corporation.

[6] The Science and Technology Policy Institute is a federally funded research and development center sponsored by the National Science Foundation and managed by RAND that provides research and analysis for the White House Office of Science and Technology Policy and other federal agencies.

[7] Shari Lawrence Pfleeger, Mark Wang, David Adamson, Gabrielle Bloom, William Butz, Donna Fossum, Mihal Gross, Terrence Kelly, Aaron Kofner and Helga Rippen. January 2003. "Facilitating Technology Transfer of Federally Funded R&D", RAND Science and Technology Policy Institute, Arlington, VA.

Several of these topics are mentioned briefly in the recommendations made by this Report, though none of them will be discussed in detail. The Findings and Recommendations in this Report are those of the PCAST.

What is Technology Transfer*?

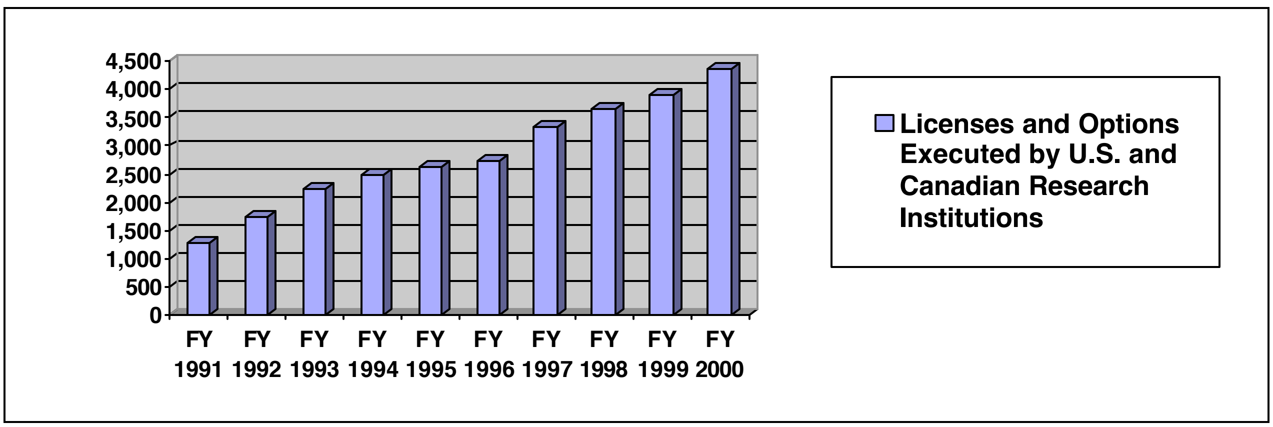
The term "technology transfer" tends to mean different things to different entities, generally giving flexibility to individuals and organizations within their practices. However, most broad definitions include:

- Technology—as an idea, practice or object resulting from research, as well as an embodiment of the technology;
- The movement of technology into a setting where it can improve a product or process in some way; and
- An entire process involving facilitators at different steps, including those who create the technology, those who incorporate the technology into a useful product, service, tool or practice, and those who further develop the technology for commercialization and use.

*Source: Pfleeger, *et al,* "Facilitating Technology Transfer of Federally Funded R&D," at note 7.

Summary of Findings

The transfer of government funded R&D involving technology to the private sector has grown significantly in the last two decades and today represents an increasingly important part of the overall industrial commercialization of technology (see graph below[*]). Equally important, the transfer of publicly funded technology is a critical mechanism to optimizing the return for this substantial taxpayer investment, particularly where other benefits are not measurable at all or are very long-term and therefore not measurable for years or even decades.



[*] Source: The Association of University Technology Managers (AUTM) Licensing Survey: FY 2000. No consistent, comparable data were collected prior to 1991.

The evolution of research from the laboratory into a setting where it can improve a product or process, or even become the basis of a new company, involves a number of different mechanisms and they vary in their effectiveness depending on the circumstances. Perhaps the simplest and least expensive is the publication and broad public dissemination of research results.

The publication of technical developments is a routine professional practice, particularly associated with university R&D. While its effects are difficult to quantify, publication is a form of technology transfer that has wide reaching consequences. Publication can be done exclusive of any effort at seeking protection of intellectual property rights, or it can be done in concert with such efforts. Using provisional patent filing processes allows researchers to publish, while protecting intellectual property rights. The majority of publications are not accompanied by any use of intellectual property protection. While the process of patenting and licensing inventions is employed by most technical fields, it is an expensive, time consuming process that has been most successfully employed for applications where there is a history of strong intellectual property protection and where the return on investment for the resources required to commercialize the invention consistently outweigh the risks of development failure. Such is the case for pharmaceutical applications of life sciences research discoveries, but it is less prevalent in other areas such as seed industry applications of plant agricultural research.

Other forms of technology transfer include, but are not limited to, Collaborative Research and Development Agreements (CRADAs), patents and licensing of intellectual property, as well as the direct transfer of technology. Furtherance of the commercialization process beyond an initial proof of concept can be enhanced through the activities of non-profit or commercial incubators that assist inventors in the early stages of business development. Government funded research performed by federal agencies, government-contracting laboratories, universities, private research institutions and industry utilize all of these technology transfer mechanisms, as well as others that tend to be more specialized depending on the area of application.

The process of commercialization of research outcomes, particularly government-funded inventions, involves a range of public and private entities, patent, copyright and trademark laws, international and domestic issues, and sometimes competing agendas and interests. Those inventions often lead to new goods and services that benefit the public and, in some cases, to new businesses with attendant creation of jobs and new wealth. However, the end result of a successful research project with a proven idea is only the beginning of the commercialization process which includes development of a product that is market-worthy, the creation of a business plan, gaining access to capital to support further development, bringing the product to the production stage, and creating a business or a new/improved product or service within an existing business or industry. The large number of steps and players in the process create a journey that requires a sound knowledge base for the navigation to be successful.

Based on the hearings held by the PCAST Panel, it is apparent that those who attempt to participate in technology transfer activities come to the table from different backgrounds and histories. For example, according to the Association of University Technology Managers, over 2000 universities and colleges have patents of one kind or another. Yet only a small number of these are research universities with technology transfer offices and not all of these have developed high competencies in the process. In the business world, companies of varying size, with a history of dealing with technology transfer are more likely to be at ease with the process than many emerging companies with an idea that deserves consideration by the marketplace, but with little prior experience in the process. Equally, success in enabling technology transfer is not necessarily "better" within industry than universities—since there is much technology resident in both sectors that is never commercialized. Federal agencies have different cultures, ranging from those with a history of providing relatively open access to inventions (*e.g.,* the Department of Agriculture) to those that work within an industry segment that recognizes the need for protection of intellectual property in order to gain access to market capital (*e.g.,* the National Institutes of Health). The variety of players, ranging from very sophisticated to unsophisticated and from highly vested to less vested, all in the game at the same time, means that the field of play is complicated.

The key for the federal government is to find a course that can be followed routinely to serve the best interests of the nation for commercialization of research, but one that allows flexibility to accommodate "extremes" when appropriate, regardless of the nature of those engaged. At one end, there are huge near-term financial markets at stake, such as those in the biotechnology area where billions of dollars are in play and nations are vying for prominence. If the U.S. does not shape its role in this sophisticated end of the spectrum carefully it could end up ceding dominance to other nations. In this case, the players are depending on the federal government to take a light hand so they can work within the existing framework that the U.S. pioneered over the past twenty years. On the other hand, there are important small market ideas, and emerging markets, that need to be nurtured where the players are not sophisticated and need guidance and support.

Although the present system is not perfect, the recent past demonstrates a record of reproducible commercial successes and creation of entirely new technology-based industries that are the envy of the world. So much have these accomplishments occurred singularly in the United States, that today there is widespread international interest in attempting to replicate this model. As a result, it is inevitable that the international assimilation of even just a few of the critical components could create new challenges to domestic competitiveness in commercial fields that have historically been dominated by the United States. *The role the government plays in this process has been and will continue to be vitally important to the future success of many technology-based industries, where basic research, technology transfer and the coordination of these activities are key factors.*

Recommendations

The PCAST review of technology transfer policies leads us to recommend:

1. Existing technology-transfer legislation works and should not be altered:

While it is unclear whether the Bayh-Dole Act of 1980 and its follow-on legislation largely facilitated the commercialization of a technological revolution or played a much more fundamental role (*i.e.,* provided the stimulus for the creation of commercial biotechnology), it is impossible to separate the two. This relationship is best documented for the life sciences, which today dominate technology transfer activities and have made commercial contributions leading to significant economic returns. The biotechnology industry and its numerous new companies are evidence of this. Other industries with different economics have benefited from these practices, though with less dramatic results and often through different licensing relationships. Incremental improvements in established products or processes and increases in productivity are not as well documented or publicized as the transformational discoveries that launched the biotechnology industry.

Because of the heavy life-sciences contribution to numerous commercialization successes, the technology transfer practices for other industries appear more fragmented. In particular, the semiconductor industry has identified troublesome intellectual property licensing issues with universities in which it has sponsored research. These appear to relate to the variability and increased complexity of negotiating technology transfer agreements when industry provides funding for university research either in a three-way partnership with the federal government or in two-party collaborations with a university. However, we believe these differences are best addressed by improving the practice of technology transfer and by addressing differences among research areas rather than by altering the legislation. Finally, this is not to say that Bayh-Dole has caused the patenting and licensing of government-funded research to replace other important technology transfer mechanisms, such as publications and CRADAs, as well as direct transfer. All of these technology transfer tools complement one another, allowing flexibility in a rapidly changing environment that demands rapid adaptation for success and where other tools will surely emerge in the future.

2. ***Federal agencies, government laboratories and the Department of Commerce need to formalize their oversight of and accountability for technology transfer:***

Leadership that recognizes and embraces the importance and accountability of technology transfer must come from the highest government levels, including the President and Cabinet Secretaries. We recommend that the President request that all agencies specifically commit to technology transfer in their individual mission statements. The Technology Transfer Commercialization Act of 2000 has, in its requirement for annual agency reporting, provided a vehicle to account for progress in this area and the Commerce Department's first report is a good step towards that goal. The annual reporting process needs to be used as a mechanism to reinforce accountability for performance and viewed in the context of important short term and long term progress objectives. This will only be achieved if senior administrative attention is devoted to reviewing and providing feedback on these reports.

We believe having the Office of Management and Budget clarify the importance of departmental reports and provide them to the Department of Commerce (DOC) would be the best way to achieve the desired outcome. This is particularly important in light of the different agency practices and attitudes, which show great variation in employee incentives/motivation for successful technology transfer, but still need to be aligned with one another. *This will only be accomplished by recognizing that the learning curve is steep for the successful practice of technology transfer, requiring considerable time (* i.e., *10 years or greater) and upfront investment to build internal and external competencies and consistent practices. However, DOC generally has few resources with which to manage its technology transfer responsibilities. While specific issues are addressed here and in each of the areas identified below, additional funding would give DOC the ability to respond to many of these concerns.*

3. ***Industry differences need to be recognized and practiced by institutions licensing government-sponsored technology, but made consistent within individual disciplines:***

Technology licensing conducted by life sciences research institutions has become very sophisticated in the last decade due to its high level of activity and commercial success. Today these technology transfer programs generally appear to be well received by licensees. In large part, this has occurred because most life sciences inventions are destined for development as pharmaceutical products, where the successful patenting of products is key to the long product development time frames and significant capital commitments. As a result, there is a template for technology transfer that has at least several consistent components that do not vary widely from transaction to transaction. In contrast, criticism arises more often for licensing practices for technologies having other industrial applications, such as those for selected segments of information technology, often because of competing interests or because the process is too slow to keep up with technology developments.

The value of intellectual property in these industries (*e.g.,* software, communications, semiconductors, etc.) is highly variable, ranging from entirely unimportant to moderately important. In these cases, the time to market is much shorter (measured in months to years, rather than many years for pharmaceuticals), and the international competition for manufacturing, as well as other factors, are much more important drivers of commercial success than for life sciences transactions. Templates for technology transfer for these industry applications are far different and much more diverse than for life sciences applications. The licensing of technologies for distinctly different industries should not be expected to occur within the same narrow parameters, although it is reasonable to assume they should all be successfully implemented under the same statute. Federal agencies should develop guidelines that allow for these differences, but at the same time insure a greater level of consistency for applications within each industry sector.

4. ***The Department of Commerce should document "Best Practices" for technology transfer, as well as refine a set of metrics to better quantify practices and their effectiveness:***

A set of documented "Best Practices" would serve a dual purpose in facilitating more rapid progress for institutions facing a new learning curve, as well as in setting expectations for first time licensees. The challenge is to align a series of models for varying industrial sectors with a wide range of differences in technology, market dynamics, intellectual property, etc. that are sufficiently specific to provide valuable guidance. Because the entire process is continuing to evolve and there is increasing global competition, identifying metrics to quantify program effectiveness is of increasing importance. Metrics need to take into account a wide range of steps in a highly complex process, as well as the ultimate product or service, but should not constrain the continued evolution or development of new technology transfer approaches. An example metric is the time to execution of a technology transfer agreement, which is increasingly important due to the growing length of time and related expense to conclude such agreements (see Recommendation 6 below). In addition, such measurements need to accommodate mission differences between the licensing institutions. For example, numerous universities are now seeing a meaningful contribution to the growth of local economies as a direct outcome of their technology transfer activities and, as a result, their priorities are now more heavily weighted by interactions with their local constituencies.

The Technology Transfer Commercialization Act of 2000 provides a vehicle for the DOC to document best practices, although the issue of metrics is somewhat more complex and requires even greater interactions between DOC and the individual agencies. DOC's recent efforts with the Interagency Working Group on Technology Transfer is another good step towards reporting and refining both best practices and metrics. However, we would like to encourage further attention on behalf of DOC towards achieving these goals among all federal agencies and towards extending their reach to include all performers of federally-funded research— universities, industry, federal laboratories, etc.

5. ***The Department of Commerce should include "education" as a part of its technology transfer mission and task the individual agencies to disseminate related materials specific to their research and development programs:***

The practice of technology transfer would be better optimized as an "active" rather than a "passive" process, which would help both with the internal education process, as well as the external marketing. General educational materials need to be developed by DOC and tailored by the individual agencies to reflect specific R&D programs. This is particularly important where inventions have multiple applications and may need to be matched-up with commercial enterprises representing several industries. In addition, some agencies and government laboratories have worked with large contracting companies (*e.g.,* defense) where they have developed longstanding and successful relationships. New invention applications might be more rapidly developed and disseminated by companies that would not otherwise be known by the agency (*e.g.,* terrorism applications), where an active marketing effort would increase the interest from potential licensees and also increase the possibility of a return on investment. DOC could increase its education efforts without the addition of meaningful resources by taking responsibility for the education initiatives conducted through the Federal Laboratory Consortium.

6. ***Individual agencies and government laboratories need to provide regular transaction "process reviews" to reduce the complexity of, and time required to complete, technology transfer transactions:***

   The time and expense required to conduct licensing activities under present circumstances is not inconsequential. For some, this is appropriate since the time to market is long term. For others, this is an issue that can lead to industry disenchantment. This is particularly true the first time a new form of agreement is executed by a relatively inexperienced licensing institution, requiring that organization to get up the "learning curve." As described above, much in the way of education can be done to minimize the pain and discomfort associated with new licensing activities. However, transaction complexity and managerial attention need to be reduced even for experienced and sophisticated organizations. Testimony provided for the PCAST Panel indicated that there are cases where the time required to complete the intellectual property process is an issue. While this is apparently not a problem in all areas, attention should be given to improving the efficiency of the process in instances where time is of the essence.

7. ***The Office of Science and Technology Policy should assist the new Department of Homeland Security in rapidly developing technology transfer policies and capabilities that meet the immediate and long-term agency needs:***

   The Department of Homeland Security (DHS) has an immediate and pressing need to rapidly *acquire* numerous directed technologies to meet a broad range of security issues. This overall process is well documented, although the relatively slow historical timeframes for these activities will be inadequate, especially involving the patenting process. Once these technologies have been used to develop effective product prototypes, proprietary product information may also need to be recycled to the private sector for rapid product mass production and distribution. The national security issues and urgency will undoubtedly create additional barriers to universities and industry. The Office of Science and Technology Policy should work with DHS to create an environment that increases the likelihood of participation by the most successful and capable industrial organizations and universities, as well as insuring that the nation's pressing security needs can be met by experienced vendors.

The urgent need for DHS to access and acquire technology raises an important point with broader implications. Technology transfer should be thought of as not just flowing from government funded programs occurring in different agencies and universities to industry, but also from industry to universities/government. The bi-directional nature of technology flow is important to all of the federal agencies, government laboratories and universities and must be taken into account when evaluating the overall mechanisms, goals and effectiveness of technology transfer.

8. ***The Government should centralize information on technology transfer into a single, accessible location:***

Technology transfer has become a very broad activity today, with many U.S. and international participants, including the government, industry, universities, private research institutions and practitioners from many professional disciplines. There would be enormous benefits to aggregating available resources, information, education and contacts into a single location, which should be made available in an electronic format. The E-Government Task Force should assess the necessary requirements for providing such a site and most likely, provide for its implementation, whereas DOC should be responsible for the site's administration. The consolidation of these components would not only facilitate the access, administration, education, monitoring and efficiency of technology transfer activities with the government, but would stimulate further interaction and responsiveness from the private sector.

A central website would also facilitate the formation of much needed technology transfer databases and create additional interest in the study of this field. For example, it would be of interest to examine and track technology flows at a finer level of granularity than the gross measurements used today (*i.e.,* engineering, life sciences, etc.), which should prove to be more helpful in identifying important trends. In the context of a relational database, the use of "clustering" tools also could help to identify the emergence of new areas of research and find new patterns in technology flows. These types of analyses would enable DOC to have a much improved base of information to guide national policy.

9. ***The Department of Commerce should study and assess the implications for technology development and transfer in a global environment, as well as the possible effects of emerging technologies:***

Research competition in many scientific disciplines is intensifying internationally and the electronic nature of communications is greatly expediting the distribution of information. This combination will most likely alter the geographical distribution of technological innovation from the way it has evolved in the past. DOC needs to document the growing international systems for technology transfer and their implications for U.S. competitiveness. In addition, U.S. industry will continue to use sources of international research as economically viable alternatives to domestic sources. Trends in these activities are important to identify to help both government and industry respond to potential technology transfer paradigm shifts in the future.

The "Innovation in America" roundtable series led by DOC is a constructive start on this topic, although that department's increasing interactions with industry and related trade associations, such as the National Venture Capital Association, will be an important and necessary part of assessing the interests of industry in going outside the United States to seek alternative sources of research. We strongly encourage these types of government/industry interactions. We also believe that the emergence of new technologies will alter the current practices of both domestic and international technology transfer. A growing interdependency of scientific disciplines for future technology development has already signaled the need for changes in technical education and training and this will likely impact the practices and complexity of patenting, licensing and other forms of technology transfer. We recommend that DOC expand its activities related to assessing and tracking emerging technologies so as to facilitate technology transfer opportunities.

10. Recent discussions about the availability of research tools that result from federally-funded research need to be monitored to insure that there is a balance in the protection of the commercial value of such inventions and assurance of access to these tools for further research and exploration:

Intellectual property remains a key component to the successful transfer and commercialization of all technology, but especially life sciences technologies. Over the last few years, the development of biological materials for use in research that may or may not also have significant commercial value has become an increasingly problematic junction for balancing the ability of researchers to freely (or at least affordably) exchange and use such materials with the rights of researchers to elect title to such inventions and license them for commercial use. NIH made a meaningful contribution to providing guidance on this topic through its December 1999 "PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES". The public discussion needs to be monitored, to either assist in sorting out complicated issues surrounding the bi-directional flow of materials used in research and/or to find new technology transfer mechanisms to deal with the changing landscape. This is a highly complex matter that has already received significant thought from many affected constituencies. A workshop may be appropriate for addressing the key policy implications.

A separate, but related issue that also requires close monitoring involves recent court decisions, pending litigation and resulting legislation that may have an impact on technology transfer, including technology that results from federal funding. A recent court case, Duke Univ. v. Madey,[8] has eliminated the experimental use exemption from claims of patent infringement for noncommercial university purposes. The court held that the experimental use exemption does not apply to research that furthers universities' "business objectives, including educating and enlightening students and faculty participating in these projects…In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate

[8] Duke Univ. v. Madey, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied,* 156 L.Ed.2d 656 (2003).

business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative."[9] While this decision appears to have its greatest impact on not-for-profit research institutions, a recent survey[10] of individuals involved in biomedical research shows that both commercial and non-commercial entities sometimes use patented research tools without a license, which they justify on the basis of a "research exemption." The outcome of this decision, whether judicial or statutory, could be an important factor in future technology transfer practices and, much like the case for research tools, would benefit from a public policy workshop.

Two additional factors are important in providing the proper context for this Report's recommendations. They are:

- ***Education and training:*** Technology transfer mechanisms in the United States have been quite successful and have created measurable economic benefit—to the admiration of the rest of the world—because there has been a wealth of talent in government funded research programs. Independent of successful mechanisms for transfer, this pattern cannot be expected to continue in the absence of strong technological education, training and a full "pipeline" of talent.

- ***Metrics and documentation:*** Because the process of technology transfer is complex, involving many steps and participants, it is very difficult to generate meaningful data to assess its effectiveness. For the same reasons, anecdotal data are readily available. We would encourage caution in interpreting anecdotal information on this subject and recommend the continued development and thoughtful study of technology transfer activities for the purpose of supporting sound policy decisions.

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[9] Duke Univ. v Madey, 307 F.3d at 1362.
[10] J. P. Walsh, A. Arora, W. M. Cohen, in *Patents in the Knowledge-Based Economy*, W. M. Cohen, S. Merrill, Eds. National Academy Press, Washington, D.C., in press.