The PCAST 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. The first part of this review reported on the federal government’s research portfolio, the summary of which can be found in the October 2002 Report: Assessing the U.S. R&D Investment.

The second part of the Panel’s review has 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. 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 research and development 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\(^2\).


\(^2\)Ibid.
While over a number of years a series of incremental legislative initiatives was introduced to facilitate the commercialization of taxpayer-financed research, The Bayh-Dole Act of 1980 and its follow-on legislation (the University and Small Business Patent Procedures Act, 1980) are credited as the first impetuses for a dramatic change in technology transfer practices in the United States. A recent study provides evidence that additional factors, such as the increasing industrial commitment to technological research and development 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 conduit for the timely and broad distribution of government funded technology to the private sector. (The latter requires a set of obligations from universities to retain and administer such rights.) The provisions of Bayh-Dole are extended to the federal laboratories, large businesses conducting federally funded R&D, intramural federally funded R&D, NASA and DOE through a series of additional federal actions.

This 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. Testimony was heard in three separate briefings from experts 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.

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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 under the co-sponsorship of Senators Birch Bayh of Indiana and Robert Dole of Kansas.

The Science and Technology Policy Institute 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 Panel 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.

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

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\(^6\)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.

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.


Summary of Findings and Recommendations:

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.

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 this 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 from 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. 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. NIH). 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 allow 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.*

The Panel’s 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 dominates technology transfer activities and has 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.

2. **Federal agencies, government contracting 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 each agency specifically commit to technology transfer in its mission statement and, most importantly, that each agency provide an annual report to account for their progress and that of their research clients and grantees, or lack thereof, of this activity. 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.

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 being 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 number 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.

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 the Department of Commerce and tailored by the individual agencies to reflect specific research and development 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.

6. Individual agencies and government laboratories need to provide regular transaction “process reviews” to reduce the complexity 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 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, in instances where time is of the essence, attention should be given to methods to improve the efficiency of the process.

7. OSTP 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: Homeland Security 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. OSTP should work with Homeland Security 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 Homeland Security 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 Department of Commerce should study and assess the implications for technology development and transfer in a global environment: 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. The Department of Commerce 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.

9. 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 RECIEPENTS 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 v. Madey, 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 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.” While this decision appears to have its greatest impact on not-for-profit research institutions, a recent survey 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 Panel’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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