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# CRS Report for Congress

# Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act

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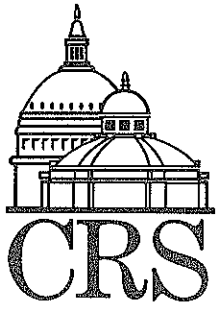
Wendy H. Schacht
Specialist in Science and Technology
Resources, Science, and Industry Division



# Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act


## Summary

Two major laws govern the dispensation of patents associated with federal research and development (R&D) activities. Both P.L. 96-418, the Stevenson-Wydler Technology Innovation Act, as amended, and P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as "Bayh-Dole" after its two main sponsors, former Senators Birch Bayh and Robert Dole), are the foundation for efforts to utilize patent ownership to encourage the commercialization of technologies and techniques that have their roots in the federal R&D enterprise. The Stevenson-Wydler Act contains provisions concerning assignment of title to inventions arising from collaborative work between federal laboratories and outside cooperating parties where no direct federal funding is involved. Bayh-Dole primarily addresses the distribution of patents resulting from federally-funded research and development performed by outside organizations, and prescribes the licensing of government-owned patents. While the result of different legislative histories and concerns, these laws were enacted to encourage the use of technologies funded by and/or developed by the government in pursuit of federal mission requirements.

Congressional interest in patent ownership as an incentive to private sector development and utilization of federally-funded R&D has been part of a legislative agenda designed to encourage increased innovation-related activities in the business community and to remove barriers to technological advancement, thereby permitting market forces to operate. Patents offer an economic incentive for companies to pursue the activities necessary to move the results of research from the laboratory to the marketplace in the form of new products, processes, or services. Ownership of title to inventions is a way to encourage the additional, and often substantial, investments in both money and time necessary to generate new and improved technologies and techniques. In an academic setting, the possession of title is expected to provide motivation for the university to license the technology to industry for further refinement in expectation of royalty payments.

This CRS report looks at both the Stevenson-Wydler Act and the Bayh-Dole Act and attempts to identify the differences and similarities inherent in the provisions of each law. The information is intended to provide a better understanding of the framework within which decisions are made concerning patent ownership and licensing given the context of on-going congressional interest in this arena. The report will be updated as warranted by congressional activity.

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# Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act

## Introduction

Two major laws govern the dispensation of patents associated with federal research and development (R&D) activities. Both P.L. 96-418, the Stevenson-Wydler Technology Innovation Act, as amended, and P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as "Bayh-Dole" after its two main sponsors, former Senators Birch Bayh and Robert Dole), are the foundation for efforts to utilize patent ownership to facilitate cooperative R&D, technology transfer, and the commercialization of technology supported by the federal government. While the result of different legislative histories and concerns, these laws were enacted to encourage the use of technologies funded by and/or developed by the federal government in pursuit of the departments' and agencies' mission requirements. However, they address intellectual property issues that arise from different R&D relationships. Stevenson-Wydler legislates the granting of title to inventions made through cooperative efforts between the government and outside partners when there is no direct federal funding to the collaborating institution. The provisions of Bayh-Dole pertain to patents resulting from R&D paid for by the government but performed elsewhere.

Congressional interest in patent ownership as an incentive to private sector development and utilization of federally-funded R&D was evident in a series of legislative debates in the mid to late 1970s. This was soon followed by expanded congressional attention to additional means of fostering technological advancement and commercialization in industry. During the 1980s (and continuing to this day), various initiatives resulted in laws designed to encourage increased innovation-related activities in the business community and to remove barriers to technology development, thereby permitting market forces to operate. Patents offer an economic incentive for companies to pursue the activities necessary to move the results of research from the laboratory to the marketplace in the form of new products, processes, or services. Ownership of title to inventions is a way to encourage the additional, and often substantial, investments in both money and time necessary to generate new and improved technologies and techniques. In an academic setting, the possession of title is expected to provide motivation for the university to license the technology to industry for further refinement in expectation of royalty payments.

This paper looks at both the Stevenson-Wydler Act and the Bayh-Dole Act and attempts to identify the differences and similarities inherent in the provisions of each law. The information is intended to provide a better understanding of the framework within which decisions are made concerning patent ownership and licensing given the

context of on-going congressional interest in this arena. It should be noted that while the original Stevenson-Wydler Act was passed prior to the Bayh-Dole Act, the amendments to P.L. 96-480 that are relevant to the current discussion were enacted after Bayh-Dole took effect. Since several of the amended provisions of Stevenson-Wydler are based upon components of Bayh-Dole, the Bayh-Dole Act will be addressed first in this report.

## Patents: In Brief

Interest in the value of intellectual property has grown as technology becomes increasingly important to the United States. It is now widely accepted that technological progress accounts for up to one-half of the nation's economic growth.[1] Patents protect the inventor's investments in generating the knowledge that is the basis for innovation. As written in the Constitution, patents are intended to promote "science and the useful arts" and serve as an incentive to the commercialization of new ideas. As R&D has become more expensive, ownership of title to inventions has been used by the federal government as a means to foster increased interest in private sector support for such efforts.

The patent system was created by Article I, Section 8, Clause 8 of the U.S. Constitution to encourage new discoveries and their reduction to practice, commonly known as innovation. The grant of a patent provides the inventor with a means to capture returns to his invention through exclusive rights on its practice for 20 years from date of filing. This is intended to encourage those investments necessary to further develop an idea and generate a marketable technology. At the same time, the process of obtaining a patent places the concept on which it is based in the public domain. In return for a monopoly right to specific applications of the knowledge generated, the inventor must publish the ideas covered in the patent. As a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar and expanded demands in the marketplace.[2]

The utility of patents to companies varies among industrial sectors. An assessment of the aircraft and semiconductor industries found that patents were not the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more

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[1]Tassey, Gregory. *The Economics of R&D Policy* (Connecticut: Quorum Books, 1997), 54. See also: Edwin Mansfield, Intellectual Property Rights, Technological Change, and Economic Growth, in *Intellectual Property Rights and Capital Formation in the Next Decade*, eds. Charls E. Walker and Mark A. Bloomfield (New York: University Press of American, 1988), 5.

[2]For more information see: Congressional Research Service, *Patents and Innovation: Issues in Patent Reform*, by Wendy H. Schacht, CRS Report 97-599, updated 24 August 1999, and Congressional Research Service, *R&D Partnerships and Intellectual Property: Implications for U.S. Policy*, by Wendy H. Schacht, CRS Report 98-862, 21 October 1998.

important.[3] In contrast, patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in those sectors, where the resulting patents are more detailed in their claims and therefore easier to defend.[4] The degree to which industry perceives patents as effective is ". . . positively correlated with the increase in duplication costs and time associated with patents."[5] In certain industries, patents significantly raise the costs incurred by nonpatent holders wishing to use the idea or invent around the patent — an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods — and are thus viewed as important. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and are considered less successful in protecting resource investments.[6]

Despite questions as to their efficacy, firms continue to patent their inventions. The number of domestic patents granted to U.S. inventors is growing.[7] This activity appears to be the result of additional perceived benefits including royalty payments, delays to imitators, and the ability to use patents as bargaining tools to meet alternative priorities of the firm.[8] The low expiration rate of high technology patents relative to patents on less sophisticated technologies may indicate the value that companies assign to such protection, even in industries where the life cycle of inventions is short.[9]

# The Bayh-Dole Act

## Rationale

P.L. 96-517, the Bayh-Dole Act evolved out of congressional interest in developing a uniform federal patent policy to encourage the commercialization of

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[3]Levin, Richard C. and Alvin K Klevorick, Richard R. Nelson, and Sidney G. Winter. Appropriating the Returns for Industrial Research and Development, *Brookings Papers on Economic Activity*, 1987, printed in *The Economics of Technical Change*, ed. Edwin Mansfield and Elizabeth Mansfield. (Vermont, Edward Elgar Publishing Co., 1993), 253.

[4]Ibid., 255 and 257. See also: Mansfield, Edwin. Intellectual Property Rights, Technological Change, and Economic Growth, in eds. Charles Walker and Mark A. Bloomfield, *Intellectual Property Rights and Capital Formation in the Next Decade*, (New York, University Press of America, 1988), 12 and 13.

[5]*Appropriating the Returns for Industrial Research and Development*, 269.

[6]Mansfield, Edwin, Mark Schwartz, and Samuel Wagner. Imitation Costs and Patents: An Empirical Study, *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

[7]National Science Foundation, *Science and Engineering Indicators 1998*, February 1998, A-373.

[8]*Intellectual Property Rights, Technological Change, and Economic Growth*, 14.

[9]Quigg, Donald J. Safeguarding Intellectual Property — Stimulus to Economic Expansion, in *Intellectual Property Rights and Capital Formation in the Next Decade*, 40.

technology resulting from government funding of research and development. While there was on-going and long-term debate over what government patent policy should entail, there was general agreement that the policy adopted should promote the utilization of inventions.[10] The intent of the legislation, as articulated in the House Judiciary Committee report to accompany the relevant bill, was to replace

> . . . the existing melange of 26 different agency policies on vesting of patent rights in government funded research . . . [with] a single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.[11]

At the time the legislation was under consideration only 5% of federally-owned patents were being used. This was one consequence of the practice by many agencies of taking title to all inventions made with federal funding while only permitting the nonexclusive licensing of contractor inventions.[12] Without title to inventions, or at least exclusive licenses, companies are less likely to engage in and fund the additional R&D necessary to bring an idea to the marketplace. Bayh-Dole, by providing universities, nonprofit institutions, and small businesses with ownership of patents arising from federally-funded R&D, offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provides the academic community an alternative way to support further research and the business sector a means to obtain a return on their financial contribution to the endeavor.

In enacting P.L. 96-517, the Congress accepted the proposition that vesting title in a contractor will encourage commercialization and that this should be used to foster innovation in specific segments of the economy. As stated in the law:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally-supported research and development; . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities; . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions. . . .[13]

The anticipated payback to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth were seen as

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[10]House Committee on Science and Technology, *Government Patent Policy*, 95th Cong., 2nd sess., May 1978, H.Prt. 4.

[11]House Committee on the Judiciary, *Report to Accompany H.R. 6933*, 96th Cong. 2nd sess., 1980, H.Rept. 96-1307, Part 1, 3.

[12]*Government Patent Policy*, 5.

[13]35 U.S.C. §200

a balance for the initial cost of the technology to the government or any potential unfair advantage to any recipient.

To achieve such goals, the Bayh-Dole Act addresses two areas of intellectual property as it pertains to the federal government: title to inventions made with federal R&D funding and licensing of government-owned patents. The relevant provisions are discussed below.

## Title to Inventions Made With Federal Funding

Each nonprofit organization (including universities) or small business is permitted to elect (within a reasonable time frame) to retain title to any "subject invention" made as a result of R&D funded by the federal government; except under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter."[14] The owner of the intellectual property must commit to commercialization of the patent within a predetermined time frame agreed to by the supporting agency and the performing organization. As stated in the House report to accompany the bill, "the legislation establishes a **presumption** [emphasis added] that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business."[15]

Certain rights are reserved for the government to protect the public interest. The government retains ". . . a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . ." The government also retains "march-in rights" that enable the federal agency to require the contractor (whether he owns title or has an exclusive license) to ". . . grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants. . ." with due compensation, or to grant a license itself under certain circumstances. The special situation necessary to trigger march-in rights involves a determination that the contractor has not made efforts to commercialize within an agreed upon time frame or that the "action is necessary to alleviate health or safety needs. . ." that are not being met by the contractor (15 U.S.C. §203).

The government is authorized to withhold public disclosure of information for a "reasonable time" until a patent application can be made. This supplements additional law that prohibits the Patent and Trademark Office from releasing information associated with a patent until it is issued. Licensing by a contractor retaining title under this Act is restricted to companies that will manufacture substantially within the United States. Initially, universities were limited in the time they could grant large companies exclusive licenses for patents derived from government-sponsored R&D (5 of the *then* 17 years of the patent). This restriction, however, was voided by P.L. 98-620, the Trademark Clarification Act of 1984. According to Senate report 98-662, extending the time frame for licensing to large

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[14]Ibid.

[15]*Report to Accompany H.R. 6933*, 3.

firms ". . .is particularly important with technologies such as pharmaceuticals, where long development times and major investments are usually required prior to commercialization."[16]

Under these provisions, several of the government-owned, contractor-operated laboratories of the Department of Energy (DOE) receive title to inventions under Bayh-Dole because they are operated by universities or nonprofit institutions. Those contractor-operated laboratories run by large firms also receive patent rights from DOE which has waived the agency's intellectual property claims under authority of the Atomic Energy Act of 1954 and through their management and operating contracts. As discussed above, certain rights continue to be retained by the government.

### Licensing of Government-Owned Inventions

Bayh-Dole also addressed the licensing of inventions to which the government retained title typically because of past agency practices or because of a public interest. Title 35 U.S.C. §209 proscribes the licensing of this type of invention. The law permits federal departments to offer nonexclusive, exclusive, or partially exclusive licenses under certain conditions and with specific rights retained by the government. These include the right to terminate the license if commercialization is not pursued as provided in the business plan or if the government needs the license for public use. The agencies are required to inform the public about the availability of a patent for licensing. Originally, notices were to be published in the *Federal Register* for a period of three months and if a company displayed intent to license, the laboratory was mandated to place an additional notice and offer 60 days for objections. However, P.L. 106-404, the Technology Transfer Commercialization Act, makes changes in these practices to decrease the time delays associated with this procedure. In light of the ability of the Internet to offer widespread notification and the necessity of time constraints faced by industry in commercialization activities, public notice is now to be provided 15 days prior to the grant of a license. In providing licenses, small businesses are given preferences and licensees must agree that ". . .any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States."

## Stevenson-Wydler Technology Innovation Act

### Background

P.L. 96-480, The Stevenson-Wydler Technology Innovation Act, as amended, was enacted to encourage use of technologies developed in the federal laboratory system. This is to be accomplished by technology transfer, the process by which technology generated in one organization, in one area, or for one purpose is applied in another organization, in another area, or for another purpose. In the defense and

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[16]Senate Committee on the Judiciary, *Report to Accompany S. 2171*, 98th Cong., 2nd sess., 1984, S.Rept. 98-662, 3.

space arenas it is often called "spin-off." Technology transfer can have different meanings in different situations. In some instances, it refers to the transfer of legal rights, such as the assignment of patent title to a contractor or the licensing of a government-owned patent to a private firm. In other cases, the transfer endeavor involves the informal movement of information, knowledge, or skills through person-to-person interaction. The crucial aspect in a successful transfer is the actual use of the product or process through which the benefits from more efficient and effective provision of goods and services can be achieved.[17]

In pursuit of mission requirements, federal departments and agencies spend approximately $79 billion per year on research and development; almost a third of this goes to support R&D performed in the government laboratory system. Such an effort has resulted in new and improved technologies and manufacturing techniques that may provide additional benefits beyond specific mission-related use. For example, while the major portion of total federal R&D spending has been in the defense arena, government-financed work has led or contributed to new commercial products and processes including, but not limited to, antibiotics, plastics, jet aircraft, computers, electronics, and genetically engineered drugs (e.g., insulin and human growth hormone). Technology transfer is one way, proponents argue, that federally-funded R&D can be further developed and applied by the private sector to meet other national needs associated with economic growth. The increasing competitive pressures on U.S. firms in the international marketplace, coupled with the government's requirements for goods and services, can make the collaboration between federal laboratories and industry through technology transfer beneficial to both sectors. Although opponents may argue that these activities detract from budgeted research, the knowledge base created by agency-supported R&D may serve as a foundation for additional commercially relevant efforts in companies while the government research enterprise is advanced through interaction with innovative firms. This transfer is facilitated by cooperative research and development agreements (CRADAs), a particular legal instrument created by P.L 99-502, the Federal Technology Transfer Act of 1986 (amending Stevenson-Wydler), and applicable to government-owned, government-operated laboratories. The right to use CRADAs was extended to government-owned, contractor-operated laboratories by an additional amendment to Stevenson-Wydler contained in P.L. 101-189, the FY1990 Department of Defense Authorizations.

## Cooperative Research and Development Agreements

A cooperative research and development agreement (CRADA) is a specific legal document (**not** a procurement contract) that defines the collaborative venture. It is intended to be developed at the laboratory level, with limited agency review. In agencies that operate their own laboratories, the laboratory director is permitted to make decisions to participate in CRADAs as a means of decentralizing and expediting the technology transfer process. However, at agencies that use contractors to run

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[17]For additional information see: Congressional Research Service, *Technology Transfer: Use of Federally Funded Research and Development*, by Wendy H. Schacht, CRS Issue Brief 85031, updated regularly.

their laboratories, specifically the Department of Energy, the CRADA also has to be approved by headquarters.

The work performed under a cooperative research and development agreement must be consistent with the laboratory's mission. In pursuing these joint efforts, the laboratory may accept funds, personnel, services, and property from the collaborating party and may provide personnel, services, and property to the participating organization. The government can cover overhead costs incurred in support of the CRADA, but is expressly **prohibited** from providing **direct** funding to the industrial partner.

The legislation does not specify the dispensation of patents derived from the collaborative work, allowing agencies to develop their own policies. Under a CRADA, title to, or licenses for, inventions made by a laboratory employee **may** be granted in advance to the participating company by the director of the laboratory (15 U.S.C. §3710a). In addition, the director may waive, in advance, any right of ownership the government might have on inventions resulting from the joint effort regardless of size of the collaborating company. At the least, the law permits the collaborating party the "option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement." The director also may negotiate licensing agreements for related government-owned inventions previously made at that laboratory to facilitate cooperative ventures.

In all cases, the government retains certain rights, including a "nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes." Under "exceptional circumstances," the government may exercise its right to require a party, to which it assigned title or granted exclusive license to an invention, to license the technology to another organization if it is necessary to address health and safety needs not being addressed; to meet requirements for public use specified by federal regulation not being met; or if the cooperating party has not performed its obligations as specified in the agreement. Information related to obtaining a patent is protected from disclosure for a period of time (15 U.S.C. §3710a) .

Typical agency activities are summarized below. It should be noted that the dispensation of title to inventions made under a CRADA involving a government-owned, contractor-operated laboratory is influenced by provisions of the Bayh-Dole Act that gives title to inventions made by those contractors that are universities or nonprofits. In addition, under the Atomic Energy Act of 1954 (P.L. 83-703), the Department of Energy has provided similar rights to all contractors as outlined in their management and operations contracts. In general:

- If an invention is made solely by an employee of a government-owned, government-operated laboratory the agency may keep title to the invention or may provide title to the collaborating party.

- If an invention is made solely by an employee of a government-owned, contractor-operated laboratory, the contractor may keep title to the invention (either under the auspices of the Bayh-Dole Act if the contractor is a university

or a nonprofit institution or under the provisions of the management and operations contract in which the Department of Energy agrees to relinquish title) and license it to the collaborating party.

- If an invention is made jointly by an employee of a government-owned, government-operated laboratory and a collaborating party, joint ownership of patent title may occur or the government may relinquish its interest in the patent.

- If an invention is made jointly by an employee of a government-owned, contractor-operated laboratory and a cooperating institution, both organizations may co-own the title.

- If an invention is made solely by a collaborating party, that party may keep title to the invention, with certain rights reserved by the government.

Laboratory personnel and former employees are permitted to participate in commercialization activities if these are consistent with the agencies' regulations and rules of conduct. Federal employees are subject to conflict of interest restraints. In the case of government-owned, contractor-operated laboratories, P.L. 101-189 required that conflict of interest provisions regarding CRADAs be included in all operating contracts. Preference in determining CRADAs is given to small businesses, companies that will manufacture in the United States, or foreign firms from countries that permit American companies to enter into similar arrangements. According to Senate report 99-283 that accompanied the legislation, "the authorities conveyed by [the section dealing with CRADAs] are permissive" to promote the widest use of this arrangement.[18]

It should be noted here that CRADAs are only one form of cooperative activity, but because they can be easily identified and quantified they tend to be the most visible. Other mechanisms include personnel exchanges and visits; licensing of patents; work for others; educational initiatives; information dissemination; the use of special laboratory facilities and centers set up in particular technological areas; cooperative assistance to state and local programs; and the spinoff of new firms. Currently, federal laboratories legislatively are prohibited from competing with the private sector and can only offer the use of expertise and equipment which is not readily available elsewhere. Technology transfer and cooperative efforts are expressly forbidden to interfere with the laboratories' R&D mission-related activities.

## Government Employee Inventions

Under Stevenson-Wydler, as amended, federal employees responsible for an invention are to receive at least 15% of royalties generated by the licensing of that government-owned patent (15 U.S.C. §3710c). The agencies may establish their own royalty sharing programs within certain guidelines contained in the legislation. The inventor may not receive more than $100,000 per year without the consent of the

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[18]Senate Committee on Commerce, Science, and Transportation, *Federal Technology Transfer Act of 1986, Report to Accompany H.R. 3773*, 99th Cong. 2nd sess., 1986, S.Rept. 99-283, 10.

President. If the federal agency has the right to an invention but chooses not to patent, the inventor, either a current federal employee or a former one, may obtain title to that invention subject to the reservation by the government of a non-exclusive, non-transferable, irrevocable, paid up license to practice or have practiced the invention on behalf of the government.

The Stevenson-Wydler Act also provides instructions on the distribution to federal agencies of royalties derived from cooperative R&D agreements (15 U.S.C. § 3710c). If, after the 15% payment to the inventor, royalty income exceeds 5% of the government-operated laboratory budget, the laboratory may retain 25% of the excess, with the remainder paid to the U.S. Treasury. The funds retained by the laboratory are to be used for expenses incurred in the administration and licensing of inventions; to reward the scientific, engineering, and technical personnel of the laboratory; to provide for personnel exchanges between laboratories; for education and training consistent with the laboratories' and agencies' missions; or for additional technology transfer activities. Royalties earned by government-owned, contractor-operated laboratories under a CRADA may be used for payments to inventors, as well as additional related education, training, R&D, and/or scientific exchanges.

## Additional Considerations

The Bayh-Dole Act and the Stevenson-Wyder Act address the ownership of inventions made under different circumstances but which have their roots in the federal R&D enterprise. As discussed above, Bayh-Dole primarily addresses the dispensation of patent title to inventions resulting from federally-funded research and development and prescribes the licensing of government-owned patents. The Stevenson-Wydler Act contains provisions concerning ownership of patents arising from collaborative work between federal laboratories and outside cooperating parties where no direct federal funding is involved. However different they may be on the surface, both laws are intended to promote the commercialization of technology. Congressional support for such efforts is founded on the idea that the process of bringing new products, processes, and services to the marketplace can generate economic growth in the form of new jobs, greater productivity, and improvements in the health and welfare of the population. Profound changes in our society have been brought about by advances in federally-funded R&D in the areas of medicine, semiconductors, computers, and materials, just to name a few.

Over the years, the legislation has been amended to reflect problems and opportunities in the implementation of these laws. During the 106th Congress, there were efforts to make changes in the way government-owned patents are licensed. P.L. 106-404, signed into law on November 1, 2000, shortens the time required by the Bayh-Dole Act (15 U.S.C. §209) to publicize the availability of technologies for licensing. This law also allows licenses for existing government-owned inventions to be included in CRADAs under changes made to the Stevenson-Wydler Act.

The legislative initiatives taken by the Congress during the past 20 years reflect the concern that companies that do not control the inventions arising from their investments (in money or effort) tend to be less likely to engage in related R&D

necessary to bring an idea to the marketplace. Under the Bayh-Dole and Stevenson-Wydler Acts, patent ownership may be provided in return for commercialization of the results of research and development. The prospect of new products and processes to improve our health, welfare, and standard of living has been viewed as promoting the public interest. Proponents of this approach contend that these benefits are more important than the initial cost of the technology to the government or any potential unfair advantage one company may have over another in their dealings with the federal departments and agencies.

However, as the environment within which R&D and innovation are performed changes, the effects of Stevenson-Wydler and Bayh-Dole may be altered. New challenges and opportunities in this area may be expected. Disputes have arisen over competing claims to intellectual property developed under government-industry ventures. Delays still exist in the negotiation of CRADAs due to disagreements over the dispensation of intellectual property. Concerns have been expressed regarding the right of drug companies to set prices on drugs that were developed in part with federal funding or in collaboration with federal agencies. Problems have been encountered in obtaining technologies for research use by federal laboratories because of apprehensions over diminished effectiveness of intellectual property if new applications are discovered. As these and other related issues continue to be explored, the information contained in this paper is designed to provide background for any additional congressional activity associated with the implementation of both the Bayh-Dole Act and the Stevenson-Wydler Act.