United States Government Accountability Office

GAO

Report to Congressional Committees

July 2009

FEDERAL RESEARCH

Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions

GAO-09-742

July 2009

FEDERAL RESEARCH

Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-09-742, a report to congressional committees

Why GAO Did This Study

The Bayh-Dole Act, passed in 1980, allows recipients of federal research funds the option to retain patents on any inventions they create using those funds. At the same time, the act provides the government with rights intended to ensure that the public benefits from these federal research investments. One of these rights is known as the "march-in" authority, which allows federal agencies to take control of a patent when they have credible information that certain conditions described in the act have been met.

Until March 2009, the Bayh-Dole Act required GAO to report periodically on its implementation. To meet that requirement, for select federal agencies, GAO reviewed (1) the policies and procedures used to determine whether march-in authority should be exercised; (2) how the march-in authority has been used; and (3) what barriers and disincentives have been encountered in exercising the march-in authority.

GAO selected four agencies for this review that accounted for 89 percent of the federal research funding for fiscal year 2006. These were the Departments of Defense and Energy (DOD and DOE), the National Aeronautics and Space Administration (NASA), and the National Institutes of Health (NIH).

GAO is not making any recommendations in this report. DOE, NASA, and NIH provided technical comments on this report that GAO incorporated, as appropriate.

View GAO-09-742 or key components.
For more information, contact Ms. Anu K. Mittal at (202) 512-3841 or mittala@gao.gov.

What GAO Found

Officials at DOD, DOE, NASA, and NIH rely on Commerce regulations for the Bayh-Dole Act and on their agencies' interpretations of the act to determine whether to exercise their march-in authority. Agency officials said that the administrative processes developed by Commerce are detailed and time-consuming, and may make it difficult to initiate and exercise a march-in proceeding. However, some officials said the detailed regulations ensure that appropriate and fair processes are followed during march-in proceedings. The agencies have chosen not to develop agency-specific guidance for a variety of reasons. For example, none of the officials believe that the regulations are onerous enough to warrant the development of agency-specific guidance and agency-specific guidance would reduce the flexibility agencies have to examine the specific circumstances of each case. In addition, an array of agency-specific regulations could hinder the transfer of research results to the market by increasing the regulatory burden on recipients of federal research funds.

None of the four agencies has chosen to exercise march-in authority. DOD, DOE, and NASA have neither discovered nor received information that would lead them to initiate a march-in proceeding or exercise their march-in authority during the last 20 years. In contrast, NIH has been petitioned formally three times, but in each case determined that the statutory requirements for march-in proceedings had not been met. Nevertheless, officials at DOD, NASA, and NIH said they value the authority because it provides leverage to promote commercialization of federally funded inventions. DOE officials disagree, in part, because no agency has ever exercised the authority. Agency officials said they do not have ongoing efforts to identify potential candidates for a march-in proceeding and primarily rely on the public, including potential competitors, to provide information that could lead to a march-in proceeding. According to these officials, their agencies would have to expend significant additional resources to track federally funded inventions because of the large number of inventions and because commercialization can take many years. Officials at DOD, NASA, and NIH said they value the march-in authority because it helps ensure that federally sponsored research results are commercialized. Also march-in authority is not the only tool to achieve the goals of the Bayh-Dole Act. For example, the government can take a patent without a license subject to reasonable compensation being paid to the patent owner or licensee that may allow for more timely interventions than would occur under the Bayh-Dole march-in process.

Federal and technology transfer officials identified four disincentives to the use of march-in authority. One of these is that the use of the march-in authority could have a "chilling effect" on federal research. These officials said that if a march-in occurred, investors would be less likely to provide the funds to commercialize federal inventions for fear of losing their investments. Also, because the march-in process can be long, these officials believe that it would have limited utility in an emergency situation. For example, the time to complete the fact-finding process in the three cases NIH reviewed ranged from 5 to 8 months.

Contents

Letter		1
	Background	4
	Federal Agencies Use Department of Commerce Regulations to Implement the March-in Authority under the Bayh-Dole Act	7
	None of the Agencies We Reviewed Has Used March-in Authority, but Three Value It as a Way to Promote Commercialization of Inventions	9
	Four Key Concerns May Create Disincentives to the Use of Bayh-Dole March-in Authority by Federal Agencies	14
	Agency Comments and Our Evaluation	17
Appendix I	**Objectives, Scope, and Methodology**	18
Appendix II	**National Aeronautics and Space Administration Official Comments**	20
Appendix III	**GAO Contact and Staff Acknowledgments**	21

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
DOD	Department of Defense
DOE	Department of Energy
GAO	Government Accountability Office
HIV	Human Immunodeficiency Virus
NASA	National Aeronautics and Space Administration
NSF	National Science Foundation
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

July 27, 2009

The Honorable Patrick J. Leahy
Chairman
The Honorable Jeff Sessions
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable John Conyers, Jr.
Chairman
The Honorable Lamar Smith
Ranking Member
Committee on the Judiciary
House of Representatives

Technological innovation is widely seen as responsible for much of the economic growth and increased standard of living in modern societies. Patent rights give inventors, or other patent owners, exclusive control over the use of their inventions for about 20 years, which promotes commercialization of new ideas and allows inventors to profit from their ideas. Patent rights ownership encourages the additional, and often substantial, investment of time and money needed to transform the technological innovations developed in the laboratory into goods, services, and processes available in the marketplace. Patent owners—including individuals, companies, and universities—may grant licenses to one or more businesses to complete this transformation and, in return, receive payments in the form of license fees or royalties.

The federal government supports technological innovation through a wide range of research activities that focus on the mission needs of various departments and agencies. In addition, it supports work in areas where a specific need has been identified that the private sector has not addressed. Although the largest share of research funding comes from the private sector, the federal government funds a majority of the nation's basic research, which produces the innovations that drive technological progress. Moreover, federal support accounts for over half of the research conducted at colleges and universities in the United States. Because the public benefits when technological advances are transformed into new goods and services in the marketplace, the federal government has an interest in facilitating the commercialization of new inventions that arise from the research that it funds.

Since its enactment in 1980, the Bayh-Dole Act has provided recipients of federal research and development funding—often referred to as contractors—the option to retain patents on the inventions they create, provided they adhere to certain requirements.[1] A main goal of the act is to promote the utilization of inventions arising from federally supported research or development, and observers have judged the act a success in this regard. Prior to 1980, when the government routinely retained the patents on federally sponsored inventions, only 5 percent of these patents were ever used in the private sector. In contrast, some stakeholders, including federal and technology transfer officials, today believe inventions that arise from federally funded research are routinely commercialized, although comprehensive data are not available on how often this happens. Each federal agency that enters into funding agreements subject to the Bayh-Dole Act is responsible for administering the act's requirements and the implementing regulations developed by the Department of Commerce.

The Bayh-Dole Act also provides the federal government with certain rights to protect the public against nonuse or unreasonable use of federally funded inventions. One of these rights, known as the "march-in" authority, authorizes federal agencies, at their discretion, to require the contractor or licensee to grant a license to any responsible entity or entities when credible information exists that certain statutory conditions in the act have been met. For example, an agency may march in if it determines that an inventor is not taking the necessary steps toward commercialization of the technology, or that such action is needed to meet public health or safety needs. [2]

Until recently, the Bayh-Dole Act also contained a requirement that GAO issue a report on how agencies have implemented the act's provisions at least once every 5 years. In consultation with your offices we began work

[1]The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a federal funding agreement, which includes contracts, grants, or cooperative agreements for the performance of experimental, developmental, or research work.

[2]The two additional statutory conditions under which agencies may exercise march-in authority are (1) the use of an invention is required by the federal government and the contractor cannot meet the government's requirements; and (2) the patent owner or exclusive licensee has failed to take certain steps to ensure that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

on this review to meet that reporting requirement. However, subsequent to our initiating this review, the Omnibus Appropriations Act for fiscal year 2009, eliminated the recurring study requirement on March 11, 2009.[3] As agreed with your offices, we have completed this review and addressed the following objectives: (1) what policies and procedures have federal agencies with significant research budgets established to determine whether march-in authority under the Bayh-Dole Act should be exercised; (2) to what extent have these selected federal research agencies used Bayh-Dole march-in authority and what do they believe are its benefits; and (3) what barriers and disincentives, if any, have these agencies encountered to the exercise of their march-in authority under the Bayh-Dole Act.

To determine which agencies to focus our review on, we analyzed federal research and development budgets for all federal research agencies. We selected the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and the National Institutes of Health (NIH) within the Department of Health and Human Services because together they accounted for 89 percent of the total federal research funding for fiscal year 2006—the most recent year for which complete data were available. For each of the objectives, we reviewed key agency documents and interviewed officials from the technology transfer offices of each agency. In addition, for each of the objectives we spoke with officials in stakeholder groups such as the Association of University Technology Managers, the Biotechnology Industry Organization, and the American Intellectual Property Law Association, as well as academics who have evaluated the Bayh-Dole Act.

We conducted our work from November 2008 to July 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[3]Pub. L. No. 111-8, Div. G, Title I, section 1301(h), 123 Stat. 829 (2009).

Background

The Bayh-Dole Act was enacted in 1980, in part, to address the low utilization rate of federal patents. At the time the bill was considered, 26 different federal agency policies existed regarding the use of results from federally funded research. Prior to Bayh-Dole's enactment, agencies frequently retained title to inventions made with federal support whether the research was performed in federal laboratories, in universities, or by individual companies. Licenses to use and further commercialize the patents on federally funded inventions were then negotiated with firms typically on a non-exclusive basis or, more rarely, for the exclusive use by one manufacturer. The Bayh-Dole Act established a governmentwide policy that gave contractors the opportunity to retain ownership of federally funded inventions. In addition, it was designed to use the patent system to promote the utilization of inventions arising from federally supported research or development and to encourage maximum participation of small business firms in federally supported research and development efforts, among other things. Many experts continue to believe that certainty in the ownership of patents and exclusivity in the right to develop the related technology are important for both large and small firms.[4]

In exchange for the right to retain ownership of federally sponsored inventions under the Bayh-Dole Act, contractors must agree to certain reporting requirements. More specifically, contractors agree to notify the funding agency within 2 months after the contractor learns that an invention has been created and to notify the funding agency within 2 years after this notification of the contractor's decision to retain title to the invention. In addition, contractors agree to apply for a patent on the invention typically within 1 year of the election of title, attempt to commercialize the invention, and to provide additional reports. These additional reports, if requested by the agency, can provide such information as utilization of the invention and patent-related information such as the filing date, patent application number and title, and patent number and issue date for the invention in any country in which the contractor has applied for a patent. Failure by the contractor to disclose the invention, elect title to it, or file a patent application within the times

[4]The Bayh-Dole Act by its terms applies to universities, non-profit organizations, and small businesses that receive federal research funding. A presidential memorandum in 1983, followed by an Executive Order in 1987, directed federal agencies, to the extent permitted by law, to establish policies for all businesses that are substantially the same as those contained in the Bayh-Dole Act.

specified, or failure to follow through with the patent application process, allows the relevant federal agency to obtain ownership of the invention.

The Bayh-Dole Act also reserved certain rights for the government to protect the public's interests. Specifically, 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," also known as a nonexclusive royalty-free license. In addition, the act provides the government march-in authority. Under this authority, the federal agency that funded the development of an invention has the right to require the contractor or exclusive licensee to grant a license in any field of use to a responsible applicant upon terms that are reasonable under the circumstances, if the agency determines that:

- the contractor has not made, and is not expected to make, efforts to commercialize the invention within an agreed upon time frame;
- public health or safety needs are not reasonably satisfied by the contractor or licensee;
- the use of the invention is required by the federal government and the contractor or licensee cannot meet the government's requirements; or
- the owner of an exclusive license is not ensuring that the invention is "manufactured substantially" in the United States and has not obtained the necessary waivers to do so.

Implementation of the Bayh-Dole Act is decentralized across the federal government. Each federal agency that enters into funding agreements subject to the Bayh-Dole Act is responsible for administering the act's requirements. However, the act directs the Department of Commerce to develop regulations to implement the provisions contained in the act, including procedures for agencies to follow regarding the exercise of the march-in authority.[5] The regulations Commerce issued in 1987 also allow agencies to develop supplemental procedures regarding their march-in authority. Although Commerce does not maintain any overall Bayh-Dole

[5]As originally enacted, the act required the Office of Federal Procurement Policy to develop these regulations. In 1984 Congress transferred this regulatory authority to the Department of Commerce. Pub. L. No. 98-620, § 501(10), 1984.

databases, other agencies rely on Commerce as a coordinator and consultant for Bayh-Dole related issues.

The regulations established by Commerce detail the procedures an agency must follow when it receives information that it believes might warrant the exercise of march-in rights. Specifically, the agency must notify the contractor, in writing, that it has information it believes might warrant the exercise of its march-in authority. As part of this notification, the agency is to provide the contractor 30 days to respond informally, either verbally or in writing, with relevant information. Once the agency has received the contractor's response, it may initiate the march-in procedures within 60 days through written notice to the contractor and its assignee or exclusive licensee, as appropriate and if known to the agency. The notice must include the reasons for the proposed march-in and the specific uses of the invention for which the agency may require licensing. Within 30 days after receiving written notice of the proposed march-in proceeding, the contractor may submit information opposing the proposed march-in to the agency in person, in writing, or through a representative. If the agency determines that the contractor's information raises a dispute over the facts of the case, it must undertake a fact-finding process that gives the contractor the opportunity to appear with counsel, submit documents, present witnesses, and question individuals presented by the agency. The results of the fact-finding process and a recommendation are presented to the head of the agency (or his or her designee) as well as to the contractor. Both the agency and the contractor have 30 days to submit written arguments to the head of the agency or designee. In addition, the contractor may request to present oral arguments. Within 90 days after the completion of the fact-finding or oral arguments, whichever is later, the agency must provide a written decision regarding whether march-in rights will be exercised. Any decision unfavorable to the contractor will be held in abeyance pending the exhaustion of the contractor's administrative and judicial appeals. At any point, the agency may terminate the fact-finding process if it decides not to exercise its march-in authority.

The time from when an agency announces a funding opportunity to the time a viable commercial product reaches the marketplace may take many years and substantial financial investment. During the period of agency funding, which may last 8 to 10 years for drugs and biologics, the agency's program, procurement, and/or grants office monitors the progress of the research and maintains contact with the contractor. In fiscal year 2007 federal agencies devoted $116 billion to conduct research on various topics related to their respective missions. Pharmaceutical-related inventions, which may arise from research sponsored by NIH, may require

an additional 10 to 15 years after the invention is made to obtain the federal approvals necessary to reach the market. According to industry officials, pharmaceutical-related inventions may require an investment of between $800 million and $1.3 billion to conduct the safety and other studies required for approval.

Additional time may be required to obtain a patent on the invention and to develop a market ready process or product. [6] More specifically, the U.S. Patent and Trademark Office issues a patent in 32 months, on average, but the time ranges from 28 months for inventions in the fields of semiconductors and electrical items to almost 44 months for computer software and communications inventions. Once a patent is granted, the patent owner has, in most instances, a period of 20 years from the date the application was filed during which time the patent owner has the right to exclude others from making, using, or selling the patented invention.

Federal Agencies Use Department of Commerce Regulations to Implement the March-in Authority under the Bayh-Dole Act

Officials at DOD, DOE, NASA, and NIH rely on Commerce regulations for the Bayh-Dole Act and on their agencies' interpretations of the act to determine whether to exercise their march-in authority. These officials told us that the administrative processes developed by Commerce for agencies to use when considering whether marching-in may be warranted are detailed and time-consuming, and may make it difficult to initiate a march-in proceeding. However, some officials also acknowledged that because the regulations are detailed, they ensure that appropriate and fair processes are followed during march-in proceedings. One official noted that there is no way to pre-empt the process and retain the necessary legal protections for all of the participants in the process. According to this official, the regulations, while detailed and time-consuming, allow everyone to be heard during the process. For example, during the fact-finding procedure the contractor has the opportunity to appear with counsel, submit documentary evidence, present witnesses, and cross-examine witnesses who the agency presents. Moreover, both the contractor and agency staff have an opportunity to rebut an agency's decision and contractors may appeal adverse decisions to the federal courts, which delays action on the agency's decision until the appeals process is concluded.

[6]The time required to obtain a patent may overlap with the period of federal funding for the research.

However, according to agency officials we spoke with, the agencies have chosen not to develop agency-specific guidance for a variety of reasons. First, none of the agency officials we spoke with believe that the regulations developed by Commerce are onerous enough to warrant the development of agency-specific guidance. Second, both agency and technology transfer officials told us that agency-specific guidance would, in essence, pre-define how the federal government would exercise its march-in authority and reduce the flexibility agencies have to examine the specific circumstances of each individual case. Third, federal officials—as well as officials from organizations that represent technology transfer offices in colleges and universities—told us that creating an array of agency-specific regulations could hinder the transfer of research results to the market by increasing the regulatory burden on contractors.[7] For example, one technology transfer official said that many universities receive funding concurrently from more than one federal agency. In such cases, these contractors could be required to follow a different set of regulations from each of their agency partners. As a result, these officials believe that Commerce should remain in charge of developing march-in regulations, rather than have individual agencies issue their own policies and procedures. Finally, technology transfer officials we spoke to also said that march-in regulations should be centralized at a high enough level to ensure consistency among federal research agencies in their march-in decisions.

Until August 2007, if federal agencies or contractors had any questions concerning Bayh-Dole Act implementation issues, including march–in procedures, they generally coordinated with officials in Commerce's Technology Administration. However, since August 2007, as a result of changes mandated by the America COMPETES Act, the Technology Administration has been disbanded and Commerce has shifted responsibility for the Bayh-Dole Act to the National Institute of Standards and Technology (NIST). Officials from two technology transfer organizations told us that, as a result of this change, the department currently has little expertise on the march-in process. Specifically, technology transfer officials told us they were concerned that NIST did not have the knowledge and experience of the Technology Administration with regard to oversight of march-in procedures and officials at one

[7]Throughout this report we refer to officials from organizations that represent technology transfer offices in colleges and universities as technology transfer officials.

organization believed that this might cause some ambiguity in facilitating agencies' implementation of the act.

NIST officials acknowledged that no one currently in their office has any experience with the march-in authority and said the process appears to be very time-consuming and complex. However, these officials told us that when the Technology Administration was disbanded, the same lawyers who worked on Bayh-Dole issues continued to provide their services, which allowed continuity in the overall legal aspects of oversight for the act. They also noted that most of the questions they have addressed for agencies concern aspects of the act other than the march-in authority. They also believe that because agencies are not required to contact NIST with questions related to the Bayh-Dole Act, that NIST's role in any future march-in proceedings will likely be very limited.

None of the Agencies We Reviewed Has Used March-in Authority, but Three Value It as a Way to Promote Commercialization of Inventions

None of the four agencies we reviewed has chosen to exercise march-in authority under the Bayh-Dole Act. DOD, DOE, and NASA have neither discovered nor received information that would lead them to initiate a march-in proceeding or exercise their march-in authority during the last 20 years. In contrast, NIH has been petitioned formally to exercise its march-in authority three times, but in each case determined that the statutory requirements for march-in proceedings had not been met. Nevertheless, officials at three of the four agencies told us they value the authority because, together with other tools, it provides them leverage to promote commercialization of federally funded inventions. In contrast, DOE officials do not believe march-in authority has significant value as leverage, in part, because no agency has ever exercised the authority.

Officials at all four agencies included in our review acknowledged that their agencies have not conducted any march-in proceedings. They further acknowledged that while they monitor contractors' compliance with reporting requirements, their agencies do not have ongoing efforts to identify potential candidates for march-in proceedings from the wide-array of federally funded inventions. These officials told us that they primarily rely on public and private sources of information, including news reports, interest groups, and potential competitors, to provide them with information that could lead to a march-in proceeding. For example, according to one official, participants in the science and technology market are very aware of emerging technologies and information on patents is publicly available, which allows interested entities to know what inventions and technologies are being developed. In addition, companies employ technology scouts to report on the technologies being produced by

other companies. Officials told us that one source of information regarding a potential march-in proceeding could be a person or business that wants to enter into a licensing agreement but is unable to negotiate agreeable terms. However, they also acknowledged that such instances are generally uncommon because most contractors are very interested in licensing their inventions.

According to the agency officials we spoke with, relying on the public for information is a more efficient and effective mechanism for tracking federally funded inventions, which would otherwise require federal agencies to expend significant additional resources to monitor a large volume of federally funded inventions for possible situations that might lead to march-in proceedings. In fiscal year 2008, NIH provided 50,980 awards, worth about $21 billion, to 2,606 institutions. The agency's awards for the previous 5 fiscal years were steady at about this same level. Monitoring such a large number of awards and institutions would be very resource intense. Moreover, because many inventions require substantial investments of time to produce a market-ready product or process, agencies would need to monitor awards and their subsequent inventions over a number of years. For example, NIH officials said that pharmaceutical inventions may take as many as 14 years to reach the marketplace. In addition, although contractors report information on inventions that result from federally funded projects, they are not required to report information on progress toward commercialization of those inventions or other details of the licensing agreements they enter into, which are considered proprietary information. Consequently, agencies do not always receive information on the extent to which licensees are making progress toward commercialization of the inventions the agencies have funded. Officials also told us that proactive efforts to track federally funded inventions are further complicated by the fact that a single invention may result in multiple licensing agreements for different uses. For example, a contractor who owns a cancer treatment could license the technology to one entity to treat eye cancer and to another to treat liver cancer.

Since Congress enacted the Bayh-Dole Act in 1980, only NIH, of the four agencies we reviewed, has received formal march-in petitions—one in 1997 and two in 2004. In each of these cases, the agency determined after a 5- to 8-month fact-finding process that the circumstances did not meet any of the statutory conditions under which march in could occur. Specifically, in 1997, NIH received a petition in which the petitioner alleged that the invention's owner and exclusive licensee had failed to take reasonable measures to bring a stem cell separation device to market and that doing

so would alleviate patient health and safety needs. NIH found no basis to initiate a march-in proceeding because it determined that the invention's owner and exclusive licensee had taken effective steps to develop the device and that it was already being marketed. In 2004, NIH received two more petitions, in which the petitioner expressed concern that the price of two drugs—one to treat HIV/AIDS and the other to treat glaucoma—made them unaffordable for many people living with these diseases, posing a threat to their health and safety. However, NIH determined that the drugs were already on the market and widely prescribed, and therefore marching in would not alleviate health and safety needs that were not already being satisfied by the producer. NIH also stated in its decisions that drug pricing is an issue more appropriately left to the Congress.[8] Furthermore, as NIH noted in its decision on the 1997 petition, the agency is "wary of forced attempts to influence the marketplace for the benefit of a single company."

Although DOE has not been petitioned to exercise its march-in authority nor has it used the authority on its own, the department used the Bayh-Dole march-in framework to review a dispute brought by a company against a contractor and its exclusive licensee over the use of two inventions that could identify gene sequences. According to the company, the contractor and its licensee had not taken effective steps to achieve substantial utilization of the inventions, and had not given the requisite preference to small businesses. While this dispute did not arise under the Bayh-Dole Act, DOE suggested, and all parties agreed, to settle the dispute using the march-in procedures detailed in the Commerce regulations. During a 30-month fact-finding process, both parties to the dispute submitted evidence and counter evidence and reviewed the draft decision prior to its release. DOE decided not to march in based on its determination, among other things, that the terms of the exclusive license were fair and that the company making the allegations had failed to offer sufficient evidence to support its contentions.

Although none of the agencies we reviewed has actually used its authority to march in, officials in three of the four agencies we contacted said they value the authority and they do not want it eliminated because it helps to ensure that federally sponsored research results are commercialized. These officials told us that the march-in authority is particularly valuable

[8]In its decision on the drug for treating HIV/AIDS, NIH also stated that the Federal Trade Commission was the appropriate agency to address allegations that the drug manufacturer had engaged in anti-competitive practices.

as leverage in informal discussions between contractors and sponsoring agencies and in license negotiations between contractors and potential licensees to encourage commercialization of technologies developed with federal funding. However, neither the agencies we reviewed nor the technology transfer organizations we contacted maintain data on the extent to which the potential for a march-in proceeding is discussed informally during negotiations.

According to some agency and technology transfer officials, the parties to licensing negotiations are usually sufficiently aware of the potential for march-in that it may not be necessary to explicitly discuss this possibility during meetings. However, neither could provide us with any metrics by which they could measure this effect, and no data exist on the extent to which contractors or licensees are aware of the potential for an agency to march in and to what extent this influences their decisions. Executives from two bio-technology firms told us that they are well aware of the Bayh-Dole Act and its march-in provision. They consider the potential for a march-in as one of several business risks, but said it is not a subject they typically discuss during licensing negotiations. Nevertheless, according to one technology transfer official, an explicit discussion of march-in authority can provide effective leverage to push a company struggling to meet its obligation to pursue commercialization of a federally funded invention. DOE officials, on the other hand, said an awareness of the march-in authority did not appear to have much influence on its contractors and their licensees. DOE officials said their contractors generally produce inventions, processes, and technologies that are intended for the market and are already strongly motivated by potential profits to move forward quickly. Consequently, these officials said it is difficult to see how the potential for a march-in proceeding under the Bayh-Dole Act would provide an additional incentive to these contractors.

Although most of the officials we spoke with value the leverage that the march-in authority provides, they said they prefer to work with contractors informally to resolve commercialization issues. For example, NIH officials noted that contractors often resolve such issues—without agency involvement—by reviewing the milestones in the licensing agreement to determine whether the licensee has met its obligations, and if it has not, the contractor may adjust the terms of the agreement based on speed and results of the licensee's efforts or revoke the license and seek a new licensee. According to one NIH official, if NIH enters such discussions its mere involvement often serves as enough leverage to encourage resolution of the problem without resorting to an explicit mention of march-in. Similarly, DOD officials said that in the early 1990s,

during a patent-related dispute between two defense contractors, one of the companies raised the possibility of petitioning DOD for a march-in proceeding to settle the disagreement. DOD entered into informal discussions with both companies, then withdrew, and the companies subsequently resolved their dispute without petitioning for a march-in.

Some officials also told us that the march-in authority is not the only available tool to achieve commercialization goals for federal research efforts or to meet the government's needs. For example, NIH officials told us that one useful tool is the agency's guidance for contractors to use when negotiating license agreements. Contractors can enter into such agreements with parties who wish to commercialize an invention. The NIH guidance recommends including specific commercialization milestones and a termination clause to ensure that inventions are commercialized by licensees. For example, if an invention has a potential therapeutic use, the agreement may include requirements to reach federal approval for various clinical trials by certain dates, as well as the anticipated date of first sale. Technology transfer officials we spoke with said that the widespread use of commercialization milestones and termination clauses reduces the likelihood that an agency would need to march in because contractors are already assuring that commercialization is achieved.

The government can also use patented technology without a license subject to reasonable compensation being paid to the patent owner or licensee, regardless of whether the invention had been developed with federal funding. This allows the federal government to use an invention without a license, if the use is "by or for the United States." Further, under federal law if the federal government uses a patent, the patent owner or licensee may sue the government to recover reasonable compensation but may not stop the government from using the invention.[9] This option might be of greater value than the Bayh-Dole march-in authority in the case of a public health emergency because it allows for rapid action and it allows the government to use inventions that incorporate federally funded technologies as well as technologies that were not federally funded. In addition, officials told us that the Bayh-Dole Act itself contains another tool—the royalty-free license—that allows federal agencies to use federally funded inventions without risk of infringing the ownership rights of the contractor or licensee. For example, federal agencies may contract with a third party to manufacture products containing such inventions for,

[9] 28 U.S.C. § 1498(a).

or on behalf of, the government. However, if the product or process contained inventions that were not developed with federal funds, the government would need to negotiate a license to use them. Finally, some agencies, including DOD, DOE, and NASA, have been granted other statutory tools that provide additional flexibility to negotiate ownership terms with contractors. For example, all three have similar statutory authorities—called "other transaction authority"—that apply to certain research efforts conducted under contracts. DOD and DOE have used this authority to obtain cutting-edge research and prototypes for their use and NASA has used its authority to negotiate ownership rights that will foster the commercialization of inventive work produced under collaborative research projects that are not being conducted specifically for the agency.

Four Key Concerns May Create Disincentives to the Use of Bayh-Dole March-in Authority by Federal Agencies

Four key disincentives inhibit federal agencies use of Bayh-Dole march-in authority. First, the potential "chilling effect" that such an action might have could deter investors from investing in the commercialization of the research results and some researchers from participating in federal research efforts. Second, the lengthy march-in process could be unworkable in an emergency or other time-critical situation. Third, commercial products or processes based on federal inventions sometimes employ multiple patents, some of which are not federally funded. Such circumstances often pose difficult, if not intractable, issues that could make marching in unattractive for federal officials seeking to commercialize an invention. Finally, agencies might be disinclined to march in if current licensees have specialized knowledge that makes them particularly well positioned to bring a product to market, and if the loss of such knowledge through a march-in proceeding might jeopardize the commercialization of an invention. This section further describes these four disincentives.

Some agency, university, and industry officials we contacted said the march-in authority could have a "chilling effect" on the willingness of venture capital firms and other investors to provide funding for the further commercial development of federally funded inventions. For example, three of the technology transfer officials we contacted said the chilling effect on investors would be increased if agencies used the march-in authority under circumstances that were not well supported by the facts. According to these officials, investors are looking for profitable technologies and inventions that either have, or are close to obtaining, a patent, which allows them to capture profits in relative safety. They said that for some investors the mere existence of an agency's march-in authority makes such investments more risky because, should an agency

actually exercise its authority, investors may believe the value of their investment could evaporate or decline significantly and these perceived risks could increase significantly.

However, executives from two bio-technology firms—both of which hold licenses to commercialize technologies developed in part with federal funds and which must raise money from investors to pursue commercialization—told us the perceived risk that an agency might march in is far less important to investors than other risks they face. For example, they cited the product's likely efficacy as perhaps the key factor for investors to consider in making such decisions. The executives added that one of the greatest concerns of their potential investors is how soon the product or process can be marketed and, as a result, return a profit on their investment. These executives expressed confidence that if licensees take care to follow the requirements of the Bayh-Dole Act, then march-ins would be rare and should not negatively affect the flow of federally funded inventions to the market. In addition, technology transfer officials noted that at the time the act was passed companies were often unwilling to enter into licensing agreements due to concerns about how agencies would use the authority. They said such concerns have diminished, in part because the small number of fact-finding proceedings has not led agencies to march in.

The march-in authority would also have a chilling effect if researchers, particularly private-sector researchers, were unwilling to apply for federally funded projects because the potential for an agency to march in creates uncertainty with regard to ownership of an invention. However, none of the officials we contacted was aware of specific instances when a researcher had declined to apply for federal funding and they said it is impossible to know the extent to which researchers decide against applying for federal funds due to such concerns. In contrast, officials at DOE said they do not believe the potential for a march in is a concern for their contractors. For example, DOE officials noted that following the release of a recent solicitation, 60 small businesses called with questions about the march-in authority. However, even after DOE officials explained the march-in authority to these callers, overwhelmingly they submitted applications.

Because the march-in process itself can be long and the outcome unknown pending a possible appeal of the agency's decision to the federal courts, the NIH officials we contacted believe march-in authority could have limited utility in an emergency situation, such as an important public health issue, that required prompt federal action. More specifically, the

Commerce regulations that govern march-in procedures provide for a quasi-judicial process that may require more time to complete than the other legislative options mentioned above. The march-in procedures allow for contractors to be represented by counsel, the opportunity to call and confront witnesses, and the chance to introduce documentary evidence and review the evidence others have presented. In the four fact-finding instances we reviewed, the time to reach a decision not to initiate march-in proceedings ranged from 5 to 30 months. According to NIH officials, the specifics of each Bayh-Dole fact-finding effort are likely to vary, but the process to determine whether a march-in proceeding is warranted will usually require at least several months to accomplish. Moreover, in the event an agency decides to march in, action on the decision may be delayed pending review by the federal courts if the contractor or licensee appeals the decision. In emergency situations, NIH officials said the government could use other legal authorities, discussed above, to obtain the necessary rights.

Officials at NASA and NIH also reported that a march-in proceeding would be complicated by the fact that most products and processes include multiple technologies covered by multiple patents, and that in many cases only some of them have been developed with federal funding. As a result, federal agencies may only have the authority to march in on one aspect of a product or process, yet marching in may negatively affect the value of all the other patented inventions associated with the product or process. For example, NIH officials described the development of a single genome test that used 17 patents from 13 organizations (3 from outside the U.S.), some of which used government funding and some did not. These officials said it would be impossible for NIH to determine that 1 of those 17 patents is not being commercialized fast enough, or not meeting a health need, in the face of its dependence on 16 other patents. Any such effort would require the cooperation of 12 other organizations, and an unknown number of licensees. The officials concluded that it would be an impossible task for NIH, or any agency, to decide to march in under those circumstances.

Officials at NIH also said that agencies might be disinclined to march in if current licensees have specialized knowledge about how to bring a particular product to market. If the loss of such knowledge would jeopardize the commercialization of an invention, agencies might be reluctant to pursue a march-in. For example, licensees may possess information such as trade secrets, other patented technologies related to product development, experience with the federal approval process, or marketing experience. If NIH were to force a contractor or licensee to grant a license to another entity, it would have to consider whether the

other patented technologies would be available to the new licensee and whether the new licensee would have the knowledge, resources, and commitment needed to commercialize the product.

Agency Comments and Our Evaluation

We provided a copy of a draft of this report to DOD, DOE, NIH, and NASA for their review and comment. In commenting on the draft, NASA stated that the report provides a balanced view of the issues related to the regulations associated with the Bayh-Dole Act. NASA also provided technical comments that we incorporated, as appropriate. NASA's overall comments are included in appendix II. DOD, DOE, and NIH did not provide overall comments, but NIH provided technical comments that we incorporated, as appropriate.

We are sending copies of this report to the appropriate House and Senate committees, interested Members of Congress, the Secretaries of the Departments of Defense and Energy, the Administrator of NASA, and the Director of NIH. The report will also be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have questions about this report, please contact me at (202) 512-3841 or mittala@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

Anu K. Mittal
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

The objectives of this report were to determine (1) what policies and procedures federal agencies with significant research budgets have established to determine whether march-in authority under the Bayh-Dole Act should be exercised; (2) the extent to which these selected federal research agencies have used Bayh-Dole march-in authority and what they believe are its benefits; and (3) what barriers and disincentives, if any, these agencies have encountered to the exercise of their march-in authority under the Bayh-Dole Act.

We sought to focus our review on those federal agencies whose combined research and development spending represent a significant portion of total federal research and development spending. To identify the federal research agencies that meet this criterion, we obtained and analyzed research and development funding data from the National Science Foundation (NSF) on preliminary federal obligations for research and development for all federal research agencies. The top four agencies receiving research and development funding were the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and the National Institutes of Health (NIH) within the Department of Health and Human Services. We judgmentally selected these four agencies as the focus of our review. We compared the combined percent of funding from the total research and development allotment for these four agencies to the total allotment for the federal government and found that these four agencies accounted for approximately 89 percent of the total federal research funding for fiscal year 2006—the most recent year for which NSF had complete data. In assessing the reliability of the NSF data, we noted that it reports a 100 percent response rate, with responses to all items; thus, we determined it was sufficient for the purposes of this analysis.

To gain insights into the history of the Bayh-Dole Act, including its provision for march-in authority, as well as to understand the context in which the law was enacted and its current environment, we reviewed the act's legislative history, including congressional hearing statements made by the act's sponsors and other stakeholders. We also reviewed the available literature on the Bayh-Dole Act's implementation and the effects it has had on federal research. To understand the law's requirements, we reviewed all provisions of the act, giving special emphasis to those sections that establish march-in authority. To understand how agencies are to implement their responsibilities under the act, we reviewed the Department of Commerce's Bayh-Dole regulations.

For each of our three objectives, we interviewed officials from the technology transfer offices and offices of general counsel at DOD, DOE, NASA, and NIH, as well as officials from the National Institute of Standards and Technology. In addition, we contacted officials in stakeholder groups such as the Association of University Technology Managers, the Biotechnology Industry Organization, the American Intellectual Property Law Association, the Association of Public and Land-grant Universities, and Essential Inventions, as well as academics who have evaluated the Bayh-Dole Act. We also contacted representatives from the biotechnology industry who invest in and/or develop federally funded technologies. We reviewed the three march-in petitions that NIH received, and NIH's determinations in these cases, to understand how NIH applies the Commerce regulations. Finally, we studied NIH's research tool guidelines to determine their impact on agency decisions on whether to conduct march-in proceedings.

We conducted our work from November 2008 to July 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Comments from the National Aeronautics and Space Administration

National Aeronautics and Space Administration
Headquarters
Washington, DC 20546-0001

July 16, 2009

Reply to Attn of: Office of the General Counsel

Ms. Anu K. Mittal
Director, Natural Resources & Environment
United States Government Accountability Office
Washington, DC 20548

Dear Ms. Mittal:

Thank you for the opportunity to review draft report, "FEDERAL RESEARCH: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions," (GAO-09-742).

We found the report to be complete, concise, and accurate. In our opinion, it provides a balanced view of the issues related to the regulations associated with the Bayh-Dole Act. Technical comments to the draft report have been provided separately.

Again, thank you for the opportunity to provide comments on the draft report and for your continued interest in technological innovation and march-in authority.

Sincerely,

Michael C. Wholley

Michael C. Wholley
General Counsel

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Anu Mittal (202) 512-3841 or mittala@gao.gov

Staff Acknowledgments

In addition to the contact named above, Cheryl Williams, Assistant Director; Richard Johnson; Amanda Leissoo; Benjamin Shouse; Elizabeth Wood; and Eugene Wisnoski made significant contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, http://www.gao.gov/ordering.htm.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548