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Report to the Chairman, Committee on the Judiciary, U.S. Senate

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TECHNOLOGY TRANSFER

Reporting Requirements for Federally Sponsored Inventions Need Revision

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GAO

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Resources, Community, and
Economic Development Division

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The Honorable Orrin G. Hatch
Chairman, Committee on the Judiciary
United States Senate

Dear Mr. Chairman:

Under the Patent and Trademark Laws Amendments of 1980, as amended (commonly known as the Bayh-Dole Act), small businesses, nonprofit organizations, and certain contractors operating government-owned laboratories may retain title to and profit from the inventions they create under federally funded research projects. Executive Order 12591, issued April 10, 1987, essentially extends these same privileges to large businesses. To gain these rights, a contractor or grantee must follow certain reporting and other requirements. Among these requirements are notifying the funding agency that an invention has been created, informing the agency that the contractor or grantee intends to retain title to the invention, filing a patent application, and submitting documentation that acknowledges the government's royalty-free license to use the invention. If the contractor or grantee fails to follow these requirements, the government may acquire title to the invention.

You requested that we conduct a study of the government's rights to inventions under the Bayh-Dole Act and Executive Order 12591. As agreed, our objectives were to determine whether federal agencies (1) ensure that contractors and grantees are complying with the provisions of the Bayh-Dole Act and Executive Order 12591 on the disclosure, reporting, retention, and licensing of inventions created under federally funded projects and (2) exercise their rights to use the royalty-free licenses to which they are entitled.

To determine compliance with the requirements, we compared data maintained by the Department of Commerce's Patent and Trademark Office (PTO), funding agencies, and selected contractors and grantees on more than 2,000 patents that were issued in calendar year 1997 and appeared to be the result of federal funds. We also obtained information developed by the Inspector General of the Department of Health and Human Services (HHS) on the reporting of inventions under National Institutes of Health (NIH) grants. To determine how the government uses its royalty-free licenses, we obtained information directly from agencies that are among the largest in terms of research funding and procurement,

compared the provisions of the Bayh-Dole Act and Executive Order 12591 with federal procurement regulations, and discussed the effects on royalties received by 10 contractors and grantees selected for site visits. Additional details on our scope and methodology are included in appendix I.

Results in Brief

Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General's draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government's royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the government is not always aware of federally sponsored inventions to which it has royalty-free rights.

Few statistics were available on how federal agencies exercise their rights to federally sponsored inventions. Agency officials said the primary benefits of the royalty-free licenses are that the government can use the underlying research without concern about possible challenges that such use was unauthorized. The licenses normally would not be a means by which the government could lower its procurement costs by avoiding the payment of royalties, as royalties are not a factor in most federal procurements.

This report includes matters for congressional consideration designed to improve the government's ability to exercise its rights in federally sponsored inventions. We note that the Congress may wish to consider enhancing the data available on these inventions by standardizing, improving, and streamlining the reporting process for inventions subject to the Bayh-Dole Act and Executive Order 12591.

Background

Prior to 1980, the government generally retained title to any inventions created under federal research grants and contracts, although the specific policies varied among the agencies. Increasingly, however, this situation had become a source of dissatisfaction. One reason was a general belief that the results of government-owned research were not being made available to those who could use them. Another was a concern that

advances attributable to university-based research funded by the government were not pursued because the universities had little incentive to seek uses for inventions to which the government held title. In addition, the rules and regulations and the lack of a uniform policy for government-owned inventions often frustrated those who did seek to use the research.

The Bayh-Dole Act was intended to address these concerns by creating a uniform patent policy for inventions resulting from federally sponsored research and development agreements. The act was applicable to small businesses, universities, and other nonprofit organizations and generally gave them the right to retain title to and profit from their inventions, provided they adhere to certain requirements. The government retained nonexclusive, nontransferable, irrevocable, paid-up (royalty-free) licenses to use the inventions.

Bayh-Dole did not apply to large businesses, generally defined as those that have more than 500 employees. However, on February 18, 1983, President Reagan issued a Presidential Memorandum to the executive branch agencies that extended the patent policy of Bayh-Dole to any invention made in the performance of federally funded research and development contracts, grants, and cooperative agreements to the extent permitted by law. In 1984, the Congress amended the Bayh-Dole Act to include contractors operating government-owned laboratories. The 1984 amendments also specified that the act did not preclude agencies from allocating rights to inventions as provided in the Presidential Memorandum, but that organizations acquiring these rights would be subject to certain requirements of Bayh-Dole. On April 10, 1987, the President issued Executive Order 12591, which, among other things, required executive agencies to promote commercialization in accordance with the 1983 Presidential Memorandum.

The Bayh-Dole Act was implemented through regulations issued by the Department of Commerce in 1987.[1] Similarly, the patent rights policies set out by the act and Executive Order 12591 are embodied in parts 27 and 52 of the Federal Acquisition Regulation (FAR).[2] The regulations define the rights and responsibilities of the parties.

[1]37 C.F.R. part 401.

[2]48 C.F.R. parts 27 and 52.

Contractors and Grantees Are Subject to Specific Reporting Requirements

Contractors and grantees are required to follow specific reporting requirements on the disclosure, election to retain title, application for patent, licensing, and commercialization of an invention subject to the Bayh-Dole Act or Executive Order 12591. Similarly, the funding agencies are supposed to ensure that the government obtains a record of the rights to which it is entitled and that these are recorded in centralized databases available to potential users of the technologies involved. The regulations set out the following rationale:

> "It is important that the Government and the contractor know and exercise their rights in inventions conceived or first actually reduced to practice in the course of or under Government contracts in order to ensure their expeditious availability to the public and to enable the Government, the contractor, and the public to avoid unnecessary payment of royalties and to defend themselves against claims and suits for patent infringement."[3]

Contractors and grantees are required by statute and regulation to meet various requirements on the use and reporting of inventions covered by the Bayh-Dole Act and Executive Order 12591. Some of the key requirements[4] are as follows:

- The contractor or grantee must disclose to the appropriate federal agency any invention created with the use of federal funds within 2 months of the date the inventor discloses the invention in writing to the contractor or grantee.
- If the contractor or grantee decides to retain title to the invention, it generally must notify the agency within 2 years of the date of disclosure that it has elected to do so. In cases in which publication, sale, or public use has initiated the 1-year statutory period in which valid patent protection can be obtained in the United States, the agency may shorten the period of election to not more than 60 days prior to the end of the statutory period.
- The contractor or grantee must apply for a patent on the invention within 1 year of its election to retain title or within 1 year of the publication, sale, or public use in the United States, whichever is earlier. In applying for a patent, the organization must add a government interest statement that discloses the government's rights to the invention.
- The contractor or grantee must provide the government a written instrument confirming the government's nonexclusive, nontransferable,

[3]48 C.F.R. 27.305-1(a).

[4]These requirements are found in 37 C.F.R. part 401 and 48 C.F.R. 52.227-11 (short form) and are generally applicable when the contractor is a small business, a nonprofit organization, or any other contractor except for those with contracts involving the departments of Defense and Energy or the National Aeronautics and Space Administration.

irrevocable, paid-up license to use the invention. The government's license is commonly referred to as the "confirmatory" license.

- The contractor or grantee must attempt to develop or commercialize the invention.
- If the contractor or grantee is a nonprofit organization, the contractor or grantee generally must give priority to small businesses when licensing the invention.
- When granting an exclusive license, the contractor or grantee must ensure that the invention will be "manufactured substantially" in the United States.
- If the contractor or grantee is a nonprofit organization, the contractor or grantee must share a portion of the royalties with the inventor(s).

Monitoring Responsibilities Are Diffused Among Many Agencies

No single federal agency is responsible for monitoring compliance with the Bayh-Dole Act or Executive Order 12591, although the Department of Commerce was given the responsibility for drafting Bayh-Dole regulations. Rather, the agency responsible for funding the contract or grant that led to the invention is also responsible for ensuring that the requirements are followed. If the contractor or grantee does not disclose the invention, does not elect title within the established periods, or elects not to retain title, the agency may acquire title to the invention if the agency makes a written request within 60 days after it learns of the failure of the contractor or grantee to make the proper disclosures or elections. The agency can also require the contractor or grantee to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant under terms that are reasonable under the circumstances if, for example, the organization does not develop or commercialize the invention or if action is needed to alleviate health or safety concerns. This is known as the government's "march-in" right.

After receiving the confirmatory license, the funding agency is required to file it with PTO. PTO then records the license in the Government Register. The Government Register was created by Executive Order 9424 in 1944 and, among other things, is the official register for the government's rights to federally sponsored inventions. Prior to May 1995, PTO maintained the Government Register in a card file. Confirmatory licenses recorded since that time are maintained in an electronic database. PTO also maintains the official patent database that provides the full text of issued patents. For federally sponsored inventions, the text should include the government interest statements submitted with the applications for patents.

Agencies Are Not Ensuring Compliance With Requirements

Government agencies, contractors, and grantees are not complying with the reporting requirements for inventions subject to the Bayh-Dole Act and Executive Order 12591. We reviewed more than 2,000 patents issued in calendar year 1997 and found that the official records on federally sponsored inventions—PTO's patent database and Government Register—were in agreement only about 6 percent of the time. We were unable to resolve many of the anomalies during follow-up work at the funding agencies and 10 contractors and grantees. Furthermore, we identified other inventions that had not been reported at all. The HHS Inspector General found similar problems in a draft report on the invention-reporting activities by 12 large grantees of NIH.

Besides being inaccurate, incomplete, and inconsistent, the databases on federally sponsored inventions can be difficult to use. Also, the reporting requirements are often redundant and complicated, placing an unnecessary burden on the agencies and their contractors and grantees. We believe the reporting requirements could be streamlined and improved.

Records on the Government's Rights Are Inaccurate, Incomplete, and Inconsistent

PTO should have two independent records of the government's rights to a federally sponsored invention—the government interest statement on the patent and the confirmatory license recorded in the Government Register. However, PTO provided us with information showing that while 2,083 patents issued in 1997 had either a government interest statement or a confirmatory license on file, only 128, or 6.1 percent, were recorded in both databases. Of the remaining 1,955 cases, 72, or 3.5 percent, appeared only in the Government Register, while 1,883, or 90.4 percent, had only a government interest statement on the patent.

PTO officials told us that they record only the information they are given by the applicants and agencies. They are not required and do not attempt to verify the data provided or to reconcile the databases with each other. Thus, they could not explain the anomalies between the data recorded in the Government Register and the data recorded on the patents. For this reason, we elected to contact each of the funding agencies for the patents in question to determine whether they could provide explanations.

Funding Agencies Did Not Resolve Anomalies

We attempted to determine the causes of the anomalies by obtaining information directly from the funding agencies. However, we were unable to identify some of the agencies when the only record was the government interest statement on the patent because the reference to the agency was

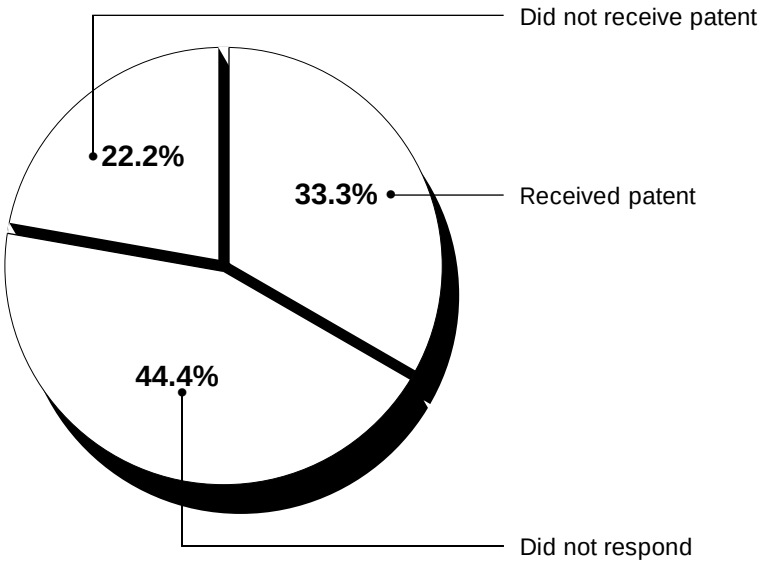
not specific. For example, some references were to the "U.S. Government" or to a federal department rather than to a specific agency. Also, sometimes no contract or grant was cited that could be referenced to a specific agency.

We selected 1,746 cases for further review, of which 72 represented cases in which only confirmatory licenses were on record and 1,674 represented cases in which only government interest statements were on record. About 92 percent of the 1,746 cases were concentrated in the five federal agencies—NIH, the National Science Foundation (NSF), the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA)—that provide the bulk of research and development funds to contractors and grantees.

For each case, we contacted the funding agency to determine why the patent database and the Government Register were in disagreement. We asked the agencies to review their files to determine whether they in fact were responsible for funding the research that led to the inventions, whether they had received the reports required from the funded organizations, and whether they had filed confirmatory licenses with PTO or verified that government interest statements were recorded on the patents. As shown in appendixes II and III, the agencies were able to explain a number of these cases; however, they were not able to resolve 1,222, or 70 percent, of the 1,746 cases forwarded to them.

Figure 1 shows the agencies' responses in the 72 cases in which confirmatory licenses were recorded in the Government Register but government interest statements did not appear on the patents. Appendix II provides the statistics for each agency queried.

Figure 1: Results of GAO's Inquiries to Agencies About Patents Issued in Calendar Year 1997 That Did Not Include Government Interest Statements



Note: Percentages do not total 100 percent because of rounding.

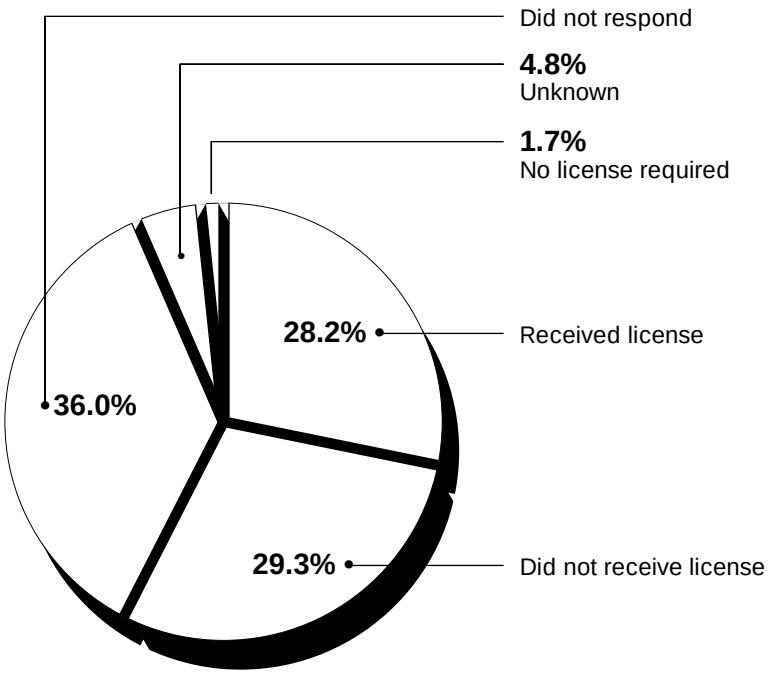
Source: GAO's analysis of data provided by government agencies.

The agencies gave varied responses about the absence of government interest statements on the 72 patents in question. For 24, or 33.3 percent, the agencies said that they had received copies of the patents, and for 21 of these, they either had ensured government interest statements were included already or had required the applicants to file corrections with PTO to include the statements. Thus, the agencies said government interest statements should have appeared on these 21 patents but did not explain the omissions. In the other three cases, the agencies said that they had received patent applications from the funded organizations but did not confirm that they included government interest statements.

In 16, or 22.2 percent, of the 72 cases, the agencies said they had not received patent applications on the inventions in question. In the remaining 32, or 44.4 percent, of the cases, the agencies did not respond to our inquiries.

Figure 2 shows the agencies' responses for the 1,674 cases in which government interest statements were recorded on the patents but confirmatory licenses did not appear in the Government Register. Appendix III provides the statistics for each agency queried.

Figure 2: Results of GAO's Inquiries to Agencies About Patents Issued in Calendar Year 1997 That Were Not Recorded in the Government Register



Source: GAO's analysis of data provided by government agencies.

According to their responses, the agencies had received confirmatory licenses from the contractors and grantees in 472, or 28.2 percent, of the cases. In 183 of these cases, the agencies said that they had filed the licenses with PTO but did not explain why they did not appear in the Government Register. In the remaining 289 cases, the agencies said that, for various reasons, they had received confirmatory licenses but had not filed them with PTO. For example, officials from NSF—which had 60 confirmatory licenses on hand that had not been filed with PTO—said they did not believe such recordation was necessary. They reasoned that the

government has an automatic license based on the provisions of Bayh-Dole regardless of whether a confirmatory license is received or filed with PTO. Other agencies did not explain why they had not filed the licenses.

In 28, or 1.7 percent, of the cases, the agencies responded that a confirmatory license was not required on a particular invention. The reasons were that the agency had not actually financed the invention, that the projects under which the inventions were created were not subject to the Bayh-Dole Act or Executive Order 12591, or that the government was actually an owner of the invention and did not need a license.

The agencies did not resolve the remaining 1,174 cases. In 491, or 29.3 percent, the agencies said they had not received confirmatory licenses from the contractors or grantees. In 81, or 4.8 percent, they said they did not know whether they had received confirmatory licenses. In the remaining 602, or 36 percent, the agencies did not respond to our inquiries.

Some Inventions Had Not Been Reported

We conducted follow-up work at 22 contractors and grantees to determine the reasons for the discrepancies on their inventions.[5] While they were able to explain many of these cases, we were still unable to resolve 81 of the 348 cases involved. Moreover, we identified 11 other inventions that had not been reported at all.

In the majority of the 348 cases, the contractors and grantees responded that they had followed the reporting requirements as they understood them, filing a confirmatory license on either the patent in question or on a parent application[6] of that patent. In 93, or 26.7 percent, of the 348 cases, the organizations provided documentation to show that they had filed confirmatory licenses with the agencies on those patents. They could not tell us why the government did not have a record of these licenses but offered possible reasons based on the documentation available in their own files. Some licenses apparently had been sent to the agencies with incorrect or missing grant numbers or did not contain patent application serial numbers. Contractor and grantee officials said that in such instances, the funding agencies may not have been able to link the licenses

[5]These contractors and grantees consisted of 14 universities, 5 other nonprofit organizations, and 3 for-profit corporations. In total, they accounted for 348, or 29.6 percent, of the 1,174 cases for which the funding agencies had not been able to explain why government interest statements had been recorded on the patents but confirmatory licenses had not been received.

[6]A parent application is the original application for a particular patent. Subsequent applications may relate back to the parent.

to particular research grants or patents. Another explanation offered was that some inventions were funded by more than one agency and the organization had sent a confirmatory license to only one of the agencies. The officials said that the agency responding might not have been the agency with the license. Still another explanation given was that some of the licenses had been filed recently and might not have been entered into an agency's database at the time we asked the agency for information.

In an additional 161, or 46.3 percent, of the 348 cases, the contractors and grantees responded that they had not filed confirmatory licenses for the patents cited but were not in error because they had filed licenses on parent applications. They told us that the confirmatory licenses filed on these parent applications specifically stated that the licenses covered all additional patents flowing from those parents. It was their understanding that this meant new confirmatory licenses were not needed for these other patents unless the inventions covered new subject matter. They also said that the agencies had agreed with this interpretation. In subsequent discussions with agency officials, they generally agreed with this interpretation, even though we could find no documentation to this effect in any written procedures.

In 13, or 3.7 percent, of the 348 cases, contractor and grantee officials provided documentation to show that they were not required to file confirmatory licenses. In nine of the cases that had government interest statements recorded on the patent applications, the officials determined that the inventions were not created under federally funded projects. The officials said that, while a correction to the patent in such an instance may have been in order, there was no need or requirement to file a confirmatory license. In three cases, they said confirmatory licenses were not required because the government was actually a co-owner of the inventions and had rights that superceded those that would have been included in any licenses. In the final case, the grantee had waived title to the invention to the inventor and had no responsibility to file a confirmatory license.

The contractors and grantees were not able to resolve the database anomalies in 81, or 23.3 percent, of the 348 cases. In 71 of these, they acknowledged that they had not filed licenses as required. In the other 10 cases, they did not locate any documentation on the inventions in question. They did not explain the omissions in any of the 81 cases, however. Each had implemented systems and processes designed to ensure that federally sponsored inventions were reported as required.

During visits to 10 contractors and grantees, we asked the contractors and grantees whether there might be federally sponsored inventions that had not been reported at all. In this regard, we reviewed other patents that were issued to them during calendar year 1997 that did not contain government interest statements and for which no confirmatory licenses were on file at PTO. In each case, we asked contractor or grantee officials to show us from the records available how they determined that the inventions were not the result of government funding.

Our review of 56 patents showed that 11, or 19.6 percent, of the 56 inventions in question had not been reported even though the inventions appeared to have been the result of government funding. Officials from the five contractors and grantees responsible for these 11 patents agreed with our findings but did not explain why the inventions had not been reported. Again, each had systems designed to ensure that all government-sponsored inventions were disclosed.

HHS' Inspector General Found NIH-Funded Inventions Were Not Being Reported

In a 1994 report concerning the reporting of inventions by a major research institute, HHS' Inspector General identified weaknesses in NIH's procedures for monitoring compliance with the provisions of the Bayh-Dole Act and recommended that NIH establish procedures to remedy these problems. In response to that report, NIH in October 1995 deployed Edison, an on-line computer system for reporting inventions. Edison uses the Internet to (1) allow the organizations NIH funds to enter data, including the required reports and notifications, in the system and (2) give NIH the ability to review and analyze the activity on any particular invention at any time.

In a recent follow-up review, the Inspector General expanded the scope to include 12 large grantees funded by NIH, the government's principal biomedical research agency. In fiscal year 1997, NIH had a budget of about $10.5 billion for outside research grants, and the 12 grantees accounted for almost $2.5 billion of this amount. The objectives of the Inspector General's review were to determine whether NIH had implemented the corrective actions recommended in the earlier report and to evaluate the adequacy of NIH's controls to ensure that grantees complied with the reporting requirements of the Bayh-Dole Act.

In July 1999, the Inspector General submitted a draft report to NIH on the most recent review and concluded that compliance with Bayh-Dole requirements remained insufficient. The Inspector General found that, of

633 medically related patents issued to the 12 grantees in calendar year 1997, 490 were recorded in Edison. The remaining 143 patents were not in Edison, and the patents did not include government interest statements. After comparing the information in the 143 patents with information from NIH's grant records, the Inspector General concluded that all 143 inventions most likely resulted from NIH-sponsored research and questioned the 12 grantees about these findings. The grantees then reviewed their records and agreed that 79, or 55.2 percent, of the 143 inventions were in fact supported with NIH's funding. The grantees also acknowledged that they had not properly notified NIH of the inventions or included a statement on their patent applications that the inventions had been created with federal support. They did not agree that the remaining 64 patents resulted from government-sponsored research.

The Inspector General concluded in the draft report that NIH cannot ensure that its grantees are complying with the requirements of the Bayh-Dole Act in all instances. The Inspector General recommended that NIH (1) use information available from PTO's patent database and NIH's grant database to identify inventions that need to be recorded in Edison, (2) improve instructions to grantees on the need for and importance of reporting invention and patent data, and (3) review the 64 patents disputed by the 12 grantees in the study to determine whether these patents represented inventions that should have been reported to the government. At the time of our review, NIH had not yet provided an official response to the Inspector General on the draft report.

The Government's Databases on Federally Sponsored Inventions Need to Be Improved

Neither the Government Register nor the patent database is a sufficient source for determining the rights the government possesses to federally sponsored inventions. Besides being inaccurate, incomplete, and inconsistent, the databases can be difficult to use. The quality of data could be improved by standardizing, streamlining, and improving the reporting requirements.

The Current Databases on the Government's Rights Are Inadequate

We could not determine the extent to which federal agencies use the Government Register or the patent database to identify inventions to which the government has royalty-free rights because there are no records of such use. Agency officials said that, while they did consult the patent database from time to time, they rarely referred to the Government Register. PTO officials said that they receive fewer than 10 requests a year to use the Government Register at PTO.

We found that both databases are inadequate in some respects. Because of the errors and omissions discussed previously, the Government Register is of limited use to an agency attempting to determine the government's rights to federally sponsored inventions. However, on the basis of our discussions with PTO and funding agency officials as well as on our own attempts to use the Government Register, we found that the Government Register would be difficult to use even if it were accurate, complete, and consistent:

- The Government Register is not easy to search for a particular type of technology. There are no summary data or search fields for the type of technology, applicant type, and so forth. A user must know the patent number or application serial number to access the license on a particular patent.
- Because of its physical location, the Government Register can be difficult to use even if the user knows the patent number. For licenses recorded prior to May 1995, records are on a card file and microfilm and are accessible only at PTO headquarters near Washington, D.C. For licenses recorded after that time, the records are on an electronic database accessible at PTO headquarters and at selected federal depository libraries throughout the nation.
- The Government Register may not reveal the existence of the government's rights to a specific patent because, as discussed earlier, some agencies require a confirmatory license only on a parent application. To identify rights to a parent application from the Government Register, the user would have to determine first that there was a parent for the patent in question and that this parent had a confirmatory license in the Government Register.
- Some confirmatory licenses may not be accessible from the Government Register even if they have been recorded. PTO officials said they do not make available information on patent applications that are in process except to the applicant or the funding agency. Thus, no other agency could determine the existence of a confirmatory license on an application in process merely by researching the Government Register. The user would have to know about the government interest in advance, determine the serial number of the application, and obtain approval from the funding agency to access the application data.

The patent database is a better source than the Government Register for determining the government's rights to federally sponsored inventions. It is more accessible than the Government Register in that the official patent records are available for inspection and a user can obtain from PTO's

Internet Web site the full text of patents issued since 1976. However, the patent database has its own problems and can be difficult to use. As discussed earlier, the government interest statement may not have been recorded on a patent or may contain insufficient information. In addition, as with the Government Register, only the applicant and the funding agency can review a patent in process, and there are no summary listings of all patents containing a government interest.

Reporting Requirements Need Revision

During our visits to federal agencies, contractors, and grantees, we discussed the problems we had identified in the databases and reporting process and the potential causes for these problems. Generally, the officials we contacted agreed that the following factors contribute to the problems in the reporting process:

- The current reporting process is complicated and repetitive. There appears to be little reason to have the contractor or grantee submit two documents—the patent containing the government interest statement and the separate instrument acknowledging the confirmatory license—for recording the same right, particularly if (1) the two records are not being used as a cross-check for each other and (2) the Government Register is rarely used.
- The process is not uniform and consistent. While there are general requirements, each agency may have its own set of policies, procedures, and forms. At any one time, an individual contractor or grantee may be dealing with multiple agencies and must know and adhere to the requirements of each agency in submitting data. The agencies themselves typically have their own computerized systems for recording these data.
- Internal controls over the process vary significantly. Because of the record keeping and reporting requirements, the larger agencies, contractors, and grantees typically have staff trained and designated for this purpose. Smaller agencies, contractors, and grantees are not able to commit as many resources and often must use staff whose primary commitment is in other areas. Overall, this leads to a wide range in the levels of expertise among those responsible for the reporting process.
- There is little direct federal oversight. The agencies may commit resources to developing tracking systems and monitoring the reports that are submitted. However, they generally do not make site visits to review the records of contractors and grantees for federally sponsored inventions. Also, the regulations contain no specific requirement, nor has there been agreement among the agencies, on whether and to what extent the agencies should require utilization reports that explain how federally sponsored inventions are being used. Without this information, it is

difficult for an agency to know whether a contractor or grantee has commercialized or developed an invention.

The officials we contacted said that the reporting requirements for inventions subject to the Bayh-Dole Act and Executive Order 12591 could be standardized, improved, and streamlined. They saw no need for a separate instrument acknowledging the confirmatory license when the government's rights are already recorded on the patent. Also, they agreed that the reporting could be reduced by creating a standardized disclosure form and by making the patent itself the instrument for documenting the election of title and the government's royalty-free license to the invention. Oversight could be enhanced by having PTO provide notice to the funding agencies about activities, such as the applicant's abandonment of the patent application, that might affect these rights.

The agency officials also said that requiring the use of a standardized utilization report would provide the funding agencies with the information they need to make informed decisions about how the contractors and grantees are commercializing and developing the inventions. Such information could be useful in determining whether the government's march-in rights should be employed as well as whether the inventions are being substantially manufactured domestically.

During our meetings with the representatives from the agencies and the funded organizations, we discussed some possible changes that could be made in the reporting requirements. These options are included in appendix IV. The officials generally agreed that these suggested changes could relieve some of the reporting burden, strengthen accountability and oversight, and improve the quality of information in the federal databases.

We also discussed these changes with PTO officials. They said that, while they did not necessarily disagree with the changes, the changes might not be consistent with an international treaty now being negotiated to standardize patent applications worldwide. They said that the standardized application being discussed would not only prevent PTO from requiring and disseminating more information, it probably also would eliminate the requirement for the government interest statement established by the Bayh-Dole Act and Executive Order 12591. We did not evaluate the potential consequences of the proposed application on current requirements because it is still in the negotiation stages and because such an evaluation was beyond the scope of our review.

The Primary Use of a License Is for Research and Infringement Protection

No governmentwide data exist on how the government actually uses its royalty-free licenses, and agencies did not have records showing how often and under what circumstances these licenses have been employed. Agency officials told us, however, that they value the royalty-free licenses because they allow the government to use the inventions without concern about possible challenges that the use was unauthorized. The agency officials also noted that, while the government can use its royalty-free licenses to reduce procurement costs in those cases in which royalties are disclosed as a cost element in the contract, such cases seldom occur.

No Centralized Records of Government Use Exist

While the Government Register and the patent database are supposed to provide a record of the rights the government has to inventions subject to the Bayh-Dole Act and Executive Order 12591, they provide no information on whether or how often federal agencies use these rights. In addition, while regulations govern certain uses of these rights, no one agency is charged with monitoring the government's activities. Thus, no governmentwide data are available on the government's use of its royalty-free licenses.

During our work at the larger funding agencies—NIH, DOD, NSF, DOE, and NASA—and two other large procurement agencies—the General Services Administration and the Department of Veterans Affairs—we asked for information that would show how often the agencies had made use of their rights to use federally sponsored inventions. While agency officials said that they value these rights, the agencies did not have records showing how often and under what circumstances they used them.

Agency officials told us they believed the major benefit of the government licenses was that the agencies could use the technology in their own research without having to pay royalties and could use the licenses to protect the government's interests in infringement suits.[7] An attorney from the Department of Justice who handles infringement suits for the government agreed that a primary advantage of the confirmatory license is that it provides an official record of the government's specific rights to a particular invention in case these rights are challenged.

[7]When there is an unauthorized use or manufacture of an invention covered by a valid claim of patent, an infringement has occurred. Under 28 U.S.C. 1498, the owner of a patent may sue the government for infringement by the government or its contractor in the United States Court of Federal Claims for money damages.

Royalties Are Not a Factor in Most Procurements

Because the government is a major procurer of goods and services, we were interested in determining whether the government's costs are reduced when it procures an invention in which it has a royalty-free license. We found that, while it is possible for the government to avoid paying royalties in those cases in which contractors are required to disclose them, royalties do not have to be disclosed in most federal procurements.

The FAR requires that contractors doing business with the government disclose certain royalty information. The purpose of the royalty disclosure is to allow the government to determine whether royalties anticipated or actually paid under government contracts are excessive, improper, or inconsistent with any of the government's rights to particular inventions, patents, or patent applications. However, companies competing for government contracts under sealed-bid procurements[8] are generally not required to provide royalty information.

If royalty information is desired or cost or pricing data are obtained in negotiated procurements, the FAR provides that information relating to any proposed charges for royalties should be requested. The FAR royalty information clause provides that, if the contract costs for royalties exceed $250, the contractor must submit detailed information on the patent involved, the licenses, and the charge. However, according to agency officials we contacted, royalties are not a factor in the vast majority of their procurement activities. For example, in fixed-price contracts or purchases made through the federal supply schedule, the agency considers the price charged rather than the company's costs. In such cases, royalty information generally would not be provided.

Agency officials said that royalties usually are not reported as a cost element even when cost or pricing data are obtained. A DOE official said that royalty disclosures in contracts have occurred more frequently in recent years because of an increase in contracts related to DOE's cleanup activities at sites where nuclear weapons were produced. He added, however, that contracts with such provisions are still rare, occurring fewer than 10 times a year. Other agency officials could not remember ever seeing a contract in which royalties were a separate cost element.

Agency officials were not able to identify specific cases in which royalties had been disallowed as a contract cost because the government had a royalty-free license. Similarly, the contractors and grantees we visited

[8]Sealed-bid procurements employ competitive bids, public opening of bids, and awards.

could not recall ever having received a reduction in a royalty payment because the sale was to the government.

Agency officials told us that they do not consider reducing government procurement costs to be a major objective of the Bayh-Dole Act or Executive Order 12591. In their view, the royalty-free license provides the government with an instrument it can use if it is unable to obtain the product in question from the vendor. They said that, in such cases, the royalty-free license allows the government to manufacture or to contract with another party to manufacture the product and sell it to the government without risk of infringement.

Conclusions

Federal agencies are not sufficiently aware of the royalty-free rights the government has to inventions subject to the Bayh-Dole Act and Executive Order 12591. This is because the two primary resources for information on federally sponsored inventions—the Government Register and the patent database—are inaccurate, incomplete, and inconsistent. These errors and omissions are the result of federal funding agencies', contractors', and grantees' not always complying with reporting requirements that are themselves often complicated and redundant.

No data are available on the extent to which the government is using its royalty-free licenses to federally sponsored inventions. Agency officials say the licenses are important because they allow federal agencies to use the underlying research without concern about possible challenges that such use was unauthorized. The licenses do not appear to be a factor in most procurements.

Matters for Congressional Consideration

The Congress may wish to consider amending the Bayh-Dole Act to standardize, improve, and streamline the reporting process for inventions subject to both the act and Executive Order 12591. The Congress could consider (1) requiring the Secretary of Commerce to develop standardized disclosure forms and utilization reports for federally funded inventions, (2) making the patent the primary control mechanism for reporting and documenting the government's rights and the only written instrument for confirming the government's royalty-free license, and (3) requiring the Patent and Trademark Office to provide information to the funding agencies to assist them in monitoring compliance.

Agency Comments and Our Evaluation

We submitted a copy of a draft of this report to the Department of Commerce for its review and comment. The Department stated that it supports most of the options outlined in the matters for consideration and appendix IV and believes that many of them can be implemented without new legislation. We agree that many of the options we set out could be accomplished without new legislation. However, we left these options as matters for consideration by the Congress because, as stated in the report, they need to be considered in conjunction with each other and some would require changes to the law.

The Department also said that the current draft of the Patent Law Treaty now being negotiated would permit the Patent and Trademark Office to require information on federal support and, if adopted, would alleviate the concerns the Patent and Trademark Office raised previously. As discussed in this report, Patent and Trademark Office officials had told us that the standardized application being considered in the treaty negotiations might eliminate the requirement for the government interest statement established by the Bayh-Dole Act and Executive Order 12591.

The Department said that it did not believe that confirmatory licenses should be eliminated, noting that the government interest statement now included in the patent application refers only to "certain rights" that the government may have to the invention. According to the Department, members of the public would have to contact external sources such as the Government Register if they want to know the scope of those rights. The Department said that it was not proposing that a further burden be placed on patent applicants.

We did not make any changes to our report as a result of the Department's comments in this area, as the options we present would not eliminate the confirmatory license. Rather, they would require that the confirmatory license acknowledgment be added to the government interest statement on the patent and that this statement set out the specific rights held by the government. Our options would eliminate the need for a separate instrument acknowledging the confirmatory license. This would reduce—not add to—the reporting burden on the applicant.

The Department also said that it did not consider appropriate our including information from a draft report by the Inspector General of the Department of Health and Human Services that concerned the reporting of inventions by grantees of the National Institutes of Health. We disagree for three reasons. First, the information in the Inspector General's draft report

is germane to the discussions and options presented in our own report because we were addressing the same issue—compliance with reporting requirements for federally sponsored inventions. Second, a representative of the Inspector General's office told us we were accurately portraying the Inspector General's draft report. Third, we clearly identified the source of the material presented as a draft report and noted that the National Institutes of Health had not yet provided formal comments.

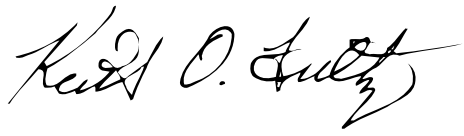
The full text of the Department's comments is in appendix V.

We conducted our work from June 1998 through July 1999 in accordance with generally accepted government auditing standards.

We will send copies of this report to the appropriate House and Senate committees; interested Members of Congress; the agencies discussed in this report; William M. Daley, Secretary of Commerce; Jacob J. Lew, Director, Office of Management and Budget; and other interested parties. We will make copies available to others on request.

If you or your staff have any questions or need additional information, please call me at (202) 512-3200. Key contributors to this report are listed in appendix VI.

Sincerely yours,



Keith O. Fultz
Assistant Comptroller General

Contents

Figures

Abbreviations

DOD	Department of Defense
DOE	Department of Energy
FAR	Federal Acquisition Regulation
GAO	General Accounting Office
HHS	Department of Health and Human Services
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
NSF	National Science Foundation
PTO	Patent and Trademark Office

Objectives, Scope, and Methodology

The Chairman of the Senate Committee on the Judiciary requested that we conduct a study of the government's rights to inventions under the Bayh-Dole Act and Executive Order 12591. As agreed, our objectives were to determine whether federal agencies (1) ensure that contractors and grantees are complying with the provisions of the Bayh-Dole Act and Executive Order 12591 on the disclosure, reporting, retention, and licensing of inventions created under federally funded projects and (2) exercise their rights to use the royalty-free licenses to which they are entitled.

To determine how federal agencies ensure that contractors and grantees are complying with the reporting requirements of the Bayh-Dole Act and Executive Order 12591 on the disclosure, reporting, retention, and licensing of inventions created under federally funded projects, we discussed the administration of the act and the executive order with officials at each of the five agencies providing the most funding for research and development: the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA). We discussed with agency officials the procedures they had implemented to ensure that contractors and grantees comply with reporting and other requirements. We also reviewed agency regulations pertaining to the administration of federally sponsored inventions.

To determine whether federally sponsored inventions are being disclosed and reported as required, we obtained information from two databases—the patent database and the Government Register—maintained by the Patent and Trademark Office (PTO). We then matched the information obtained to determine whether, for each patent issued in calendar year 1997, both a government interest statement and a confirmatory license were filed with PTO. For the 1,746 cases in which the documentation was incomplete, we contacted the funding agencies to obtain explanations, asking the agencies to complete a data sheet on each case.

To determine the cause of the reporting problems and database anomalies, we judgmentally selected 22 contractors and grantees that owned some of the patents in our analysis. These assignees accounted for 348 cases in which discrepancies had not been resolved during our work with the funding agencies. We asked the contractors and grantees to determine why the discrepancies occurred.

From the group of 22 contractors and grantees, we judgmentally selected and made site visits to 10—4 universities, 5 other nonprofit organizations, and 1 for-profit corporation—for a detailed analysis of their reporting compliance. For this group, we judgmentally selected a total of 56 additional patents that were issued in calendar year 1997 but for which no government rights had been recorded. We asked the contractors and grantees to review the patents and to explain how they determined that parties other than the government had funded the inventions covered by the patents.

Where appropriate, we requested documentation to support the explanations for the anomalies we identified in the databases. However, in most cases, we did not independently verify the data we obtained from the agencies, contractors, and grantees.

To determine whether federal agencies exercise their rights to use the royalty-free licenses to which they are entitled, we held discussions with officials from NIH, NSF, DOD, DOE, NASA, the Department of Veterans Affairs, and the General Services Administration and reviewed pertinent records they made available. We also reviewed agency regulations and federal procurement laws to determine when federal rights to inventions are to be disclosed and used in the procurement process. We also discussed the issue of how federal procurements affect royalty payments with the 10 contractors and grantees selected for site visits.

We discussed overall problems and potential remedies for the reporting and use of federally sponsored inventions with officials from the federal agencies, contractors, and grantees included in our review. We also discussed these issues as well as specific options for new reporting requirements with two special groups of these officials. One such group was the Interagency Working Group on Technology Transfer, a group of federal agency personnel involved in technology transfer programs. The other group consisted of participants at the annual convention of the Association of University Technology Managers, a nonprofit organization formed to assist technology administrators at universities and other nonprofit organizations in the effective transfer of technology to the public.

We conducted our work from June 1998 through July 1999 in accordance with generally accepted government auditing standards.

Results of GAO's Inquiries About Patents Issued in Calendar Year 1997 That Had a Confirmatory License but No Government Interest Statement on Record With PTO

Agency	Received copy of patent	Did not receive copy of patent	No response	Total
Department of Commerce			1	**1**
Department of Defense				
Air Force	1	6	11	**18**
Army			3	**3**
Navy	1		7	**8**
Department of Energy	7		3	**10**
National Institutes of Health	15	10	7	**32**
Total	**24**	**16**	**32**	**72**

Source: GAO's analysis of data provided by the agencies cited.

Results of GAO's Inquiries About Patents Issued in Calendar Year 1997 That Had a Government Interest Statement but No Confirmatory License on Record With PTO

Agency	Not subject to Bayh-Dole or E.O.	Confirmatory licenses received	Confirmatory licenses not received	Unknown	No response	Total
Agency for International Development			7			**7**
Department of Agriculture	3	4	24			**31**
Department of Commerce						
National Institute for Standards and Technology			2			**2**
National Oceanic and Atmospheric Administration			3			**3**
Other		6	4		4	**14**
Department of Defense						
Ballistic Missile Defense Organization				4		**4**
Defense Advanced Research Projects Agency	7	6		43	33	**89**
Defense Threat Reduction Agency					1	**1**
Department of the Air Force		26	26		30	**82**
Department of the Army	1	6	12		58	**77**
Department of the Navy		5	31		36	**72**
National Security Agency			1			**1**
Department of Education					1	**1**
Department of Energy	12	223	98		9	**342**
Department of Health and Human Services						
Food and Drug Administration					1	**1**
National Institutes of Health		116	168		379	**663**
Public Health Service				32		**32**
Other					23	**23**
Department of Transportation						
Federal Aviation Administration			1			**1**
U.S. Coast Guard					1	**1**

(continued)

Agency	Not subject to Bayh-Dole or E.O.	Confirmatory licenses received	Confirmatory licenses not received	Unknown	No response	Total
Department of Veterans Affairs		2	3			**5**
Environmental Protection Agency		5	2	2		**9**
National Aeronautics and Space Administration	3	13	8		26	**50**
Nuclear Regulatory Commission	1					**1**
National Science Foundation		60	101			**161**
Tennessee Valley Authority	1					**1**
Total	**28**	**472**	**491**	**81**	**602**	**1,674**

Source: GAO's analysis of data provided by the agencies cited.

Options for Standardizing, Streamlining, and Improving Reporting Requirements Under the Bayh-Dole Act and Executive Order 12591

In this report, we state that the Congress may wish to consider amending the Bayh-Dole Act to standardize, improve, and streamline the reporting process for inventions subject to both the act and Executive Order 12591. Specifically, such changes could include (1) requiring the Secretary of Commerce to develop standardized disclosure forms and utilization reports for federally sponsored inventions, (2) making the patent the primary control mechanism for reporting and documenting the government's rights and the only written instrument for confirming the government's royalty-free license, and (3) requiring the Patent and Trademark Office (PTO) to provide information to the funding agencies to assist them in monitoring compliance.

During our meetings with representatives from federal funding agencies, contractors, and grantees, we discussed options for changes to the reporting requirements. The officials generally agreed that the types of changes suggested below could improve the quality of data available and reduce the reporting burden. Officials from PTO told us that they did not disagree with these suggestions. However, they pointed out that an international treaty is being negotiated that would standardize patent applications and could affect the types of information that could be required on a patent application.

The options we discussed are as follows:

- Eliminating the requirement that the contractor or grantee submit a confirmatory license as a separate written instrument on each invention. These instruments are not always submitted or used, and the license itself can be more easily documented on and accessed from the patent itself. In effect, this change would appear to eliminate the need for the Government Register.
- Requiring the Department of Commerce to develop, and by regulation require the use of, a standardized invention disclosure form for all federal agencies, contractors, and grantees. Under the current procedures, each contractor or grantee generally has its own form. A standardized form would make the procedure uniform and consistent among all the agencies, contractors, and grantees.
- Making the patent the only instrument for documenting the confirmatory license. This would entail eliminating the current requirement that the contractor or grantee file a separate election to retain title. Instead, within 2 years of disclosure (or within 1 year if publication, sale, or public use of the invention has initiated the 1-year statutory period in which valid patent protection can be obtained in the United States), require the contractor or

grantee to file a patent application with PTO. This would reduce a step in the process for both the applicant and the agency and, in most cases, shorten the time between the date the contractor or grantee realizes it has an invention and the date it applies for a patent.

- Requiring that the government interest statement on the patent application include the name of each specific agency that funded the research, the contract or grant number(s) under which the invention was created, and a provision stipulating that the government has a nonexclusive, paid-up, royalty-free right to the use of the invention.
- Requiring that the contractor or grantee provide a copy of each patent application—including divisionals, continuations, and continuations-in-part—to the funding agency.[1] This would inform the funding agency that the contractor or grantee has filed the application within the required time and that the agency has a record of all patent applications related to the original invention disclosure. Since patent applications are standard for all applicants, this also means that all funding agencies receive standardized forms.
- Requiring PTO to (1) inform each funding agency named in a government interest statement that PTO has received a patent application on the invention and (2) provide the serial number of the application to the agency. This provides a cross-check for the funding agency to ensure it has received the patent application. Also, the agency has the serial number if it needs to interact with PTO.
- Requiring PTO to inform the funding agency of major events—such as the abandonment of an application—that would affect the government's rights during the applicant's prosecution of the patent. This would allow the funding agency to take timely action at any point its rights to the invention are threatened.
- Requiring PTO to show in its Patent Gazette—the official journal on patents and trademarks—that the issued patent is subject to a government interest. This would provide notice to the funding agency and the public that the patent has been issued and that the government has rights to the invention. Anyone wanting more information could then access the patent from PTO's Internet Web site or official patent files.
- Permitting PTO to charge the applicant a fee for an application that contains a government interest section. The fee should be commensurate with PTO's additional costs for its services under the revised requirements.

[1]A parent application is the original application for a particular patent. Subsequent applications may relate back to the parent either as a divisional, a continuation, or a continuation-in-part. A divisional is a later application that is carved out of a pending application and discloses or claims only subject matter disclosed in the earlier application. A continuation is a second application for the same invention claimed in a prior application that discloses and claims only subject matter disclosed in prior applications and introduces into the case a new set of claims. A continuation-in-part repeats some substantial portion or all of the earlier application but adds matter not disclosed in the earlier case.

This is in keeping with PTO's position of being self-sufficient through fees. The fee would be paid by the applicant and would be one additional factor the contractor or grantee would need to consider in deciding whether to file a patent application. However, the additional cost of the government interest fee should be offset to some extent by the reduced costs of the lesser reporting burden on the contractor or grantee.

- Requiring the Department of Commerce to develop a uniform utilization report whereby contractors and grantees holding title to federally sponsored inventions must report annually on the utilization of each invention. These utilization reports could be used to provide information on the status of development, the date of first commercial sale or use, and the gross royalties received by the contractor or grantee. The regulations already allow—but do not mandate—agencies to require their contractors and grantees to provide these types of data. Among other things, a utilization report on every invention would help the funding agency to determine whether the contractor or grantee is actively pursuing development and commercialization of the invention—one of the agency's oversight responsibilities for inventions subject to the Bayh-Dole Act and Executive Order 12591.

Some of these changes could be made by the Department of Commerce through revisions to the existing regulations. However, the Congress may need to consider changes to the law because (1) the changes need to be made in conjunction with each other and (2) such actions as eliminating the need for the Government Register, establishing additional requirements for inventions created under Executive Order 12591, and placing additional requirements on PTO require congressional action. Also, the Congress may wish to consider the impact of any treaty—such as the one now being negotiated—that would affect the types of information that could be required on the patent application.

Comments From the Department of Commerce

THE SECRETARY OF COMMERCE
Washington, D.C. 20230

AUG 2 - 1999

Mr. Keith O. Fultz
Assistant Comptroller General
Resources, Community and Economic Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fultz:

Thank you for the copies of the GAO draft report entitled *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision* (GAO/RCED-99-242). The Department of Commerce supports most of the recommended options in the report and believes that many of them can be implemented without any new legislation.

However, the Department does not believe that confirmatory licenses should be eliminated as recommended in the first option. Since the statement of government support now required to be in any patent application of a government contractor or grantee refers to "certain rights," the public would have to contact an external source, such as the Government Register, to learn the scope of those rights. On the other hand, the Department is not proposing that a further burden be placed on patent applicants.

In this respect, the Reporting Requirements section accurately reflects a previous concern of the Patent and Trademark Office about the present required statement of government support because of ongoing international negotiations. But this requirement may not be a problem if the current draft of the Patent Law Treaty is adopted, which permits contracting states to require such information.

Finally, the discussion in the section on the Health and Human Services Inspector General of the conclusions and data from a pending draft report by that Inspector General does not seem appropriate in view of the preliminary nature of that report.

Sincerely,

William M. Daley

Key Contacts and Staff Acknowledgments

GAO Contacts

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Acknowledgments

In addition to those named above, Mark Abraham, Deborah Ortega, Paul Rhodes, and Mindi Weisenbloom made key contributions to this report.

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