



June 2018

FEDERAL RESEARCH

Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions

Accessible Version

GAO Highlights

Highlights of [GAO-18-327](#), a report to the Chairman, Committee on the Judiciary, House of Representatives

Why GAO Did This Study

The federal government spends approximately \$137 billion annually on research and development—mostly at DOD, DOE, NASA, and NIH—to further agencies' missions, including at federal labs. Multiple laws have directed agencies and labs to encourage commercial use of their inventions, in part by licensing patents, to private sector companies and others that aim to further develop and bring the inventions to market.

GAO was asked to review agency practices for managing inventions developed at federal labs, with a particular focus on patent licensing. This report examines (1) challenges in licensing patents and steps taken to address and report them and (2) information to guide establishing financial terms in patent licenses at DOD, DOE, NASA, and NIH. GAO reviewed relevant literature, laws, and agency documents, including patent licenses from 2014, to match the most recent NIST summary report when the licenses were requested, and GAO interviewed agency officials and knowledgeable stakeholders, including organizations that assist federal labs in licensing patents.

What GAO Recommends

GAO is making seven recommendations, including that Commerce instruct NIST to fully report the range of challenges in federal patent licensing in its annual reports to Congress and facilitate information sharing among agencies. Commerce, DOD, DOE, NASA, and NIH generally agreed with GAO's recommendations and are taking steps to implement them.

View [GAO-18-327](#). For more information, contact John Neumann at (202) 512-3841 or neumannj@gao.gov.

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What GAO Found

Federal agency and laboratory (lab) officials identified challenges in licensing patents across the federal government, and agencies have taken some steps to address and report them. Patent licensing is a technology transfer activity that allows, for example, federal inventions to be legally transferred to the private sector for commercial use. Specifically, officials at the Departments of Defense (DOD) and Energy (DOE), National Aeronautics and Space Administration (NASA), and National Institutes of Health (NIH), as well as external stakeholders, noted challenges in having researchers identify potentially patentable inventions. DOD, DOE, and NIH officials also cited having inadequate internal systems to keep track of inventions developed in the labs. In addition, several stakeholders stated that licensing patented inventions can be lengthy and bureaucratic, which may deter companies from licensing. The agencies reported taking steps to address these challenges, such as implementing model license agreements across labs to expedite the process.

Selected Challenges in Licensing Federal Inventions and Steps Taken to Address Them

Challenges:	Steps to address challenges:
<ul style="list-style-type: none">• Researchers not identifying potentially patentable inventions• Using inadequate systems to track inventions• Difficulty processing license agreements	<ul style="list-style-type: none">• Training and incentivizing researchers to effectively identify potentially patentable inventions• Exploring ways to leverage capabilities of other agencies' systems that track inventions• Implementing special license agreements across labs to expedite process for startups

Sources: GAO analysis of relevant literature and agency and external stakeholder interviews. | GAO-18-327

The Department of Commerce has delegated to its National Institute of Standards and Technology (NIST) to annually report agencies' technology transfer activities, including patent licensing. Although NIST has reported some challenges, it has not fully reported the range of challenges identified by agency and lab officials and stakeholders. NIST officials stated that they were generally aware of the challenges but had not considered including them to a greater degree in their annual reports to Congress. By fully reporting the range of challenges in federal patent licensing, NIST has the opportunity to further ensure that Congress is more aware of challenges that limit agencies' efforts and ways for potentially addressing those challenges.

Federal agencies and labs have limited information to guide officials when establishing the financial terms of patent licenses. For example, while federal labs can use comparable licenses to help establish financial terms, their access to information on comparable licenses from other labs varies, and such information is not formally shared among the agencies. Based on its established interagency role, NIST is best positioned to assist agencies in sharing information on comparable licenses, in accordance with leading practices for interagency collaboration. By doing so, NIST would provide federal agencies and labs with useful information that can help them better establish financial terms and successfully license inventions.

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Abbreviations

AIA	Leahy-Smith America Invents Act
AUTM	Association of University Technology Managers
Commerce	Department of Commerce
CRADA	cooperative research and development agreement
DOD	Department of Defense
DOE	Department of Energy
FLC	Federal Laboratory Consortium
HHS	Department of Health and Human Services
iEdison	Interagency Edison
LES	Licensing Executives Society
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
R&D	research and development
Stevenson-Wydler Act	Stevenson-Wydler Technology Innovation Act of 1980
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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June 19, 2018

The Honorable Bob Goodlatte
Chairman
Committee on the Judiciary
House of Representatives

Dear Mr. Chairman:

The federal government spends approximately \$137 billion annually on research and development (R&D) to help further agencies' missions, including at federal laboratories (lab).¹ The intellectual property generated by this research—including inventions—has application beyond federal agencies' immediate, mission-related goals if the private sector can bring the inventions to market.² For example, government research has led to new products and processes for the commercial marketplace, including antibiotics, plastics, airplanes, computers, microwaves, and bioengineered drugs. However, a 2013 Office of Science and Technology Policy report raised concerns that only a small portion of the inventions arising from government research have been commercialized by the private sector, and that the United States is potentially missing critical opportunities to improve the nation's standard of living, create new jobs, maintain international competitiveness, and enhance the overall economy, among other things.³

Technology transfer is the process of transferring scientific findings from one organization to another for the purpose of further development and

¹We use the term lab in a broad sense to include all federally funded labs and R&D centers. Annual federal R&D spending (obligations) averaged \$137 billion for fiscal years 2015 to 2017.

²Section 4 of the Stevenson-Wydler Technology Innovation Act of 1980, as amended, defines "invention" as any invention or discovery that is or may be patentable or otherwise protected under title 35, United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. § 2321 et seq.). Pub. L. No. 96-480 § 4 (codified as amended at 15 U.S.C. § 3703(7)). Intellectual property is defined as creative works or ideas embodied in a form that can be shared or can enable others to re-create, emulate, or manufacture them. Patents, trademarks, copyrights, and trade secrets are forms of intellectual property protection.

³White House Office of Science and Technology Policy and the National Institutes of Health, *White House Lab-to-Market Inter-Agency Summit: Recommendations from the National Expert Panel* (Washington, D.C.: May 20, 2013).

commercialization.⁴ A series of federal laws and executive orders spanning nearly 40 years have directed federal agencies to enhance their labs' beneficial impact on society through technology transfer. For example, the Stevenson-Wydler Technology Innovation Act of 1980 (Stevenson-Wydler Act) states that its purpose is to improve the economic, environmental, and social well-being of the United States by, among other things, stimulating improved utilization of federally funded technology developments by nonfederal entities.⁵ Accordingly, the act provides that the federal government, where appropriate, shall transfer federally owned or originated technology to state and local governments and to the private sector.

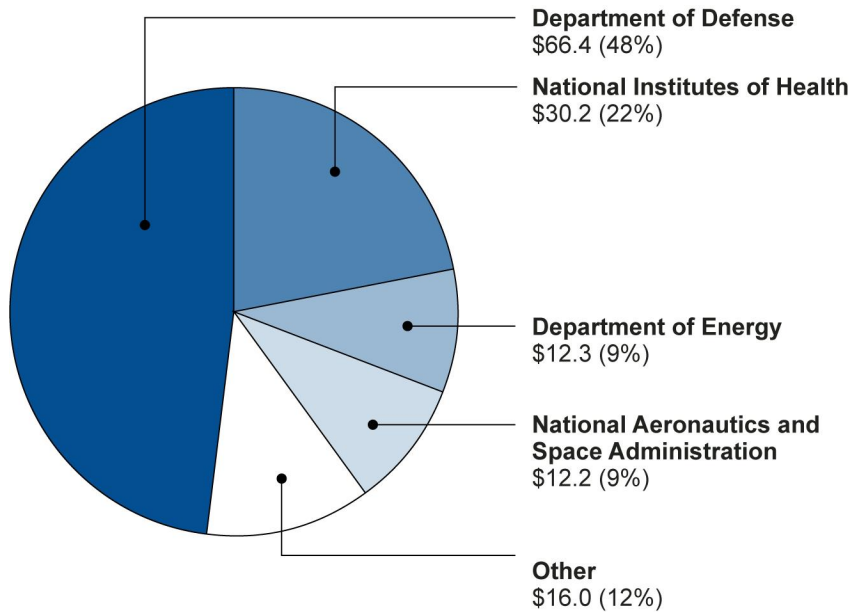
From fiscal years 2015 to 2017, four federal agencies consistently had the highest annual federal R&D spending: the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and the National Institutes of Health (NIH) within the Department of Health and Human Services (HHS).⁶ Together, these four agencies accounted for nearly 90 percent of total federal R&D spending on average, as shown in figure 1.

⁴In some cases, technology transfer involves the transfer of legal rights, such as licensing a government-owned patent to a private sector entity. Technology transfer also includes collaboration between private companies and federal labs, for example, in the testing of advanced batteries. In other instances, technology transfer involves the informal transmission of information, knowledge, and skills through person-to-person or organization-to-organization interaction. Commercialization is the process of developing marketable products or services and producing and delivering products or services for sale.

⁵Pub. L. No. 96-480, § 3, 94 Stat. 2311, 2312 (codified as amended at 15 U.S.C. § 3702).

⁶We use the term spending to refer to agency obligations on R&D, as reported by the National Science Foundation, National Center for Science and Engineering Statistics, *Survey of Federal Funds for Research and Development, FYs 2015–17* (Arlington, Va.: Apr. 5, 2017). Total R&D spending includes all direct, incidental, or related costs, for both intramural and extramural R&D, and does not directly correspond to the R&D spending used to develop, patent, and license inventions at federal labs.

Figure 1: Federal Research and Development Spending by Agency, Average for Fiscal Years 2015 to 2017 (Dollars in Billions)



Source: GAO analysis of National Science Foundation data. | GAO-18-327

One way federal agencies transfer technology is by licensing patents on inventions generated by R&D at federal labs.⁷ This licensing aims to put federal inventions in the hands of those equipped to further develop the inventions into marketable products accessible to the public or to find other practical applications for them.⁸ Examples of inventions developed at DOD, DOE, NASA, and NIH labs can be found in appendix I. Numerous statutory and regulatory requirements have been established to help ensure that agencies commercialize inventions arising from R&D at federal labs. The Department of Commerce (Commerce) is responsible for government-wide functions related to patenting, including granting patents through the United States Patent and Trademark Office (USPTO).

⁷A patent is an exclusive right granted for a fixed period of time to someone who invents or discovers (1) a new and useful process, machine, manufacture, or composition of matter or (2) any new and useful improvement of such items. A patent owner can prevent others from making, using, selling, or offering for sale the patented invention in the United States, or importing it into the United States without authorization. A patent owner can license or assign the patent rights.

⁸According to Department of Commerce officials, “practical application” is important in the law because some inventions that involve, for example, defense technologies are not for commercial use per se, other than for being sold to DOD.

Commerce is also responsible for functions related to licensing of federally owned inventions, including reporting federal agencies' technology transfer activities to Congress and issuing regulations, both of which it delegated to the National Institute of Standards and Technology (NIST).

Over the years, we and others have reported on a range of challenges that agencies face in commercializing inventions arising from R&D at federal labs.⁹ You asked us to review agency practices for managing intellectual property developed at federal labs, with a particular focus on the licensing of patented inventions (patent licensing) to nonfederal parties that might use the patented inventions to manufacture products. This report examines, for DOD, DOE, NASA, and NIH and their labs, (1) challenges that federal labs face in patent licensing, steps taken to address those challenges, and the extent to which NIST has reported them and (2) the extent to which federal agencies and labs have information on processes, goals, and comparable licenses to guide establishing patent license financial terms.

For both objectives, we reviewed statutes and regulations applicable to patent licensing to describe the legal framework governing federal patent licensing and license financial terms. To obtain views on patent licensing practices across the federal government, we conducted 60 semistructured interviews, including 38 with agency and lab officials. We interviewed officials from DOD, DOE, NASA, and NIH, as well as from nine federal labs across these agencies. We interviewed officials at multiple labs at each agency and selected them to obtain a variety of perspectives on patent licensing, including variation in whether they were contractor-operated (two labs) or government-operated labs (seven labs); the volume and type of licensing activity; and other agency-specific considerations, such as whether they use a service center model.¹⁰

⁹GAO, *Technology Transfer: Federal Laboratory Consortium Should Increase Communication with Potential Customers to Improve Initiatives*, [GAO-15-127](#) (Washington, D.C.: Oct. 3, 2014); *Defense Technology Development: Technology Transition Programs Support Military Users, but Opportunities Exist to Improve Measurement of Outcomes*, [GAO-13-286](#) (Washington, D.C.: Mar. 7, 2013); and *Technology Transfer: Clearer Priorities and Greater Use of Innovative Approaches Could Increase the Effectiveness of Technology Transfer at Department of Energy Laboratories*, [GAO-09-548](#) (Washington, D.C.: June 16, 2009).

¹⁰A service center model uses a central technology transfer office to serve multiple labs.

In addition, we conducted 22 interviews with external stakeholders—including academic researchers (4), partnership intermediaries (11) (i.e., organizations that assist federal labs and businesses in licensing federal patents), industry representatives and companies (3), and professional trade organizations and universities (4)—that were knowledgeable about federal patent licensing practices. Partnership intermediaries were selected based on lists of partnership intermediaries associated with the selected labs and agencies that the agencies submitted and referrals from other partnership intermediaries. To select other stakeholders, we used snowball sampling based on referrals obtained from prior engagements, our review of academic literature, and referrals from stakeholder interviews during the engagement. We also interviewed officials from NIST and USPTO. The information we obtained from these interviews is not generalizable to all agency and lab officials and external stakeholders, but we determined that our selection of interviewees was appropriate to obtain varied perspectives on the patent licensing process and related challenges and that the selection would generate valid and reliable evidence to support our work.

To understand the level of patent licensing activity and the terms in patent licenses at federal labs, we requested data from each agency on licenses that were active as of the end of fiscal year 2014.¹¹ To assess the reliability of the data on active patent license agreements, we asked agency and lab officials questions about the accuracy and completeness of the data and asked them to confirm specific information. Based on these steps, we found the data to be sufficiently reliable for understanding the overall level of licensing activity in the labs, for identifying licenses that became effective in fiscal year 2014, and as a source of information for those licenses. We also requested from each agency and reviewed the subset of licenses that became effective in fiscal year 2014.

To address the first objective, we first conducted a literature search.¹² We broadened our search beyond articles published in peer-reviewed journals to identify studies, such as dissertations, conference proceedings, and organizational studies issued by research institutes or

¹¹We requested data for licenses active at the end of fiscal year 2014 to match the data in the NIST fiscal year 2014 summary report, which was the most recent when the data were requested.

¹²See the selected bibliography following the appendixes.

studies issued by government agencies.¹³ For example, we conducted both subject and keyword searches related to patent licensing in various databases.¹⁴ We performed these searches and identified 23 studies from 2000 to 2016—2016 was the year for which the most recent information was available at the time of our review.

We reviewed relevant agency documentation and interviewed the agency and lab officials and external stakeholders identified above to obtain their perspectives on areas of the patent licensing process identified from our review of relevant federal statutes and regulations.¹⁵ Using information obtained from the interviews, we conducted a content analysis of responses. Challenges in each area were identified from the content analysis based on the frequency and consistency of responses from agency and lab officials and stakeholders. We also examined other relevant agency documentation, including NIST's fiscal year summary reports to Congress from fiscal years 2013 through 2015—the most recent reports available—to determine the extent to which challenges in federal patent licensing had been reported.

To address the second objective, we reviewed relevant economic literature on establishing the financial terms of patent licenses and other related licensing terms. From the literature, we identified economic principles that apply to structuring financial terms to promote the commercial use of inventions. We reviewed all relevant documentation describing licensing practices at the agency and lab levels that DOD, DOE, NASA, and NIH provided. This included documentation describing, among other things, processes and goals for establishing license terms, including financial terms. We reviewed each document to identify (1) factors considered in establishing financial terms; (2) data sources used in the process; (3) methods, such as calculations or guidelines, for setting financial terms; (4) guidance on when or how to use various types of financial terms; and (5) goals applicable to financial terms. We also

¹³“Organizational studies” refers to those studies published by nongovernmental organizations, such as the Heritage Foundation and the Science and Technology Policy Institute.

¹⁴These include OCLC WorldCat, Web of Science, DIALOG (SciSearch, Social SciSearch, MEDLINE, Chembase), Scopus, ProQuest, SSRN, NBER, and LEXIS.

¹⁵The basis for the areas of the federal patent licensing process we chose was our review of part 404 of title 37 of the *U.S. Code of Federal Regulations* and the Federal Laboratory Consortium's *Technology Transfer Desk Reference: A Comprehensive Guide to Technology Transfer*, 6th ed. (Cherry Hill, N.J.: 2013).

reviewed narratives and written responses describing lab practices for establishing financial terms in patent licenses that the agencies and labs provided in response to our requests. To identify patents at the labs under the four agencies we reviewed and the extent to which they patent in similar technology fields, we searched the assignee field in USPTO's PatentsView database for patents issued since 2000 using search terms associated with the four agencies and their contractor labs, if applicable.¹⁶ The list of assignees for the patents from the initial search was reviewed to eliminate patents that may not have been assigned to the four agencies. In total, the search yielded 20,612 patents assigned to the four agencies.¹⁷ To examine similarities across technology areas, we used PatentsView data on technology sectors and fields classified according to the World Intellectual Property Organization (WIPO) international classification system for patents.¹⁸

We conducted this performance audit from June 2016 to June 2018 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.

¹⁶These search terms included the name of the agency, the lab, and the lab contractor (if applicable).

¹⁷The 20,612 patents should not be considered an exhaustive list of patents assigned to these agencies or their contractor labs. While many patents associated with each agency were found, some contractor labs may be underrepresented because of challenges in separating out patents associated with the lab from those associated with a larger organization. However, additional patents would only add to the potential for overlap in technology fields.

¹⁸WIPO is a specialized agency of the United Nations, with 191 member states. The organization's mission is to lead the development of a balanced and effective international intellectual property system that enables innovation and creativity for the benefit of all. According to the organization, the International Patent Classification, established by the Strasbourg Agreement of 1971, provides for a hierarchical system of language-independent symbols for classifying patents and utility models according to the different areas of technology to which they pertain.

Background

This section outlines the legal framework under which agencies and federal labs license patents and general stages of the patent licensing process.

Legal Framework for Patent Licensing

Prior to 1980, federal agencies generally retained title to any inventions developed through federally funded research—whether extramural, that is, conducted by universities and contractors, or intramural, conducted by federal agencies in their own facilities. By the late 1970s, there was increasing debate in Congress over ways to allow the private and public sectors better access to federally owned inventions by, among other things, creating a uniform policy for those seeking to license inventions developed in federal labs. In the 1980s, Congress began passing a series of key laws that have provided the foundation for federal technology transfer activities, including patenting and licensing inventions that are developed in federal labs and funded by federal dollars. One of the first technology transfer laws, the Stevenson-Wydler Act, established technology transfer as a federal policy and required federal labs to set up Offices of Research and Technology Applications (which, for our purposes, we refer to as technology transfer offices) and devote budget and personnel resources to promoting the transfer of federal technologies to the private sector.¹⁹ In 1980, another key law, the Bayh-Dole Act allowed not-for-profit corporations, including universities, and small businesses to retain title to their federally funded inventions.²⁰ In 1984, through amendments made to the Bayh-Dole Act, Commerce became responsible for issuing regulations to implement the act.²¹

¹⁹Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701-3715, 3719-23).

²⁰Patent and Trademark Law Amendments Act, Pub. L. No. 96-517, 94 Stat. 3015 § (codified in 35 U.S.C. § 200-211), commonly referred to as the Bayh-Dole Act. In 1987, by Executive Order 12,591, 52 Fed. Reg. 13,414 (Apr. 22, 1987), and Executive Order 12,618, 52 Fed. Reg. 48,661 (Dec. 24, 1987). The policy expressed in the Bayh-Dole Act directed at not-for-profit corporations, universities, and small businesses was expanded to apply to all recipients of federal funds, regardless of size, including large businesses.

²¹Trademark Clarification Act of 1984, Pub. L. No. 98-620, § 501(10) (amending 35 U.S.C. § 206). Prior to the 1984 amendments, the Office of Federal Procurement Policy was authorized to develop these regulations.

The Stevenson-Wydler Act was amended by the Federal Technology Transfer Act of 1986, which (1) established the Federal Laboratory Consortium (FLC); (2) required that technology transfer efforts be considered positively in employee performance evaluations; and (3) empowered federal agencies to permit the directors of government-owned, government-operated labs to enter into cooperative research and development agreements (CRADA) and to negotiate license agreements for inventions created in the labs.²² The FLC began largely as a forum for the education, training, and networking of federal technology transfer officials to promote the integration of technical knowledge that federal departments and agencies developed into the U.S. economy. Over time, the FLC's role would include serving as a clearinghouse—a central point for collecting and disseminating information—for federal technologies and assisting outside entities in identifying available federal technology. Within Commerce, NIST is the designated host and financial administrator of the FLC.

Additional laws were adopted to help further the development of federally owned inventions for commercial use. Among them was the National Competitiveness Technology Transfer Act of 1989, which directed federal agencies to propose, for inclusion in contracts, provisions to establish technology transfer as a mission of government-owned, contractor-operated labs and permitted those labs, under certain circumstances, to enter into CRADAs.²³ In addition, the Technology Transfer Commercialization Act of 2000 required Commerce to provide Congress with summary reports on agencies' patent licensing and other technology transfer activities.²⁴ Since 2007, Commerce has delegated to NIST the role of providing to Congress an annual report summarizing technology transfer at federal agencies.²⁵ NIST's role as the lead in an interagency collaborative effort in federal technology transfer grew further when

²²Pub. L. No. 99-502, § 2, 100 Stat. 1785, 1785, (amending Pub. L. No. 96-480, adding § 12, codified as amended at 15 U.S.C. § 3710a(a)).

²³Pub. L. No. 101-189, div. C, tit. XXXI, pt. C, § 3133(d)(1)(A), 103 Stat. 1352, 1678.

²⁴Pub. L. No. 106-404 § 10(a)(3), 114 Stat. 1742, 1747 (codified at 15 U.S.C. 3710(g)(2)).

²⁵In 2007, the America Creating Opportunities to Meaningfully Promote Excellence in Technology Education and Science (COMPETES) Act eliminated Commerce's Technology Administration, which had been responsible for collecting information on all federal agencies' technology transfer activities and submitting the information to Congress and the Office of Management and Budget. Pub. L. No. 110-69 § 3002(a)(1), 121 Stat. 572, 586 (2007).

Commerce delegated to the agency the additional responsibility of coordinating the Interagency Working Group for Technology Transfer.²⁶ Commerce also has delegated to NIST its authority to promulgate implementing regulations pertaining to patenting and licensing at federal labs. In 2011, Congress passed the Leahy-Smith America Invents Act (AIA) that further affected technology transfer activities by federal labs through comprehensive changes made to the U.S. patent system.²⁷

Federal Labs

Federal labs are typically managed under either a government-operated or a contractor-operated model. Commerce regulations prescribe the terms, conditions, and procedures that government-operated labs are to use to license their inventions for commercial use or other practical applications.²⁸ Government-operated labs are usually owned or leased by the federal government and are predominantly staffed by federal employees. Contractor-operated labs, on the other hand, operate facilities and equipment that are owned by the federal government, but the staff is employed by a private or nonprofit contractor that operates the lab under a contract with the federal government.²⁹ Contractor-operated labs typically license their technologies under the authority of the Bayh-Dole Act, applicable regulations, and their contracts, which generally give

²⁶Through Department Organization Order 30-2A, Commerce delegated to NIST the responsibility of coordinating the Interagency Working Group for Technology Transfer, which was established in 1987 by Executive Order 12591. The working group includes heads of representative agencies and their directors, or designees, of federal labs who identify and disseminate approaches in technology transfer to the agencies and labs.

²⁷Pub. L. No. 112-29, 125 Stat. 284 (2011). Signed into law on September 16, 2011, the act implemented changes to the patent system that included giving the inventor with the earliest filed patent application—not the earliest inventor—the right to the patent, creating within USPTO the Patent Trial and Appeal Board that replaced the Board of Patent Appeals and Interferences, and establishing three new proceedings for challenging issued patents. Pub. L. No. 112-29 §§ 3, 6, 7, 18.

²⁸The regulations define “practical application” to mean “to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.” 7 C.F.R. § 404.3(d).

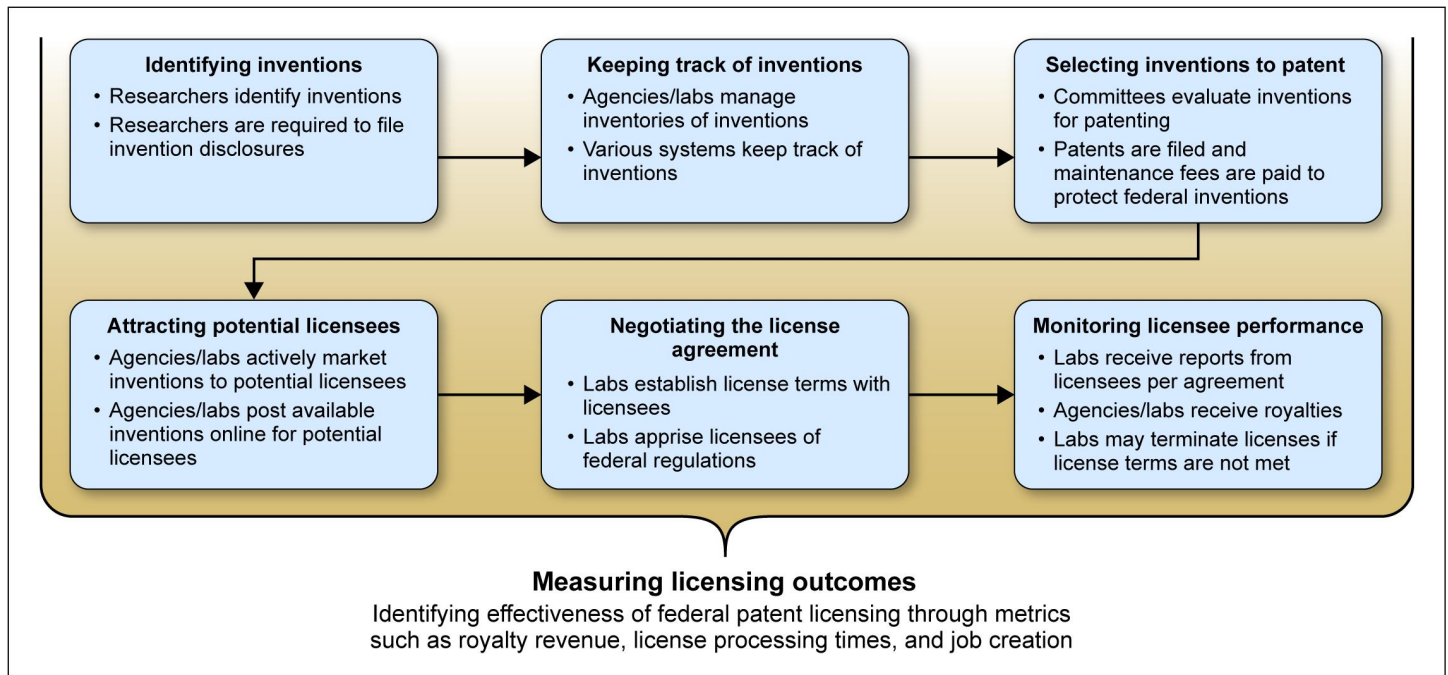
²⁹Federal Laboratory Consortium, *FLC Technology Transfer Desk Reference*.

contractor-operated labs more flexibility in licensing their technologies.³⁰ Contractors that manage and operate labs include universities, private companies, nonprofit organizations, or consortia thereof. As discussed below, whether a lab is government-operated or contractor-operated will affect how that lab licenses inventions because each type operates under a different set of licensing regulations and requirements.

The Federal Licensing Process

The pathway of an invention from lab development to commercial product can end at any point, and products may not always reach, or find success in, the marketplace. Figure 2 shows the seven general areas of the patent licensing process at federal labs.

Figure 2: Federal Patent Licensing Process



Source: GAO analysis based on review of regulations and agency documentation. | GAO-18-327

³⁰For example, contractor-operated labs are not required to obtain a commercialization plan prior to licensing. A commercialization plan is a detailed description of an applicant’s plan for development of the invention, marketing of the invention, or both.

Identifying Inventions

The patent licensing process begins with researchers identifying inventions—a process that primarily relies on researchers disclosing their inventions to lab officials, mostly through the lab director or directly to an agency’s technology transfer office. Various laws and regulations establish a uniform policy for determining who holds the rights to government employees’ inventions.³¹ Some government-operated labs allow or encourage researchers to publish their research, including research describing inventions, for public dissemination, such as in research journals. Contractor-operated labs are required to disclose inventions to the agency within 2 months after notifying contractor personnel responsible for patent licensing activities. Labs must then decide within 2 years after the disclosure whether to retain title to the invention.³² The contract then must file its initial patent application on the invention to which it elects to retain title within one year after election of title. If the contractor-operated lab does not disclose the invention or elect to retain title within the times specified in the law and regulations, it will convey title to the invention to the funding agency upon written request.³³

Keeping Track of Inventions

Once an invention has been identified and disclosed, federal agencies and labs keep track of the invention. How they do so varies in degree of automation and centralization. For example, systems that keep track of lab inventions can range from spreadsheets to automated software that tracks all patent licensing and other technology transfer activities. Also, such systems can be centralized, with oversight at the agency level, or decentralized, with independent oversight at the lab level—which is generally the case at contractor-operated labs. Some contractor-operated labs manage their federally funded inventions through the Interagency

³¹ See, for example, 35 U.S.C. § 202; 37 C.F.R. pt. 501.

³² 37 C.F.R. § 401.14.

³³ According to USPTO officials, the same is applicable to the failure to file or prosecute patent applications, or maintain or defend issued patents in administrative proceedings, in any given country.

Edison (iEdison) reporting system, which is owned and managed by NIH.³⁴

Selecting Inventions to Patent

Before applying for patent protection through USPTO, agency and lab officials review the invention—often using evaluation committees and patent attorneys—to consider a number of factors, including whether it is patentable, it furthers the lab’s mission, and patenting the invention is likely to bring it to commercial use or practical application. The agency must file a patent application within 1 year of the first publication, public use, sale, or offer for sale of the invention or lose U.S. patent rights to that invention.³⁵ Not all patents will be licensed out to companies for a variety of reasons, including national security considerations. The average time from filing to issuing a patent, or when an application is abandoned, is about 2 years, according to USPTO. Patent applications are often rejected, modified, and refiled, and various fees are associated with filing and prosecuting a patent application. However, according to USPTO, patent maintenance fees that allow federal labs to maintain their patents in force are among the most significant fees.³⁶

Attracting Potential Licensees

Agencies and labs use a variety of methods to attract potential licensees, including those from industry, universities, and nonprofits.³⁷ For example, agencies may post their inventory of patented inventions online, publish them in academic journals, or highlight them at public events. Agencies and labs actively engage with the private sector by, for example,

³⁴iEdison allows government grantees and contractors to report federally funded subject inventions, patents, and utilization data via the web to the government agency that issued the funding award. More than 30 U.S. federal funding agency offices use iEdison.

³⁵Contractor-operated labs typically apply for patents on inventions within 1 year of the election of title, while providing additional reports to the agency on their progress in commercializing the inventions.

³⁶Agencies are to pay maintenance fees to USPTO at 3.5, 7.5, and 11.5 years after the date of issue, with the associated fees increasing over the life of the patent. USPTO officials stated that a patent for an invention, known as a utility patent, is granted for a term that usually ends 20 years from the date the federal lab or inventor first filed for the patent, subject to the payment of appropriate maintenance fees.

³⁷A licensee, in this context, is an entity that gains a legal license to exercise a patent for an invention from its owner (i.e., a federal lab or contractor).

attending conferences where companies can network with federal researchers and federal technology transfer officials. In addition, technology transfer offices often work with partnership intermediaries—such as local or state entities and nonprofit organizations—to support their efforts, including reaching out to potential licensees.³⁸ Labs have other mechanisms to help attract potential licensees to further develop their inventions. For example, CRADAs can help facilitate licensing or the transfer of knowledge from a lab to a licensee, and new inventions that arise under a CRADA are typically made available to the partner via an option to license.

Negotiating the License Agreement

The technology transfer offices and legal counsel are generally responsible for crafting and negotiating the terms of the patent license, sometimes with input from other lab officials. Negotiations are often an iterative process in which both the lab and the licensee request adjustments to the terms of the license. Laws and regulations specify some terms that government-operated labs must include in their licenses. Among others, a typical license includes terms related to (1) financial compensation (if applicable), (2) the degree of exclusivity of the license, (3) the U.S. manufacturing requirement, (4) retained rights for the government, (5) termination of the license, and (6) enforcement of licenses.

Financial terms may include up-front fees; minimum payments; royalties, usually based on sales; and milestone payments, among others. Federal labs typically establish financial terms on a case-by-case basis that are tailored to the specifics of the technology, licensee, and market conditions.³⁹ License agreements may be nonexclusive, partially

³⁸Partnership intermediaries are authorized by 15 U.S.C. § 3715 to help federal agencies or laboratories with technology transfer to increase the likelihood of success.

³⁹There are certain limited exceptions for special licensing programs—often targeted at start-ups—in which the terms of the license may be preset. For the purposes of our report, start-ups are newly created small businesses.

exclusive, or fully exclusive, and may be limited to some fields of the invention's use or to specific geographic areas.⁴⁰

Government-operated labs must publicly announce their intent to grant an exclusive license for at least 15 days. After this period, comments and objections are considered. Negotiations then begin with the proposed licensee or, if the licensee has changed, another public announcement of the new licensee may be required. Government-operated labs are required to obtain a commercialization plan from a potential licensee regardless of the degree of exclusivity. Contractor-operated labs, which typically retain title to their inventions under the authority of the Bayh-Dole Act, are not subject to the requirement to obtain a commercialization plan from a prospective licensee before granting a license; however, they are subject to requirements specified in their contracts regarding patent licensing. In addition, they are not subject to the same notification requirements as government-operated labs.⁴¹

The law also contains some other provisions pertaining to patent licenses originating from federal labs. For example, the law generally gives preference to small businesses that are capable of bringing the invention to practical application. There is a general preference for products that incorporate federal inventions to be manufactured substantially in the United States; however, on a case-by-case basis, agencies may waive this requirement. Applicable law also reserves certain rights for the government to protect the public's interests in federally funded inventions. For example, the government retains a royalty-free license to use inventions that are contractor owned or that are licensed exclusively. In addition, the Bayh-Dole Act provides the government march-in authority when certain statutory conditions have been met. Under this authority, an agency may grant a license to an invention developed with federal funding even if the invention is exclusively licensed to another party if, for example, it determines that such action is needed to alleviate public health or safety needs which are not reasonably satisfied by the

⁴⁰For the purposes of this report, an exclusive license grants the licensee the sole right to use, manufacture, and sell a patented invention, and a partially exclusive license is an exclusive license that is limited to some fields of the invention's use or to some specified geographic areas.

⁴¹The applicable acquisition regulations for patents and licensing at DOE contractor-operated labs are found at 48 C.F.R. 970.5227-3, 48 C.F.R. 970.5227-10, and 48 C.F.R. 970.5227-12.

contractor, assignee, or their licensee.⁴² A federal lab can also terminate a license when the licensee is not meeting its commitment to achieve practical application of the invention. The lab can also, through the license, grant permission to a licensee to pursue patent infringement cases.

Monitoring Licensee Performance

Federal license agreements generally require licensees to report periodically on their commercialization.⁴³ For instance, labs generally put specific monitoring requirements in the license agreements, including milestones and reporting requirements. Through the agreements, government-operated labs have the right to terminate or modify licenses if certain requirements are not met.⁴⁴ Government-operated labs must submit written notices to the licensees and any sublicensees of their intentions to modify or terminate licenses, and allow 30 days for the licensees or sublicensees to remedy any breach of the licenses or show cause why the licenses should not be modified or terminated.⁴⁵ Contractor-operated labs also monitor licensee performance in much the same way; however, they are subject to a different set of regulations.

Measuring Licensing Outcomes

Federal labs are responsible for measuring the outcomes of their activities in all areas of the patent licensing process by developing metrics and evaluation methods. Measuring licensing outcomes help labs assess the effectiveness of their patent licensing efforts. Soon after the passage of AIA, President Obama issued a memorandum in October 2011 to the heads of executive departments and agencies calling for, among other things, (1) developing strategies to increase the usefulness and accessibility of information about federal technology transfer opportunities; (2) listing all publicly available, federally owned inventions on a public government database; and (3) improving and expanding its

⁴²35 U.S.C. § 203(a)(1), (2); see also 37 C.F.R. § 401.14(j).

⁴³35 U.S.C. § 209(d)(2); see also 37 C.F.R. § 404.5(b)(6).

⁴⁴35 U.S.C. § 209(d)(3); see also 37 C.F.R. § 404.5(b)(8).

⁴⁵37 C.F.R. § 404.10.

collecting of metrics for Commerce's annual technology transfer summary report.⁴⁶

Technology Transfer and Agency Mission

Federal law states that it is Congress's policy and objective to use the patent system to promote the commercialization and public availability of inventions, and that technology transfer, including federal patent licensing, is the responsibility of each laboratory science and engineering professional. No single federal agency is responsible for managing technology transfer activities government-wide. Rather, each federal agency involved in technology transfer designs its own program to meet technology transfer objectives, consistent with its other mission responsibilities.

⁴⁶Memorandum on Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses, DCPD 201100803 (Oct. 28, 2011).

Federal Labs and Stakeholders Identified Challenges in Patent Licensing, and Agencies Have Taken Some Steps to Address Them, but NIST Has Not Fully Reported Such Challenges

Federal agency and lab officials and external stakeholders have identified challenges across the federal patent licensing process, but NIST has not fully reported such challenges. Specifically, DOD, DOE, NASA, and NIH officials at the agency and lab levels, as well as external stakeholders, cited challenges related to all seven areas of the patent licensing process. In addition, officials and stakeholders cited challenges in one area that cuts across the entire process: prioritizing patent licensing as part of agencies' missions. In its annual reports to Congress on federal labs' performance in patent licensing activities, NIST has discussed some challenges identified by agency and lab officials and external stakeholders but has not fully reported on the range of challenges they have experienced.

Federal Labs and Stakeholders Identified Challenges across the Patent Licensing Process, and Agencies Have Taken Some Steps to Address These Challenges.

DOD, DOE, NASA, and NIH officials at the agency and lab levels, as well as external stakeholders, identified challenges in all seven areas of the patent licensing process, including identifying inventions, keeping track of inventions, and negotiating license agreements.⁴⁷ They also cited challenges in prioritizing patent licensing as part of agencies' missions. Based on our analysis of relevant literature and on interviews with external stakeholders, many of these challenges are occurring government-wide. DOD, DOE, NASA, and NIH have taken some steps to address the challenges in each area of the patent licensing process.

⁴⁷The areas of identifying inventions, keeping track of inventions, and negotiating license agreements were selected for illustrative purposes only.

Challenges in Implementing the Patent Licensing Process

DOD, DOE, NASA, and NIH officials at the agency and lab levels, as well as external stakeholders, identified challenges in all seven areas of the patent licensing process, including not identifying inventions, keeping track of inventions in inadequate systems, and difficulty negotiating license agreements. For example, several DOD, DOE, NASA, and NIH officials stated that some researchers do not have adequate training in identifying potentially patentable inventions. When a federal researcher does not disclose to lab officials an invention developed in a federal lab, the opportunity to assess the invention's potential for commercial use may be lost. Federal officials cited various reasons why researchers do not disclose inventions. Navy officials, for example, stated that researchers are often intimidated by the overall invention disclosure process and tend to focus on their research rather than consider what could be patentable. Officials at one NASA lab noted that they have come across a few contractor employees who do not see the benefit of filing invention disclosures, and sometimes researchers are too busy to engage in the patenting process.

Our analysis of relevant literature and interviews with stakeholders also showed that researchers not identifying and disclosing inventions is a government-wide challenge. For example, one stakeholder stated that researchers at federal labs generally have limited understanding of the patenting process, including an understanding of what constitutes patentable subject matter and how to conduct a prior art search on the technology to determine whether it is patentable.⁴⁸

DOD, DOE, NASA, and NIH officials stated that they are taking a variety of actions to help address this challenge. For example, some agency and lab officials stated that labs conduct training to educate researchers about the patenting process, inform researchers about requirements to disclose inventions, and incentivize them by acknowledging their efforts through

⁴⁸Prior art is information relevant to a claimed invention and may include prior patents, patent applications, or nonpatent publications describing a technology, among other things.

awards and monetary incentives—such as potential royalty distributions—when their inventions reach commercial success.⁴⁹

In addition, DOD, DOE, and NIH officials described their agencies' systems for keeping track of inventions developed in the labs as inadequate or in need of improvement. How agencies and labs keep track of such inventions can range from spreadsheets to sophisticated databases that manage all technology transfer activities, including keeping track of patented inventions and licenses. Currently, DOD has a decentralized approach to keeping track of inventions, which, according to DOD officials, needs improvement given how large the agency is.

Several stakeholders we interviewed also noted that the challenge of keeping track of inventions exists government-wide. According to some stakeholders, federal labs not only have inadequate systems to keep track of their own inventions but also limited information on the kinds of inventions being developed in federal labs across the government. The result is that agencies risk being unaware of research across the labs, which can limit their ability to leverage other federal research efforts. For example, one stakeholder stated that there can be research conducted independently at three or four labs under different agencies but little interaction among those labs about the research.

DOD, DOE, and NIH officials stated that they have made efforts to improve their current systems for keeping track of inventions. Specifically, DOE officials reported that they have developed a plan to leverage the capabilities of the iEdison reporting system to unify the agency's data management process. Air Force and NIH officials stated that they have contacted NASA, which has a centralized system for tracking inventions, about leveraging its expertise.⁵⁰ NASA officials reported that they have been hosting regular webinars with other agencies to determine whether NASA's tracking system could help meet other agencies' needs.

Furthermore, agency and lab officials and stakeholders noted that federal labs face challenges in negotiating license agreements because the

⁴⁹For example, the head of the agency or lab is required to pay each year the first \$2,000 and thereafter at least 15 percent of the royalties or other payments to federal researchers from license agreements based on their inventions. 15 U.S.C. § 3710c.

⁵⁰NASA's system used in tracking patent licensing and other technology transfer activities is called the NASA Technology Transfer System. The system is operated at the lab level and is accessible to NASA officials at headquarters.

licensing process is lengthy and uniquely regulated, which can deter companies from licensing federal inventions. Stakeholders stated that the federal licensing process can take anywhere from about 3 months to more than 2 years. Some stakeholders stated that from their point of view taking a year to negotiate a license agreement is too long. One stakeholder said that such lengthy processes are particularly difficult for start-ups, which often need to finalize license agreements in 3 months.

DOD, DOE, NASA, and NIH officials said they are taking steps to address companies' concerns about the time it takes to negotiate a license agreement. For instance, NASA, NIH, and Navy officials told us that they have developed model license agreements to help guide companies through the process, and NASA and NIH have special license agreements for start-ups to shorten the licensing process.⁵¹

For more detail on challenges in the seven areas of the patent licensing process that agency and lab officials and external stakeholders identified, see appendix II.

Challenges in Prioritizing Patent Licensing

DOD, DOE, NASA, and NIH face challenges in prioritizing patent licensing as part of their agency missions. For example, DOD and DOE officials stated that an agency's mission affects patent licensing activities. DOD officials stated that the agency's primary mission is protecting the warfighter and that patent licensing is a secondary benefit to the agency. According to DOE officials, the nuclear security labs do not focus on patenting but instead on developing technologies associated with a weapons program.

In addition, several stakeholders we interviewed stated that some agencies and labs do not have a culture that prioritizes patent licensing. In particular, one stakeholder stated that at some federal labs, patent licensing is not reflected in performance evaluation management plans, which can help incentivize lab personnel to engage in patent licensing

⁵¹The Startup NASA License and the agency's QuickLaunch provide standardized licensing terms and types of licenses that are available without negotiation. According to HHS officials, NIH also had a start-up license program with standardized non-negotiable terms from fiscal years 2012 to 2015, with the program ending after technology transfer activities at NIH were decentralized. However, HHS officials stated that the National Cancer Institute revamped the initiative and continues to offer it with the goal of reducing negotiation time periods.

activities. A few stakeholders stated that at some labs where management does not prioritize patent licensing activities, researchers' careers can be negatively affected if they engage in patent licensing activities.

Some agency and lab officials stated that they have taken steps to overcome such challenges. For example, officials at one Navy lab stated that the lab has management support and nine patent attorneys to assist in the reviews of researchers' invention disclosures. Also, officials at one NIH lab stated that the lab has strong management support and a good royalty stream from successful inventions that pay for patenting and other reinvestments, which allows the lab to not draw from its appropriations.

NIST Has Reported Some Challenges Faced by Federal Labs in Areas of Patent Licensing but Has Not Fully Reported on the Range of Such Challenges

In its three most recent fiscal year summary reports to Congress, NIST identified some challenges faced by federal labs in areas of patent licensing and has assisted agencies in addressing challenges in their patent licensing activities. However, NIST does not fully report on the range of challenges that agency and lab officials and stakeholders identify.

NIST collaborates with agencies to gather patent licensing data for its summary reports to Congress. For example, according to agency officials, NIST engages with agencies to inform them about new requirements in technology transfer and helps them identify their successes in conducting technology transfer activities. NIST also provides administrative support to the FLC, which offers training to federal technology transfer specialists through workshops; publishes a desk reference on federal patent licensing, laws, and regulations; and has commissioned studies on efforts to develop federal inventions for commercial use.⁵² Further, NIST developed a survey in 2016 on agency technology transfer processes. NIST officials stated that the survey is aimed in part at improving federal labs' decisions on whether to spend money on applying for patents, whether patents will facilitate the commercialization of technology, and what data are needed to make those determinations. NIST officials stated that the agency continues to analyze the survey data and currently plans to report its findings in fiscal year 2018.

While NIST has identified in its annual summary reports to Congress some challenges that federal labs face in patent licensing and other technology transfer activities, it has not fully reported the range of challenges that agencies and labs face in patent licensing. For example, in its fiscal year 2015 summary report—its most recent report—on federal

⁵²Federal Laboratory Consortium, *FLC Technology Transfer Desk Reference*; Federal Laboratory Consortium, *The Green Book: Federal Technology Transfer Legislation and Policy*, 5th ed. (Cherry Hill, N.J.: 2013); Indiana University, Kelley School of Business, Indiana Business Research Center, *Innovation Partnership Networks in the Midwest: A Pilot Project of the Federal Laboratory Consortium Midwest* (Bloomington, Ind.: Indiana University, 2013); and Raymond L. Sterling, *Utility Locating Technologies: A Summary Of Responses to a Statement of Need Distributed by the Federal Laboratory Consortium for Technology Transfer* (Federal Laboratory Consortium, 2000).

technology transfer, NIST reported that the federal intramural research budget has been relatively consistent over the years but not that DOD, DOE, NASA, and NIH face challenges in prioritizing patent licensing as an agency mission.⁵³ The report also mentions that there is no uniform federal system for tracking research that employees in federal labs published but not that DOE, for example, has faced challenges in keeping track of inventions developed in its labs. In addition, we found that although the report mentions that the Department of Veterans Affairs is facing challenges with its labs disclosing inventions, it does not mention similar challenges at DOD. NIST officials stated that they were generally aware of the challenges identified by agency and lab officials and external stakeholders but had not considered including such challenges to a greater degree in the summary reports to Congress.

We have previously reported on Congress's goal to make the federal government more results oriented through reporting of agency performance information to aid decision making by agency executives, Congress, and program partners.⁵⁴ Specifically, we have reported how the effective implementation of good governance can help address government challenges in five key areas involving agency performance and management: (1) instituting a more coordinated and crosscutting approach to achieving meaningful results, (2) focusing on addressing weaknesses in major management functions, (3) ensuring that agency performance information is useful and used in decision making, (4) sustaining leadership commitment and accountability for achieving results, and (5) engaging Congress in identifying management and performance issues to address.⁵⁵ By fully reporting the range of

⁵³Department of Commerce, National Institute of Standards and Technology, *Federal Laboratory Technology Transfer Fiscal Year 2015: Summary Report to the President and the Congress* (Gaithersburg, Md.: December 2017). The federal intramural research budget includes the budget for intramural programs and the budget for contractor-operated labs.

⁵⁴GAO, *Managing for Results: Agencies Should More Fully Develop Priority Goals under the GPRM Modernization Act*, [GAO-13-174](#) (Washington, D.C.: Apr. 19, 2013); *Managing for Results: GPRM Modernization Act Implementation Provides Important Opportunities to Address Government Challenges*, [GAO-11-617T](#) (Washington, D.C.: May 10, 2011); *Results-Oriented Government: GPRM Has Established a Solid Foundation for Achieving Greater Results*, [GAO-04-38](#) (Washington, D.C.: Mar. 10, 2004); and *Agencies' Strategic Plans Under GPRM: Key Questions to Facilitate Congressional Review*, [GAO/GGD-10.1.16](#) (Washington, D.C.: May 1997).

⁵⁵[GAO-11-617T](#), and GAO, *Government Performance: GPRM Modernization Act Provides Opportunities to Help Address Fiscal, Performance, and Management Challenges*, [GAO-11-466T](#) (Washington, D.C.: Mar. 16, 2011).

challenges in federal patent licensing—such as those outlined in this report—and including that information in its annual summary reports to Congress, NIST has the opportunity to further ensure that Congress is more aware of challenges that limit agencies’ efforts in patent licensing and ways for potentially addressing those challenges. To identify these challenges, NIST could, for example, leverage its survey, past FLC studies, and agency reports.

Federal Agencies and Labs Have Limited Information on Processes, Goals, and Comparable Licenses to Guide Establishing Financial Terms in Patent Licenses

Federal agencies and labs have limited information on processes, goals, and comparable licenses to guide establishing the financial terms in patent licenses. DOD, DOE, NASA, and NIH labs generally do not document their processes for establishing the financial terms of patent licenses and instead rely on the expertise of technology transfer staff. Furthermore, existing agency and lab guidance does not consistently link the practice of establishing license financial terms to the statutory goal of promoting commercial use of inventions. In addition, although many federal labs rely on comparable licenses to aid them in setting the terms of new licenses, labs have varying levels of access to information about such licenses.

Federal Agencies and Labs Have Limited Documentation of Their Processes for Establishing the Financial Terms of Patent Licenses

DOD, DOE, NASA, and NIH labs have limited documentation of their processes for establishing the financial terms of patent licenses. Such documentation is limited at both the agency level and the lab level.⁵⁶

⁵⁶In addition, the *Technology Transfer Desk Reference*, made available to agencies and labs through the FLC, provides a list of factors to consider in setting financial terms but does not cover other aspects of the process, such as methods for establishing the financial terms.

At the agency level, the four agencies we reviewed had some documentation on patent licensing in general, such as policies, procedures, guides, and handbooks, but had limited information on how to establish financial terms.⁵⁷ For example, the Air Force and the Navy had handbooks on technology transfer that include brief passages on financial terms. However, agency officials noted that these handbooks were either outdated or under revision.⁵⁸ At DOE, labs collaborated to develop two agency-level documents on patent licensing: one for lab officials on using equity in licenses and a licensing guide for licensees. These documents describe the general structure of various types of financial terms and, in the document on using equity, factors to consider regarding its use in a license, but do not discuss methods for establishing financial terms. NASA and NIH have policies and procedures for patent licensing that mention the types of financial terms that are normally found in licenses but do not cover other aspects, such as methods for establishing financial terms. All four agencies reported that they gave their labs discretion to develop their own processes for establishing financial terms.

At the lab level, DOD, DOE, NASA, and NIH generally had not documented their processes for establishing financial terms in patent licenses. Based on documentation provided by NASA, NIH, and DOD, few labs at these agencies had issued additional documentation on the patent licensing process.⁵⁹ DOE labs had documented the patent licensing process in general, and 6 out of 17 DOE labs provided documentation that covered aspects of establishing financial terms. For

⁵⁷The agency-level documentation includes some that applies military department-wide (i.e., Air Force, Army, and Navy). GAO reviewed documents provided for coverage of four potential aspects of the process for establishing financial terms: (1) factors to consider, (2) sources of information, (3) methods for developing financial terms, and (4) use of specific types of financial terms. Factors may include a variety of considerations associated with the invention, the market, and the prospective licensee, such as the licensee's technical ability or the licensee's plan to address a public need. According to agency officials, license terms are typically negotiated based on specific circumstances in addition to any agency efforts to understand the value of the invention.

⁵⁸The Navy handbook includes information on the types of financial terms that can be included and factors to consider but generally does not cover methods for establishing the terms, although it contained one example of guidance on how to set minimum annual fees.

⁵⁹DOD subcomponents and labs had some documentation of their process, including two handbooks, which had brief passages on financial terms, and some training materials, which in one case contained more detailed information on establishing financial terms.

example, one DOE lab document contained a set of licensing principles that help clarify what financial terms a license usually contains, their purpose, and how to structure the financial terms in patent licenses. In addition, agency and lab officials at NASA and DOE reported using tools, such as financial term calculators, at some of their labs, which aid technology transfer staff in valuing technologies.

Agency and lab officials reported that they generally rely on the expertise of technology transfer staff to establish and vet appropriate financial terms.⁶⁰ Accordingly, agencies and labs reported that they have taken some steps to develop, share, and retain expertise among staff in their technology transfer offices. The agencies we reviewed reported that some technology transfer staff participate in training opportunities provided by professional organizations like the Association of University Technology Managers (AUTM) or the Licensing Executives Society (LES), as well as the FLC and the agencies.⁶¹ In addition, some agencies and labs reported that internal working groups and regular meetings are opportunities to share licensing expertise. At DOD, officials stated that on a case-by-case basis, labs may use the expertise of their partnership intermediary to help establish financial terms.

However, according to agency and lab officials and stakeholders, federal labs face challenges in acquiring, developing, and retaining expertise in patent licensing for their technology transfer offices. Specifically, some agency officials, lab officials, and stakeholders cited issues such as losing experienced technology transfer staff to retirement or to the private sector, having difficulties in hiring staff with expertise in part because of limited funding, and facing a limited pool of prospective employees to hire with the expertise to value and license inventions. A few stakeholders said that government training in the business aspects of patent licensing

⁶⁰Labs use a variety of methods to establish financial terms, ranging from identifying comparable licenses, or benchmarks, to direct valuation (e.g., calculations based on potential costs, sales, and other information). The financial terms often include up-front fees, minimum annual payments, royalties (often a percentage of sales), and milestone payments. Contractor-operated labs are also able to take equity in a licensee as part of the compensation for the license. For additional details on fiscal year 2014 licenses and their contents, see app. III.

⁶¹AUTM is a nonprofit organization that supports and enhances the global academic technology transfer profession through education, professional development, partnering, and advocacy. LES is an independent, professional organization that facilitates global intellectual property commerce through education, networking, standards development, and certification.

is inadequate and not widespread.⁶² In addition, some stakeholders had concerns about consistency in licensing practices both within the labs and across labs. For example, some of these stakeholders said that the outcome of license negotiations can depend on the specific licensing professional handling the license. Varying levels of expertise may lead to inconsistency in licensing practices, including establishing financial terms, as can undocumented processes.

Under the federal standards for internal control, management should design control activities by, for example, clearly documenting them in management directives, administrative policies, or operating manuals, to achieve objectives and respond to risks.⁶³ Furthermore, documentation can act as a means to retain organizational knowledge and provide some assurance that an approach is operational across the lab or agency.⁶⁴

Agency and lab officials stated that they had not documented their processes for establishing financial terms for various reasons. For example, lab officials stated that establishing financial terms is often complex and varies based on the specific circumstances applicable to each potential license, which may limit what can be documented. Some agency and lab officials stated that labs need flexibility in negotiating terms to make adjustments based on the circumstances and therefore officials do not want to be prescriptive. A few agency and lab officials also noted that there are benefits to having streamlined processes. Furthermore, a few agency and lab officials described negotiating license terms as a craft or art that requires expertise and said that documenting this will not enhance licensing by itself.

However, some agency and lab officials and stakeholders said that it is possible to document some aspects of the process. A few stakeholders we interviewed noted that even if each agreement is unique, it is still possible to develop guidelines or outline a methodology for establishing

⁶²The extent of training varies by agency and lab. For example, NIH officials reported that the agency provided training on technology valuation agency-wide in 2017. On the other hand, a DOD lab official expressed concerns that the lab does not have expertise in establishing financial terms. Some lab officials also noted that they have to pay for their own membership to organizations such as AUTM, which offers on-demand training.

⁶³GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

⁶⁴The specific documentation needed will depend in part on the size, level of expertise, and hiring practices of each technology transfer office.

financial terms. A few agency and lab officials stated that they are investigating opportunities to standardize their processes or would be open to documenting them. For example, one agency official told us that the agency plans to update existing documents with specific information about royalty ranges so labs do not have to constantly “reinvent the wheel.” Some labs also described steps that they take to establish financial terms, such as methods for valuing inventions, without being prescriptive. By documenting processes for establishing the financial terms of licenses while maintaining enough flexibility to tailor the specific terms of each license, the four agencies could have more reasonable assurance of consistency across their labs regardless of the expertise of staff.

Federal Agency and Lab Documentation Does Not Consistently Link Financial Terms to the Goal of Promoting Commercial Use

Agency and lab documentation does not consistently link establishing financial terms in patent licenses to the goal of promoting commercial use of inventions. As noted above, federal law states that it is Congress’s policy and objective to use the patent system to promote the commercialization and public availability of inventions, and that technology transfer, including federal patent licensing, is the responsibility of each laboratory science and engineering professional.⁶⁵

Agency-level documentation at NASA contains a provision that clearly links establishing financial terms to the goal of promoting commercial use of inventions—that is, “terms should be negotiated that provide the licensee incentive to commercialize the invention.” NIH’s documentation mentions financial terms in the context of protecting the public from nonuse, which is one aspect of promoting commercial use, and also mentions the goal of obtaining a fair financial return on investment from the licensed invention.⁶⁶ DOD and DOE agency-level documents mention

⁶⁵See 15 U.S.C. § 3710; 35 U.S.C. § 200.

⁶⁶ According to NIH officials, specific terms, including financial terms, provide an incentive to develop inventions into marketable products that support public health. For example, NIH officials stated that minimum annual royalties incentivize a licensee to put a product on the market because such royalties are not immediately creditable and therefore remain a sunk cost for licensees until products are sold. In addition, NIH officials stated that their licensees are held accountable to detailed commercial development plans and timelines.

the general goal of promoting the commercial use of inventions without specifically linking it to the financial terms.⁶⁷ At the lab level, DOD documents generally do not address the goals for financial terms.⁶⁸ Of 17 DOE labs, 4 had a statement in their documentation to link financial terms to the goal of promoting commercial use of inventions.⁶⁹

DOD, DOE, NASA, and NIH officials we interviewed stated that getting the technology into the marketplace is their primary goal in licensing but also mentioned other goals related to financial terms that support their mission. In addition, some agency and lab officials described using revenues from licenses as a means to provide a reward to inventors for their work or to obtain a fair return on investment for research conducted by federal agencies. Furthermore, lab officials we interviewed mentioned the flexibility of revenues from licenses as helpful in funding activities, such as additional research, training, and patent prosecution.

Some agency officials and stakeholders we interviewed expressed concerns about competing goals for establishing financial terms. For example, a few stakeholders stated that licensing professionals may be motivated to negotiate for increased license revenue because it reflects positively on them professionally. Further, some stakeholders expressed concerns about labs taking a short-term view of some licensees, particularly small companies, because they have less ability to pay initially and thus may offer less certain revenues.⁷⁰

Our review of relevant economic literature and interviews with stakeholders suggest that license financial terms set with goals other than promoting commercial use in mind, such as short-term revenue maximization, may undermine that longer-term goal. For example, high up-front license fees typically provide more guaranteed short-term

⁶⁷While agency-level documents rarely discussed goals in the context of financial terms, two documents (one at each agency) had limited statements regarding goals for specific financial terms, such as equity, that are consistent with the goal of commercial use.

⁶⁸One DOD lab training document stated that maximizing revenue is not the goal.

⁶⁹Some other DOD and DOE labs had stated goals for license financial terms that did not directly connect to commercial use, such as making sure that the terms do not place an undue burden on the lab or provide sufficient benefit to the lab.

⁷⁰On the other hand, a stakeholder and an agency official expressed concerns that labs may establish financial terms that are too low, which may provide little incentive to develop the technology.

revenue to the licensor than other forms of payment but can also reduce the capital available to develop a product successfully. Labs with other goals in mind when establishing financial terms may be at risk of establishing them in ways that run counter to the goal of promoting commercial use.⁷¹

NIST plays an important role in providing regulations and guidance to agencies regarding patent licensing. Commerce has delegated to NIST the authority to promulgate implementing regulations pertaining to patenting and licensing at federal labs—that is, regulations that indicate how agencies are to implement statutory provisions, including the goal of, among other things, promoting commercial use of inventions. NIST has developed regulations, but they do not link the financial terms of federal patent licenses and the statutory goal of promoting commercial use of inventions.⁷²

As the host of the FLC and a coordinator for the Interagency Working Group for Technology Transfer, NIST also plays a role in supporting the development of interagency guidance on patent licensing that covers, among other topics, establishing financial terms in licenses. However, existing interagency guidance provides limited information regarding the goals for financial terms. For example, the FLC desk reference contains a statement that links royalty rates to the goal of promoting commercial use but does not clarify how the goal applies to other financial terms. Furthermore, the FLC desk reference states that labs are entitled to market-based compensation for their intellectual property. However, licenses are structured differently to accomplish different goals and a primary focus on obtaining market-based compensation may undermine the goal of promoting commercial use.

As the lead agency on the government-wide effort to find commercial uses or practical applications for federally funded inventions, NIST has been delegated the responsibility to promulgate regulations pertaining to patenting and licensing at federal labs, including implementing the

⁷¹Some agency and lab officials stated that they may make adjustments to the financial terms based on the specific needs of the licensee. Some agency and lab officials reported that they take some steps to mitigate risks associated with competing goals, such as implementing conflict of interest procedures and appeals processes and preventing researchers from negotiating financial terms. We did not conduct a detailed assessment of the effectiveness of those measures in counteracting risks.

⁷²37 C.F.R. pts. 401, 404.

statutory goal of promoting commercial use. NIST officials stated that a change to the regulations could be made as part of an upcoming rule-making process. However, in doing so, a stakeholder and agency officials noted that any changes to the regulations should avoid prescriptive language that mandates specific practices. NIST officials also stated that they could update relevant guidance on this issue through one of their current efforts. By clarifying the link between establishing federal patent license financial terms and the goal of encouraging commercial use, through the upcoming rule-making process and updating relevant guidance, NIST would have better assurance that financial terms in patent licenses are targeted to that goal.

Federal Agencies and Labs Have Varying Amounts of Information on Comparable Licenses, but Such Information Is Not Shared across Agencies

According to agency and lab officials, comparable license information can be used as a point of reference to guide establishing financial and other terms in new patent licenses. Just as real estate agents look at sales of comparable houses when setting the selling price of a house, patent licensing professionals can look at licenses for comparable inventions when determining what financial terms to include in a new license.

However, federal labs have varying amounts of information on comparable licenses when establishing financial terms. NASA and NIH each have an agency-wide system that enables each lab to access information from other labs at the agency, including the financial terms in previous licenses. NIH agency officials reported that technology transfer offices have access to thousands of previous licenses and refer to such information frequently to help establish the financial terms of new licenses. Labs at DOE and DOD are generally responsible for tracking their own licenses and do not have access to information on comparable licenses from other labs in their agencies. According to DOE officials, under DOE contracts and relevant law, license information at the agency's contractor-operated labs is considered business sensitive and a contractor-owned record that resides at the labs, which limits DOE's ability to share it. Officials at DOE and DOD's military departments reported that they have investigated and continue to investigate systems that would provide greater access to information on financial terms but have encountered some obstacles, such as network security requirements, that they have not yet overcome.

To bolster their access to comparable license information, some federal labs obtain private sector license information. For example, some lab officials we interviewed said that they have occasionally purchased benchmarking guides and access to other private sector license information through organizations such as AUTM and LES. According to some lab officials and stakeholders, private sector license information is useful for understanding acceptable royalty rates in industry and may cover certain technology areas or inventions that are new to the lab. However, access to private sector license information is typically ad hoc and can be limited by its cost, according to agency and lab officials. Some agency and lab officials stated that they would like increased access to private sector information on comparable licenses. For example,

according to agency officials at DOE, there is an effort under way to obtain benchmark financial terms from labs and universities with comparable R&D portfolios.

Although lab officials and stakeholders said that private licensing information can be helpful for understanding financial terms acceptable to the market, using private license information may not always be appropriate for government licenses. Private licenses are often structured to maximize revenue for the licensor—not necessarily to promote commercial use or practical application, according to stakeholders. Our review of economic literature and interviews with stakeholders and agency officials suggest that licenses are structured differently to accomplish different goals. For example, a few stakeholders and agency officials noted that federal licenses would typically be less exclusive and have different financial terms than those in the private sector, where there is a greater emphasis on generating revenue from R&D investments.⁷³ Some stakeholders and agency officials also stated that in general the value of a government license may be different from that of a private license for a similar technology because of the rights the government retains on its licenses. In addition, according to agency and lab officials and stakeholders, government inventions tend to be in an earlier stage of development than those in the private sector, potentially making it more difficult to find licenses for comparable inventions in the private sector.

Some agency and lab officials and a few stakeholders stated that it would be valuable for federal labs to have greater access to information on financial terms in government licenses to help establish a benchmark for financial terms. Our analysis of approximately 21,000 patents assigned to DOD, DOE, NASA, and NIH and issued since 2000 shows that different agencies may patent inventions in similar technology fields.⁷⁴ All four agencies we reviewed had patented inventions in 26 of 35 technology fields covered by the patents, and all had 10 or more patents in 9 of the

⁷³One stakeholder noted that industry averages should be used as a guide to establishing royalty rates to avoid undercutting private licensing.

⁷⁴NIH patents are assigned to HHS. Accordingly, all HHS patents were used for determining the extent to which NIH is patenting in specific technology areas. DOE and NASA patents include patents assigned to contractor-operated labs. Design and plant patents were excluded from the analysis of WIPO technology fields.

35 technology fields.⁷⁵ DOD and DOE, including DOE contractor-operated labs, had more patents in a wider range of fields than the other agencies. On the other hand, HHS's patents are more focused on fields such as biotechnology and medical technology. However, even in the area of biotechnology, there were hundreds of patents issued to the other three agencies. Although other information would be needed to determine whether the agencies' inventions are truly comparable, their having patents in the same technology fields suggests that some government-wide information on financial terms could be useful to federal labs.

Under internal control standards for the federal government, management should externally communicate the necessary quality information to achieve the entity's objectives; this includes communicating with and obtaining quality information from external parties using established reporting lines.⁷⁶ The four agencies we reviewed communicate and share information through several collaborative efforts to improve federal patent licensing, including the FLC and the Interagency Working Group for Technology Transfer. For example, agency officials said they share experiences, ideas, and best practices related to patent licensing informally through these groups. However, there is no formal sharing of information on financial terms in patent licenses among federal labs, according to NIST officials.

We have previously reported that federal agencies engaged in interagency collaborative efforts should identify and address needs by leveraging their resources to obtain additional benefits that would not be available if they were working separately.⁷⁷ NIST plays a leading role in these interagency collaborative efforts on patent licensing, including gathering and sharing information among the labs. As the administrative host for the FLC, NIST has already supported an effort to share information about available technology. NIST is also responsible for gathering information from technology transfer agencies, including gross license income, and submitting summary reports to Congress annually

⁷⁵ In 22 of these 26 technology fields, we identified more than 200 total patents. Substantial shares of these patents were assigned to multiple agencies, not concentrated at a single agency.

⁷⁶ [GAO-14-704G](#).

⁷⁷ GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

and sharing them with the public.⁷⁸ Furthermore, NIST has initiated a survey of practices at federal technology transfer offices and shared some preliminary information with the agencies. By facilitating the formal sharing of comparable license information, NIST could help provide agencies and labs with benchmarks for evaluating which financial terms are best suited to licensing inventions successfully.

NIST officials stated that gathering and sharing comparable license information could be done as part of their existing efforts but that there are obstacles to doing so. Specifically, NIST officials stated that this effort would add to the reporting burdens of agencies, may require additional resources, and would need to take into account data security and proprietary information considerations. Agency officials also stressed that any effort to share license terms would have to ensure that confidential and proprietary information from licensees, including specific financial terms from a particular license, is not divulged.⁷⁹

Conclusions

Federal labs under DOD, DOE, NASA, and NIH face challenges at various stages of the patent licensing process, and agencies have taken some steps to address such challenges. For example, ensuring that researchers identify and disclose inventions is a government-wide challenge, according to interviews with external stakeholders and our analysis of relevant literature. However, such challenges in federal patent licensing are not fully reported by NIST, the lead agency delegated by Commerce to provide annual summary reports to Congress on federal technology transfer activities. By fully reporting the range of these challenges that agencies and labs face, NIST can ensure that Congress has greater awareness of these challenges. To help identify these challenges, NIST could, for example, leverage its survey of practices at federal technology transfer offices, past FLC studies, and agency reports.

⁷⁸License income is the amount of income that agencies receive as a result of the financial terms in their licenses. Currently, NIST does not gather granular information on the individual financial terms.

⁷⁹Access to such information would have to balance the need to keep proprietary business information confidential as required by the Federal Trade Secrets Act. See 18 U.S.C. § 1905.

In addition, DOE, DOD, NASA, and NIH documentation does not consistently link establishing financial terms in patent licenses to the statutory goal of promoting commercial use. As the lead agency on the government-wide effort to find commercial uses or practical applications for federally funded inventions, NIST has been delegated the responsibility to promulgate regulations pertaining to patenting and licensing at federal labs, including implementing the statutory goal of promoting commercial use. By clarifying the link between establishing patent license financial terms and the goal of encouraging commercial use, through the upcoming rule-making process and updating relevant guidance, NIST would have better assurance that financial terms in patent licenses are targeted to that goal.

Further, federal labs have varying amounts of information on comparable government licenses when establishing financial terms. However, there is no formal sharing of information on financial terms in patent licenses among federal labs, according to NIST officials. NIST plays a leading role in interagency collaborative efforts on patent licensing, including gathering and sharing information among the labs. By facilitating the formal sharing of comparable license information, NIST could help provide agencies and labs with benchmarks for evaluating which financial terms are best suited to successfully licensing inventions.

To establish financial terms, DOD, DOE, NASA, and NIH labs rely on the expertise of their technology transfer staff and take a number of steps to build and share expertise, but had limited documentation of their processes for establishing the financial terms of patent licenses. Agency and lab officials explained that there is a need for flexibility, and thus not every aspect of their processes can be documented in detail. By documenting processes for establishing the financial terms of licenses while maintaining enough flexibility to tailor the specific terms of each license, the four agencies could have more reasonable assurance of consistency across their labs regardless of the expertise of staff.

Recommendations for Executive Action

We are making seven recommendations, including three to Commerce and one each to DOD, DOE, NASA, and NIH:

- The Secretary of Commerce should instruct NIST to fully report the range of challenges in federal patent licensing, such as those outlined in this report, by, for example, leveraging its survey of practices at

federal technology transfer offices, past FLC studies, and agency reports and including that information in its summary reports to Congress. (Recommendation 1)

- The Secretary of Commerce should instruct NIST to clarify the link between establishing patent license financial terms and the goal of promoting commercial use, through appropriate means, such as the upcoming rule-making process and updating relevant guidance. (Recommendation 2)
- The Secretary of Commerce should instruct NIST to facilitate formal information sharing among the agencies to provide federal labs with information on financial terms in comparable patent licenses, as appropriate. (Recommendation 3)
- The Secretary of Defense should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 4)
- The Secretary of Energy should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 5)
- The Administrator of NASA should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 6)
- The Director of NIH should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 7)

Agency Comments

We provided a draft of this report to Commerce, DOD, DOE, NASA, and NIH for review and comment. All provided written responses, which are reproduced in appendixes IV-VIII. Commerce and NIH also provided technical comments, which we incorporated as appropriate.

Commerce agreed with all three of our recommendations to the agency. In general, the agency stated that it will work through interagency groups, such as the Interagency Working Group for Technology Transfer and the FLC, to address our recommendations, including by creating a specific

section in its annual reports to Congress with more details on challenges agencies and labs face in patent licensing and by examining and implementing solutions to facilitate the sharing of information among agencies. According to Commerce, such solutions could include identifying licensing officers who have expertise and creating a community of practice in which they can share best practices and approaches for establishing license terms.

DOD, DOE, and HHS agreed, and NASA partially agreed, with the recommendation that they or their labs document processes for establishing financial terms in patent licenses. In its written response, DOD said it will direct the military departments and appropriate defense agencies to have their labs establish documentation of their licensing processes as appropriate. In their written comments, DOE, HHS, and NASA noted the complexity and nuances associated with negotiating license agreements, such as understanding the market for the technology and the level of risk involved. Further, DOE and NASA noted challenges that limit their ability to document processes and emphasized the importance of maintaining flexibility in establishing financial terms in patent licenses. We agree that some flexibility in establishing financial terms of patent licenses is important. DOE, HHS, and NASA all identified steps they would take to ensure that at least some processes for establishing financial terms are documented.

We are sending copies of this report to the appropriate congressional committees; the Secretaries of Commerce, Defense, and Energy; the Administrator of NASA; and the Director of NIH. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or neumannj@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 IX.

Sincerely yours,



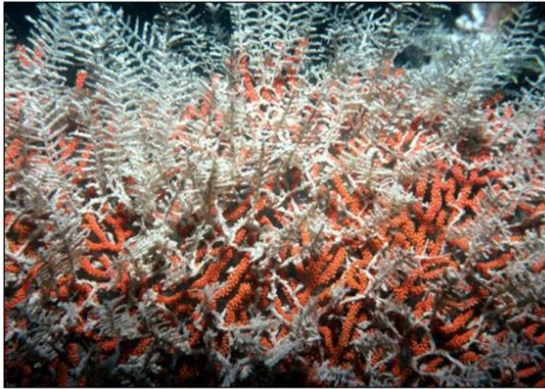
Letter

John Neumann
Director, Natural Resources and Environment

Appendix I: Examples of Inventions Developed in Federal Labs

Figure 3 presents examples of inventions developed in federal laboratories under the Department of Defense, Department of Energy, National Aeronautics and Space Administration, and National Institutes of Health.

Figure 3: Examples of Inventions Developed in the Department of Defense, Department of Energy, National Aeronautics and Space Administration, and National Institutes of Health Federal Laboratories



Anti-HIV proteins from coral reefs

Researchers at the National Cancer Institute's Molecular Targets Laboratory have discovered that a class of proteins called Cnidarins—found in coral reefs off Australia's northern coast—is capable of blocking the human immunodeficiency virus (HIV) from penetrating T-cells. According to the National Institutes of Health, the Cnidarins may represent important new leads for HIV microbicides or for systemic therapeutics for HIV.

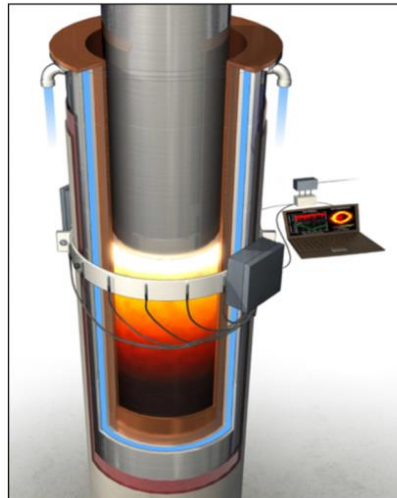


Refrigeration-free vaccines

According to the Air Force Research Laboratory's Materials and Manufacturing Directorate, researchers have developed technology that offers stabilization processes for biologically active materials in the form of high molecular weight and water-free protein ionic liquids. According to Air Force officials, the invention offers a solution to delivering therapeutic and diagnostic reagents without refrigeration in hot-climate, remote areas.

Cell-phone cameras

Digital image sensors based on complementary metal oxide semiconductors (CMOS) were developed in the 1990s at the Jet Propulsion Laboratory under the National Aeronautics and Space Administration (NASA). Since then, they have become a universal piece of technology behind cell-phone cameras; by 2015, the CMOS market reached nearly \$10 billion, according to NASA.



Identification of defects in industrial metals

The National Energy Technology Laboratory under the Department of Energy (DOE) has issued patent licenses for its measurement technology called Arc Position Sensing (APS). According to DOE, APS was developed for industry—including the aerospace industry—that focuses on specialty metals. The technology helps operators identify arc distribution conditions during arc melting to improve material yield, safety systems, and energy use.

Sources: GAO summary of agency information; National Institutes of Health, courtesy of the Australian Institute of Marine Sciences (photo, upper left); Department of Defense (photo, upper right); NASA (photo, lower left); DOE (photo, lower right). | GAO-18-327

Appendix II: Selected Descriptions of Challenges Federal Labs Face in Patent Licensing

The following are additional descriptions of challenges in the seven areas of the patent licensing process as well as challenges in prioritizing patent licensing faced by federal laboratories (lab) that were identified by external stakeholders and by agency and lab officials at the Department of Defense (DOD), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), and the National Institutes of Health (NIH)—as well as steps agencies and labs have taken to address those challenges.

Challenges in the Seven Areas of the Patent Licensing Process

Identifying Inventions

DOD, DOE, NASA, and NIH officials reported challenges in identifying inventions that lab researchers developed. When a federal researcher does not disclose to lab officials an invention developed in a federal lab, the opportunity to assess the invention's potential for commercial use may be lost.

Federal officials cited various reasons why researchers do not disclose inventions. For instance, several DOD, DOE, NASA, and NIH agency and lab officials stated that some researchers do not have adequate training in identifying potentially patentable inventions. Some agency and lab officials pointed to other reasons why invention disclosures may not be filed, such as researchers not having enough incentive to disclose their inventions. Navy officials stated that researchers are often intimidated by the overall invention disclosure process and tend to focus on their research rather than consider what could be patentable. Officials at one NASA lab noted that they have come across a few contractor employees who do not see the benefit of filing invention disclosures, and sometimes researchers are too busy to engage in the patenting process. According to National Institute of Standards and Technology (NIST) officials, some researchers decide not to disclose an invention because they believe filing a patent application, which includes a filing fee, could take away

money from the research itself, and most federal researchers are not motivated by the potential for receiving royalty distributions.¹

Our analysis of relevant literature and interviews with stakeholders also showed that researchers not identifying and disclosing inventions is a government-wide challenge. One stakeholder stated that researchers at federal labs generally have limited understanding of the patenting process, including an understanding of what constitutes patentable subject matter and how to conduct prior research on the technology to determine whether it is patentable.²

DOD, DOE, NASA, and NIH agency and lab officials stated that they are taking a variety of actions to help address these challenges. For example, some agency and lab officials stated that labs conduct training to educate researchers about the patenting process, inform researchers about statutory requirements to disclose inventions, and incentivize them by acknowledging their efforts through awards and monetary incentives when their inventions reach commercial success.

Keeping Track of Inventions

DOD, DOE, and NIH officials described their agencies' systems for keeping track of inventions developed in the labs as inadequate or in need of improvement. How agencies and labs keep track of such inventions can range from spreadsheets to sophisticated databases that manage all technology transfer activities, including keeping track of patented inventions and licenses.

Currently, DOD has a decentralized approach to keeping track of inventions, which, according to DOD officials, needs improvement given how large the agency is. Each military department has its own systems to track and store information on inventions developed in the labs.³ Officials

¹For example, the head of the agency or lab is required to pay each year the first \$2,000 and thereafter at least 15 percent of the royalties or other payments to federal researchers from license agreements based on their inventions. 15 U.S.C. § 3710c.

²Prior art is information relevant to a claimed invention and may include prior patents, patent applications, or nonpatent publications describing a technology, among other things.

³DOD and its departments use various systems to keep track of inventions developed in their labs, including internally developed Access-based systems, low-budget commercial software systems, and Excel spreadsheets.

from DOD and the departments describe the systems as inadequate to keep track of the agency's inventions. For example, Navy officials described the department's in-house system to track inventions as "plagued by outages" and thus ineffective. According to officials, the Army funds systems that track inventions, but these systems are different from each other and not connected to headquarters and have been suspended since 2015.⁴

We have previously reported on federal agencies' challenges in monitoring technology transfer activities, including tracking inventions developed in the federal labs.⁵ Several stakeholders we interviewed also noted that keeping track of inventions is a government-wide challenge. According to some stakeholders, federal labs not only have inadequate systems to keep track of their own inventions but also limited information on the kinds of inventions being developed in federal labs across the government. The result is that agencies risk being unaware of research across the labs, which can limit their ability to leverage other federal research efforts. One stakeholder specifically noted that the Interagency Edison (iEdison) reporting system—which allows federal grantees and contractors to report federally funded inventions to the agency that issued the funding award, including inventions developed by some contractor-operated labs—is difficult to navigate and needs improvement. Another stakeholder stated that there can be independent research at three or four labs under different agencies but little interaction among those labs about the research. Information on federal lab inventions can also be accessed publically through the Federal Laboratory Consortium (FLC) website; however, NIST officials stated that the website's information on

⁴Army officials reported that the department's patent and technology transfer database was shut down by Army network security officials in 2015 because the system did not meet Army network security requirements. According to Army officials, the database did not track other key information—such as patent applications, disclosures, and licenses. While the Army labs have generally used spreadsheets to track their inventions, officials stated that they do not know whether all of the labs have put the information into spreadsheets and how far back the data have been kept.

⁵GAO, *Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology*, [GAO-03-47](#) (Washington, D.C.: Oct. 31, 2002), and *Federal Research: DOE Is Addressing Invention Disclosure and Other Challenges but Needs a Plan to Guide Data Management Improvements*, [GAO-15-212](#) (Washington, D.C.: Jan. 30, 2015).

inventions relies on agencies to submit accurate information, which may be limited by the agencies' tracking systems.⁶

DOD, DOE, and NIH officials stated that they have made efforts to improve their current systems. For example, since our 2015 report on the agency's challenges with its data management systems that track federally funded inventions, DOE officials reported that they have developed a plan to leverage the capabilities of the iEdison reporting system to unify the agency's data management process.⁷ While DOD officials stated that the agency has been unsuccessful in purchasing software to track inventions across the agency, Air Force officials said they are developing a pilot program and seeking new software to manage the Air Force's inventions, and they expect the pilot program to increase the number of invention disclosures. Air Force and NIH officials stated that they have contacted NASA, which has a centralized system for tracking inventions, about leveraging the agency's expertise.⁸ NASA officials reported that they have been hosting regular webinars with other agencies to determine whether NASA's tracking system could help meet other agencies' needs.

Selecting Inventions to Patent

DOD, DOE, NASA, and NIH agency and lab officials cited selecting inventions to patent as a challenge because of the expense of patenting fees.⁹ According to some agency and lab officials we interviewed, fees

⁶The Federal Laboratory Consortium's website, FLCBusiness.com, allows external users to search for technologies available for potential licensing throughout the federal government.

⁷See [GAO-15-212](#).

⁸NASA's system used in tracking patent licensing and other technology transfer activities is called the NASA Technology Transfer System. The system is operated at the lab level and is accessible to NASA officials at headquarters.

⁹The United States Patent and Trademark Office charges federal agencies all patent fees at the same rate as large corporations, including filing, examination and maintenance fees. The first maintenance fee is due at 3.5 years at a cost of \$1,600, the second maintenance fee is due at 7.5 years at a cost of \$3,600, and the third maintenance fee is due at 11.5 years at a cost of \$7,400. Under the patent regulations, government organizations are classified as large entities and therefore pay undiscounted maintenance fees. Most fees, including maintenance fees, are discounted by 50 percent for small entities and by 75 percent for micro entities. U.S. institutions of higher education generally qualify for discounted fees. The agency sets and adjusts fees set by Congress in 35 U.S.C. § 41. Specifically, 35 U.S.C. § 41(h)(1) authorizes discounted fees only for small business concerns, independent inventors, and nonprofit organizations.

paid to the United States Patent and Trademark Office (USPTO) affect their decision on whether to patent an invention. For example, DOE officials stated that budget constraints force them to make decisions about whether they should file a patent or engage in other agency activities. NIH officials stated that the agency maintains fewer patents because of the patent maintenance fees and the agency's tight budgets.¹⁰

NASA officials reported that one step the agency is taking to deal with the costs of maintaining its issued patents is to identify technologies with low licensing potential and allow the patents to expire if they fail to attract licensees. NASA has created a searchable database that catalogs thousands of expired NASA patents already in the public domain, making them freely available to industry for unrestricted commercial use.

Attracting Potential Licensees

Federal labs under DOD, DOE, NASA, and NIH face challenges that limit their ability to attract potential licensees, according to agency and lab officials. Even officials at NASA, described by NIST officials as one of the best agencies in promoting its inventions to industry, said the agency is not selecting among multiple licensees and would like to have more companies license its patents.

There are various reasons why federal labs struggle to attract companies interested in licensing their inventions, according to agency and lab officials we interviewed. First, several agency and lab officials cited that the number of entities that want to license inventions is generally not large. Second, some agency and lab officials identified inadequate promotion of federal inventions and licensing opportunities to companies, including start-ups, as a factor. Third, some agency and lab officials also noted that their inventions are often in the early stages of development and thus pose more of a risk for companies to license.

Based on our analysis of relevant literature and interviews with stakeholders, difficulty in attracting industry to license inventions

¹⁰In addition, stated NIH officials, high patent fees can affect research collaborations with universities and federal labs because USPTO also assesses undiscounted patent fees for such collaborations, which can become a burden for universities that would normally pay lower patent fees by filing individually. According to USPTO officials, offering discount eligibility to federal agencies may raise legal concerns with respect to international obligations.

developed in federal labs is a government-wide challenge. According to several stakeholders, industry perceives federal labs as not friendly to the private sector when it comes to patent licensing, especially for start-ups. For example, one stakeholder said that it is rare that federal agencies want to license to a start-up, and that more often the labs want a “safer route” by licensing inventions to large companies that already have a steady revenue stream. Another stakeholder said that DOE’s contractor-operated labs in particular tend to not issue exclusive licenses to start-ups and prefer to license to large companies because the agency sees those companies as presenting less of a risk.¹¹ In addition, stakeholders stated that federal inventions are often not yet commercially viable, which can deter companies from licensing federal inventions. One stakeholder, for example, stated that NASA officials may think that NASA technology is more developed than it is and therefore underestimate how long it will take a company to develop it for practical application, the millions of dollars needed to develop it, and whether it can be manufactured for commercial use.

DOD, DOE, NASA, and NIH officials stated that they are taking steps to attract potential licensees by, for example, conducting local outreach to attract companies and working on improving their databases so that companies can learn about federal inventions available for licensing. For instance, NASA officials stated that the agency’s comprehensive database accessible to potential licensees uses a wide variety of search criteria and attracted 6 million unique visitors in 2016.

Negotiating the License Agreement

Agency and lab officials and stakeholders noted that federal labs face challenges in negotiating the license agreement because the process is (1) lengthy and (2) uniquely regulated, which can deter companies from licensing federal inventions.

¹¹In general, according to stakeholders, exclusive licenses help protect start-ups as they try to develop the technology, whereas large companies that have more resources are generally more receptive to nonexclusive licenses. Nonexclusive licenses give companies more protection from patent infringement because more than one licensee can be granted rights to the invention.

Patent Licensing Process Timelines

Stakeholders stated that the federal licensing process can take anywhere from about 3 months to more than 2 years. Some stakeholders stated that from their point of view taking a year to negotiate a license agreement is too long. One stakeholder said that such lengthy processes are particularly difficult for start-ups, which often need to finalize license agreements in 3 months. Another stakeholder noted that the federal government in general does not understand how urgent it is for companies to complete the licensing process in a timely manner. Although actions on the part of both the labs and companies can cause delays, if the overall process is time-consuming, prospective licensees will tend to move onto something else instead, according to agency and lab officials and stakeholders.

Based on our analysis of licensing information provided by the agencies, we found that the amount of time from receipt of an application for a license to signature of the license by the lab varies widely. Specifically, based on this measure of the length of the process, approximately 60 percent of 132 licenses effective in fiscal year 2014 took at most 6 months for DOD, DOE, NASA, and NIH labs to process.¹² Officials at one Navy lab stated that issuing an invention license to a company within 6 months is “highly unusual,” and officials at one NASA lab stated that the fastest they have issued a license was a week because the start-up was prepared and ready to go. For more on our analysis of licensing information from DOD, DOE, NASA, and NIH, see appendix III.

Regulated Patent Licensing Process

Several agency and lab officials also noted that federal regulations associated with patent licensing can deter companies from licensing federal inventions. Such regulations include requirements that are unique to federally funded and federally owned inventions, including that products arising from the invention must be substantially manufactured in the United States and that the government may retain rights to the invention and terminate the license agreement if the licensee does not take steps to commercialize the technology. In particular, NASA officials stated that venture capital firms sometimes oppose the government

¹²The number of licenses at DOD, DOE, NASA, and NIH that we reviewed only include commercial licenses, which give the licensee the right to sell a product incorporating a licensed invention.

retaining rights for federal technology used by start-ups that they fund. According to DOD and DOE officials, federal regulations require a level of documentation or explanation that can deter some companies from licensing inventions developed in federal labs. Based on interviews with stakeholders, as well as our analysis of relevant literature, company concerns about federal regulations is a government-wide challenge that federal labs face in licensing their inventions.

For example, according to NIST officials, the U.S. manufacturing requirement can influence whether companies consider licensing federal inventions, because manufacturing in the United States can be more expensive than manufacturing in other countries.¹³ NIST officials also stated that some prospective licensees initially become concerned when they are told about march-in authority, because it applies to federally funded inventions and contractors. However, once companies are told that it is a legal requirement and that the provision has never been exercised, they generally become more comfortable with it.¹⁴

DOD, DOE, NASA, and NIH agency officials said they are taking steps to address companies' concerns about the time it takes to negotiate a license agreement and their unfamiliarity with federal licensing requirements. For instance, NASA, NIH, and Navy officials told us they have developed model license agreements to help guide companies through the process, and NASA and NIH have special license agreements for start-ups to shorten the licensing process.¹⁵ Also, DOE

¹³According to NIH officials, the U.S. manufacturing requirement can affect companies that only have established manufacturing facilities located outside the United States.

¹⁴According to a few agency and lab officials we interviewed, the threat of march-in authority, which may only be used in circumstances specified by statute, has been helpful in making sure contractors develop inventions for commercial use. We have previously reported on federal implementation of march-in authority: GAO, *Federal Research: Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions*, [GAO-09-742](#) (Washington, D.C.: July 27, 2009).

¹⁵The Startup NASA License and the agency's QuickLaunch provide standardized licensing terms and types of licenses that are available without negotiation. According to HHS officials, NIH also had a start-up license program with standardized non-negotiable terms from fiscal years 2012 to 2015, with the program ending after technology transfer activities at NIH were decentralized. However, HHS officials stated that the National Cancer Institute revamped the initiative and continues to offer it with the goal of reducing negotiation time periods.

created an agency-wide licensing guide to help prospective licensees navigate federal licensing requirements.¹⁶

Monitoring Licensee Performance

DOD, DOE, NASA, and NIH agency and lab officials we interviewed identified limited resources and inadequate monitoring systems as factors that make it difficult to monitor licensee performance.

NASA and NIH officials reported that the number of license agreements has increased in their labs and that they do not have enough resources to monitor licenses.¹⁷ DOD officials stated that the agency's technology transfer offices have traditionally been understaffed and that the agency's monitoring systems are inadequate for tracking the status of issued licenses. Officials at one DOE lab stated that collecting royalties from licensees can be difficult because the lab does not have enough funds to support that activity. In addition, agencies may rely on the same systems they use to keep track of inventions to monitor licensee performance, and as previously discussed, these systems are in need of improvement.

Some stakeholders we interviewed noted that monitoring licensee performance is a government-wide challenge. They explained that sometimes licensees do not pay fees if they are not contacted, and a few stakeholders stated that federal labs have limited funding and resources to monitor contracts effectively. One stakeholder recalled one agency that did not communicate with a licensee for 2 years after the license agreement was signed. According to another stakeholder, ineffective monitoring of licensee performance may limit federal labs' ability to determine whether a company is developing federal inventions for commercial use per the terms and conditions of the license agreement.

Some agency and lab officials stated that they have taken steps to regularly monitor licensees. In particular, at NASA and NIH—where monitoring of licensee performance is centralized at the agency level—

¹⁶Department of Energy, Technology Transfer Working Group, *Licensing Guide and Sample License*, (published by Innovation: America's Journal of Technology Commercialization and Technology Ventures Corporation, no date).

¹⁷NASA officials stated that the agency's centralized automated system produces reports on labs' monitoring efforts for the agency to review. NIH officials stated that establishing a centralized office dedicated to monitoring licensee performance has helped them assess whether licensees are developing NIH inventions.

officials have programmed systems to remind staff to check on licensee performance.

Measuring Licensing Outcomes

Federal labs, including those under DOD, DOE, NASA, and NIH, also face challenges in effectively measuring patent licensing outcomes, based on our interviews with stakeholders and analysis of relevant literature. According to one stakeholder, labs need metrics to assess whether a licensee has made progress on developing the invention for commercial use and whether the lab needs to get the license back and give it to another company.

However, some stakeholders we interviewed stated that although the 2011 presidential memorandum on technology transfer called for strategies to establish metrics, federal labs are still struggling to implement metrics for measuring technology transfer outcomes, including patent licensing activities. Stakeholders we interviewed and our analysis of relevant literature have indicated that federal labs in general track the numbers of patents, licenses, and revenues instead of using metrics that identify direct economic impacts from patent licensing and other technology transfer activities. In agencies where such metrics do exist, they may be applied inconsistently across labs. For example, officials at one DOE lab stated that DOE metrics are generally not consistent across the agency's labs.¹⁸

DOD, DOE, NASA, and NIH agency officials stated that they are working to improve their metrics and incorporate metrics beyond tracking numbers of patents, licenses, and revenues. For example, in addition to measuring the numbers of patents and licenses issued, NASA and Air Force officials stated that they are also measuring factors that affect the length of time it takes for their labs to process licenses. Such information, officials said, will help them expedite the licensing process.

¹⁸DOE officials stated that the agency's technology transfer office has a metrics committee that is working to streamline the process of gathering information from its labs to help DOE measure its patent licensing outcomes. Also, DOE's Advanced Research Projects Agency—Energy collects data on the formation of new companies and funding from the private sector in measuring outcomes of inventions reaching the marketplace.

Prioritizing Patent Licensing as an Agency Mission

DOD, DOE, NASA, and NIH face challenges in prioritizing patent licensing as part of their agency missions, which can affect the entire patent licensing process.

For example, DOD and DOE agency and lab officials stated that an agency's mission affects patent licensing activities. DOD officials stated that the agency's primary mission is protecting the warfighter and that patent licensing is a secondary benefit to the agency. According to DOE officials, the nuclear security labs do not focus on patenting but instead on developing technologies associated with a weapons program.

In addition, several stakeholders we interviewed stated that some agencies and labs do not have a culture that prioritizes patent licensing. In particular, one stakeholder stated that at some federal labs, patent licensing is not reflected in performance evaluation management plans, which can help incentivize lab personnel to engage in patent licensing activities. A few stakeholders stated that at some labs where management does not prioritize patent licensing activities, researchers' careers can be negatively affected if they engage in patent licensing activities.

DOD, DOE, NASA, and NIH agency and lab officials cited limited resources to conduct the range of activities related to patent licensing. For example, sometimes there is just one person at a DOD lab overseeing technology transfer activities, according to DOD agency and lab officials. Officials at one NIH lab stated that many labs across the agency do not receive enough royalties to offset their patent licensing costs. In its fiscal year 2015 report—its most recent report—to Congress on federal technology transfer activities, NIST reported that the federal intramural research budget, which include patent licensing activities, has generally not increased in the past 4 fiscal years.¹⁹ Several agency and lab officials stated that budget constraints affect the extent to which they can engage in patent licensing activities—including patent enforcement, which can cost millions of dollars and presents challenges for federal labs, according to DOE officials.

¹⁹The federal intramural research budget includes the budget for intramural programs and the budget for contractor-operated labs.

**Appendix II: Selected Descriptions of
Challenges Federal Labs Face in Patent
Licensing**

Some agency and lab officials stated they have taken steps to overcome such challenges. For example, officials at one Navy lab stated that the lab has management support and nine patent attorneys to assist in the reviews of researchers' invention disclosures. Also, officials at one NIH lab stated that the lab has strong management support and a good royalty stream from successful inventions that pay for patenting and other reinvestments, which allows the lab to not draw from its appropriations.

Appendix III: Patent License Summary for Licenses Effective in Fiscal Year 2014

Tables 1 through 3 and figures 4 through 6 are based on 222 patent licenses that became effective in fiscal year 2014, and associated data, provided by the Department of Defense (specifically the Army, Navy, and Air Force), Department of Energy, National Aeronautics and Space Administration, and National Institutes of Health.¹ They include both data provided by the agencies² and information compiled directly from the licenses.³ The tables and figures are provided for informational purposes and are not generalizable to all patent licenses.

¹The tables and figures in this appendix exclude amendments to patent licenses, joint ownership agreements, assignment agreements, and government use licenses. Although we sought to identify all patents licenses that became effective in fiscal year 2014, we were unable to examine the underlying systems containing the data to confirm that no licenses were missing. From these data, we identified 222 licenses that became effective in fiscal year 2014 and requested signed copies. In some cases, federal laboratories (lab) were unable to provide all of the information requested either because it is not regularly tracked in their systems or was not available for specific licenses. To assess the reliability of the data associated with these licenses, we asked agency and lab officials general questions about the accuracy and completeness of the data and requested that agencies confirm specific information about licenses.

²These include the exclusivity of the license, the date on which the lab received an application for the license, the size of the licensees (i.e., whether they qualified as small businesses or start-ups), and patents issued. We merged the list of issued patents provided by the agencies with data from the PatentsView database to obtain information on the associated World Intellectual Property Organization technology fields.

³Using the signed licenses, we confirmed information, such as the effective date and the type of license, and compiled information about the financial terms. For 132 of these licenses that were commercial (i.e., they allowed for the sale of products incorporating the licensed invention) and for which data on the application date was available, we compared the application date to the date the lab signed the license as a proxy for the length of the process. Some contractor-operated labs do not use a formal application and were thus unable to provide such dates or provide the dates when they received commercialization plans or when terms were first discussed. Seven licenses were excluded based on data quality issues.

**Appendix III: Patent License Summary for
Licenses Effective in Fiscal Year 2014**

Table 1: License Types by Agency, Exclusivity, and Size of Licensee for Licenses Effective in Fiscal Year 2014

License type	Agency				Exclusive ^a		Licensee size ^b				Total
	DOD ^e	DOE	NASA	NIH	Yes	No	Small business	No data ^c	Start-up	No data ^c	
Commercial ^d	33	66	19	32	78	72	107	9	30	55	150
Noncommercial ^d	0	50	13	9	12	60	54	0	4	19	72
Total	33	116	32	41	90	132	161	9	34	74	222

Legend: DOD = Department of Defense; DOE = Department of Energy; NASA = National Aeronautics and Space Administration; NIH = National Institutes of Health.

Source: GAO analysis of DOD, DOE, NASA, and NIH licenses. | GAO-18-327

^aThis category identifies whether licenses are exclusive in full or in part.

^bA small business is defined under 37 C.F.R. 404.3(c). In this case, a start-up is defined as “a new company formed specifically to license and develop the technology being licensed.”

^cFor some licenses, data on licensee size were not tracked or provided by the agency or lab.

^dCommercial licenses give the licensee the right to develop and sell a commercial product incorporating a licensed invention. Noncommercial licenses include research, evaluation, and option licenses, which do not allow for the sale of a commercial product without obtaining another license.

^eDOD licenses include only those identified from data provided by the Army, Navy, and Air Force for their respective labs.

**Appendix III: Patent License Summary for
Licenses Effective in Fiscal Year 2014**

Table 2: Top 10 Technology Fields for Issued and Licensed Patents in Fiscal Year 2014 Licenses at DOD, DOE, NASA, and NIH

Primary WIPO field	Number of issued patents that were licensed^a	Number of licenses associated with those patents
Biotechnology	93	49
Measurement	48	17
Chemical engineering	27	8
Audio-visual technology	27	4
Computer technology	24	15
Materials, metallurgy	21	15
Electrical machinery, apparatus, energy	21	11
Pharmaceuticals	15	15
IT methods for management	14	6
Basic materials chemistry	13	20

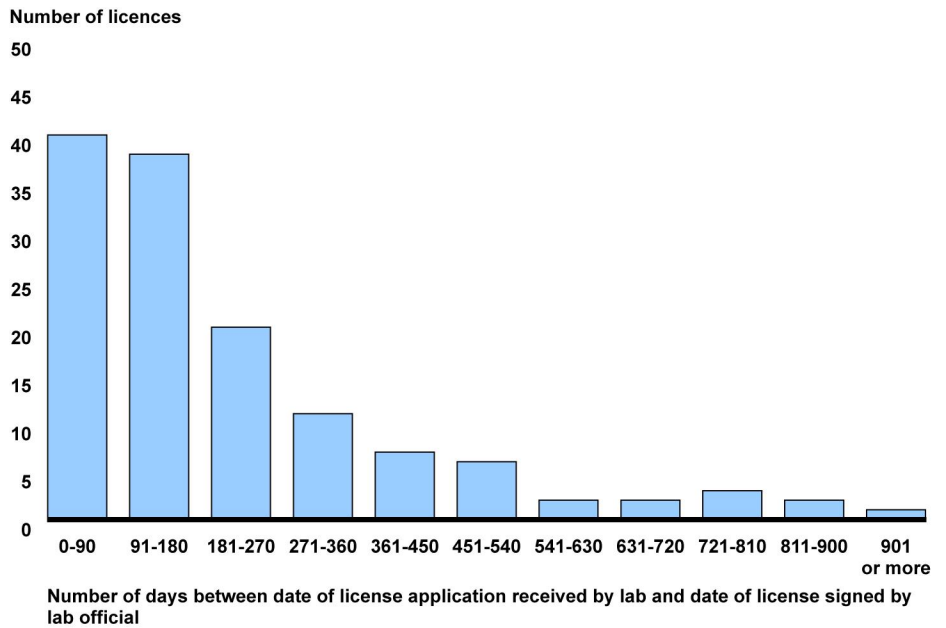
Legend: DOD = Department of Defense; DOE = Department of Energy; IT = information technology; NASA = National Aeronautics and Space Administration; NIH = National Institutes of Health. WIPO=World Intellectual Property Organization.

Source: GAO analysis of DOD, DOE, NASA, and NIH licenses. | GAO-18-327

Note: This includes both commercial and noncommercial licenses with patents in these technology fields. The number of licenses is a count of licenses that include one or more patents in a given technology field; licenses for multiple patents in different primary technology fields are counted as one license in each field.

^aThis includes U.S. patent numbers provided by the agencies as of fiscal year 2017. The totals do not include patent applications or foreign patents that may have been licensed.

Figure 4: Time from License Application Date to Signature of Commercial Patent Licenses Effective in Fiscal Year 2014 at DOD, DOE, NASA, and NIH



Source: GAO analysis of license agreements and application dates provided by Department of Defense (DOD), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), and National Institutes of Health (NIH). | GAO-18-327

Note: In some cases, federal agencies or labs used other dates as proxies for license application dates. For example, one lab provided the date on which the terms of the license were first discussed with the licensee. Another lab provided the date on which the licensee submitted the commercialization plan. Some labs do not track this information; therefore, not all DOD, DOE, NASA, and NIH licenses we reviewed were included in the figure. The figure includes data on 132 of the 150 commercial licenses.

Table 3: Use of Financial Terms in Commercial and Noncommercial Licenses Effective in Fiscal Year 2014 at DOD, DOE, NASA, and NIH

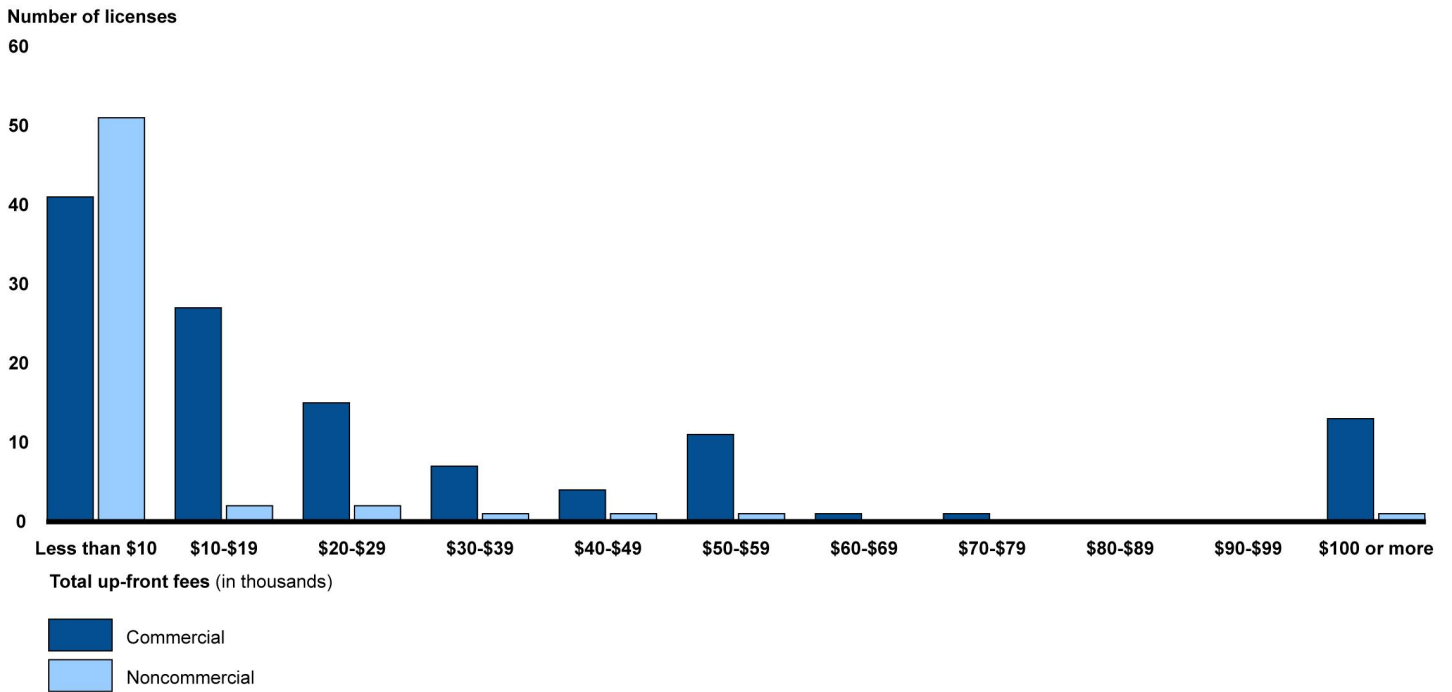
License type	No cost to licensee (percent)	Up-front fees (percent)	Minimum payments (percent)	Milestone payment (percent)	Equity (percent)	Earned royalties (percent)			
						Net sales	Gross sales	Other	Total
Commercial	na	84	84	24	5	68	17	7	89
Noncommercial	18	82	10	na	na	na	na	na	na

Legend: DOD = Department of Defense; DOE = Department of Energy; na = not applicable; NASA = National Aeronautics and Space Administration; NIH = National Institutes of Health.

Source: GAO analysis of DOD, DOE, NASA, and NIH licenses. | GAO-18-327

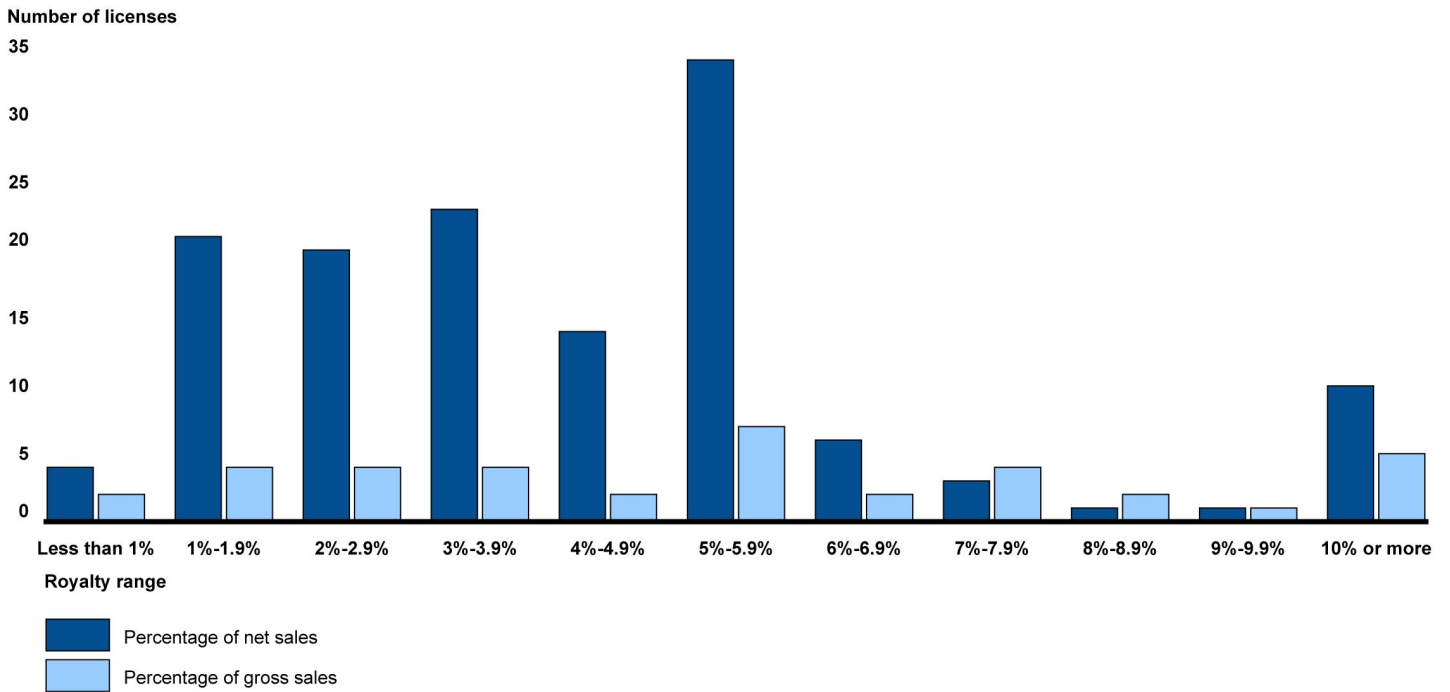
Notes: Percentages of licenses incorporating various financial terms. Data for 6 of the 150 commercial licenses were not available. Milestone payments include any financial terms that depend on a defined event other than (1) the signing of the license, (2) a volume of sales of a product, or (3) a standard reporting period. Minimum payments include any type of recurring dollar payment that must be made in order to maintain the license, such as minimum annual royalties.

Figure 5: Total Up-front Fees in Commercial and Noncommercial Licenses Effective in Fiscal Year 2014 at DOD, DOE, NASA, and NIH



Source: GAO analysis of patent license data and agreements provided by Department of Defense (DOD), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), and National Institutes of Health (NIH). | GAO-18-327

Figure 6: Use of Specific Royalty Rates in Commercial Licenses Effective in Fiscal Year 2014 at DOD, DOE, NIH, and NASA (Royalties Based on a Percentage of Net or Gross Sales)



Source: GAO analysis of patent license data and agreements provided by Department of Defense (DOD), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), and National Institutes of Health (NIH). | GAO-18-327

Appendix IV: Comments from the Department of Commerce



UNITED STATES DEPARTMENT OF COMMERCE
The Secretary of Commerce
Washington, D.C. 20230

May 24, 2018

Mr. John Neumann
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Neumann:

Thank you for the opportunity to review and comment on the Government Accountability Office (GAO)'s draft report titled *Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions* (GAO-18-327).

On behalf of the Department of Commerce, I have enclosed our comments on the draft report.

We concur with the recommendations and will take steps to implement them. If you have any questions, please contact MaryAnn Mausser, Department of Commerce Audit Liaison, at (202) 482-8120.

Sincerely,

A handwritten signature in black ink that reads "Wilbur Ross".

Wilbur Ross

Enclosure

**Department of Commerce's Comments on
GAO Draft Report titled *Federal Research: Additional Actions Needed to Improve Licensing
of Patented Laboratory Inventions*
(GAO-18-327)**

The Department of Commerce has reviewed the draft report, and we offer the following comments for GAO's consideration. Page numbers refer to page numbers in the report unless otherwise stated.

General Comments

Overall, it should be recognized that negotiating licenses is not a formulaic process and requires training and experience similar to any professional skill. Congress specifically directed Federal agencies to give priority to small businesses in the licensing process. Dealing with a small startup and a large multinational corporation are very different processes, for example. The degree of development, potential market, price, profit margin, exit strategy, required development funding, ability to attract investment, manufacturing cost and location, barriers to market entry, and a host of other factors affect the terms offered. Training and communication are very important, as noted in the report, and we support those principles.

Comments on Recommendations

The Government Accountability Office (GAO) made three recommendations to the Department of Commerce in the report.

- **Recommendation 1:** The Secretary of Commerce should instruct NIST to fully report the range of challenges in Federal patent licensing, such as those outlined in this report, by, for example, leveraging its survey of practices at Federal technology transfer offices, past studies conducted by the Federal Laboratory Consortium for Technology Transfer (FLC), and agency reports, and include that information in its summary reports to Congress.

Commerce Response: The Department of Commerce concurs with this recommendation.

NIST will work with the Interagency Workgroup for Technology Transfer to identify and provide further details and greater breadth regarding challenges in licensing in the annual report on Federal technology transfer. NIST will create a specific section to address this recommendation.

- **Recommendation 2:** The Secretary of Commerce should instruct NIST to clarify the link between the establishment of patent license financial terms and the goal of promoting commercial use, through appropriate means, such as the upcoming rulemaking process and updating relevant guidance.

Commerce Response: The Department of Commerce concurs with this recommendation.

As noted, NIST is undertaking a review of all technology transfer processes of the Federal Government as part of the President's Management Agenda Cross Agency Priority Goal. This process includes an extensive comment period that NIST will closely analyze. This recommendation is noted for action by NIST. The final form of the actions to implement this recommendation, whether regulatory, policy, or otherwise, will be addressed in the outcome of the larger review process. As NIST is still in the data collection period, NIST has not yet determined the exact disposition of this matter.

- **Recommendation 3:** The Secretary of Commerce should instruct NIST to facilitate formal information sharing among the agencies to provide Federal labs with information on financial terms in comparable patent licenses, as appropriate.

Commerce Response: The Department of Commerce concurs with this recommendation.

NIST will work with the Interagency Workgroup for Technology Transfer and Federal Laboratory Consortium for Technology Transfer to examine and implement potential solutions. There is a great deal of concern regarding the security of a database with specific financial terms, as these terms are considered proprietary information of the company. Maintaining such a database would require a very high level of security and access control. Additionally, there are issues with information sharing across Government-operated and contractor-operated facilities with regards to business proprietary information from third-party sources. However, a range of potential solutions is possible, including identifying licensing officers in the various agencies with expertise to create a community of practice in various sectors and share best practices and approaches. NIST will also work with the aforementioned parties on any policy or guidance that can be incorporated in the FLC's Desk Reference, other training material, or other sources of information. As noted in response to recommendation 2, the larger review of Federal practices in this area is likely to influence the final form of the response to this recommendation.

Appendix V: Comments from the Department of Defense



RESEARCH
AND ENGINEERING

OFFICE OF THE UNDER SECRETARY OF DEFENSE
3030 DEFENSE PENTAGON
WASHINGTON, DC 20301-3030

MAY 23 2018

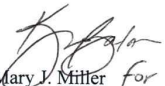
Mr. John Neumann
Director, Natural Resources & Environment
U.S. Government Accountability Office
441 G Street, NW
Washington DC 20548

Dear Mr. Neumann:

This is the Department of Defense (DoD) response to the GAO Draft Report, GAO-18-327, 'FEDERAL RESEARCH: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions,' dated April 23, 2018 (GAO Code 100934).

The Department is providing official written concurrence with the one recommendation directed to DoD, Recommendation 4 without comments.

The primary action officer concerning this matter is Dr. Jagadeesh Pamulapati, whom you may reach at (571) 372-6372 or by email at jagadeesh.pamulapati.civ@mail.mil.


Mary J. Miller for
Performing the Duties of the
Assistant Secretary of Defense
for Research and Engineering



RESEARCH
AND ENGINEERING

OFFICE OF THE UNDER SECRETARY OF DEFENSE

3030 DEFENSE PENTAGON
WASHINGTON, DC 20301-3030

GAO DRAFT REPORT DATED APRIL 23, 2018
GAO-18-327 (GAO CODE 100934)

**“FEDERAL RESEARCH: Additional Actions Needed to Improve Licensing of Patented
Laboratory Inventions”**

**DEPARTMENT OF DEFENSE COMMENTS
TO THE GAO RECOMMENDATION**

RECOMMENDATION 4: The Secretary of Defense should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 4).

DoD RESPONSE: The DoD concurs with the recommendation. Upon issuance of the final GAO Report, DoD will prepare guidance for the Military Departments and appropriate Defense Agencies directing them to have their labs establish documentation of their licensing processes as appropriate.

Appendix VI: Comments from the Department of Energy



Department of Energy
Washington, DC 20585

May 23, 2018

Mr. John Neumann
Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

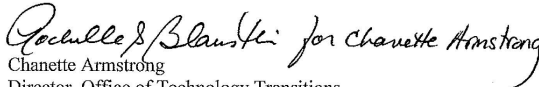
Dear Mr. Neumann:

Thank you for providing a draft copy of the Government Accountability Office (GAO) report, "Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions (GAO-18-327)." We have reviewed the draft report and provide the following comments below.

The Department intends to coordinate with the national labs to develop and document common practices in an attempt to make consistent some of the approaches to negotiating patent license financial terms. Although specific processes for establishing financial terms cannot be prescribed from the Department level, we will work with the labs to document minimum processes in order to mitigate some inconsistencies and ease inefficiencies across the national labs.

If you have any questions, please contact me, or Clara Asmail, clara.asmail@hq.doe.gov, 202-586-5471.

Sincerely,


Chayette Armstrong
Director, Office of Technology Transitions

Enclosure



Response to Report Recommendations

Recommendation: The Secretary of Energy should ensure that the agency or its labs document processes for establishing financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 5)

Management Response: Concur

Negotiating terms for patent licensing is influenced by variety of different factors related to the condition of the technology and intended market as well as specific attributes of the parties. There are many complex and nuanced considerations that the professional licensing negotiator must always consider, including the: “readiness” of the technology and degree to which additional R&D or marketing investments may be needed; risk involved in those investments compared to incumbent and competing solutions; size of the market and its elasticity to adopting new technologies; license exclusivity, or non-exclusivity, and field of use; availability of inventor for continued co-development; and resources at the potential licensee to include financial, business, technical and marketing strengths. Especially for licensing negotiators of technologies developed at federal labs these factors are weighed against urgencies and alternate pathways to move the technology toward practical application. Because of the many and nuanced dimensions that impact license negotiations, it would be impractical to develop a prescriptive approach to establish patent license financial terms.

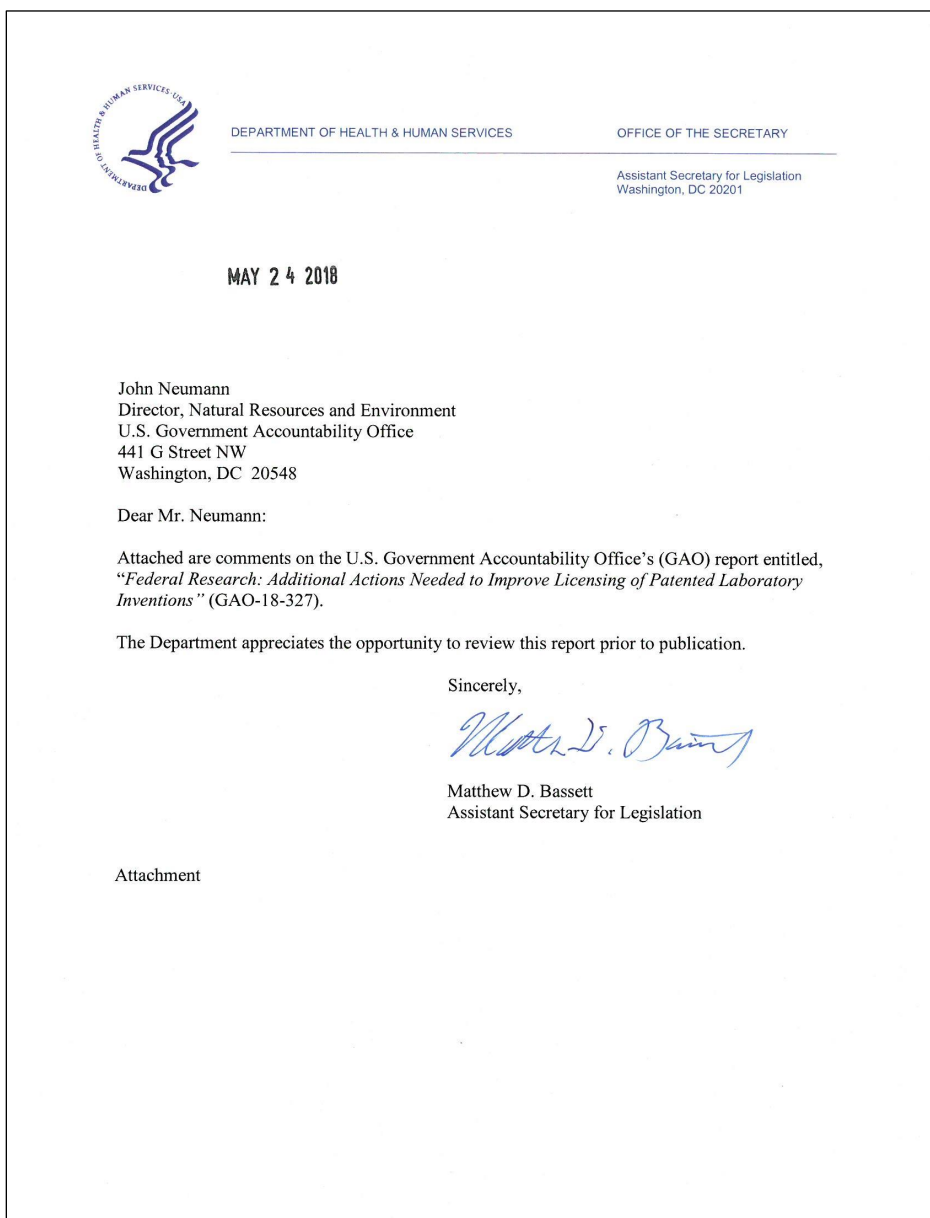
Several statutes including Bayh-Dole Act, the Stevenson-Wydler Act, the Federal Technology Transfer Act, and the National Competitiveness Technology Transfer Act of 1989 (NCTTA), authorize the contractor-operated DOE laboratories to retain title to inventions created using federal funding, pursue patent protection, and license those inventions to third parties. While DOE establishes certain requirements for its lab contractors related to licensing DOE technologies, those requirements relate to non-financial considerations such as U.S. Competitiveness and successor contractor issues.¹ The financial portions of license agreements for national laboratory technologies are between the lab contractor and the licensing entity (licensee).

Nevertheless, the Department of Energy agrees that some standardization of practices by documenting minimum processes can mitigate some inconsistencies and ease efficiencies across the national labs. The DOE intends to encourage the labs that when practical with regard to time and funding resources, to make use of market analyses and benchmarking tools and services that are commercially available. DOE will coordinate with the labs to collect documentation and develop guidance that can guide the labs as they negotiate patent licenses especially for effective information gathering and basic guidelines for establishing and leveraging communities of practice. The documentation of internal best practices to be developed will complement the Licensing Guide and Sample License which was developed by DOE labs responsible for licensing patents and intended to raise awareness among potential licensees about general DOE patent license terms to be expected.

The estimated completion date for this activity is July 30, 2019.

¹ See 48 C.F.R. §970.5227-3.

Appendix VII: Comments from the Department of Health and Human Services



GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - FEDERAL RESEARCH: ADDITIONAL ACTIONS NEEDED TO IMPROVE LICENSING OF PATENTED LABORATORY INVENTIONS (GAO-18-327)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

GAO Recommendation 7:

The Director of the National Institutes of Health (NIH) should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license.

HHS Response:

HHS concurs with GAO's recommendation.

The report notes four potential aspects of the process for establishing financial terms:

1. Factors to consider
2. Sources of information
3. Methods for developing financial terms
4. Use of specific types of financial terms

NIH will develop materials to include all four aspects of the process and provide materials for technology transfer staff by October 1, 2018. NIH will share its materials with the Interagency Working Group for Technology Transfer.

The financial terms of licenses typically include upfront fees, minimum annual payments, running royalties as a percentage of sales, milestone payments, a percentage of sublicensing revenue, and a percentage of the cash value of an acquisition of a small company or a unit focusing primarily on the licensed technology.

NIH already conducts one-on-one and group training for licensing specialists. NIH will develop and post for internal use more detailed information than what is covered in training sessions. The materials will include the requirements for a licensee to provide detailed commercialization plans/development timelines with their license application and descriptions of the use of the types of royalties that are negotiated. The materials will provide an explanation of how these aspects of licensing focus licensees' efforts toward translating an invention into a product to support public health needs.

Training materials will also convey complexity and nuance of negotiating terms for commercial patent licenses. The terms are based on variables such as the type of technology; the development stage of the technology (usually very early); the breadth of the patent claims and its status (pending or issued, United States and foreign); the market size and risk involved in developing the product; potential degrees of exclusivity and fields of use of the technology; the size of the company and its needs; and the availability of the government's inventor to assist with questions and testing. A company may agree to take on greater responsibility to address higher-risk or less lucrative markets to benefit the public but may ask for lower royalty rates in return. Ultimately, negotiations between NIH and the company include these aspects.

Appendix VIII: Comments from the National Aeronautics and Space Administration

National Aeronautics and Space Administration
Office of the Administrator
Washington, DC 20546-0001



May 24, 2018

Mr. John Neumann
Director
Natural Resources and Environment
United States Government Accountability Office
Washington, DC 20548

Dear Mr. Neumann:

The National Aeronautics and Space Administration (NASA) appreciates the opportunity to review and comment on the Government Accountability Office (GAO) draft report entitled, "Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions" (GAO-18-32) dated April 23, 2018.

In the draft report, GAO makes one recommendation to the NASA Administrator intended to improve license financial terms for its labs while maintaining flexibility to tailor the financial terms of each license.

Specifically, GAO recommends the following:

Recommendation 1: The Administrator of NASA should ensure that the Agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the financial terms of each license.

Management's Response: Partially concur. Setting financial terms for commercial patent licenses is complicated and nuanced. Just as each technology, application, and market is different, so are the financial terms of each license. Relevant factors include the development stage of the technology; potential degrees of exclusivity; whether the Government has an inventor available to assist with questions and testing; the field of use; the length of time it will take to bring the product to market; resources available for market analysis; the skill and experience of the licensing agent; and many other considerations. Further complicating this process, setting financial terms of licenses is usually an iterative process between the Government and potential licensees. It is a negotiation.

It is, therefore, not surprising that none of the agencies examined under this audit have documented established guidelines for establishing financial terms of patent licenses. Nonetheless, NASA has, as the audit report notes, published considerations and parameters as well as stated intentionality in setting terms.

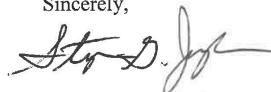
While the parameters we consider for financial terms are established, the methods and processes for gathering this information vary depending on available resources. Nevertheless, while it may not be possible to predict available resources or clearly predict the financial terms of licenses without knowing the parameters of each deal, NASA agrees that it can make efforts to standardize, document, and communicate the minimum process by which it sets financial terms of patent licenses.

We are convening the NASA licensing managers this summer for a meeting, and we will use that time to discuss standardization of documentation of processes. The goal will be to produce two documents, one an internal set of instructions for setting financial terms and the other a public-facing set of guidelines for how NASA sets terms.

Estimated Completion Date: NASA will have draft guidelines for setting financial terms of patent licenses completed by June 15, 2018. This draft will be shared with Headquarters and Field Centers' technology transfer management and the NASA Office of General Counsel. A final version of each will be completed by August 15, 2018, at which time the internal standards will be shared internally with all Field Centers' technology transfer staff. NASA will post the external-facing document on its technology licensing Web site by September 30, 2018. NASA will also share its final products with the Interagency Working Group for Technology Transfer by October 31, 2018.

Once again, thank you for the opportunity to review and comment on the subject draft report. If you have any questions or require additional information, please contact Daniel Lockney (Program Executive for Technology Transfer) on (202) 358-2037, or G. Michael Green (Space Technology Mission Directorate Chief of Staff) on (202) 358-4710.

Sincerely,



Stephen G. Jurczyk
Associate Administrator (Acting)

Appendix IX: GAO Contact and Staff Acknowledgments

GAO Contact

John Neumann, (202) 512-3841 or neumannj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Robert J. Marek (Assistant Director), James D. Ashley, Kevin S. Bray, Virginia A. Chanley, Ellen L. Fried, Sarah C. Gilliland, Cheryl M. Harris, Robert Letzler, Gregory A. Marchand, Christopher P. Murray, Emmy L. Rhine Paule, Dan C. Royer, Ardith A. Spence, Vasiliki Theodoropoulos, and Reed Van Beveren made key contributions to this report.

Appendix X: Accessible Data

Data Tables

Data Table for Figure 1: Federal Research and Development Spending by Agency, Average for Fiscal Years 2015 to 2017 (Dollars in Billions)

- Department of Defense: \$66.4 (48%)
- National Institutes of Health: \$30.2 (22%)
- Department of Energy: \$12.3 (9%)
- National Aeronautics and Space Administration: \$12.2 (9%)
- Other: \$16.0 (12%)

Data Table for Figure 4: Time from License Application Date to Signature of Commercial Patent Licenses Effective in Fiscal Year 2014 at DOD, DOE, NASA, and NIH

Intervals	Frequency
0-90	40
91-180	38
181-270	20
271-360	11
361-450	7
451-540	6
541-630	2
631-720	2
721-810	3
811-900	2
More than 900	1

Data Table for Figure 5: Total Up-front Fees in Commercial and Noncommercial Licenses Effective in Fiscal Year 2014 at DOD, DOE, NASA, and NIH

Total upfront fees	Commercial	Non-commercial
Less than \$10,000	41	51
\$10,000-\$19,000	27	2
\$20,000-\$29,000	15	2
\$30,000-\$39,000	7	1
\$40,000-\$49,000	4	1

Total upfront fees	Commercial	Non-commercial
\$50,000-\$59,000	11	1
\$60,000-\$69,000	1	0
\$70,000-\$79,000	1	0
\$80,000-\$89,000	0	0
\$90,000-\$99,000	0	0
\$100,000 or more	13	1

Data Table for Figure 6: Use of Specific Royalty Rates in Commercial Licenses Effective in Fiscal Year 2014 at DOD, DOE, NIH, and NASA (Royalties Based on a Percentage of Net or Gross Sales)

Royalty range	Percentage of net sales	Percentage of gross sales
Less than 1%	4	2
1%-1.9%	21	4
2%-2.9%	20	4
3%-3.9%	23	4
4%-4.9%	14	2
5%-5.9%	34	7
6%-6.9%	6	2
7%-7.9%	3	4
8%-8.9%	1	2
9%-9.9%	1	1
10% or more	10	5

Agency Comment Letters

Text of Appendix IV: Comments from the Department of Commerce

Page 1

May 24, 2018

Mr. John Neumann

Director, Natural Resources and Environment

U.S. Government Accountability Office 441 G Street, NW

Washington, DC 20548

Dear Mr. Neumann:

Thank you for the opportunity to review and comment on the Government Accountability Office (GAO)' s draft report titled Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions(GAO-18-327).

On behalf of the Department of Commerce, I have enclosed our comments on the draft report.

We concur with the recommendations and will take steps to implement them. If you have any questions, please contact MaryAnn Mausser, Department of Commerce Audit Liaison,

at (202) 482-8120.

Wilbur Ross

Enclosure

Page 2

Department of Commerce's Comments on

GAO Draft Report titled Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions

(GAO-18-327)

The Department of Commerce has reviewed the draft report, and we offer the following comments for GAO' s consideration. Page numbers refer to page numbers in the report unless otherwise stated.

General Comments

Overall, it should be recognized that negotiating licenses is not a formulaic process and requires training and experience similar to any professional skill. Congress specifically directed Federal agencies to give priority to small businesses in the licensing process. Dealing with a small startup and a large multinational corporation are very different processes, for example. The degree of development , potential market, price, profit

margin, exit strategy, required development funding, ability to attract investment, manufacturing cost and location, barriers to market entry, and a host of other factors affect the terms offered. Training and communication are very important, as noted in the report, and we support those principles.

Comments on Recommendations

The Government Accountability Office (GAO) made three recommendations to the Department of Commerce in the report.

Recommendation 1:

The Secretary of Commerce should instruct NIST to fully report the range of challenges in Federal patent licensing, such as those outlined in this report, by, for example, leveraging its survey of practices at Federal technology transfer offices, past studies conducted by the Federal Laboratory Consortium for Technology Transfer (FLC), and agency reports, and include that information in its summary reports to Congress.

Commerce Response: The Department of Commerce concurs with this recommendation.

NIST will work with the Interagency Workgroup for Technology Transfer to identify and provide further details and greater breadth regarding challenges in licensing in the annual report on Federal technology transfer. NIST will create a specific section to address this recommendation.

Recommendation 2:

The Secretary of Commerce should instruct NIST to clarify the link between the establishment of patent license financial terms and the goal of promoting commercial use, through appropriate means, such as the upcoming rulemaking process and updating relevant guidance.

Commerce Response: The Department of Commerce concurs with this recommendation.

Page 3

As noted, NIST is undertaking a review of all technology transfer processes of the Federal Government as part of the President's

Management Agenda Cross Agency Priority Goal. This process includes an extensive comment period that NIST will closely

analyze. This recommendation is noted for action by NIST. The final form of the actions to implement this recommendation, whether regulatory, policy, or otherwise, will be addressed in the outcome of the larger review process. As NIST is still in the data collection period, NIST has not yet determined the exact disposition of this matter.

Recommendation 3:

The Secretary of Commerce should instruct NIST to facilitate formal information sharing among the agencies to provide Federal labs with information on financial terms in comparable patent licenses, as appropriate.

Commerce Response: The Department of Commerce concurs with this recommendation.

NIST will work with the Interagency Workgroup for Technology Transfer and Federal Laboratory Consortium for Technology Transfer to examine and implement potential solutions. There is a great deal of concern regarding the security of a database with specific financial terms, as these terms are considered proprietary information of the company. Maintaining such a database would require a very high level of security and access control. Additionally, there are issues with information sharing across Government- operated and contractor-operated facilities with regards to business proprietary information from third-party sources. However, a range of potential solutions is possible, including identifying licensing officers in the various agencies with expertise to create a community of practice in various sectors and share best practices and approaches. NIST will also work with the aforementioned parties on any policy or guidance that can be incorporated in the FLC's Desk Reference, other training material, or other sources of information. As noted in response to recommendation 2, the larger review of Federal practices in this area is likely to influence the final form of the response to this recommendation.

Text of Appendix V: Comments from the Department of Defense

Page 1

Mr. John Neumann

Director, Natural Resources & Environment

U.S. Government Accountability Office 441 G Street, NW

Washington DC 20548

Dear Mr. Neumann:

This is the Department of Defense (DoD) response to the GAO Draft Report, GAO-18-327, 'FEDERAL RESEARCH: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions,' dated April 23, 2018 (GAO Code 100934).

The Department is providing official written concurrence with the one recommendation directed to DoD, Recommendation 4 without comments.

The primary action officer concerning this matter is Dr. Jagadeesh Pamulapati, whom you may reach at (571) 372-6372 or by email at ja gadeesh.pam ulapati.civ@mail.mil.

Mary J. Miller

Performing the Duties of the Assistant Secretary of Defense for Research and Engineering

Page 2

GAO DRAFT REPORT DATED APRIL 23, 2018

GAO-18-327 (GAO CODE 100934)

“FEDERAL RESEARCH: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions”

DEPARTMENT OF DEFENSE COMMENTS

TO THE GAO RECOMMENDATION

RECOMMENDATION 4:

The Secretary of Defense should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 4).

DoD RESPONSE: The DoD concurs with the recommendation.

Upon issuance of the final GAO Report, DoD will prepare guidance for the Military Departments and appropriate Defense Agencies directing them to have their labs establish documentation of their licensing processes as appropriate.

Text of Appendix VI: Comments from the Department of Energy

Page 1

May 23, 2018

Mr. John Neumann Director

Natural Resources and Environment

U.S. Government Accountability Office 441 G Street, N.W.

Washington, D.C. 20548

Dear Mr. Neumann:

Thank you for providing a draft copy of the Government Accountability Office (GAO) report, "Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions (GAO-18-327)." We have reviewed the draft report and provide the following comments below.

The Department intends to coordinate with the national labs to develop and document common practices in an attempt to make consistent some

of the approaches to negotiating patent license financial terms. Although specific processes for establishing financial terms cannot be prescribed from the Department level, we will work with the labs to document minimum processes in order to mitigate some inconsistencies and ease inefficiencies across the national labs.

If you have any questions, please contact me, or Clara Asmail, clara.asmail@hq.doe.gov, 202- 586-5471.

Sincerely,

Chanette Armstron

Director, Office of Technology Transitions

Enclosure

Page 2

Response to Report Recommendations

Recommendation: The Secretary of Energy should ensure that the agency or its labs document processes for establishing financial terms, while maintaining flexibility to tailor the specific financial terms of each license. (Recommendation 5)

Management Response: Concur

Negotiating terms for patent licensing is influenced by variety of different factors related to the condition of the technology and intended market as well as specific attributes of the parties.

There are many complex and nuanced considerations that the professional licensing negotiator must always consider, including the: "readiness" of the technology and degree to which additional R&D or marketing investments may be needed; risk involved in those investments compared to incumbent and competing solutions; size of the market and its elasticity to adopting new technologies; license exclusivity, or non-exclusivity, and field of use; availability of inventor for continued co-development; and resources at the potential licensee to include financial, business, technical and marketing strengths. Especially for licensing negotiators of technologies developed at federal labs these factors are weighed against urgencies and alternate pathways to move the

technology toward practical application. Because of the many and nuanced dimensions that impact license negotiations, it would be impractical to develop a prescriptive approach to establish patent license financial terms.

Several statutes including Bayh-Dole Act, the Stevenson-Wydler Act, the Federal Technology Transfer Act, and the National Competitiveness Technology Transfer Act of 1989 (NCTTA), authorize the contractor-operated DOE laboratories to retain title to inventions created using federal funding, pursue patent protection, and license those inventions to third parties. While DOE establishes certain requirements for its lab contractors related to licensing DOE technologies, those requirements relate to non-financial considerations such as U.S. Competitiveness and successor contractor issues.¹ The financial portions of license agreements for national laboratory technologies are between the lab contractor and the licensing entity (licensee).

Nevertheless, the Department of Energy agrees that some standardization of practices by documenting minimum processes can mitigate some inconsistencies and ease efficiencies across the national labs. The DOE intends to encourage the labs that when practical with regard to time and funding resources, to make use of market analyses and benchmarking tools and services that are commercially available. DOE will coordinate with the labs to collect documentation and develop guidance that can guide the labs as they negotiate patent licenses especially for effective information gathering and basic guidelines for establishing and leveraging communities of practice. The documentation of internal best practices to be developed will complement the Licensing Guide and Sample License which was developed by DOE labs responsible for licensing patents and intended to raise awareness among potential licensees about general DOE patent license terms to be expected.

The estimated completion date for this activity is July 30, 2019.

¹ See 48 C.F.R. §970.5227-3.

Text of Appendix VII: Comments from the Department of Health and Human Services

Page 1

John Neumann

Director, Natural Resources and Environment

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548 Dear Mr. Neumann:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions" (GAO-18-327).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Matthew D. Bassett

Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - FEDERAL RESEARCH: ADDITIONAL ACTIONS NEEDED TO IMPROVE LICENSING OF PATENTED LABORATORY INVENTIONS (GAO-18- 327)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

GAO Recommendation 7:

The Director of the National Institutes of Health (NIH) should ensure that the agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the specific financial terms of each license.

HHS Response: HHS concurs with GAO's recommendation.

The report notes four potential aspects of the process for establishing financial terms:

1. Factors to consider
2. Sources of information
3. Methods for developing financial terms
4. Use of specific types of financial terms

NIH will develop materials to include all four aspects of the process and provide materials for technology transfer staff by October 1, 2018. NIH will share its materials with the Interagency Working Group for Technology Transfer.

The financial terms of licenses typically include upfront fees, minimum annual payments, running royalties as a percentage of sales, milestone payments, a percentage of sublicensing revenue, and a percentage of the cash value of an acquisition of a small company or a unit focusing primarily on the licensed technology.

NIH already conducts one-on-one and group training for licensing specialists. NIH will develop and post for internal use more detailed information than what is covered in training sessions.

The materials will include the requirements for a licensee to provide detailed commercialization plans/development timelines with their license application and descriptions of the use of the types of royalties that are negotiated. The materials will provide an explanation of how these aspects of licensing focus licensees' efforts toward translating an invention into a product to support public health needs.

Training materials will also convey complexity and nuance of negotiating terms for commercial patent licenses. The terms are based on variables such as the type of technology; the development stage of the technology (usually very early); the breadth of the patent claims and its status (pending or issued, United States and foreign); the market size and risk involved in developing the product; potential degrees of exclusivity and fields of use of the technology; the size of the company and its needs; and the availability of the government's inventor to assist with questions and testing. A company may agree to take on greater responsibility to address higher- risk or less lucrative markets to benefit the public but may ask for lower royalty rates in return.

Ultimately, negotiations between NIH and the company include these aspects.

Text of Appendix VIII: Comments from the National Aeronautics and Space Administration

Page 1

May 24, 2018

Mr. John Neumann Director

Natural Resources and Environment

United States Government Accountability Office Washington, DC 20548

Dear Mr. Neumann:

The National Aeronautics and Space Administration (NASA) appreciates the opportunity to review and comment on the Government Accountability Office (GAO) draft report entitled, "Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions" (GAO-18-32) dated April 23, 2018.

In the draft report, GAO makes one recommendation to the NASA Administrator intended to improve license financial terms for its labs while maintaining flexibility to tailor the financial terms of each license.

Specifically, GAO recommends the following:

Recommendation 1: The Administrator of NASA should ensure that the Agency or its labs document processes for establishing license financial terms, while maintaining flexibility to tailor the financial terms of each license.

Management's Response: Partially concur.

Setting financial terms for commercial patent licenses is complicated and nuanced. Just as each technology, application, and market is different, so are the financial terms of each license.

Relevant factors include the development stage of the technology; potential degrees of exclusivity; whether the Government has an inventor available to assist with questions and testing; the field of use; the length of time it will take to bring the product to market; resources available for market analysis; the skill and experience of the licensing agent; and many other considerations. Further complicating this process, setting financial terms of licenses is usually an iterative process between the Government and potential licensees. It is a negotiation.

It is, therefore, not surprising that none of the agencies examined under this audit have documented established guidelines for establishing financial terms of patent licenses. Nonetheless, NASA has, as the audit report notes, published considerations and parameters as well as stated intentionality in setting terms.

Page 2

While the parameters we consider for financial terms are established, the methods and processes for gathering this information vary depending on available resources. Nevertheless, while it may not be possible to predict available resources or clearly predict the financial terms of licenses without knowing the parameters of each deal, NASA agrees that it can make efforts to standardize, document, and communicate the minimum process by which it sets financial terms of patent licenses.

We are convening the NASA licensing managers this summer for a meeting, and we will use that time to discuss standardization of documentation of processes.

The goal will be to produce two documents, one an internal set of instructions for setting financial terms and the other a public-facing set of guidelines for how NASA sets terms.

Estimated Completion Date: NASA will have draft guidelines for setting financial terms of patent licenses completed by June 15, 2018. This draft will be shared with Headquarters and Field Centers' technology transfer management and the NASA Office of General Counsel. A final version of each will be completed by August 15, 2018, at which time the internal standards will be shared internally with all Field Centers' technology transfer staff. NASA will post the external-facing document on its technology licensing Web site by September 30, 2018.

NASA will also share its final products with the Interagency Working Group for Technology Transfer by October 31, 2018.

Once again, thank you for the opportunity to review and comment on the subject draft report. If you have any questions or require additional information, please contact Daniel Lockney (Program Executive for Technology Transfer) on (202) 358-2037, or G.

Michael Green (Space Technology Mission Directorate Chief of Staff) on (202) 358-4710.

Sincerely,

Stephen G. Jurczyk

Associate Administrator (Acting)

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