FLC

Federal Laboratory Consortium
for Technology Transfer

# Technology Transfer **Desk Reference**

## A COMPREHENSIVE GUIDE TO TECHNOLOGY TRANSFER

federallabs.org


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for Technology Transfer

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# **Desk Reference**

## A COMPREHENSIVE GUIDE TO TECHNOLOGY TRANSFER

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*Prepared by the*
Federal Laboratory Consortium for
Technology Transfer
www.federallabs.org

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**SECTION FOUR**
INTELLECTUAL PROPERTY

# GLOSSARY

| | |
|---|---|
| **AAU** | Association of American Universities |
| **AIA** | America Invents Act |
| **AURP** | Association of University Research Parks |
| **AUTM** | Association of University Technology Managers |
| **CFR** | Code of Federal Regulations |
| **CRADA** | Cooperative Research and Development Agreement |
| **CSG** | Council of State Governments |
| **EPC** | European Patent Convention |
| **FAR** | Federal Acquisition Regulation |
| **FFRDC** | Federally Funded Research and Development Centers |
| **FLC** | Federal Laboratory Consortium |
| **FOIA** | Freedom of Information Act |
| **FTE** | Full-Time Employee |
| **FY** | Fiscal Year |
| **GOCO** | Government Owned, Contractor Operated |
| **GOGO** | Government Owned, Government Operated |
| **IAA** | Inter-Agency Agreement |
| **IIA** | Inter-Institutional Agreement |
| **IP** | Intellectual Property |
| **L2M** | Lab To Market |
| **LESI** | Licensing Executives Society International |
| **MEP** | Manufacturing Extension Partnership |
| **MOA** | Memorandum of Agreement |
| **MOU** | Memorandum of Understanding |
| **NGA** | National Governors Association |
| **NIST** | National Institute of Standards and Technology |
| **NSTC** | National Science and Technology Council |

| | |
|---|---|
| **NTIS** | National Technical Information Service |
| **OTA** | Office Other Transaction Agreement/Authority |
| **ORD** | Office of Research and Development |
| **ORTA** | Office of Research and Technology Applications |
| **PCT** | Patent Cooperation Treaty |
| **PIA** | Partnership Intermediary Agreement |
| **PTAC** | Procurement Technical Assistance Center |
| **R&D** | Research and Development |
| **RD&D** | Research and Technology Development and Deployment Subcommittee |
| **RFP** | Request for Proposal |
| **S&E MEP** | Scientist and Engineer Manufacturing Extension Partnership |
| **SBA** | U.S. Small Business Administration |
| **SBDC** | Small Business Development Center |
| **SBIR** | Small Business Innovation Research |
| **SOW** | Statement of Work |
| **SSTI** | State Science and Technology Institute |
| **STEM** | Science, Technology, Engineering, and Math |
| **STTR** | Small Business Technology Transfer (Program) |
| **T2** | Technology Transfer |
| **TRL** | Technology Readiness Level |
| **TTO** | Technology Transfer Office |
| **USC** | United States Code |
| **USP** | Unsolicited Proposal |
| **USPTO** | United States Patent and Trademark Office |

Section One

# INTRODUCTION

## 1.1 Overview

The federal government annually spends billions of dollars on the research and development (R&D) activities performed by federal laboratories. Through the federal technology transfer (T2) process, federal laboratories share the benefits of this national investment in R&D with all segments of society.

The FLC is a formally chartered, nationwide network of over 300 federal laboratories, agencies, and research centers that foster commercialization best-practice strategies and opportunities for accelerating federal technology development from the labs into the marketplace.

The FLC Technology Transfer Desk Reference presents a comprehensive introduction to the federal technology transfer process; the technology transfer initiatives, procedures, and mechanisms that are used to implement technology transfer; and legislation and related executive orders. Although the technology transfer initiatives and mechanisms described in the Desk Reference are promoted and supported by much of the federal government, the specific activities and procedures of each organization may vary, and the material presented here may need to be adapted for a particular laboratory or agency depending on their corresponding agency or organization's policies and procedures.

The primary goal of the Desk Reference is to help technology transfer practitioners become effective facilitators of technology transfer by explaining what technology transfer is and why it is necessary, relating the processes and mechanisms that make it happen, and describing issues and procedures useful in identifying and transferring technologies from the government sector to the private sector. To this end, the Desk Reference provides a thorough overview of the basic elements of technology transfer. It also provides the background, concepts, and practical knowledge required to assist Office of Research and Technology Applications (ORTA) personnel and other technology transfer practitioners, including management and laboratory researchers—whether in government or in industry—to facilitate the transfer of federally funded technologies from the laboratory to the marketplace.

The FLC Technology Transfer Desk Reference comprises the following interrelated sections:

- **Section One: Introduction**—Provides an overview of technology transfer, federal technology transfer policy, and the benefits of technology transfer for all participants.
- **Section Two: The Office of Research and Technology Applications (ORTA)—The Technology Transfer Office—**Examines the role and responsibilities of the ORTA, the organization tasked by technology transfer legislation with facilitating technology transfer at the laboratory level.

- **Section Three: The Technology Transfer Process: Collaboration and Commercialization**—Provides a model for a typical technology transfer process.
- **Section Four: Intellectual Property**—Focuses on the importance of intellectual property to technology transfer, protecting intellectual property, patenting and licensing an invention, and royalties.
- **Section Five: Organizations Supporting Technology Transfer**—Provides information about the federal and nonfederal organizations that support technology transfer and how to use their resources.
- **Section Six: Marketing and Communications Outreach**—Examines how to market federal technology, providing practical information in areas such as establishing a technology transfer marketing plan, demonstrating the value of technology, marketing technology, and negotiating with a potential partner.

Also included are appendices that provide an overview of technology transfer legislation and related executive orders (Appendix A) and major legislative themes in federal technology transfer (Appendix B).

## 1.2 Technology Transfer Background

### 1.2.1 Federal Technology Transfer Defined

There are many definitions of technology transfer. For this Desk Reference, the phrase "federal technology transfer" refers typically to transfers between federal laboratories and any nonfederal organization, including private industry, nonprofit organizations, academia, and state and local governments as mandated by a series of federal laws, regulations, and executive orders dating back to 1980 (see Appendix A). In addition, to encompass the original intent of Congress to make full use of the results of the R&D investment of federal facilities in the nation's economy, as well as to recognize that technology transfer activities vary by agency and may not necessarily include transfer of a physical technology or invention, the Federal Laboratory Consortium for Technology Transfer (FLC) developed the following definition for federal technology transfer:

Technology transfer is the process by which existing knowledge, facilities, or capabilities developed under federal research and development funding are utilized to fulfill public and private needs.

Technology transfer can also occur between federal agencies, although the primary emphasis is on transfers to all types of nonfederal organizations. Technology transfer mechanisms can also be used by a federal laboratory to bring in outside materials, technologies, or knowledge that can assist the laboratory with achieving its goals. This might, in fact, be a lower-cost alternative to developing a technology or expertise entirely within the laboratory.

### 1.2.2 Congressional Policy and Goals for Federal Technology Transfer

In 1980, Congress began enacting legislation aimed at ensuring that the country benefited to the maximum extent possible from national investment in R&D, legislating that:

"It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development. To this end the Federal Government shall strive where appropriate to transfer federally owned or originated technology to state and local governments and to the private sector" (15 USC 3710[a][1]).

As Congress further noted: "Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional" (15 USC 3710[a][2]). Thus, the express purpose of the congressional mandate to implement the transfer of technology developed in federal laboratories to the private sector is to use that technology to develop better and more useful products for the marketplace that will benefit the nation and the economy.[1]

With this initial legislation and policy, as revised and amended over the years, Congress began providing the means and mechanisms by which the nation would gain the full benefit of this annual R&D expenditure. Consistent with this policy, the overarching goals of federal technology transfer programs are to make the most of the expertise of both government and nongovernment scientists and engineers, increase the return on investment of the federal R&D budget, and help federal agencies meet mission requirements, while enhancing U.S. competitiveness in the world economy and U.S. security.

### 1.2.3 Agency Variations Affecting Federal Technology Transfer

While the policies, goals, and definition of federal technology transfer are clear, variations among federal agencies on several important criteria can affect technology transfer programs and must be considered for both implementation and assessment. These variations may drive the operation of the federal laboratory technology transfer office, the mechanisms used or emphasized by each agency and lab, how intellectual property rights are applied, how technologies are marketed, and how to best assess performance.

The different models for managing and operating federal labs provide one example of agency variations reflected in technology transfer programs. Federal labs are typically managed under two general models: the government-owned, government-operated (GOGO) model and the government-owned, contractor-operated (GOCO) model. GOGO laboratories are usually owned or leased by the federal government and staffed by federal employees who are supported by nonfederal contract employees. GOCO laboratories are institutions where the facilities and

1 The legislation mandating and implementing technology transfer is codified in the U.S. Code (see 15 USC 3710); a summary of the legislation and executive orders relevant to federal technology transfer is provided in Appendix A, "Highlights of Technology Transfer Legislation and Relevant Executive Orders." The primary resource for a comprehensive presentation of principal statutory and executive order policies constituting the framework of the federal technology transfer program is provided in *Federal Technology Transfer Legislation and Policy: The Green Book,* 6th edition, 2018, published by the FLC.

equipment are owned by the federal government, but the staff is employed by a private or public contractor that operates the laboratory under a contract with the federal government. The GOCO contractors are usually a conglomerate including for-profit and/or nonprofit companies and at least one university that is located near the GOCO lab. The type of laboratory management can affect various aspects of the technology transfer mission at the lab, including intellectual property protection (see Section Four, "Intellectual Property").

Each agency may also have a variety of authorizations for using available transfer mechanisms. While all agencies are subject to overarching legislation, each agency may also have unique statutory authorizations for actions specific to its labs. The Federal Technology Transfer Mechanisms Database, which is available on the FLC website,[2] identify and describe a wide variety of mechanisms. Click on "Search" for the agencies that use the mechanisms and links to their websites, where information about each agency's use of the mechanisms and samples of the mechanisms can be found.

## 1.3 The Benefits of Involvement in Technology Transfer

Federal technology transfer benefits all of society by making the results of federal research available to meet societal needs, leveraging taxpayer investment in federal research capabilities to the benefit of the nation. Selected benefits of federal technology transfer to participant groups are highlighted below.

### 1.3.1 Benefits to the Government

The government derives benefits from technology moving out of the laboratories, as well as technical expertise coming into the laboratories, to ultimately achieve a federal agency's mission to work for the public benefit. Technology transfer activities can assist with accomplishing mission-oriented R&D; for example, academic or industrial researchers provide necessary expertise on collaborative efforts (e.g., development of therapeutics, vaccines, missile guidance systems, drones, or software), thus leveraging all parties' research dollars. In the other direction, the government benefits when technology moves out of the laboratories because federally funded R&D is being put to new or expanded uses. This also results in a better return on investment and expedites the rapid movement of technology to the field. The government and individual laboratories also benefit financially to the extent that the technology transfer provides royalty payments to the government.

Given the belief that a healthy U.S. economy will be based on the commercial exploitation of innovative and expanded technologies, the government benefits from the stronger economy fostered by successful technology transfer programs.

2 See https://federallabs.org/learning-center/t2-toolkit/agreement-templates.

### 1.3.2 Benefits to Industry

For industry, involvement in technology transfer projects can increase awareness of government needs, giving commercial companies the opportunity to better serve government customers. As is the case for the government partner, the business partner can leverage R&D costs by building on relevant existing R&D in or through new collaborations with federal laboratories, resulting in improved and more cost-effective technology development. Business partners may also benefit by using government facilities (e.g., for product testing), rather than building new facilities, and using the expertise of federal scientists and engineers.

From a product point of view, exclusive licenses to government technology may provide a private-sector firm the needed edge in entering the marketplace, and government collaboration in general may reduce the product development cycle and time to market.

### 1.3.3 Benefits to Academia

Researchers at universities and nonprofit organizations can benefit financially from various parts of the entire technology transfer spectrum (e.g., as participants in proposals and joint ventures for R&D grants). Individual researchers may benefit intellectually from close contact with leading technologists in both government and industry. Ongoing technology-oriented projects also offer a useful incentive for student involvement and can provide students with valuable experience and contacts when entering the job market.

### 1.3.4 Benefits to Laboratory Professionals

For the individual scientist or technologist in a federal laboratory, benefits include possible financial gain from awards and royalty payments, in addition to exposure to cutting-edge research, personal satisfaction, and professional recognition gained from holding a patent or participating in the launch of a new product. The collaboration with other scientists and technologists from industry and academia may improve the employee's ability to accomplish mission tasks and provide the knowledge that one is a strong contributor to government-mandated technology transfer processes.

### 1.3.5 Benefits to Economic Development

While federal technology transfer benefits national economic growth and competitiveness, these national-level benefits are a compilation of those realized at local, regional, and state levels. State and local governments are supported and enhanced in their economic development efforts by partnering with federal labs via technology transfer initiatives. These collaborations, in areas such as education, health, crime-fighting, and many others, may result in job creation, better products, improved quality of life, and a more positive future for citizens.

## 1.4 Technology Transfer Works

Technology transfer has fostered mutually beneficial technology partnerships among federal laboratories, industry, nonprofit organizations, and academia. These innovative partnerships have significantly contributed to the mission accomplishment of each member agency and laboratory and have enhanced the economic well-being of the nation. They are a practical demonstration of the synergistic benefits of technology transfer for greater society. The FLC Awards Program annually recognizes federal laboratories and their industry partners for outstanding technology transfer achievements.

The FLC success stories and awards[3] are good examples of successful, innovative technology transfer partnerships that illustrate the benefits of technology transfer for the government, the laboratory, and industry.

3 See Labs in Action success stories at https://federallabs.org/flc-highlights/labs-in-action/overview. For more information on awards, see https://federallabs.org/flc-highlights/awards/awards-program-overview.

Section Two

# THE OFFICE OF RESEARCH AND TECHNOLOGY APPLICATIONS (ORTA)—THE TECHNOLOGY TRANSFER OFFICE

## 2.1 What is an ORTA?

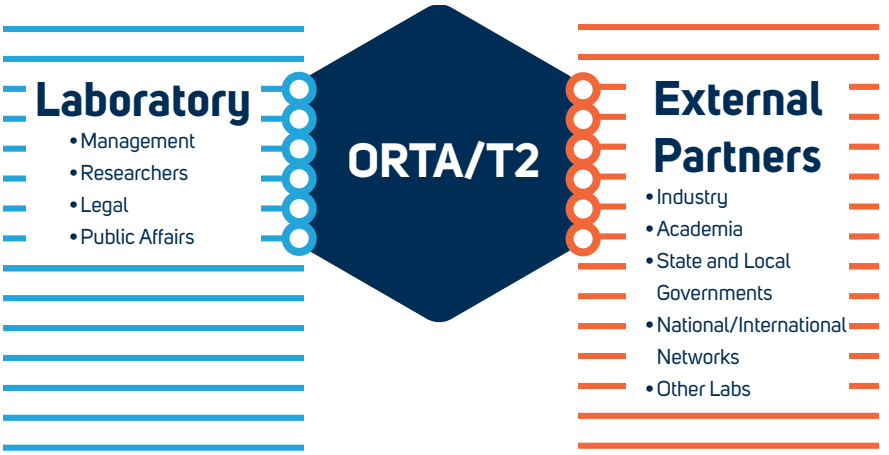
The Office of Research and Technology Applications (ORTA, often pronounced OR-tuh) is the name given to technology transfer offices by the Congress in the Stevenson-Wydler Technology Innovation Act of 1980 (see 15 USC 3710[b]). Whether it is called an ORTA, T2 office, technology transition office, technology partnership office, or some other combination of terms, this guide uses the term ORTA as the generic functional name of the unit that performs the technology transfer mission.

ORTA is a necessary component of each federal laboratory. Federal laboratories with more than 200 scientists are required to make funds available for one or more full-time equivalent positions or staff for its ORTA and to support technology transfer functions at the agency and at its laboratories. Within these guidelines, there is a great deal of flexibility regarding the structure and function of these offices. They may be combined or shared across laboratories, or the function may be performed by a single technology transfer unit for an entire agency. While most ORTAs across agencies share a great deal in common (15 USC 3710[c]), they often have unique roles assigned depending on the individual agency or federal laboratory's mission, policies, and procedures.

## 2.2 ORTA Responsibilities

Like the academic technology transfer offices, ORTAs function as the technology transfer facilitator, connecting people inside the laboratory (the developers of technology and the initiators of technology transfer) and those outside the laboratory (the "customers" or "end users" for the technology). The typical role of the T2 office as a laboratory's technology transfer "nexus" is illustrated in Figure 2-1.

**FIGURE 2-1** | The T2 Office as the Link Between Lab and Technology Transfer Customers




The required functions of the ORTA are described by statute (15 USC 3710[c]) and are as follows:

- Prepare assessments of selected R&D projects and technologies in the laboratory that may have potential commercial applications
- Provide and disseminate information to state and local governments and private industry about potentially applicable federally owned or originated technologies, products, processes, and services
- Cooperate with and assist the FLC for technology transfer, the National Technical Information Service (NTIS), and other organizations that link the R&D resources of the laboratory and the federal government to potential users in state and local governments and private industry
- Provide technical assistance to state and local government officials; and
- Participate where feasible, in regional, state, and local programs designed to facilitate or stimulate the transfer of technology for the benefit of the region, state, or local jurisdiction in which the federal laboratory is located.

This list is contained in the original text creating the ORTA, but changes and additions to statutes have expanded the initial functions of ORTAs to include the following responsibilities:

- Management of intellectual property/negotiation of licenses for intellectual property (1980; see 15 USC 3710 [c & d])
- Cooperative Research and Development Agreements under the Federal Technology Transfer Act of 1986 (see 15 USC 3710[a])

- Reporting on technology transfer activities (see 15 USC 3710[f])
- Other types of related agreements as described in Section Three, and
- Coordinating technical assistance from the federal laboratory in response to requests for assistance from external entities.

To perform these functions, the ORTA may need to communicate the laboratory's technological advantage to external parties, while carefully maintaining compliance with applicable policies and procedures. These communications typically include:

- Informing potential partners of the laboratory's technology and technical capabilities
- Describing to the partner the value of utilizing the technology
- Promoting throughout the laboratory the understanding that technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional
- Working closely with technical staff and laboratory management to identify potential mission needs
- Understanding and appreciating issues related to commercial markets and commercialization, such as production and distribution
- Training laboratory personnel on technology transfer
- Evaluating technologies for commercial potential, novelty, patentability, and partnership opportunities for optimal public benefit; and
- Marketing inventions and laboratory capabilities.

Some common training provided by the ORTA to the federal laboratory includes:

- Technology transfer legislation and requirements
- Technology transfer mechanisms and procedures
- Basics of intellectual property
- Benefits of technology transfer to the laboratory and to the inventors; and
- Benefits of technology transfer for the U.S. economy and global competitiveness and technology transfer success stories and lessons learned.

### 2.2.1 ORTA Structure

The structures of ORTAs vary based on the mission of the laboratory or the federal agency.

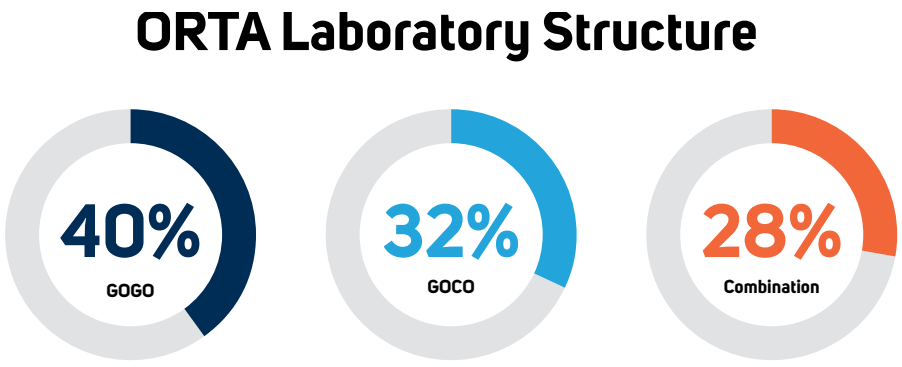
There are few studies about the structure of ORTAs, and some information is available in the public domain. In a broad study published in 2011 by the Institute for Defense Analyses (IDA), Hughes et al. (2011) listed several key factors that influenced the structure of ORTAs based on interviews across offices. This section uses those key factors to address ORTA structure across agencies. In 2018, the National Institute for Standards and Technology (NIST) published the results of a study of ORTA structure based on data from the Interagency Working Group for Technology Transfer that presents helpful base statistical information. This information is supported by other studies of university technology transfer offices (TTOs). One study funded by NIST and performed by the University of Michigan Economic Growth Institute (Austic et al., 2019) found four common characteristics at top-performing TTOs:

- Culture: The organization values T2.
- Champions: T2 is supported at all levels.
- Incentives: Resources and support to participate.
- Collaboration: Focus on partnership.

Similarly, to the idea of culture, the first factor in the IDA study by Hughes et al. (2011) was the mission of the federal laboratory. This theme is constant throughout this reference because mission is a critical factor. If the ORTA is not in sync with the mission, it can be very difficult to get the resources and cooperation needed. The ORTA should be integrated into the success of the federal laboratory and in sync with management priorities and direction. The mission determines the goals of the ORTA and sets the overall direction of the office.

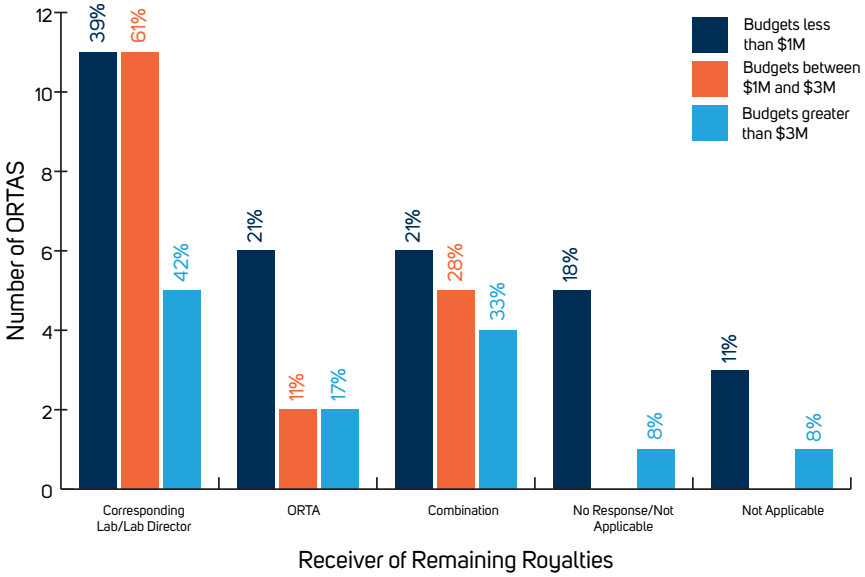
The second factor noted in Hughes et al. (2011) is laboratory management. The study emphasizes the difference between GOGO and GOCO laboratories. The key difference noted was the driver. Contractors are often specifically tasked with the T2 function as a condition of the contract performance. Government-operated laboratories are mandated to interpret and follow the laws and regulations consistent with their authorizing language. Gingrich (2018) noted the relative breakout of ORTA structure across agencies, including several agencies that have a mix of management structures at their laboratories.

**FIGURE 2-2** | ORTA Laboratory Structure




Austic et al. (2019) then note the importance of having a champion. The ORTA needs to have the support of management to be successful. This usually means finding ways to incentivize the management to participate. Increased collaboration and potential Cooperative Research and Development Agreement (CRADA) funds are often a good incentive. Gingrich et al. (2020) noted how agencies treat royalty income. While using the funds to boost the ORTA is sometimes necessary, many organizations use royalties after paying the inventor share as an incentive back to the laboratory.

**FIGURE 2-3** | The Receiver of Remaining Royalties by Budget Category




*Note: (n=58).*

This sometimes requires finding allies and proving worth if T2 is it not already built into the organization's culture. Promoting successful outcomes and demonstrating value can lead to further results. The FLC can help communicate value through examples of awards and success stories.

The next factor influencing ORTA structure in Hughes et al. (2011) is Congress. Executive branch emphasis can also be included in this category. The amount of support and oversight and priority given to T2 from the President or Congress can vary significantly across agencies. Major technology transfer legislation is most often in response to a perceived need to stimulate economic growth. Emphasis on the use of federal research to create and commercialize technologies as a leadership priority can make additional resources available and provide for greater support from management. Understanding the dynamic of these priorities is helpful to structuring the office and obtaining resources.

Agency leadership and laboratory director support is the fourth factor discussed by Hughes et al. (2011). This is related to the leadership/champion factor explained in Austic et al. (2019). When leadership understands and supports the concept that technology transfer is fundamental to accomplishing the laboratory's mission objectives, it allows for greater resources, flexibility, and creativity from the ORTA. Where the ORTA is aligned in the organization is of significant importance, including the level at which the ORTA reports, to the Director versus an office within the organizational structure (Hughes et al., 2011).

The fifth factor is the organization of the T2 function. Agencies have differing structures for the ORTA. The centralization or decentralization of various technology transfer functions varies. Larger departments and agencies often have a main policy office and then ORTAs at the laboratory level. Others do not have a centralized policy office but delegate directly to the primary subagencies. In some cases, agencies have a single ORTA that supports the entire agency structure that may be augmented by laboratory staff. The location of ORTAs within an agency and laboratory can affect the visibility of technology transfer.

Coupled with the organization of the ORTA are the responsibilities of the ORTA and the expertise available. Many ORTAs have other related functions beyond patents, licensing, and CRADAs, for example, other research agreements such as confidentiality (CDAs), material transfer (MTAs), research collaborations (RCAs), data use (DUAs), and memoranda of understanding (MOUs). These are generally related to the ORTA function and modified by the unique mission of the organization to which the ORTA reports. As noted in the first part of this section, ORTAs are typically an intersection of science, business, and legal activities, and must possess thorough understanding of federal rules and regulations, agency policies and procedures, and market niche. A sound scientific background is a plus. Having the expertise to bridge these disciplines is a hallmark of T2 staff and the ORTAs themselves. This expertise provides unique advantages to the organization's mission depending on the interpretation of legislation and regulations by the ORTA and legal staff.

The next factor listed in Hughes et al. (2011) are the researchers, which connects to the idea of incentives in Austic et al. (2019). The alignment of mission and management is important, but the day-to-day operations of the ORTA are carried out by the individual researchers. Section Three goes into greater depth on supporting researchers. From an organizational perspective, one of the key factors for a successful ORTA is to provide value and service to the researchers.

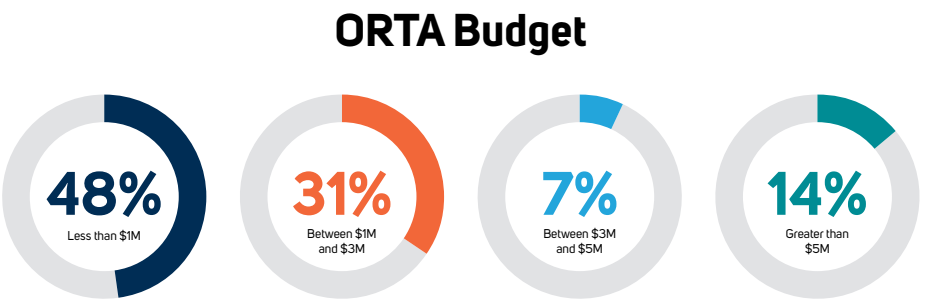
Even with less stringent ethics requirements on startups and even in an environment that encouraged faculty startups, only 5% of researchers at high-performing university TTOs showed interest in starting their own company (Austic et al., 2019). Starting a business is not a high motivator among federal laboratory employees. Simply put, top researchers are in their current position and field because they like doing research. If someone is interested, they can be assisted, but what many researchers need is not to become experts in business or T2, but to have support of an ORTA that makes these interactions less burdensome.

The next factor from Hughes et al. (2011) is the government-industry relationship. To be successful, potential partners need to know the agency exists. In Austic et al. (2019), focusing on the partnership is seen as one of the primary factors in a successful T2. This is accomplished in many ways and depends on the resources available. The FLC can be a major asset in this area, particularly for ORTAs with more limited resources. The FLC tools, such as FLC Business, a comprehensive search engine for federal patents, can provide a platform for discovering inventions and even providing information on the federal laboratories' function and faculties. Even for large agencies that have their own patent discovery tools, FLC Business can enhance these tools by providing a government-wide search that may lead parties back to an agency or laboratory they did not anticipate. Getting out to meetings and events to communicate capabilities and discuss specific inventions that are available is needed. The FLC hosts events to support and facilitate this interaction, and many laboratories run events within their own area. It is said that T2 is a contact sport; there simply is no partnership without contacts, as the entire goal is to bridge internal and external parties. A critical factor is training and encouraging researchers. Researchers go to meetings in their fields and present their findings. If they know the basics of T2, they are prepared to connect with interested parties and bring them to the ORTA. Other common mechanisms are the use of partnership intermediaries and in some larger offices a marketing team.

The last factor is resources. It is easier to get work accomplished if you have the resources to do it, including funding and people. As discussed in the first section, an ORTA is required by statute, and it is to receive resources. But it is not commonly a budgetary line item, and T2 is often seen as an unfunded mandate. If the above factors align, it is easier to get resources, but in most cases, the ORTA is continually competing for resources.

As seen in Gingrich (2018a), many ORTAs operate with a budget under $1 million annually. This can restrict some activities, but conversely, organizations like the FLC can help to stretch available resources.

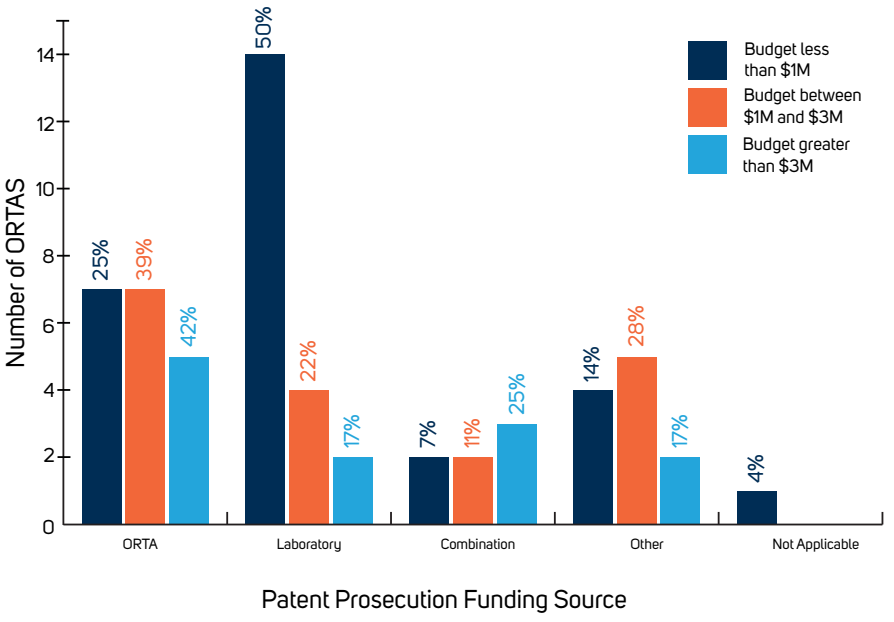
**FIGURE 2-4** | ORTA Budget Distribution




There are additional ways, other than direct funding, to fund T2 operations. As seen earlier, some ORTAs receive a portion of royalty income. Some offices view this as refocusing the mission toward funding generation; in others it is just part of the operation.

While patents are expensive and often part of the ORTA's function, how patent prosecution and maintenance is funded varies. Gingrich et al. (2020) demonstrate that funding for IP may be in the ORTA budget, the laboratory research budget, or a combination. The same report demonstrates that when patents compete internally at the laboratory for research dollars, patenting is diminished.

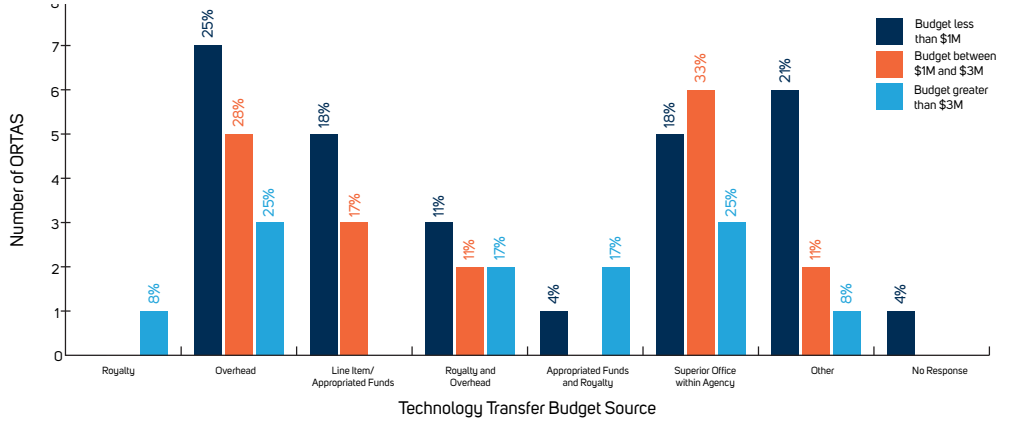
**FIGURE 2-5** | Patent Prosecution Funding Source by Budget Category




*Note: (n=58).*

In addition to the size of the budget, the source of the ORTA budget is another consideration. As presented by Gingrich et al. (2020), there is no set pattern for where an ORTA obtains its funding within the organization.

**FIGURE 2-6** | Sources of Funding for ORTAs by Budget Category

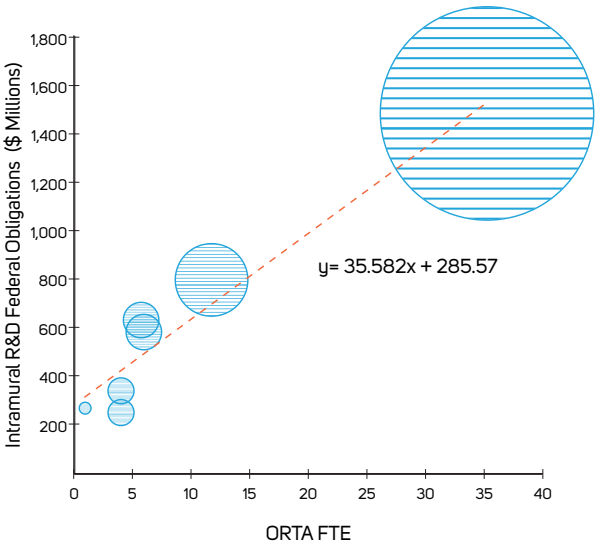



*Note: (n=58).*

A common issue for ORTAs is proper levels of staffing. As noted earlier, not all ORTAs perform exactly the same functions, and the staff required will depend on the duties performed. However, a few studies provide some useful information.

Data from the agency ORTA survey was presented by Gingrich (2018b). The data showed a low correlation between the number of STEM (science, technology, engineering, and math) employees and ORTA size, but some correlation was seen based on the laboratory or agency funding according to the following graph:

**FIGURE 2-7** | ORTA FTE vs Intramural R&D Federal Obligations per Department/Agency




Using this correlation (solving for x), a research budget of about $1 billion translates to about 20 ORTA full-time employees (FTEs). For more information regarding Intramural R&D, visit https://uis.unesco.org/node/3079700

Other sources of data are also useful for comparison. AUTM, formerly the Association of University Technology Managers, conducts a survey of university TTOs annually. According to the *AUTM 2020 Licensing Activity Survey* (AUTM, 2020), averages in key areas for IP include:

- Patent applications per TTO staff : 6.34
- Patent applications per $10 million of research: 2.14
- Licenses per licensing FTE: 8.31
- Licenses per $10 million of research: 1.21; and
- Startups per $10 million of research: 0.13

As was noted at the beginning of this section, the mission of the ORTA is highly dependent on the mission of the organization it supports. While these pieces of information are informative, they must be used in the context of the assigned duties and related functions performed by the ORTA.

Section Three

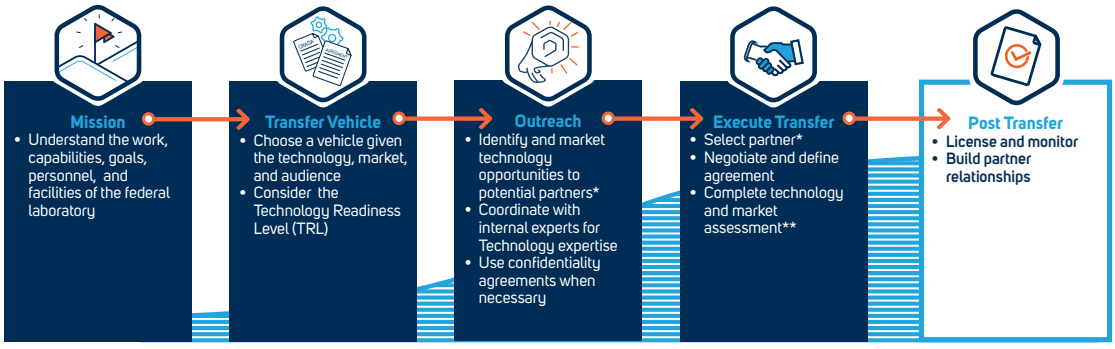
# THE TECHNOLOGY TRANSFER PROCESS: COLLABORATION AND COMMERCIALIZATION

## 3.1 Introduction

T2, which is often likened to a "contact sport," is primarily a function of person-to-person relationships between an internal party and an external party. The T2 office is in a unique position to bring multiple parties to the table to create new solutions, and the goal is to create a win-win situation for all parties. Bringing collaborative partners in contact with local, county, state, and federal economic development programs can increase the financial and technology resources needed to succeed. The T2 process can vary greatly between transactions and requires flexibility. However, this chapter describes a basic framework that covers the various components and how they work together to support the federal laboratorymission. The model in this section is only one suggestion out of many possibilities for structuring the T2 process.

The most typical starting place is within the mission of the federal lab. For example, the starting place could be a need for a specific tool or technology from an external party or a disclosed invention that requires assessment and further development. Sometimes the idea comes from an external party who can see some advantage in using the lab's capabilities. Either way, the T2 process is often more of an art than a science, and T2 opportunities rarely follow a similar development process. However, this section provides a model for the typical T2 process conducted by a T2 office at a federal lab.

**FIGURE 3-1** | Model for the Typical T2 Process




***Partners:** Partners may be involved at any stage of the T2 process. Partners are typically more heavily involved as the TRL score increases. Partners are not subject to the Federal Acquisition Regulation (FAR), and labs may choose the partner most suited to the technology opportunity.

****Market Assessment:** A market assessment may be conducted at any point in the T2 process.

## 3.2 Focus on the Mission

At its core, T2 at a federal lab is focused on enabling the lab to achieve its mission. Understanding the mission of the federal lab is essential, as it is both the starting place and the end goal of the transactions of the ORTA or T2 office (TTO). T2 supports the research and development program by providing pathways to transfer or transition a product from the federal lab to a partner that can make and sell the product or service—transforming the idea into reality.

This requires a detailed understanding of the work being conducted in the federal lab, the lab's capabilities, and its specialized facilities. In this area, the main customer is the federal lab leadership and management and how they define program success. T2 personnel should concentrate on developing an in-depth understanding related to the federal lab's:

- Core competencies;
- Areas of technical excellence;
- Unique facilities and personnel;
- Overall facilities and equipment;
- Intellectual property portfolio;
- Potential to take on work; and
- Existing collaborations and partners.

Whenever possible, the T2 professional should learn about the program direction though common sources of information, such as:

- Program briefings, overviews, and strategic planning sessions;
- The budget request and priority research areas; and
- Public affairs articles and areas of interest.

## 3.3 Scientists and Engineers (S&E)

The T2 office normally does not determine the direction of the research program. Beyond the overall technical program of the federal lab, individual scientists and engineers (sometimes called principal investigators [PIs]) are the internal customers for the T2 professional. Finding scientists who are open-minded helps to build a successful community and track record of success within the lab. Understanding researchers requires some level of internal sales, communication, and education regarding the value of T2. This will be of importance when turning their ideas and research into practical application.

When talking to scientists and engineers, it is helpful to steer toward the programmatic goal rather than the scientific goal. Focusing on the importance of the research and why it is the mission of the lab can help develop a better understanding of the intended outcome. When understanding what the scientists are trying to accomplish, it is important to relate to the federal lab's mission, and this may help to identify the best approach to a partnership. When meeting with scientists and engineers, it is helpful to understand their background by reviewing:

- Past/current patent applications;
- Published reports; and
- Any databases or listings of experts and areas of expertise.

Understanding the goal of the work before jumping into the potential mechanisms will help avoid coming to see the mechanism (e.g., CRADA or license) as the goal itself.

## 3.4 Partners

Partners may be other federal agencies, universities, small or large companies, etc. The partner's functions can be as funders, co-inventors, providers of materials, contractors, or invention developers with various agreements including CRADAs and NDAs. Partners may be licensees or, in case of a joint invention, the licensors. Please refer to section 3.7 for additional information.

## 3.5 Identify the Transfer Vehicle

After determining the goal and need, the T2 office should develop a transfer strategy and determine the transfer vehicle (e.g., CRADA, license, etc.) best suited to the technology, market, and audience. Considerations when determining the most appropriate T2 vehicle may include:

- Maturity of the technology;
- Type of resources required for the development/commercialization effort;
- Nature and status of the industry;
- External economic factors;
- Budgetary constraints;

- Nature of the target audience;
- Whether the goal is spin-on (the agency wants to develop technology that it will use itself—e.g., military applications), or spin-off (e.g., an environmental test kit);
- Whether the S&E already has a potential partner;
- Whether the request is from an external party and the type of external party (e.g., for-profit, academic); and
- Ownership of the invention.

After evaluating goals and desired outcomes, it is helpful to have a preliminary discussion of the different mechanisms available to accomplish the goal with the lightest burden on all parties. Matching the mechanism and the desired outcome will help the science and engineering staff understand that the ORTA/TTO is on the same team and has the same goals.

## 3.6 Technology Maturity

As noted above, the maturity of the technology is an important factor in finding the proper vehicle and right partner for transfer. There are several ways to categorize technology maturity. Congressional budgets often use the terms "basic research" and "applied research." While these often mean understanding scientific principles versus engineering solutions to a specific problem, it is very difficult to categorize things cleanly according to these terms. Several agencies have adopted "Technology Readiness Levels" (TRLs). TRLs are useful for further describing the maturity level of technology.

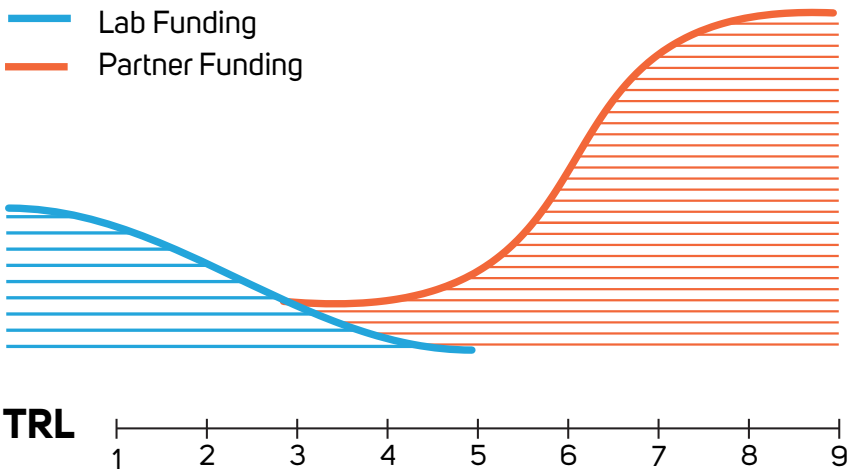
Agencies have adopted slightly different versions of the wording of the TRLs used, but they do tend to follow a basic pattern of nine levels:

1. Basic scientific principles;
2. Formulation of the concept and application;
3. Experimentation and proof of concept;
4. Lab scale validation;
5. Testing under relevant environment;
6. Prototype demonstration under relevant environment;
7. System prototype demonstration;
8. System testing and verification; and
9. Actual proven technology.

Sometimes TRLs 1-3 are described as research, TRLs 4-6 as development, and 7-8 as a demonstration. TRL 9 is generally regarded as ready for full-scale deployment.

The idea of technology readiness maps is used to market and partner readiness as well. The term "valley of death" is commonly used in technology transfer to describe the gap between a bench-scale invention and a market-ready condition—a phenomenon in large part tied to funding. Many inventions born of research are not ready for out-of-the-box deployment. A partner is needed to share associated costs for advancing the technologies into the later stages of development. This may require capital investments, as agencies often do not have the budget to fully deploy all new technologies.

**FIGURE 3-2** | Technology and Partner Readiness Gaps




In many cases, there is more than one valley, but generally the valley of death is the development stage. As a concept is developed and the publications are printed, the scientist may be ready to move on. The basic science applications are done, and the agency considers it ready. This typically is in the range of TRL 3 to 4. Agencies often cannot further fund the development, but industry may not be able to find investors. The technical risk is great, and the cost of development lies ahead and requires funds. There is not a working product and no revenue from sales. Once a technology advances to about TRL 6 or 7 and a prototype can be demonstrated, communicating the market potential is more practical. Working with potential partners to clearly understand the readiness of the technology and the need to work with investors or help partners to continue development is the focus of bridging the valley. Programs such as the Small Business Innovation Research (SBIR) program and similar state programs may be of great assistance and are targeted in this area.

## 3.7 Outreach—Identifying Potential Markets and Partners

Now that you know the goal and the right approach and mechanism, it's time to find a partner. T2 is by nature a connection between internal and external parties. The T2 office performs a critical role in connecting the federal lab with private industry, academia, state and local organizations, and professional and trade organizations. This includes identifying potential partners and performing marketing outreach efforts to make T2 opportunities known to the private sector.

### 3.7.1 Identifying Potential Partners

A federal lab, depending on the availability of funds, may provide funds via SBIR to qualifying small businesses to further develop the technology and thus help bring it to market. Exploring potential collaborations and external parties should include understanding the partners' needs and how those needs align with the mission of the program. Both parties look for a win-win situation that advances the lab's mission while creating a business opportunity. In most cases, the federal government is not making and distributing products, so it is not a competition but a collaboration to the same end.

Where areas of excellence or core competencies in the federal lab can be identified, typically the T2 professional will use several techniques to find the best fit:

- Engage with your S&E and get their ideas—ask researchers to identify their peers outside of the federal lab;
- Identify and interact with relevant professional and trade organizations and exhibits at their conferences;
- Use web-based commercial tools for technology assessment and determination of market potential;
- Talk with state, county, and regional economic development organizations; and
- If needed, use professional T2 consultants.

The S&E you are working with can also be the best advocate for collaborative work, as they are often experts with extensive networks of colleagues and past collaborators. The lab will decide who is a good match for a collaboration. This is not the same as acquisitions and does not follow the Federal Acquisition Regulation (FAR).

If the external party generates the request, then the T2 professional will need to work with the S&E to find a suitable match. The same thought process contributes to finding the match, but it may start with the external idea and then require finding a willing S&E, which can be aided by considering the following:

- Understand the partner's request;
- Determine whether it fits in the lab scope;
- Identify interested parties internally;
- Make introductions only when the internal parties express interest; and
- Don't try to force it; look for mutual interest.

When inventions are jointly developed and owned by another party, certain activities may have a requirement to deal with a particular party as a partner.

For CRADAs, the statute requires that the collaborating party be offered the opportunity to negotiate an exclusive license (15 USC 3710[a][b)]). These licenses do come with some restrictions that are further described in the section:

- A fully paid-up government use license is required;
- That the partner allows for the use of the technology under reasonable terms to others, or the government may issue such a license under exceptional circumstances such as health and safety needs or failure to allow public use of the invention. These licenses can be appealed in the same manner as march-in rights (35 USC 203); and and
- CRADA inventions that are exclusively licensed to the partner do not require public notice (35 USC 209[e]).

For inventions created under a federally funded agreement (e.g., cooperative agreement or contract), where the funding agency is substantially involved in the project development, the funded party has rights to elect to patent the invention (35 USC 202[a]). If the funded party chooses not to elect such title, the funding agency may, at its discretion, decide to seek patent protection for the invention. Regardless of which party takes the lead in patent filing and prosecution, both grantee institution and federal inventors will still have inventor rights, in accordance with the U.S. Patent Law. In such instances, the ORTA is allowed to consolidate rights (either to the government or to the other party) through licensing (via Inter-Institutional Agreements) or assignment with the coinventing party (see 35 USC 202[e]). The potential advantage to licensing these rights is to make the invention more readily available by reducing the number of negotiating organizations, particularly for exclusive licenses. Note that the coinventing party cannot be required to grant these rights (35 USC 202[c][8][f][1]).

### 3.7.2 Marketing and Outreach

An active marketing or outreach campaign may be necessary to find suitable partners or to inform external parties about opportunities available in the federal laboratories. Some T2 offices are large enough to have a dedicated marketing team with business development expertise and access to resources with which to solicit partners, obtain funding, or generate industry/collaborative interest. This is often done by the T2 professional using many of the same techniques. Some techniques that have been used effectively by federal agencies include the following:

- **Innovator's contact with peers**—Direct contact between inventors and their peers through professional societies and conferences is a highly effective method for creating interest in specific innovations outside of the federal lab.
- **FLC events**—The FLC and other similar organizations sponsor national forums where private-sector companies are invited to visit federal lab displays and talk with federal lab personnel.
- **Technology briefs**—Short written or video summaries of technologies and their potential commercial uses can be widely distributed to targeted populations via mail, email, or a website. Live webinars by the inventors can also be effective.
- **Presentation at professional and trade associations**—These associations bring together professionals with similar interests and can provide a forum to discuss opportunities in the laboratories. Advertisements in professional magazines have also proven effective.
- **Small-business workshops**—Workshops targeted toward small businesses in specific technology areas are often sponsored by laboratories. State economic development organizations and the Small Business Administration may be potential partners in sponsoring these workshops.
- **Technology roundtables**—Discussion forums can be organized around a particular technology area, with representation sought from one or more laboratories, private industry, academia, and state and local governments.
- **Advertisements and articles in R&D magazines**—Targeted exposure of federal lab technologies in R&D magazines can provide effective connections among parties with similar interests.
- **Web posting**—Potential partners search for partnership or licensing opportunities through federal lab/facility websites, T2 search engines, and social networking groups.
- **Advertisement on sam.gov**—Widely read by many U.S. technology companies, sam.gov provides a forum for broad dissemination about possible opportunities in the federal lab.

## 3.8 Confidentiality

Confidentiality is a legal matter; please refer to your agency or federal lab counsel.

It is generally best to begin any discussion on a nonconfidential basis. The initial discussion may not be fruitful, and it is best to remain unencumbered. Confidentiality carries some long-term burdens and should be considered when it is mission essential. A good practice is to state that the conversation is considered nonproprietary and to insist that materials provided for review are not marked as proprietary.

For federal employees, 18 USC 1905 makes disclosure of proprietary information a potential criminal violation.

If it looks as though there is a potential match for a partnership, it may be necessary for each party to enter into a Confidential Disclosure Agreement (CDA) or Nondisclosure Agreement (NDA) for discussions to proceed. Even in these cases, it is essential to have each party clearly identify what information is covered by the agreement and a clear ending or release date. This may be one year or three years, for example, but it is generally not a best practice to agree to keep information confidential in perpetuity as it may limit future work at the lab.

It is often a good idea to note in any final document, such as a CRADA or license, that the agreement supersedes any previous arrangements. This simplifies the responsibilities and keeps control in a single agreement rather than in multiple places.

T2 has some specific authorities available for confidentiality:

- **CRADAs**
  - 15 USC 3710[a][c][7][A] limits disclosure of partner proprietary information or trade secrets received.
  - 15 USC 3710a[c][8] allows discretion for up to five years for CRADA information from release under the Freedom of Information Act.
- **Patents**
  - 35 USC 205 allows agencies to withhold information for a reasonable time in order to file a patent.

## 3.9 Execute the Transfer—Negotiating the T2 Agreement

### 3.9.1 It's Negotiable

Many of the terms in T2 agreements are negotiable within the parameters of the federal authorities in statute and regulation. T2 is more discretionary than acquisitions (15 USC 3710a [a]) 35 USC 207[a][3]). Whether the T2 vehicle is a license agreement, a CRADA, ois negotiating an agreement with the private sector can be a complex process. Both federal and private-sector parties need to identify early in the process what they hope to gain from the agreement. Flexibility may be key. Many factors that concern the federal lab, the technology, and the potential partner will need to be considered when negotiating an agreement that is advantageous to all parties:

**Considerations for the Federal Lab**

- What is the relevance of the technology to the federal lab's mission?
- What are the benefits to and needs of the federal lab?
- What federal resources will be required? Will additional partners, contractors, or funding be needed?

**Considerations Regarding the Technology**

- What is the stage of development for the technology?
- What resources will be required to bring it to commercialization?
- What additional "know-how" will be needed?
- What are the potential fields of use?
- What is the size of the market for the technology?
- For patent-pending technologies, will the patent attract licensees?

**Considerations Regarding the Partner**

- What is the size of the partner (e.g., a company or university) and what are its resources?
- What is its ability to develop, manufacture, market, and distribute the commercialized product?
- What are the potential profits?
- What is the need to protect proprietary data and to obtain a competitive advantage?
- Are there trademark, copyright, or proprietary material opportunities?

### 3.9.2 Not Negotiable

While much of an agreement is negotiable, several items are not:

- The federal government, as the sovereign, cannot agree to be bound by the laws of a state or other entity (U.S. Const. art. 1, § 8).
- There are some limited exceptions to the Freedom of Information Act of 2016, but the requirements cannot be waived or extended beyond the exceptions.
- Federal licenses must include the conditions in (35 USC 209 and 37 CFR 404):
    - The goal is practical application (e.g., not licensed to keep the invention out of the market to reduce competition);
    - Under U.S. manufacturer for sale of licensed products. In the U.S. it is required (waiver is possible);
    - Used for Government use;
    - Used as Periodic reporting;
    - Public notice of at least 15 days for exclusive licenses not under a CRADA; and
    - Plan to develop and market.
- Government works cannot receive copyright (the partner's works can) (see USC Title 17 § 105, 2010).
- Some agencies require indemnification (this is not consistent across agencies). A federal agency cannot provide indemnification to the licensee.

Note, it will be important to work with General Counsel in situations when non-negotiable requests arise from partners, and there may be legal implications.

## 3.10 Technology and Market Assessment

An important part of the T2 process is the formal assessment of which technologies in the federal lab have transfer potential and the types of resources available at that facility for T2, including those technologies disclosed to the T2 office. The purpose of this assessment is to prioritize technologies that can benefit from full-scale evaluation. The T2 professional will use a variety of techniques to determine the potential of candidate technologies for commercialization. This may be done internally, or an evaluation can be sourced out to external parties (typically for a fee).

Not all innovations disclosed to the ORTA/TTO can be commercialized. Patenting requires the payment of extensive fees, time from either internal or external attorneys, time from the ORTA/TTO, and time from the inventor. If the technology cannot reasonably be commercialized, these costs may be questionable considering the intent of practical application. Determining the available federal lab resources, technology portfolio strategy, and processes with the greatest transfer potential and value helps balance the cost with the benefit to the mission.

When evaluating technologies, consider broad applications rather than only the specific application that was the target of the research. For example, some technologies for military applications may have a very different use in the private sector. Because a technology may be commercialized for purposes different from the original intent, it is useful to consider the commercial potential from diverse viewpoints. One way to evaluate technologies is by convening a multidisciplinary team with diverse technical backgrounds to broadly consider the technology's potential. While this is not always possible, the following may broaden the exploration of alternate applications:

- Use brainstorming techniques to encourage divergent and creative thinking about possible uses of the technology.
- Select the most promising ideas for further discussion and identification of potential markets.
- If more options appear to be needed, determine who inside and outside the federal lab should be consulted and assign responsibilities for determining the following:
    - Estimate of the capital requirements needed to bring the technology to commercialization;
    - Manufacturing process needed;
    - Patent likelihood;
    - Potential of other forms of intellectual property (IP) protection;
    - Competitive advantage possibilities;
    - Market niches;
    - Possible field-of-use licenses (Patents can be licensed for more than one field of use. For example, a patent can be licensed for both medical and electronics applications);
    - Potential problems related to classified technologies; and
    - Financial potential for the selected technology.

After completing technology assessment, the ORTA/TTO may consider preparing formal or informal technology commercialization plans for each candidate technology. Such plans can provide the technology developer and federal lab managers with critical information regarding the technology's potential and the steps necessary to accomplish transfer. A plan may include the following:

- Abstract of technology evaluation findings;
- Description of technology;
- Technology soundness and innovation;
- Technology Readiness Level;
- Commercial potential;
- Manufacturing and production issues;
- Management and ownership;
- Financial potential; and
- Transfer options.

## 3.11 Special Considerations

**U.S. Preference**—Preference should be given to business units located in the United States, particularly companies that agree to manufacture the technology substantially in the United States (15 USC 3710a[c][4][B]; 35 USC 204; 35 USC 209[b]). To secure a maximum "payoff" on taxpayers' investment in R&D, federal T2 policy is designed to ensure that U.S. businesses and U.S. workers receive preference in the commercialization of the technology. A waiver may be needed if the technology cannot be reasonably manufactured in the United States.

**Small Business**—Special consideration should be given to small businesses (15 USC 3710a[c][4][A]; 35 USC 209[c]). Small businesses represent a significant number of U.S. workers and are often more willing than larger companies to accept risk and to innovate (Highfill et al., 2020). But small businesses generally do not have the R&D funds and other capital resources to commercialize technology, so considering the unique needs of small businesses is a concern for federal parties.

**Conflicts of Interest**—Before negotiating agreements, it is important to be familiar with conflict-of-interest policies. Federal agencies and their laboratories are concerned with avoiding the appearance of impropriety in their dealings with private-sector parties. Generally, conflict-of-interest provisions regulate the use of public jobs for personal gain (see 18 USC 208; 18 USC 209). The Department of Justice has found that technology-transfer-related income to inventors is not considered external funding (Dellinger, 1993). Legal interpretation of conflict-of-interest provisions as they apply to T2 negotiations may be needed.

**Freedom of Opportunity/Fairness of Opportunity**—There is no requirement for an open or competitive process for CRADAs. Some agencies opt to provide notice of collaboration opportunities, which may be made available to interested parties in as much detail as possible and to as wide an audience as possible. This is particularly useful when a partner has not been identified or when CRADAs involve multiple parties.

### 3.11.1 Private-Sector Considerations

When private companies are evaluating potential partners, they have noted some common themes as areas of concern regarding working with federal laboratories:

- **Risk vs. Potential Return on Investment**—Private companies are generally looking for an investment that will create a return, which may be affected by the following:
  - Realistic opportunity for potential profits;
  - Sufficient market size;
  - Replacement costs for an improvement (it may be better or cheaper, but the replacement cost is not worth the difference in price);
  - Cost of developing a marketable product;
  - High potential for a return on an investment;
  - Current products on the market and those currently being developed (competitors);
  - The potential life cycle of the technology;

- Ability to obtain capital investment; and
- Patent landscape when applicable.

- **Speed of the Process**—The private sector often views federal laboratories as slow and bureaucratic. The ability to quickly move new technologies to the marketplace is often a competitive advantage.

### 3.11.2 State and Local Government Considerations

State and local governments are interested in promoting new business in the community or deploying new technology to improve communities. Some common concerns and motivators include public perception, potential environmental impacts, and potential creation of new jobs.State and local governments are also typically the consumers of infrastructure-related products. From roads and bridges to the power grid, water supplies, and police, fire, and other services, state and local governments may have an additional concern beyond promoting local businesses. This can lead to partnerships between the lab as a research provider, a company as the maker/distributor, and the state or local government as the user providing services in the community.

## 3.12 Licensing

Like other types of agreements, a license is a contract or agreement between the ORTA and the external party. It is the contractual transfer of rights and associated conditions to a technology and is governed by federal statutes and regulations. The goal of licensing by the ORTA/TTO is to achieve practical application of the technology, meaning that the technology is being used by someone selling, operating, or making it available (35 USC 200; 35 USC 201[f]). The ability to obtain a license is also an incentive for external parties to enter into a CRADA (15 USC 3710a[b][1]) by understanding the rights to IP in advance. Government agencies typically don't commercialize technology, so there is a need to partner with industry in order to move basic and early-stage research and development into the marketplace and into the hands of the public. Licensing benefits economic development and ensures a return on the taxpayer investment, as well as a return to the inventors and the federal lab.

The ORTA has a great deal of flexibility in managing the patent and license portfolio on behalf of the government (35 USC 207[a][3]). The granting of a license may be exclusive, nonexclusive, or restricted to a particular field of use and/or to a particular geographic territory (partially exclusive). While an exclusive license is generally preferable to the private-sector party because it keeps the competition from practicing the invention, the ORTA must demonstrate that this exclusivity is required either to call forth investment capital or to promote use by the public (35 USC 209[a][1]). Under statutory criteria for assessing an exclusive license request under 37 CFR 404.7 and 35 USC 209, a federal agency must find all of the following:

- The exclusive license best serves the interests of the federal government and the public.
- The exclusive license is necessary for practical application of the technology to be achieved.

- The exclusive license is required to attract investment capital.
- The proposed scope of exclusivity is appropriate.
- Competition will not be substantially reduced.

If there is competitive licensing interest, preference should be given to a small business.

Care should be used to ensure full utilization of the technology across all fields. Private-sector parties may be willing to acquire a license that is restricted to the particular field of use in which their company specializes or the specific geographic territory in which they do business (this is especially true when they see the costs of foreign patent protection). For example, if a medical device sensor can be used for road monitoring, restricting the field of use may lead to achieving practical application in multiple fields by more companies, all while ensuring opportunities for investment.

### 3.12.1 Communicating Available Technologies

Finding a suitable partner for a license is typically not easy. While your scientists may have a brilliant idea, making it into a commercial application is still very difficult and generally requires a great deal more money than the federal laboratory has available. While larger agencies and federal laboratories have systems to report, store, and communicate availability, many others do not have the resources to invest. From a partner point of view, knowing where to look to discover technologies is not as obvious as it may seem.

The FLC can help make technologies discoverable through FLC Business. FLC Business was designed as an application to make federal lab IP discoverable as a one-stop shop across agencies. The goal of FLC Business is to guide potential partners not to the FLC, but rather directly to the ORTA that will negotiate an agreement. This tool can complement agency or laboratory databases or search tools.

Several federal agencies and laboratories use partnership intermediaries (15 USC 3715). Partnership intermediaries are state and local government or nonprofit organizations that can help to identify partners and increase deals. A Partnership Intermediary Agreement (PIA) is a broadly available mechanism, described further in Section Five, but not all agencies use PIAs. PIAs may be funded, or they may be unfunded when there is a mutual interest.

Most formal license negotiations start with an application as required by 35 USC 209 and 37 CFR 404. The license application includes information such as the list of intellectual property and materials being requested, the type of license requested, the proposed field of use, the duration, and a robust research and commercial development plan. A lot of upfront work happens before the negotiation of a license. The federal agency must determine whether a particular partner is going to be a good long-term partner. And in the case of an exclusive license, it is a requirement that the federal agency advertises the availability of the exclusive license for at least 15 days and allows the public to comment or for other interested parties to submit license applications. This public notice can be posted anywhere publicly (e.g., on the Federal Register, FLC website, or other appropriate public sites).

### 3.12.2 The Anatomy of a License and Negotiation

Most federal agencies have license templates and model agreements. The basic elements of license agreements include:

- Introduction;
- Definitions;
- Grant of license language;
- Royalty structure;
- Licensee diligence;
- Reports and payments;
- Termination clause;
- Patent prosecution language;
- Infringement;
- Indemnification;
- Assignment;
- Communications between licensor and licensee; and
- Other miscellaneous terms and conditions to the license.

Royalties are monetary payments that can typically cover but are not limited to an execution royalty, a minimum annual royalty, benchmark achievements, earned royalties on net sales, sublicensing, and patent expenses. Factors that influence negotiations on the setup of the royalty structure are the stage of development to the technology, the type of product, the market value of the product, the uniqueness of materials, the scope of the patent coverage, the market timing, and the "content" of the technology in the final product. The distribution and use of royalty income received by federal agencies is covered under 15 USC 3710c. Additional information about the royalty payments can be found in Section Four. For GOGO laboratories, the authority to patent and license is in 35 USC 207 and 37 CFR 404. For contractor-operated federal laboratories, licensing falls under 35 USC 202 and 37 CFR 401.

The signature of a license isn't the end of the process; licenses start relationships.

## 3.13 Post-Transfer Activities: Monitoring and Assisting Partners

The post-transfer phase occurs after all negotiations are complete. During this phase, the T2 office monitors the performance of the parties involved and ensures that the agreements of the transfer are implemented. The T2 office's role does not end when an agreement is successfully negotiated. Follow-up activities include the following:

- Maintaining a liaison role to ensure that the agreement is being successfully executed;
- Resolving problems that arise;
- Renegotiating/modifying agreements if situations warrant;
- Ensuring that the technology is being commercialized successfully and that milestones are being met;
- Maintaining records of activities and sharing "lessons learned";
- Bringing additional government IP to the attention of the partner; and
- Introducing potential third-party partners for sublicensing or joint development.

Collaboration and commercialization are the heart of T2. The basic goal of T2 is to form the connection between the work of the federal laboratory and an external party to advance the mission of the federal lab through commercialization toward practical application of new products and services. While there are many factors to consider, these partnerships are one of the most rewarding parts of T2 that both accomplish the mission and lead to the technologies of the future.

Section Four

# INTELLECTUAL PROPERTY

Intellectual property and associated rights are major issues in technology transfer. This section addresses IP with special attention to the patent process—from applying for a patent to licensing a patented product. The topic of IP—particularly patents, copyrights, and licensing—is immense and requires considerable legal expertise to cover thoroughly. Clearly, this section cannot address all the details of IP law and strategy, but it does provide a basic introduction so that appropriate legal advice can be sought when the need arises.

The main topics in this section are:

- What intellectual property is and why it is important;
- Role of intellectual property in technology transfer;
- Patents and the examination process;
- Copyrights, software, mask works, trademarks, and trade secrets; and
- Protecting proprietary information.

## 4.1 What Intellectual Property Is

Intellectual property (i.e., intangible) assets include products of the human intellect—such as inventions, discoveries, technologies, creations, developments, or other forms of expressing an idea—whether or not the subject matter is protectable under the laws governing the different forms of IP. Intellectual property is that subset of intellectual assets that can be legally protected and is defined by the forms of protection that have been enacted into law. The major forms of protection are patents, plant variety protection certificates, copyrights, trade secrets, and trademarks. Software may also sometimes be protected by both copyright and patent; it depends on the particular software. Just as our legal system provides rights and protection to owners of real (i.e., tangible) property such as real estate, it also provides rights and protection to owners of IP. The rights to IP can be bought, sold, leased, rented, or otherwise transferred between parties. The transfer of IP rights can affect the marketability of a product as well as the selection of a producer or manufacturer of a product; therefore, the respective rights to IP often involve considerable discussion among the parties in a technology transfer endeavor.

## 4.2 Why Intellectual Property Is Important

On the macro level, IP plays a tremendously important role in our industrialized world. Continuation of our high standard of living depends to no small degree on scientific and technical advances. Legal systems that protect IP rights (particularly patents) help incentivize investment in inventive and creative activities that lead to commercialization of scientific and technical advances.

In addition, a legal system that provides for IP rights and protections also establishes a method to protect personal recognition for important creative and inventive contributions. The possibility of recognition for an important contribution and its accompanying prestige often serves as a powerful motivator for the would-be writer or inventor. For example, the copyright or patent helps establish the genius responsible for that Nobel Prize-winning book or important medical breakthrough.

The path from inception to commercialization of new technology generally requires the investment of significant financial, time, research, development, manufacturing, and marketing resources. Each step on this path holds a significant risk of failure. The costs for these various resources are great enough that the finances necessary to go forward usually must come from investors other than the inventor. Potential investors in the new technology will want as much assurance of potential success as possible before risking their money.

For example, the patent system gives the patent holder an advantage by excluding competitors from certain technological avenues of competition for a limited time. Knowing that the inventor's competitors cannot legally use the patented technology, potential investors have a greater incentive to take a risk with their money and other resources to support bringing the new product to market. Ultimately, upon successful commercialization of the technology, the IP of a company becomes one of its most valuable assets.

## 4.3 Role of Intellectual Property in Technology Transfer

To obtain the maximum benefits from the federal R&D investment, Congress has determined that, whenever appropriate, federally owned or originated technology should be transferred to private industry, state and local governments, and/or universities for commercialization. This technology transfer process uses knowledge, facilities, or capabilities developed under federal funding to fulfill public or private domestic needs. A key element of this effort is to capitalize on the IP resulting from R&D activities at federal agencies. Contractors at the agencies should be encouraged to report their inventions. Government employees should also be encouraged to assist the agencies with patenting their inventions and further developing the IP, often through CRADAs with private industry. IP can also be used by licensing partners that will commercialize these inventions.

### 4.3.1 Intellectual Property and CRADAs

All types of IP can arise from collaborative efforts under a CRADA. However, data and inventions tend to be the most common products that result. The U.S. Code provides guidelines for the treatment of IP within a CRADA. The allocation of IP rights should be structured to achieve the mutual objectives of the partners and the government's goal of transferring technology from the laboratory to the private sector. That goal is most likely to be achieved when IP rights are placed in the hands of the private sector and when the private sector is given some measure of exclusivity for a reasonable period and for specified fields of use or market segments.

There may be background IP such as inventions, patents, data, software, and know-how, as well as IP that arises from the CRADA effort. For background inventions and patents, that is, inventions and patents that existed before the creation of the CRADA, the guiding principle is to promote technology transfer. If the background inventions and patents are owned by the government, they may be licensed to the partner, perhaps on an exclusive basis subject to 35 U.S.C. 209. If the background intellectual property is owned by the partner, government use for the purpose of procurement or research should be negotiated, preferably on a royalty-free basis.

For inventions arising from the CRADA effort, there are three cases to consider: government employees as sole inventors, jointly invented IP, and the partner's employees as sole inventors. In the first two cases, whenever a government employee is involved as an inventor, the guiding principle is that the inventions should be made available to the partner on reasonable terms and conditions. Depending on the situation, this might entail the federal laboratory either licensing or assigning rights to the partner. In both cases, the government retains a nonexclusive license to use the invention for government purposes.

When the partner's employees are the sole inventors, the government should normally not be required to pay royalties for use. Generally, the partner should be able to retain all other rights for patents, copyrights, and technical data that its employees invent with the CRADA. In other words, the government normally retains a nonexclusive license to use the invention for government purposes.

Overall, the intent is to serve the public good, and the government recognizes that a successful commercial product resulting from a CRADA may be more beneficial to the public interest than trying to maximize near-term payback to the government.

## 4.4 Patents

### 4.4.1 What Is a Patent?

A patent for an invention is a grant of a property right by the government to the inventor, who may assign all or any part of his or her rights to others. It gives the owner of the patent the right, among other things, to exclude anyone else from making, using, selling, offering to sell, and importing the invention for the life of the patent. Patents are issued by the U.S. Patent and Trademark Office

(USPTO) and are valid throughout the United States, its territories, and its possessions. If patent protection is desired in other countries, applications must be filed in those countries, where laws and regulations governing the patent application process may differ from those in the United States.

A patent is a written instrument issued by the USPTO, an agency of the Department of Commerce. A patent is obtained through a complex and usually lengthy administrative proceeding requiring a unique blend of scientific and legal skills to navigate. As written documents, patents have a distinctive style. Details about the laws, regulations, policies, guidance, and training to the U.S. patent process can be found using the Manual of Patent Examining Procedure on the USPTO website. The Manual of Patent Examining Procedure is the go-to guide for patent application requirement, preparation, filing, prosecution, and maintenance . The first part contains the title, a list of any related application data, and a list of references (usually other patents). The text of the patent may be divided into sections describing the technical field, background art (i.e., the relevant technology that is previously known), a summary, a detailed description, claims, abstract, and drawings, where applicable. The "claims" constitute the heart of the patent. The claims consist of a numbered list of items, written in legal style, which constitutes what is covered by the patent.

The level of detail required to be disclosed in a patent is such that someone "skilled in the art" must be able to make and use the invention. This means that anyone who is technically proficient in the technology area represented by the invention must be able to understand from the patent exactly how the invention works and how it is to be constructed.

Patents are granted to inventions that are new. That means the invention isn't known or obvious.

### 4.4.2 What Is "Prior Art"?

Prior art is the body of technology related to the invention that is publicly known at the time of filing a patent application. Typically, this consists of patents, published patent applications, and academic papers, but it could include web pages and videos. If the inventor publishes an academic paper disclosing the invention, the paper becomes prior art one year after publication. This may bar the inventor from receiving a patent.

### 4.4.3 Who Is an Inventor?

An inventor is someone who comes up with something new and useful His or her invention may lead to a patent or may be held as proprietary materials or methods. To be an inventor on a patent, a person must have conceived some or all of the invention. "Conception" is the formation in the inventor's mind of a definite and permanent idea of the complete and operative invention, as it is, thereafter, to be applied in practice and as claimed in the patent. More than one inventor can be listed on a patent application, and everyone who contributed to this concept should be included. Performing work under the direction of others ("being a pair of hands") or performing work that is not inventive does not qualify one as an inventor. Work that is not inventive may, nevertheless, be extremely valuable and crucial to the success of the project giving rise to the invention.

### 4.4.4 Types of Patents

There are three types of regular nonprovisional U.S. patents:

- **Utility:** The most common type, covering virtually any inventions that are useful;
- **Design:** Covers the unique shape or ornamental appearance of an object, such as uniforms, dresses, computer housings, automobile bodies, buildings, shoes, game boards, etc.; and
- **Plant:** Covers asexually reproducible plants such as flowers and fruit trees.

In addition, the Plant Variety Protection Act covers sexually propagated varieties such as soybeans and tubers (e.g., potatoes). The owner of a Plant Variety Protection Certificate has the right to exclude others from multiplying, selling, importing and exporting, and stocking the protected variety. However, the protected variety may be used to breed new varieties. Farmers may both sell seed of the protected variety as a commodity (for use in food or feed) and save seed to be used in the production of a crop for use on their own farms.

### 4.4.5 What to Patent

The patent statutes (35 USC 101 *et seq.*) state that whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement to these categories, may obtain a patent (subject to the conditions discussed below). This means that patentable subject matter includes any new and useful:

- Industrial, business, or technical process or method;
- Machine or apparatus;
- Article that is made, including all manufactured articles;
- Chemical compositions, including mixtures of ingredients and new chemical compounds;
- Improvements, including new uses of old devices or new combinations of well-known components;
- Software; and/or
- Synthesized (artificial) and/or modified biological materials.

Although these classes are quite broad, a few subject areas are generally not patentable, including:

- Printed matter;
- Purely scientific or mathematical principles;
- Physical phenomena (for example, electricity or magnetism);
- Abstract ideas;
- Laws of nature;
- Biological materials unchanged from their natural form (products of nature); and
- Immoral inventions (for example, a new method of making/purifying illicit drugs with no known medicinal purpose).

Other inventions, while potentially patentable, receive special protection from the USPTO—these are inventions subject to the Invention Secrecy Act of 1951. Every patent application filed with the USPTO is reviewed to determine whether it describes or claims an invention that, if publicly disclosed, might have a detrimental effect on U.S. national security interests. Such patent applications may require the imposition of a secrecy order. A patent application under secrecy order will continue to be examined by the USPTO, but it will not issue a patent unless and until the secrecy order is rescinded.

Finally, as times and technology change, the range of inventions that can be patented also changes. The courts are constantly reinterpreting what constitutes patentable subject matter and what is potentially patentable.

### 4.4.6 Key Patent Conditions

The key conditions required to obtain a patent are that the invention must differ from prior art, not be obvious to someone of ordinary skill in the art, and have utility. As stated in 35 USC Sections 102 and 103, a patent cannot be obtained if:

- The invention was previously known;
- The invention does not have utility;
- The invention was described in print or patented anywhere or was in public use or on sale more than a year before the date of a provisional application;
- The invention had previously been made by someone else who did not conceal it; or
- The differences between the subject matter to be patented and the prior art are such that the subject matter would have been obvious at the time to a person having ordinary skill in the art.

When a patent attorney says that an invention must be "novel," this means that all of the elements of the invention cannot be previously known, disclosed, or used. At least one element of the invention must be different from the prior art. When the attorney says that an invention must not be "obvious," this means that the invention must function differently or produce surprising results from what is expected by those having ordinary skill in the particular field.

### 4.4.7 Who Can Apply

In the United States, a patent application can be filed only by the inventor or on behalf of the inventor by the employer. The inventor must be an individual or a group of individuals (co-inventors) and cannot be a corporation, partnership, joint venture, or other business entity or an artificial intelligence. An inventor may, however, assign his or her right in the invention to other individuals or to legal entities such as corporations or the government, and those entities may file the patent application as an "applicant." Usually, when an invention is created as part of an employee's duties, the rights must be assigned to the employer as part of the terms and conditions for employment.

There are no personal qualifications for being an inventor. Anyone, regardless of age, nationality, mental competency, or any other characteristic may apply so long as they are the true inventor. All inventors should be included in the patent application, even those employed by external entities such as contractors or university faculty.

### 4.4.8 Protection Provided by Patents

A patent gives the patent owner the right to prevent others from making, using, selling, offering to sell, or importing the invention. If an individual or corporation is engaged in any of these activities (or an essential part of them) without the patent owner's permission, the owner may file a lawsuit for patent infringement. For government-owned patents, it is up to the Department of Justice to enforce the government's rights. However, for those patents, the right of enforcement may be granted to licensees (35 USC 207[a][2]). Usually, this right of enforcement for government-made inventions is granted only in the case of exclusive licenses. The patent owner may obtain an injunction against the infringer of the patent ordering the infringer not to make, use, sell, offer to sell, or import the invention for the life of the patent. The patent owner may also be awarded monetary damages. For jointly owned inventions, both parties have equal and undivided rights, under the U.S. Patent Law. A joint owner of a U.S. patent may make, use, or nonexclusively license the invention or any interest in the invention without regard to the other owner(s) and without regard to the size of the joint owner's share in the patent unless there is some other contract/agreement between the parties stating otherwise.

With respect to patent violations by the U.S. government or a contractor working for the government, a patent holder cannot prevent the government from infringing a patent; however, he or she can sue the government for reasonable compensation (28 USC 1498).

### 4.4.9 Types of Utility Patent Applications

The patenting process entails the submission of highly technical and extremely important documents to the USPTO that begins with the patent application. The patent filing and prosecution process involves a complex set of laws, regulations, policies, and procedures, and it is best practice to hire a patent attorney or a patent agent to assist with the patenting process. For federal invention, a patent application is usually prepared by a patent attorney or a patent agent with the assistance of the inventor, based upon the invention disclosure and considering all relevant prior art publications and patents available. For inventions having utility, there are two types of patent applications: the regular nonprovisional and the provisional application.

#### 4.4.9.1 Nonprovisional Patent Application

A nonprovisional application, also known as a regular nonprovisional utility patent application, begins the USPTO examination process and ultimately may lead to an issued patent. The regular nonprovisional patent application is a complex document and is filed under the provisions of 35 USC 111(a). The regular nonprovisional application must fully describe (enable) the invention and contain a complete written description of the invention, any necessary drawings, the required filing fee, claims, and an oath or declaration. The claims are extremely important, as they set out the characteristics, components, and boundaries of the invention claimed.

#### 4.4.9.2 Provisional Patent Application

U.S. law permits filing for provisional patent applications (35 USC 111[b] and 35 USC 119[e])Filing a provisional patent application in the United States permits the establishment of an initial "effective, or priority, filing date" but does not begin the examination process. The filing date of the provisional patent application does not serve as the basis for measuring the 20-year term of patent protection.

A provisional patent application serves several purposes. First, it can protect an invention against a competing patent application by establishing an earlier filing date, and it can protect against a potential claim that a publication or public disclosure prevents the invention from being patented. Because the rest of the world's patent systems bar patents for inventions that have been previously disclosed publicly, a U.S. provisional patent application allows inventors to publish or give presentations on their inventions without a threat of losing patentability for up to a year. However, the protection provided by a provisional patent application is only as good as the information and data contained in the application. If detailed public disclosure of the invention is contemplated, the contents of the application must be sufficiently detailed to address the planned public disclosure.

The provisional application must fully describe (enable) the invention and contain a complete written description of the invention, any necessary drawings, and the required filing fee but—unlike a complete nonprovisional patent application—does not have to contain claims, an oath, or a declaration. The provisional application is kept in confidence by the USPTO, will not be examined, cannot mature into a U.S. patent, and will expire 12 months after the filing date. To begin the patent application examination procedure, the inventor must file, within 12 months of the filing date of the provisional application, a complete, regular, nonprovisional patent application that references the provisional application the inventor wishes to rely on for the "effective filing date."

However, the 20-year life of the patent begins from the filing date of the regular nonprovisional patent application—not the provisional application. Having an "extra" year is a benefit when marketing and locating licensees.

### 4.4.10 Patent Application Timing

Timing is critical when filing a patent application. In the United States, a provisional or nonprovisional patent application must be filed within one year of the first printed publication, public use, sale, or offer for sale of the invention; otherwise, the opportunity to obtain a patent is lost. In most other countries, the application must be filed before any public disclosure of the invention, meaning that there is no grace period between the first public disclosure and the date the application is filed.

Regardless of the one-year grace period in the United States, premature public disclosure of an invention should be avoided, as it may jeopardize the ability to obtain a patent. Invention review should be obtained from legal counsel or the T2 office to protect the invention before it is publicly disclosed.

The time required to examine "prosecute" a patent at the USPTO is usually at least two years. The time required for examination depends on many factors, including the technological field of the invention, staffing levels at the USPTO, and the body of prior art. In many cases, applications are rejected, modified, and resubmitted—either within a single application process or as a related series of applications. Rejected applications are eligible for an appeals process.

A patent application is published within 18 months of the priority date unless the applicant makes a specific request for nonpublication and agrees not to "foreign file" in other nations ("1120 – Eighteen-Month Publication of Patent Applications" uspto.gov). Publication is preferred because it allows greater use of the technology and avoids hidden patent applications. The priority date is the earliest filing date of a patent application or the filing date of a provisional application upon which the (EA) patent application is based. In any case, after the patent is issued, the USPTO publishes the patent specification and accompanying drawings. Summaries of patents issued each week are published every Tuesday in the Official Gazette of the USPTO. See https://www.uspto.gov/learning-and-resources/official-gazette. Online searches for issued patents and published patent applications can be conducted at https://www.uspto.gov/patents/search. Online searches for issued patents and published patent applications can be conducted at https://www.uspto.gov/patents/search. searches for issued patents and published patent applications can be conducted at https://www.uspto.gov/patents/search. Online searches for issued patents and published patent applications can be conducted at https://www.uspto.gov/patents/search.

### 4.4.11 Foreign Patents

As mentioned previously, the patent grant provides protection and confers rights to a patentee only within the United States, its territories, and its possessions. If protection and rights are desired in international jurisdictions, a patent must be obtained in each country in which the applicant wishes to exercise such rights.

The value of filing a foreign patent application for an invention can be difficult to determine. Foreign patents may be valuable if the international markets for a given technology are large or the need is great. On the other hand, the cost and efforts to secure foreign patents can be greater than the eventual returns (e.g., royalties, license fees, or other compensation) because it is necessary to file and prosecute a patent application for each country or group of countries in which the patent owner is seeking patent rights. Government regulations encourage leaving international rights with the inventor unless the organization chooses to exercise those rights. The government's interest in these rights should be determined before foreign filing.

There are alternative routes to obtaining patent protection in foreign countries. Patent applications may be filed directly with the country's patent office (for example, the German patent office), with a regional patent office (for example, under the European Patent Convention [EPC]), or through mechanisms provided under the Patent Cooperation Treaty (PCT). The EPC covers most but not all European countries. There are also regional organizations such as the African Regional Intellectual Property Organization, the African Intellectual Property Organization, and the Eurasian Patent Convention.

By filing one international patent application under the PCT, the applicant can simultaneously seek patent protection for an invention in each of a large number of countries. In addition, a PCT application may be filed to delay the actual patent application entry into examination in a foreign country or region, thereby substantially delaying the costs associated with foreign filing. Filing a PCT application also allows for postponement of major costs in foreign countries while the invention is still being evaluated for patentability and commercial potential. The PCT mechanism will also provide an inventor with the results of an international patent search and a preliminary examination report regarding patentability before the inventor must enter into costly patent prosecution in the individual countries.

As previously mentioned, the laws and regulations for patent applications can vary widely in other countries. Most countries, for example, do not provide a one-year grace period between the first public disclosure and the date of the patent application. If the patent owner intends to apply for foreign patents or wants to keep the option of a foreign patent available, he or she must adhere to foreign rules, even though U.S. regulations may not be as stringent.

In many cases, federal laboratories do not apply for foreign patents because the costs are judged to be greater than the benefits. However, foreign filing of patent applications for certain medical- or biotech-related inventions may be advisable where the market for the invention and the licensing potential justify the expense. Every invention should be evaluated individually for foreign patenting and licensing potential.

By agreement with foreign defense agencies, inventions owned by the Department of Defense (DoD) may be offered for filing by those agencies in their countries. In return for the effort and expense of such filing, the foreign government receives a royalty-free, nonexclusive license to practice the invention under the foreign patent. Federal laboratories may consult with licensees to determine whether patent rights may be commercially valuable in other countries.

## 4.5 How to Patent an Invention

Before beginning the patent application process (see Figure 4-1), the inventor should be aware of what may be required for a patent application and prepare accordingly. In particular, maintenance of a laboratory notebook during the invention process is good practice. Information contained in the laboratory notebook can be important later in the invention process (e.g., to prove the dates on which something was done). It is also in the inventor's best interest to be well acquainted with the prior art—both during the invention process and when beginning the formal application process. Finally, the inventor is responsible for filling in the necessary forms when initiating an invention disclosure or patent application.

**FIGURE 4-1** | Patent Process Overview


### 4.5.1 Purpose of the Laboratory Notebook

A laboratory notebook, when properly filled out, is a useful record of all original work in a form that is acceptable as evidence in the event that legal conflicts arise concerning the patent application or, later, the patent itself. When properly documented, dated, and witnessed, the entries in a laboratory notebook may:

- Provide proof of who is an inventor;
- Demonstrate the novelty of the invention by proving that the invention was made before any publicly known or available prior developments or concepts;
- Demonstrate that the invention is not obvious (entries showing false leads and negative results are often used to prove that an invention was not obvious at the time); and/or
- Alert patent attorneys to potential statutory problems (e.g., meeting the deadline to file an application within one year of a public disclosure).

### 4.5.2 How to Keep a Laboratory Notebook

(Note: Industries and government organizations are moving toward the implementation of electronic laboratory notebooks. Some are using dual systems with a goal of going completely electronic. The information below applies to nonelectronic notebooks.)

There is no specific format for the laboratory notebook; however, it is preferred that the notebook be bound and contain pre-numbered pages. When using the laboratory notebook, keep the following guidelines in mind:

- Record data directly into the notebook. Do not make notes on loose paper for later recopying.
- To show reduction to practice of invention, an entry should describe the purpose of an experiment or test, the method or means chosen to perform it, and the results obtained—both favorable and unfavorable.
- Entries should record all ideas, experiments, and tests, as well as related activities such as conferences and the making of test equipment.
- Do not erase any part of an entry; instead, draw a line through the material to be deleted.
- Always make entries in ink to avoid any suspicion of alterations.
- Use pages in numeric order.
- Keep the notebook intact—do not tear pages out or remove affixed material.
- Do not leave blank pages or portions of pages without drawing a line through the blank area.
- If material is affixed to a page, such as taping in a sketch, sign and date the affixed material so that the signature is partially on the notebook page and partially on the affixed material. (Affixing material should be reserved for material that cannot be written directly on the notebook page.)
- Entries should be in chronological order.
- Separate sheets and photographs affixed to pages should be referred to in a notebook entry.
- Separate sheets describing an important idea, experiment, or test should be witnessed.
- Do not change or revise drawings in the notebook; make new ones.
- Initial and date any corrections.
- Sign and date each page of the laboratory notebook as it is completed.
- Joint work should be signed by all contributors, and the text should indicate which work is attributable to which inventor.
- Any entry that relates to a possible patentable invention should be signed and dated by two witnesses who can understand the nature of the invention, with their signatures under the saying, "performance observed and understood by."
- Promptly prepare an invention disclosure for anything new or unexpected that is likely to lead to a patentable invention.

### 4.5.3 Prior Art Searches

Understanding similar patents and publications can help a prospective inventor better understand the position of a proposed invention with respect to its prospects for obtaining a patent. In some cases, where the inventor is very familiar with an industry or technical field or is on the threshold of an emerging technology, it may not be necessary to conduct a formal prior art search through the existing patent database, but it is always a good practice to conduct a search. (Online searches may be conducted at www.uspto.gov/patents/search or at other websites.) Inventors and patent attorneys have an obligation to disclose known prior art to the Patent Office. The Patent Office will also do a search as part of the patent examination process.

### 4.5.4 Disclosure Forms

Once a prospective inventor determines that he or she would like to seek a patent, the appropriate disclosure forms should be completed promptly and submitted to the appropriate agency/laboratory office, which can also provide the forms.

Procedures vary in each agency, but the forms will generally include:

- A detailed description of the invention, including enough information to ensure that reviewers have a clear understanding of what the invention entails; and
- The inventor's name(s) and dates for documenting the history of the invention. Detailed instructions are provided with the forms.

### 4.5.5 Naming Co-Inventors

It is of critical importance that a patent application correctly identify the inventors of the invention described therein. Because patent applications must be filed under the name or names of the inventors, a determination of inventorship is made for every application. An inventor is someone who has contributed to the conception of at least one allowed claim of a patent application. Prior to issuance of the patent, the actual naming of inventors should be reviewed based on the claims of the "to be issued" patent. Inventorship is a legal determination that is made by a patent attorney and depends on the specific circumstances surrounding the making of the invention. Inventors must avoid naming other persons as joint inventors if they did not make a contribution to the claimed invention, since such action could render the patent invalid. Likewise, a patent that is subsequently issued from a patent application omitting a person who is a true inventor is potentially invalid. Also, it is important to have knowledgeable witnesses who can corroborate the inventor's testimony regarding the invention; moreover, joint inventors cannot corroborate each other's testimony.

When a patent is granted to joint inventors, the issue of patent ownership becomes a major concern. A joint owner of a U.S. patent may make, use, sell, offer to sell, or import the invention, or take any action related to his or her interest in the invention without regard to the other owner(s) and without regard to the size of the joint owner's share in the patent, unless there is some contract stating otherwise. If the invention is assigned to the government, the government owns the patent. Those inventors assigned to the government are entitled to a share of the license royalties if the invention is licensed by the government.

In cases of joint federal-nonfederal invention ownership, the technology transfer office may work with the federal legal counsel to jointly manage the invention. When the nonfederal entity is a government contractor, it will often assign its rights to the federal entity. Academic institutions may often want to jointly manage the invention. This is typically performed using an inter-institutional agreement (IIA). Model IIAs for NIH can be found at Resources | Technology Transfer (nih.gov). An IIA is considered to be a form of patent license. AUTM has a model IIA that is commonly used by university T2 professionals.

### 4.5.6 Invention Evaluation Process

#### Initial Technical Evaluation

When the patent disclosure forms have been submitted to the appropriate agency office and checked for correctness, they may initially be forwarded to a technical evaluator or technical evaluation committee with knowledge of the subject area identified in the patent disclosure forms. The invention is then evaluated to determine its significance and relation to the mission of the organization.

#### Invention Evaluation Committee

The next step, which usually determines whether a patent application is filed with the USPTO or any foreign patent office, is a review by the laboratory's invention evaluation committee. This committee generally consists of three or more technical experts with some perspective of the related commercial environment, along with a patent counsel, other organization or laboratory stakeholder, and a technology transfer expert as either committee members or advisers. The inventor may or may not be a participant in the invention evaluation committee review process; it depends on the organization. The reasons for selecting a technology for patenting include the desire to minimize liability for patent infringement for government-developed material, to encourage technology transfer and commercialization of government R&D, and to reflect the technical achievements of individuals or laboratories.

The specific guidelines used by invention evaluation committees typically include some or all of the following:

- Usefulness in advancing ongoing projects;
- Applicability to other projects;
- Value to the agency's mission and in minimizing potential patent infringements;
- Potential dollar volume of future procurement;
- Commercial potential (licensing, with or without royalties);
- Usefulness for public health or welfare;

- Humanitarian need/applications;
- Scientific or technical merit;
- Whether patent protection is likely to be necessary for the commercial use of the invention; and
- Whether the invention's primary use is as a research tool.

Upon a vote by the committee, either a patent application is pursued; the committee determines that further development of the technology or other information is required before a decision is made; or the government expresses no interest in filing an application and the invention disclosure is inactivated. If the government has no interest in promoting commercialization, the inventor may retain rights to the invention and pursue a patent application at his or her own expense if no conflict of interest would arise (see 15 USC 3710d and 15 USC 3710a[c][3][A]). The government will generally retain a license to use the invention for governmental purposes.

If the government elects to patent the invention, the agency or laboratory will arrange for the application to be prepared, and the inventor will be asked to review the description, drawings, and claims for technical accuracy. Any forms that are necessary for filing with the USPTO will be completed by patent counsel or the inventor, as required.

### 4.5.7 Patent Application Drafting

Government patent applications are drafted by patent attorneys or patent agents who are registered with the USPTO. The patent attorney can identify the invention and describe it in the format required for filing a patent application. The attorney also handles ownership issues and legal requirements associated with filing the patent application. The patent attorney represents the inventors before the USPTO during the patent examining process.

### 4.5.8 Patent Office Action

After a patent application is received at the USPTO, it is assigned to an examiner who has technical training in the field of the invention. The examination process includes a study of the prior art and additional information filed with the application, and an independent search of the patent and technical literature to determine if the invention is novel, useful, and nonobvious. The examiner also determines whether the application discloses the invention in adequate detail. The examiner then issues the first office action, in which each claim is either allowed or rejected or an objection is indicated.

Claims are usually rejected in the first office action, which is usually completed by the examiner within two to three years of the patent application filing date, depending on the technology being considered. The patent attorney is responsible for working with the examiner and must respond to the USPTO within a specified time, usually three months. For each claim that is rejected, the attorney may challenge the decision or amend the claim, which may require additional information from the inventor.

The USPTO examiner will review the responses and either allow or reject (or object to) each claim. When an unresolved disagreement has developed between the examiner and the attorney, the examiner will make the rejections and objections final and issue a final office action. A final rejection may be appealed to the Board of Patent Appeals. Further appeals to the federal courts are possible but rarely pursued because of the expense. In the rare case of a final objection, the matter may be petitioned to the Commissioner of the USPTO.

### 4.5.9 Patent Issued

If all pending claims are allowed, the examiner sends the attorney a notice of allowance. The attorney then pays the issue fee within three months. About three months after the issue fee is paid, the patent is printed and issued. The issued patent is publicly available at https://www.uspto.gov. Overall, a patent is typically issued within two to five years, depending on the technology. Patent protection begins when the patent is issued and extends for 20 years as calculated from the original filing date.

### 4.5.10 Post-Issuance Matters

The America Invents Act of 2011 allows members of the public and/or those alleged to have infringed on a patent to petition the USPTO for a post-patent grant issuance review to challenge one or more claims within nine months after the grant of a patent. These "post-grant" reviews provide opportunities to ensure that patents meet the high standards of the law.

### 4.5.11 Patent Maintenance

After issuance, a U.S. patent is active for four years. Keeping the patent active thereafter requires the payment of maintenance fees. An escalating series of fees is paid for years 5 through 7, 8 through 11, and 12 through 20. Individual inventors and small businesses are charged fees that are usually half of those paid by large organizations, including the government.

## 4.6 Invention Rights

### 4.6.1 Inventions Made by Government Employees

Whenever a government employee makes an invention, he or she is subject to application of E.O. 10096, providing for a uniform patent policy for the government with respect to inventions made by government employees and for the administration of such policy, as implemented in 37 CFR. 501. The allocation of invention rights between the employee and the government is based on the following:

- The inventor is entitled to all rights if there was no government contribution in hours, funding, facilities, etc., and the invention was not related to the inventor's official duties.
- The government is entitled to all rights if the invention was made during working hours or government funds, facilities, equipment, materials, or information were used, including the time or services of other government employees on official duty; or the invention is directly related to or made in consequence of the inventor's duties.

- Based on this framework, there are three possible outcomes:
    - The government will be entitled to all rights and the inventor to none, and the inventor is required to assign the rights to the government.
    - The government may be entitled to a license to use or practice the invention, and the inventor executes a license to the government.
    - The inventor may be entitled to all rights and the government to none, and the inventor need not sign over any of the rights to the government.

When the government is entitled to retain rights, the inventor may still be entitled to retain all rights if the government's contribution is insufficient equitably to justify a requirement of assignment or if the government determines not to pursue patenting or otherwise to promote commercialization of the invention. Retention of these rights by the inventor is subject to the government's right to freely use the invention for governmental purposes and must accord with government employee conflict-of-interest statutes, regulations, and policies.

If the resulting rights determination is adverse to the inventor, the inventor may appeal the government's decision to the Department of Commerce. Timelines for submitting an appeal are typically set forth in the decision letter.

Even if the invention was made before the inventor became a government employee or is clearly unrelated to his or her duties, it is wise to request and receive an invention rights decision to remove any potential cloud upon the title of the invention. If asked to complete a form pertaining to invention rights, the government employee may want to obtain assistance from the agency legal counsel or retain private legal counsel before completing the form.

### 4.6.2 Inventions Made by Federal Funding Recipients

The Bayh-Dole Act, codified in 35 USC 200 *et seq.*, applies to inventions made as a result of a federal funding agreement such as a grant, cooperative agreement, or contract. The act permits recipients of federal funding to elect to take title to any invention that arises under the federal funding agreement. If the recipient of the federal funding agreement elects to take title, the recipient must file patent applications, seek commercialization opportunities, and report back to the funding agency on its efforts to obtain utilization of the invention. In exchange, the government receives a nonexclusive, nontransferable, irrevocable, paid-up license to make or practice the invention or have the invention made or practiced on behalf of the United States.

The recipients of federal funding agreements do not always elect to retain title to the inventions arising under their agreements. Likewise, they sometimes fail to comply with the requirements and deadlines imposed by the Bayh-Dole Act. In these two situations, the government can require that the federal funding recipient assign rights to the invention to the government. The government may then license the invention as if it were arising from a government organization or laboratory. Usually, however, the federal funding recipient will also retain a nonexclusive license to practice the invention.

The federal funding recipient may also request that the government permit the recipient's employee-inventor to retain rights to the invention. If the government permits this, the federal agency retains a royalty-free, nonexclusive license to the invention and will require the recipient's employee-inventor to meet his or her obligations with respect to filing and prosecuting patent applications and otherwise comply with the goals of the Bayh-Dole Act, such as periodic reporting regarding the utilization or efforts to obtain utilization of the invention.

## 4.7 Copyrights

Copyrights provide legal protection for products of the mind that are tangibly expressed and fixed in some medium, such as writings, paintings, movies, music, sculpture, and computer software. The work must contain some original expression, which can also exist in the form and arrangement of the material. However, as noted below, there is no copyright in government works.

Copyright categories include but are not limited to:

- Nondramatic literary works such as fiction, nonfiction, poetry, textbooks, reference works, etc., including computer software;
- Works of the performing arts, such as musicals, drama, motion pictures;
- Works of the visual arts, such as photographs, paintings, prints, maps, globes, technical drawings, models, etc.; and
- Sound recordings.

Unlike a patent, a copyright protects the form of expression rather than the subject matter of the work. To obtain a copyright, the work must be independently created and possess some degree of creativity. Purely factual works are not copyrightable. But reformatted works might be if the level of creativity in the reformatting meets the copyright office standard of originality. For example, the actual factual data in databases is not copyrightable, but the computer method of accessing the database might be patentable, or the way the data is arranged or formatted might be the subject of copyright.

Copyright protects original works of authorship that have been expressed tangibly and fixed in some medium. The work need not be directly perceptible so long as it may be communicated with the aid of a machine or device like a microfiche reader, CD or DVD player, or computer.

Ideas, procedures, methods, systems, processes, concepts, principles, discoveries, or devices, as distinguished from a description, explanation, or illustration, are not protected by copyright. Copyright protects only the expression of an idea. A copyright confers no protection for function. A patent is the appropriate mechanism for protection of functional items.

Copyright protection is initiated with the creation of a work, without requirement of registration or notice. Registration of copyrights with the federal government is optional. However, registration is required in order to prosecute infringers. A work can be registered by submitting an application, copies of unpublished or published works, and the appropriate filing fee to the Copyright Office (Library of Congress) registration portal at https://www.copyright.gov/registration.

Generally, a copyright owner has the exclusive right to do or authorize certain activities, including:

- Reproduce the copyrighted work;
- Prepare derivative works;
- Distribute copies of the work to others or the public; and
- Perform or display the work publicly.

Copyright protection for individuals (i.e., not works made for hire) extends for the author's lifetime plus 70 years. For a jointly developed work, the protection is for the lifetime of the last surviving author plus 70 years. For works made for hire, which covers most work done by employees where the employer automatically gets copyright privileges, copyright protection extends for 95 years from the date of the first publication or 120 years from the date of creation, whichever occurs first.

Federal law (17 USC 105) states that copyright protection is not available for any works by U.S. government employees, including government-developed software, with very limited exceptions (e.g., NIST can and does copyright and license Standard Reference Data). The government may, however, hold copyrights that are assigned to it or hold copyright protection in foreign countries. If a work was authored jointly by a government employee and a nongovernment employee, those portions of the work authored by the government employee are not copyrightable. Scientific and trade journals may be unaware of the prohibition contained in 17 USC 105 and sometimes request

that government authors execute documents assigning copyright to the journal. In this case, the government employee is advised to inform the publisher in writing that "I am a Federal Government employee and the article [name of article] was written as a part of my official duties. Therefore, it is a work of the U.S. government and as such may not be eligible for protection under the copyright laws."

The prohibitions of 17 USC 105 do not apply to contractors working for the government. Contractor-operated government labs can protect creative works by their employees because their employees are not federal government employees. However, the government receives a license to use these works for its purposes.

## 4.8 Mask Works

Mask works are three-dimensional images or patterns used in fabricating integrated circuits on semiconductor chips. The Semiconductor Chip Protection Act of 1984 established a new type of intellectual property protection for mask works that are fixed in semiconductor chips. Although protection for mask works is not copyright protection, the law provides that an owner, subject to certain limitations, has the exclusive right to perform or authorize certain activities, including:

- Reproducing the mask work by optical, electronic, or any other means; and
- Importing or distributing a semiconductor chip product in which the mask work is embodied.

A mask work must be original and is protected for 10 years after registration or its first commercial exploitation, whichever occurs first.

## 4.9 Trademarks

Trademark protection can be obtained for any word, symbol, logo, sound, color, combination, or other device that is used to distinguish goods and services from those of competitors. Variations of trademarks include service marks, collective marks, and certification marks. All are considered "marks." Service marks indicate the source and quality of a service, while collective marks indicate membership in a cooperative, association, organization, or other group of like-minded persons. Certification marks are intended to certify regional or other geographic origin, material, mode of manufacture, quality, accuracy, or other characteristics of someone's goods or services, or that the goods were produced, or services performed by members of a particular union or other organization.

Under U.S. law, trademark rights are established by using a distinctive mark in commerce. Unregistered marks are referred to as "common law marks." In the United States, there are two registration systems: federal and state registration. Although there is no requirement to register a trademark, registration will confer greater rights of use and enforcement for the owner, since exclusive rights in common law marks are limited to the geographic areas in which they have been used commercially. A state registration confers protection only within that state, while a federal registration may confer protection across the United States and its territories. Registration is

important because it puts the public on notice that a party claims trademark rights and specifies the territory and nature of the business in which rights are claimed. A trademark registration gives the holder a presumption that it owns a valid and protectable trademark for the covered goods or services. While that presumption can be challenged with evidence, it puts the burden on the challenger to prove the registered mark is invalid.

The ® and ™ symbols provide public notice of claims of ownership of the adjacent trademark. The ™ symbol is recognized as an abbreviation for "trademark" and may be used for common law marks that are in use but not federally registered. The ® symbol denotes that the trademark is federally registered with the USPTO. Do not use ® with a mark that does not have a federal registration—it is a violation of federal law.

The owner of a trademark can exclude others from using a similar mark on similar goods that would be likely to confuse consumers as to the source of the goods. This right pertains for as long as the owner owns the mark. Federal trademark registration must be renewed every 10 years. State trademarks have various terms and require renewal. Many federal trademarks exist, although federal agencies vary in their authority to pursue trademark protection and how revenue from their trademarks may be used (see, for example, 10 USC 2260).

## 4.10 Trade Secrets

A trade secret is any commercial formula, device, pattern, process, or information that affords its owner an economic or competitive advantage over others who do not know it. A trade secret derives its protection by being withheld from all except authorized users. Commercially sensitive information that would be compromised by being made public can be protected as a trade secret. Obviously, patent or copyright protection would not be sought for something that cannot be made public. However, trade secrets are often more valuable than patents.

Unlike patents, copyrights, and trademarks, there is no formal governmental procedure for establishing ownership of a trade secret. The two requirements for establishing a trade secret are novelty and secrecy. The level of novelty need not be great. Secrecy, however, is essential. In the event of a lawsuit, the owner of a trade secret must show that adequate precautions were taken so that an individual accused of stealing a trade secret cannot claim that he or she did not know the information was secret. These precautions include the use of confidential disclosure agreements, security precautions against third parties entering an area where trade secrets are kept, stamping documents with a confidentiality label, limiting access to the documents, and informing individuals with access to trade secrets about the need for security.

The improper disclosure or distribution of trade secrets is covered under federal law (18 USC 1905) and 18 USC 1831 *et seq.*), as well as state laws. Misappropriation of a trade secret can entail both civil and criminal penalties. A lawsuit may be filed in state court according to the laws of that state to defend the trade secret and claim damages. Moreover, if a criminal charge should be brought against a federal employee, the federal government could not defend the employee because it would be prosecuting him or her.

Generally, data generated at federal laboratories does not qualify as a trade secret, although it may qualify for protection from release as proprietary under the Freedom of Information Act or it may be protected from disclosure for a reasonable period in which to prepare and file a patent application. Under CRADAs, however, certain types of confidential data generated as part of the CRADA may be protected from disclosure for up to five years. If a trade secret is provided to a federal laboratory by the CRADA partner, it must be protected from disclosure. Government employees are responsible for protecting the financial or proprietary business information of potential vendors or collaborators.

## 4.11 General Guidelines for the Management of Proprietary Data

The T2 office should develop a policy that states the importance of protecting proprietary information and establishes guiding principles for carrying out that policy and negotiating the restrictions on the use of the data. General guidelines for such a policy are to:

- Limit the acceptance of proprietary data to information that is essential to the success of the project or program objectives;
- Limit the use of proprietary data to essential activities or to individuals who need to know;
- Determine where the proprietary data are to be accessed and stored;
- Do not agree to protect orally transmitted data or information unless it is promptly reduced to writing by the owner or sponsor and appropriately marked with a legend; and
- Categorize information received and place legends on proprietary data that specifically identify the restrictions for use and disclosure of the information or data.

An office policy should require identifying the office or personnel responsible for the management of proprietary data. Those responsibilities include:

- Determination of what proprietary information is essential to the project or program objectives;
- Overall protection of proprietary data;
- Assurance that each employee is aware of the confidential nature of proprietary data and the responsibility to protect it;
- Formal receipt of proprietary data;

- Assurance that private-sector parties abide by the terms of any nondisclosure agreements they have signed; and
- Immediately report any allegations of misuse or misappropriation of proprietary data to the servicing legal office.

## 4.12 A Quick Reference

Table 4-1 summarizes the methods for protecting intellectual property rights discussed in this section.

| Method | Description | Term | Subject of Protection |
|---|---|---|---|
| **Patent** | Serves as a contract between the government and an inventor whereby, in exchange for the inventor's complete disclosure of the invention, the government gives the inventor the right to exclude others from making, using, selling, offering to sell, and importing the patented invention | 20 years from date of filing application | Process, machine, manufacture, composition of matter, original design, certain agricultural plants, or any improvements thereof |
| **Copyright** | Provides exclusive right granted by the U.S. government to authors, composers, artists, or their assignees to copy, exhibit, distribute, perform their works, or prepare derivative works | Life of creator plus 70 years | Products of the mind that are produced intangible expressions, writings, paintings, movies, music, sculpture, or computer software |
| **Trade Secret** | Provides the right to withhold any commercial formula, device, pattern, process, or information that affords a businessperson an advantage over others who do not know it | As long as secrecy is maintained | Any commercial formula, device, pattern, process, or information that is secret, substantial, or valuable |
| **Trademark, Trade Name, Service Mark** | Establishes the right to a unique expression that identifies goods or services for commercial purposes | As long as use is continuous | Word(s), name, symbol, device, numeral, picture, sound, color, or any combination thereof |

## 4.13 Licensing

Section Three, "The Technology Transfer Process," includes a complete discussion describing how to license an invention, as well as royalty and payment issues.

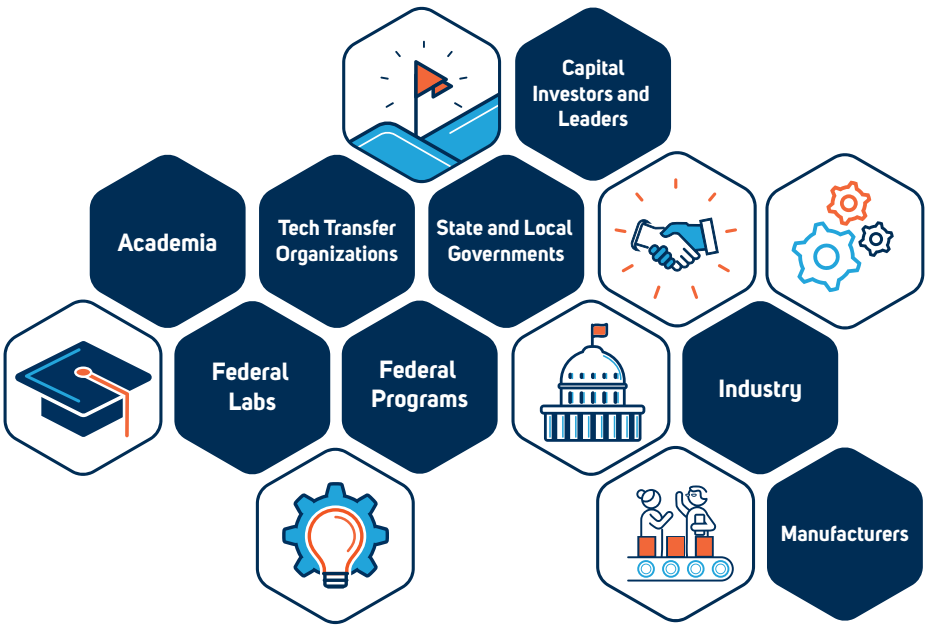
## Section Five

# ORGANIZATIONS SUPPORTING TECHNOLOGY TRANSFER

A repeated theme throughout this Desk Reference is that technology transfer is not a solo activity. While the various sections have touched on some of the groups, it is helpful to think of T2 as an ecosystem that involves many organizations working toward the overall outcome of commercialization of research results. These organizations include federal laboratories, other government programs, academia, state and local governments, investors and lenders, industry (entrepreneurs, small businesses, large businesses), business support, manufacturers, and others. The parts of this ecosystem are interdependent, and knowing how and when to interact can help an ORTA accomplish its mission.

While this section is not an exhaustive list—new groups are added, and some disappear over time—it is presented as an introduction to the ecosystem and the broad network that makes T2 happen. The following groups are potential contacts to help your efforts flourish. Many of the descriptions are taken directly from the organizations' own sites.

**FIGURE 5-1** | Organizations Supporting Technology Transfer



## 5.1 FEDERAL ORGANIZATIONS

This section provides information on the roles played by federal organizations, the relationships among them, and the resources they make available to assist with technology transfer activities.

### 5.1.1 Federal Labs

**As a Partner**

- While T2 is the mission of the ORTA at your lab, it is a community across federal labs. You are part of a larger whole that exists across organizations. There may be joint inventions and joint research. This network across federal labs is why the FLC exists as an organization to support the T2 community.

**As a User**

- Sometimes the end user of research is a federal agency. In these cases, it is a customer, and the tech transfer mission is all about the spin-on to a federal user community. For example, the DoD has an enormous procurement organization focused on new equipment to support the warfighter. As a user community, federal agencies open new markets and are customers for the end products of research.

### 5.1.2 Federal Technology Transfer

A variety of organizations, including those below, are directly involved in coordinating interagency technology transfer for federal agencies and labs.

- Federal Laboratory Consortium for Technology Transfer (FLC) (www.federallabs.org)—The FLC was organized in 1974 and formally chartered by the Federal Technology Transfer Act of 1986 to promote and strengthen technology transfer nationwide. The FLC is the nationwide network of all federal R&D laboratories and centers as well as their parent departments and agencies. It provides a forum to develop strategies and opportunities for linking laboratory mission technologies and expertise with the marketplace, and provides opportunities for its member laboratories to collaborate in technology transfer activities with the private and public sectors.
    - Department of Commerce (DOC) (www.commerce.gov) —The Secretary of Commerce is the responsible person referenced in the Stevenson-Wydler Act and the Bayh-Dole Act. Within DOC:
    - National Institute of Standards and Technology (NIST) (www.nist.gov)—Is delegated the regulatory and appeals functions, is directly named to support the FLC, and operates the Manufacturing Extension Partnership.
    - National Technical Information Service (NTIS) (www.ntis.gov)—The largest central resource for government-funded scientific, technical, engineering, and business-related information, NTIS disseminates scientific and technical information generated by federally funded research and development.
    - U.S. Patent and Trademark Office (USPTO) (www.uspto.gov)—Operates the patent and trademark process for the United States.

- Minority Business Development Agency (www.mbda.gov)—A federal agency dedicated to the growth and global competitiveness of minority business enterprises.
- The Economic Development Administration (EDA) (https://eda.gov/about/) is focused exclusively on economic development and plays a critical role in facilitating regional economic development efforts in communities across the nation.
- Interagency Working Group for Technology Transfer (IAWGTT)—Convened by DOC/NIST, the IAWGTT identifies and disseminates creative approaches to technology transfer from federal laboratories through an interagency task force. The group is made up of T2 leads from federal agencies and legal counsel.
- National Science and Technology Council (NSTC)/Lab to Market Subcommittee (L2M)—This subcommittee has been a White House coordinated policy group that deals with T2-related issues. The group was started in 2015 and is operational as of the publish date of this document. The NSTC is at the direction of the President and re-forms based on current administration needs.
- Small Business Administration (SBA) (www.sba.gov)—SBA is the Cabinet-level federal agency fully dedicated to small business and provides counseling, capital, and contracting expertise as the nation's go-to federal resource and voice for small businesses.

- SCORE (www.score.org)—The nation's largest volunteer network of expert business mentors is dedicated to helping small businesses get off the ground, grow, and achieve their goals. Since 1964, it has provided education and mentorship to more than 11 million entrepreneurs. SCORE is a 501(c)(3) nonprofit organization and a resource partner of the SBA.
- Small Business Development Centers (SBDCs)—SBDCs provide counseling and training to small businesses, and work with the SBA to develop and provide informational tools to support business startups and existing business expansion.
- The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs—SBIR and STTR (see www.sbir.gov) are highly competitive programs that encourage domestic small businesses to engage in federal research/research and development (R/R&D) with the potential for commercialization. Through a competitive awards-based program, SBIR and STTR enable small businesses to explore their technological potential and provide the incentive to profit from its commercialization. Including qualified small businesses in the nation's R&D arena stimulates high-tech innovation, and the United States gains entrepreneurial spirit as it meets its specific R&D needs.
- Procurement Technical Assistance Centers (PTACs) (www.aptac-us.org)—PTACs are dedicated to helping businesses succeed in public-sector marketplaces. Funded, in part, by the U.S. Department of Defense, PTACs provide no-cost advising on all aspects of selling to the federal, state, and local governments.

### 5.1.3 Federal Manufacturing Support

Making new products is part of the commercialization process. While federal labs are rarely direct manufacturers, T2 partners can sometimes use help and support. Some helpful organizations are:

- Hollings Manufacturing Extension Partnership (MEP) (www.nist.gov/mep)—MEP is a public-private partnership with centers in all 50 states and Puerto Rico dedicated to serving small and medium-sized manufacturers.
- Manufacturing USA (www.manufacturingusa.com)—A national network created to secure U.S. global leadership in advanced manufacturing through large scale public-private collaboration on technology, supply chain, and workforce development.

**Academia**

- The Association of Public and Land-grant Universities (www.aplu.org)—A research, policy, and advocacy organization dedicated to strengthening and advancing the work of public universities in the United States, Canada, and Mexico. The association's membership consists of over 200 public research universities, land-grant institutions, state university systems, and affiliated organizations.
- Association of American Universities (AAU) (www.aau.edu)—Founded in 1900, the AAU is composed of America's leading research universities. AAU's 65 research universities transform lives through education, research, and innovation.
- Council on Government Relations (www.cogr.edu)—An association of leading research universities affiliated with medical centers and independent research institutes. They are the national authorities on the financial and regulatory infrastructure and the corresponding compliance requirements associated with managing federal research grants and contracts within research institutions.
- The American Association of Community Colleges (www.aacc.nche.edu)—The primary advocacy organization for the nation's community colleges.

## 5.2 State and Local Governments

- SSTI (www.ssti.org)—Formerly the State Science and Technology Institute. Since 1996, SSTI has worked to share lessons learned from a nationwide network of practitioners and policymakers dedicated to creating a better future through science, technology, innovation, and entrepreneurship. SSTI conducts research on common performance standards, identifies best practices, analyzes trends in and policies affecting the innovation economy, and fosters greater connection and cooperation among and between all public, private, and nonprofit organizations encouraging prosperity.

- The National Governors Association (NGA) (www.nga.org)—The bipartisan organization of the nation's governors promotes visionary state leadership, shares best practices, and speaks with a collective voice on national policy. Its members are the governors of the 50 states and five territories.
- Council of State Governments (CSG)—The Council of State Governments is the nation's largest nonpartisan organization serving elected and appointed officials from all three branches of government. The mission of CSG is to champion excellence in state government.
- Partnership intermediaries—A federal laboratory may work with a partnership intermediary (PI) (see 15 USC 3715), which is an agency of a state or local government that facilitates a federal lab's T2 activities by helping companies or educational institutions with the use of federal technology. Through a Partnership Intermediary Agreement (PIA), a PI assists the laboratory's T2 office, including serving as a technology broker and providing services that increase the likelihood of success in the conduct of the laboratory's cooperative or joint activities with small businesses or educational institutions.
- FLC Partnerships (https://federallabs.org/engage/ways-to-engage/labs-seeking-partners)—The FLC partners with like-minded government and industry organizations and academic institutions aimed at connecting federal innovations with industry to accelerate technology transfer. Through sharing communicative efforts in print and online publications, social media, exhibit space, and other means, the FLC and its partners work to provide valuable resources and support to all members of the T2 community.
- The U.S. Economic Development Administration provides a useful link to many state economic development organizations at https://www.eda.gov/

## 5.3 Other Technology Transfer Organizations

- AUTM (www.autm.net)—Formerly known as the Association of University Technology Managers, AUTM is the nonprofit leader in efforts to educate, promote, and inspire professionals to support the development of academic research that changes the world and drives innovation forward. The AUTM mission is to support and advance technology transfer worldwide.
- Licensing Executives Society International (LESI) (www.lesi.org)—Founded in 1973 and incorporated in 2000, LESI is the umbrella organization of national and regional associations for licensing executives. A board of directors and a board of delegates consisting of representatives of all national and regional societies oversee the activities of LESI.

## 5.4 Industry

- Innovation Research Interchange (www.iriweb.org)—Home to a worldwide network of cross-industry leaders driving innovation and new growth, this organization represents small specialty companies, large global corporations, government labs, and universities.
- Association of University Research Parks (AURP) (www.aurp.net)—Since 1986, AURP has been the pioneer guiding leaders to cultivate communities of innovation at global anchor institutions such as universities, municipalities, federal labs, and corporations. AURP is a dynamic one-stop shop network of university research park and innovation district professionals coupled with innovation suppliers and aligned ecosystem institutions.
- U.S. Chamber of Commerce (www.uschamber.com)—The U.S. Chamber of Commerce is the world's largest business organization. Members range from the small businesses and chambers of commerce across the country that support their communities to the leading industry associations and global corporations that innovate and solve the world's challenges and to the emerging and fast-growing industries that are shaping the future.

## 5.5 Capital

- National Venture Capital Association (www.nvca.org)—As the voice of the U.S. venture capital and startup community, NVCA advocates for public policy that supports the American entrepreneurial ecosystem.
- American Bankers Association (www.aba.com)—The banking industry's champion, the ABA provides its members with the education, advocacy, tools, and insights they need to succeed.

## Section Six

# MARKETING AND COMMUNICATIONS OUTREACH

To enable the public's access to federal technology transfer educational resources and to the range of technology transfer outreach activities, the following information is offered:

| Agency | Links |
|---|---|
| **Office of Naval Research (ONR)** | http://www.navytechtransfer.navy.mil |
| **Department of Homeland Security (DHS)** | https://www.dhs.gov/science-and-technology/technology-transfer-program |
| **U.S. Department of Agriculture (USDA)** | https://www.ars.usda.gov/ott/office-of-technology-transfer/. |
| **National Institutes of Health (NIH)** | Technology Transfer at NIH |
| **U.S. Geological Survey (USGS)** | Tech transfer: Technology Transfer \| U.S. Geological Survey (usgs.gov)<br><br>General outreach: External and Citizen Engagement, Web, and Social Media \| U.S. Geological Survey (usgs.gov)<br><br>Communications and outreach: Featured Stories \| U.S. Geological Survey (usgs.gov)<br>Science Snippets \| U.S. Geological Survey (usgs.gov)<br>Educational Resources \| U.S. Geological Survey (usgs.gov) |

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## Appendix A

# HIGHLIGHTS OF TECHNOLOGY TRANSFER LEGISLATION AND RELEVANT EXECUTIVE ORDERS

Since 1980, Congress has enacted a series of laws to promote technology transfer and to provide technology transfer mechanisms and incentives. The intent of these laws and related executive actions is to encourage the pooling of resources among federal laboratories, private industry, and academia to develop potential commercial technologies.

Highlights of major technology transfer legislation and relevant executive orders are discussed on the following pages. A table summarizing the major legislative themes is provided as Appendix B.

**Finding Technology Transfer Laws, Executive Orders, and Regulations**
The technology transfer laws have been embodied (codified) in the U.S. Code (USC), which provides a single source uniting the provisions of each law. The primary section covering technology transfer is Title 15 (Commerce and Trade),

- 15 USC 3710 through 3714cover the findings of Congress, the purpose of the legislation, definitions, and the establishment of various offices to carry out the intent of the legislation.
- 15 USC 3705 through 3708 provide for the establishment of Cooperative Research Centers, grants, and cooperative agreements. Affiliated with universities or nonprofit institutions, Cooperative Research Centers engage in research that supports technological innovation, and they provide assistance and training to individuals and small businesses. The centers must also use the expertise of federal laboratories, where appropriate.
- 15 USC 3710 through 3710d cover the establishment of federal technology transfer offices (i.e., ORTAs); the FLC; CRADAs; cash awards for inventions, innovations, computer software, or other outstanding contributions; and the sharing of royalties or licensing fees with laboratory inventors.

The complete text of these USC sections and other technology transfer legislation and executive actions can be found in the FLC's 2018 publication, Federal Technology Transfer Legislation and Policy: The Green Book, available in print or e-book form or as a PDF download from the FLC website at https://federallabs.org/learning-center/t2-toolkit/the-flc-greenbook. uExecutive orders generally can be found at https://www.federalregister.gov/executive-orders. Presidential memoranda starting from 1993 can be found at https://obamawhitehouse.archives.gov/briefing-room/presidential-actions/presidential-memoranda.

Regulations governing the licensing of government-owned inventions, including those made under CRADAs, are found in the Code of Federal Regulations (CFR) at 37 CFR 404. The CFR can be accessed at www.ecfr.gov.

Summaries of the technology transfer legislation and executive actions are provided below.

***Legislation and Executive Action Highlights Executive Order 10096(1950)***
Executive Order 10096, "Providing for a Uniform Patent Policy for the Government With Respect to Inventions Made by Government Employees and for the Administration of Such Policy," established federal policy that all rights to inventions made by government employees were assigned to the government if the invention was made within the scope of their employment; during working hours; or with a contribution by the government of facilities, equipment, materials, funds, information, or the time or services of other government employees on official duty. However, if the contribution of the government to the invention is insufficient to justify a requirement of assignment of the invention to the government of the entire right, title, and interest to such invention, or if the government has insufficient interest in an invention, the employee retains title to the invention. In such cases, the government reserves a nonexclusive, irrevocable, royalty-free license in the invention with the power to grant licenses for all governmental purposes.

***Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480)***
The Stevenson-Wydler Act of 1980 is the first of a continuing series of laws to define and promote technology transfer. It made it easier for federal laboratories to transfer technology to nonfederal parties and provided outside organizations with a means to access federal laboratory developments.

The primary focus of the Stevenson-Wydler Act concerned the dissemination of information from the federal government and getting federal laboratories more involved in the technology transfer process. The law requires laboratories to take an active role in technical cooperation and to set apart a percentage of the laboratory budget specifically for technology transfer activities. The law also established an ORTA in each laboratory to coordinate and promote technology transfer.

***Bayh-Dole Act of 1980 (P.L. 96-517)***
The Bayh-Dole Act of 1980, together with the Patent and Trademark Clarification Act of 1984 (98-620), established more boundaries regarding patents and licenses for federally funded research and development. Small businesses, universities, and not-for-profit organizations were allowed to obtain titles to inventions developed with federal funds. GOGO laboratories were permitted to grant exclusive patent licenses to commercial organizations.

### *Small Business Innovation Development Act of 1982 (P.L. 97-219)*

The Small Business Innovation Development Act of 1982 established the Small Business Innovation Research (SBIR) program, requiring agencies to provide special funds for small-business R&D connected to the agencies' missions. SBIR was reauthorized through 2008 by the Small Business Research and Development Enhancement Act of 2000. At the time of this update, the SBIR program has been extended by Congress through 2025.

SBIR is a highly competitive program designed to encourage innovation, as well as the commercialization of products and processes developed by small businesses through federal funds. Each year, participating federal departments and agencies are required to reserve 2.5% of their extramural R&D budgets for SBIR awards. These agencies designate SBIR R&D topics and accept proposals. SBIR awards or grants are awarded competitively to small U.S.-owned commercial businesses with fewer than 500 employees that submit proposals addressing topics published by the agencies. Following the submission of proposals, agencies make SBIR awards based on technical merit, degree of innovation, and future market potential. Small businesses that receive awards or grants then begin a three-phase program. The SBIR program provides four years of confidentiality for data created in the program, and the small-business awardee obtains title to the inventions. A 2002 SBA SBIR Policy Directive forbade the SBIR awardee from partnering/subcontracting with a federal laboratory. However, on a case-by-case basis, the SBA may grant a waiver from this provision if the awarding agency provides sufficient justification, as outlined in the SBIR policy directive. For more information on the SBIR program, visit www.sbir.gov.

### *Federal Technology Transfer Act of 1986 (P.L. 99-502)*

The Federal Technology Transfer Act of 1986 was the second major piece of legislation to focus directly on technology transfer. All federal laboratory scientists and engineers are required to consider technology transfer an individual responsibility, and technology transfer activities are to be considered in employee performance evaluations.

This 1986 law also established a charter and funding mechanism for the previously existing FLC. It enabled GOGO laboratories to enter into CRADAs and to negotiate licensing arrangements for patented inventions made at the laboratories. It also required that government-employed inventors share in royalties from patent licenses. Further, the law provided for the exchange of personnel, services, and equipment among the laboratories and nonfederal partners.

Other specific requirements, incentives, and authorities were added, including the ability of GOGO laboratories to grant or waive rights to laboratory inventions and intellectual property as well as to grant permission for current and former federal employees to participate in commercial development to the extent that there is no conflict of interest.

### *Executive Order 12591 (1987)*

Executive Order 12591, "Facilitating Access to Science and Technology," was written to ensure that federal laboratories and agencies assist universities and the private sector by transferring technical knowledge. The order required agency and laboratory heads to identify and encourage individuals who would act as conduits of information among federal laboratories, universities, and the private sector. It also underscored the government's commitment to technology transfer and urged GOGOs to enter into cooperative agreements to the limits permitted by law.

The order also promoted the commercialization of federally funded inventions by requiring that, to the extent permitted by law, laboratories grant contractors the title to patents developed in whole or in part with federal funds, as long as the government is given a royalty-free license for use.

### *Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418)*

The Omnibus Trade and Competitiveness Act of 1988 emphasized the need for public-private cooperation in realizing the benefits of R&D, established centers for transferring manufacturing technology, established Industrial Extension Services and an information clearinghouse on state and local technology programs, and extended royalty payment requirements to nongovernment employees of federal laboratories. It also changed the name of the National Bureau of Standards to the National Institute of Standards and Technology (NIST) and broadened its technology transfer role, including making NIST the FLC's host agency.

### *National Competitiveness Technology Transfer Act of 1989 (P.L. 101-189)*

The National Competitiveness Technology Transfer Act of 1989 provided additional guidelines and coverage for the use of CRADAs, extending to GOCO laboratories essentially the same ability to enter into CRADAs that previously had been granted to GOGO laboratories by the Federal Technology Transfer Act of 1986. To protect the commercial nature of the agreements, the act allowed information and innovations that were created through a CRADA, or brought into a CRADA, to be protected from disclosure to third parties.

The act also provided a technology transfer mission for the Department of Energy's (DOE) National Nuclear Security Administration laboratories.

### *American Technology Preeminence Act of 1991 (P.L. 102-245)*

The American Technology Preeminence Act of 1991 contained several provisions covering the FLC and the use of CRADAs. The mandate for the FLC was extended to 1996, the requirement that the FLC conduct a grant program was removed, and a requirement for an independent annual audit was added.

With respect to CRADAs, the act included intellectual property as potential contributions under CRADAs. The exchanging of intellectual property among the parties to an agreement was allowed, and the Secretary of Commerce was asked to report on the advisability of creating a new type of CRADA that would allow federal laboratories to contribute funds to the effort covered by the agreement (which is no longer permitted). It also allowed laboratory directors to give excess equipment to educational institutions and nonprofit organizations as a gift.

***Small Business Research and Development Enhancement Act of 1992 (P.L. 102-564)***
This act established the Small Business Technology Transfer (STTR) program. STTR is a three-phase program similar to the SBIR program in many ways. The key differences are that STTR funding is available from five agencies only, and the small business must partner a minimum of 30% of the effort with a U.S. college or university, nonprofit research organization, or federally funded research and development center (FFRDC). The designated agencies select R&D topics, accept proposals, and award grants for a three-phase program that mirrors the SBIR program. Awards are based on small-business/nonprofit research institution qualifications, degree of innovation, and future market potential. The STTR program was reauthorized through 2009 by the Small Business Technology Transfer Program Reauthorization Act of 2001. The STTR program provides early-stage R&D funding directly to small companies working cooperatively with researchers at other research institutions. The objectives of the STTR program are to bridge the funding gap between basic research and commercial products and to provide a way for researchers to pursue commercial applications of technologies. Unlike SBIR, a small business may partner with a federal laboratory that is an FFRDC without the need of a waiver from the SBA. For more information about the program, visit www.sbir.gov.

***National Department of Defense Authorization Act for 1994 (P.L. 103-160)***
This act broadened the definition of a laboratory to include weapons production facilities at the DOE.

***National Technology Transfer and Advancement Act of 1995 (P.L. 104-113)***
This law amended the Stevenson-Wydler Act to make CRADAs more attractive to both private industry and federal laboratories and scientists. The law provides assurances to U.S. companies that they will be granted sufficient intellectual property rights to justify prompt commercialization of inventions arising from a CRADA with a federal laboratory and gives the collaborating party in a CRADA the right to choose an exclusive or nonexclusive license for a pre-negotiated field of use for an invention resulting from joint research under a CRADA. The CRADA partner may also retain title to an invention made solely by its employees in exchange for granting the government a worldwide license to use the invention. The law also revised the financial rewards for federal scientists who develop marketable technology under a CRADA—increasing the annual limit of payment of royalties to laboratories from $100,000 per person to $150,000.

In addition, the act permanently provided the FLC with funding from the agencies.

### *Technology Transfer Commercialization Act of 2000 (P.L. 106-404)*

This act recognizes the success of CRADAs for federal technology transfer and broadens the CRADA licensing authority to include preexisting government inventions to make CRADAs more attractive to private industry and increase the transfer of federal technology. The act permits federal laboratories to grant a license for a federally owned invention that was created prior to the signing of a CRADA. In addition, the act requires an agency to provide a 15-day public notice before granting an exclusive or partially exclusive license and requires licensees to provide a plan for development and/or marketing of the invention and to commit to achieving a practical application of the invention within a reasonable period; however, the act exempts from these requirements the licensing of any inventions made under a CRADA.

### *Energy Policy Act of 2005 (P.L. 109-58)*

This act established within the DOE a technology transfer coordinator as the principal adviser to the secretary on all matters related to technology transfer and commercialization, a technology transfer working group to coordinate technology transfer activities at DOE labs (with oversight by the technology transfer coordinator), and an energy technology commercialization fund to provide matching funds with private partners to promote energy technologies for commercial purposes.

### *America COMPETES Act of 2007 (P.L. 110-69)*

This act authorized programs in multiple agencies focused on the overarching themes of increasing funding for basic research; strengthening teacher capabilities and encouraging student opportunities in STEM educational programs; enhancing support for higher risk, higher reward research; and supporting early-career research programs for young investigators. The primary impact on technology transfer included the elimination of the Department of Commerce Office of Technology Administration and the associated Under Secretary, which had the principal reporting and analytical responsibilities for technology transfer activities government-wide (these duties were reassigned within Commerce).

### *America Invents Act of 2011 (P.L. 112-29)*

This law made major changes to the U.S. patent system. The most prominent was changing it from a first-to-invent system to a hybrid first-inventor-to-file system. The inventor with the earliest filed patent application, not the earliest inventor, is entitled to the patent. This harmonized the U.S. patent system with much of the rest of the world with the goal of making it more efficient, more predictable, and easier for entrepreneurs to simultaneously market products worldwide. The law also allowed filing of patent applications by the owners of interests in the invention rather than exclusively by the inventor. This simplified the processing of inventions when inventors are obligated to assign their inventions to their employer. The law also established administrative procedures for challenging patents in order to improve patent quality.

***Presidential Memorandum*—*Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses (2011)***

This memorandum recognized the importance to our nation's economic growth and strength of federal laboratory technology transfer and instructed agencies to increase the successful outcomes of these activities significantly over the next five years, while simultaneously achieving excellence in their basic and mission-focused research activities. It focused on methods to streamline the federal government's technology transfer and commercialization process, facilitate commercialization through local and regional partnerships, and develop appropriate goals and means for measuring progress. Specifically, the memorandum required agencies with federal research laboratories to develop and implement their own mission-specific plans to improve the rate of technology transfer and, thereby, improve the economic impact of federal research. These plans included agency-defined goals and metrics to measure progress and evaluate the success of new efforts to encourage technology transfer activities.

## Other Legislation

Other laws that are part of the technology transfer effort include:

- The National Cooperative Research Act of 1984 (P.L. 98-462) established several R&D consortia (e.g., Semiconductor Research Corp. and Microelectronics and Computer Technology Corp.) and eliminated some of the antitrust concerns of companies wishing to pool R&D resources.
- The Trademark Clarification Act of 1984 (P.L. 98-620) permitted patent license decisions to be made at the laboratory level in GOCO laboratories and permitted contractors to receive patent royalties to support the R&D effort. Private companies were also permitted to obtain exclusive licenses.
- The Japanese Technical Literature Act of 1986 (P.L. 99-382) improved the availability of Japanese science and engineering literature in the United States.
- The National Institute of Standards and Technology Authorization Act for FY 1989 (P.L. 100-519) permitted contractual consideration for intellectual property rights other than patents in CRADAs and included software developers as eligible for technology transfer awards.
- The Defense Authorization Act for FY 1991 (P.L. 101-510) established model programs for national defense laboratories to demonstrate successful relationships between the federal government, state and local governments, and small businesses, and permitted those laboratories to enter into a contract or a Memorandum of Understanding with an intermediary to perform services related to cooperative or joint activities with small businesses.
- The National Defense Authorization Act for FY 1993 (P.L. 102-484) extended the potential for CRADAs to some DoD-funded FFRDCs not owned by the government.

## Appendix B

# MAJOR LEGISLATIVE THEMES IN FEDERAL TECHNOLOGY TRANSFER

### *Statutory Authority*

DoD guidance strictly holds that any resource transfer between the DoD activity and another activity must be covered by statutory authority. In addition to the DOC authorities in Title 15 of the U.S. Code, DoD regularly uses these authorities:

### *Educational Partnerships*

Educational partnerships (10 USC 2194)—Partnerships can be established between a DoD laboratory and an educational institution. The educational institution can be a local school district, a university, or another nonprofit institution. Partnership goals are improving education in science, math, business, law, and technology transfer. The laboratory can assist the partner by providing lab equipment, teaching classes, offering sabbatical opportunities, involving faculty and students in projects, and giving academic credit. No funding or intellectual property rights may be transferred under the partnership.

### *Prize Authority*

DoD Prize Authority (10 USC 2374a)—DoD authority for prize challenges is generally presumed to be coextensive with the DOC prize authority found at 15 USC 3719. This establishes reporting requirements for DoD activities.

### *Work for Others (Testing)*

Work for Others (Testing) (10 USC 2539b)—This authority allows sale of DoD resources outside the government. Most commonly this is utilized for allowing commercial testing with unique government facilities, but this authority can also be used for lease or sale of government equipment or information. Many elements of the statute are not delegated to laboratories. Results from tests performed under this agreement are protected from public release.

### *Work for Others (Services)*

Work for Others (Services) (10 USC 2563)—Allows DoD industrial facilities to sell articles and services. This authority overlaps 10 USC 2539b, but it was initially intended to allow commercial use of manufacturing facilities owned by the DoD for load balancing. The services can include engineering services. The facilities or services must be otherwise commercially unavailable, and the purchaser must strictly indemnify the United States.

***Software Licenses***

Software Licenses (10 USC 2514 note, P.L. 113-66 § 801, extended by P.L. 117-81 § 832)—Allows DoD laboratories to license software on a similar basis to licensing inventions. The software must not be released publicly by the laboratory. Availability of the software for license must be published, and potential licensees must be given a fair opportunity to license the software. Software can be protected from disclosure and licensed for royalties.


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