FLC Technology Transfer Desk Reference

A Comprehensive Introduction to Technology Transfer

- *Technology Transfer Overview*
- *The Role of the FLC*
- *Cooperative Research and Development Agreements*
- *Intellectual Property Issues*

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FOREWORD

The *Federal Laboratory Consortium Technology Transfer Desk Reference* presents a comprehensive introduction to technology transfer and technology transfer initiatives and mechanisms, as well as to the Federal Laboratory Consortium for Technology Transfer (FLC). The technology transfer initiatives and mechanisms described in this desk reference are promoted and supported by the federal government and apply to all federal agencies and departments. However, 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.

Objectives

The goal of the *Desk Reference* is to help technology transfer practitioners become effective facilitators of technology transfer by:

- Explaining what technology transfer is, why it is necessary, and describing the mechanisms that make it happen
- Describing procedures that can be used to identify and transfer technologies from the government sector to the private sector
- Tracing the history of technology transfer legislation
- Examining the role of the FLC and other technology transfer organizations in facilitating technology transfer
- Encouraging a commitment to the mission of technology transfer.

The *FLC Technology Transfer 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 FLC Laboratory Representatives, Office of Research and Technology Applications (ORTA) personnel, and other technology transfer practitioners—whether in government or industry—to facilitate the transfer of federally funded technologies from the laboratory to the marketplace.

Organization

The *FLC Technology Transfer Desk Reference* comprises the following interrelated topics:

- **Section One, Technology Transfer Overview**—Provides information on the background and legislative history of technology transfer and discusses the tools of technology transfer,

including technology transfer organizations, programs, and mechanisms.

- **Section Two, The Role of the FLC in Technology Transfer**—Examines the mission, goals, and objectives of the FLC; outlines the history of the Consortium; describes its organization and structure; and details the technology transfer activities and services provided by the FLC.
- **Section Three, Cooperative Research and Development Agreement (CRADA)**—Examines the legislative authority, purpose, characteristics, and intellectual property issues relating to CRADAs, and provides links to agency/laboratory CRADA websites.
- **Section Four, Intellectual Property Issues**—Focuses on the importance of intellectual property to technology transfer, protecting intellectual property, patenting and licensing an invention, and royalties.

Also included is an appendix that provides an overview of technology transfer legislation and related Executive Orders.[1]

[1] For a comprehensive guide to technology transfer legislation and Executive Orders, see the FLC's *Federal Technology Transfer Legislation and Policy* (the "Green Book"), 2005.

TABLE OF CONTENTS

Section One TECHNOLOGY TRANSFER OVERVIEW

1.1 TECHNOLOGY TRANSFER BACKGROUND 1-1
1.2 LEGISLATIVE HISTORY OF TECHNOLOGY TRANSFER 1-5
1.3 TOOLS OF TECHNOLOGY TRANSFER 1-8
1.4 TYPES OF FEDERAL LABORATORIES 1-20
1.5 SUMMARY: THE BENEFITS OF INVOLVEMENT IN TECHNOLOGY TRANSFER 1-21

Section Two THE ROLE OF THE FLC IN TECHNOLOGY TRANSFER

2.1 WHAT IS THE FEDERAL LABORATORY CONSORTIUM? 2-1
2.2 HISTORY OF THE FLC 2-4
2.3 FLC TECHNOLOGY TRANSFER ACTIVITIES AND SERVICES 2-9

Section Three COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

3.1 LEGISLATIVE AUTHORITY 3-2
3.2 PURPOSE OF CRADAs 3-2
3.3 CHARACTERISTICS OF A CRADA 3-3
3.4 CRADAs AND INTELLECTUAL PROPERTY 3-4

Section Four INTELLECTUAL PROPERTY ISSUES

4.1 WHAT IS INTELLECTUAL PROPERTY? 4-1
4.2 WHY INTELLECTUAL PROPERTY IS IMPORTANT 4-2
4.3 FORMS OF PROTECTION 4-2
4.4 HOW TO PATENT AN INVENTION 4-11
4.5 LICENSING AN INVENTION 4-18
4.6 ROYALTY AND PAYMENT ISSUES 4-20
4.7 ROLE OF INTELLECTUAL PROPERTY IN TECHNOLOGY TRANSFER 4-22
4.8 SUMMARY OF PATENT/LICENSE BENEFITS 4-24

APPENDIX

OVERVIEW OF TECHNOLOGY TRANSFER LEGISLATION AND RELEVANT EXECUTIVE ORDERS A-1

Section One
TECHNOLOGY TRANSFER OVERVIEW

Section One of the *FLC Technology Transfer Desk Reference* provides an overview of technology transfer as it applies to federal laboratories. It includes a definition of technology transfer, including the goals and purpose of federal technology transfer activities, and an overview of the legislative history of technology transfer. This section also describes the various tools of technology transfer, including such resources as technology transfer organization, programs, and mechanisms for implementing technology transfer. In addition, it details the technology transfer process and provides a summary of the benefits of technology transfer that includes a cross-section of technology transfer success stories.

1.1 TECHNOLOGY TRANSFER BACKGROUND

What is Technology Transfer?

Although there are many definitions of technology transfer, generally speaking, technology transfer is the process by which technology or knowledge developed in one place or for one purpose is applied and used in another place. This broad definition covers a wide variety of procedures or mechanisms that can be used to transfer technology and is not necessarily restricted to federal activities.

However, the federal government has for many years been actively supporting and encouraging technology transfer with respect to federally generated technologies. Therefore, the phrase "technology transfer" most often refers specifically to transfers occurring between federal laboratories and any nonfederal organization, including private industry, academia and state and local governments. The Federal Laboratory Consortium for Technology Transfer (FLC), which was formally chartered by Congress to facilitate technology transfer in the United States (see Section Two), has developed the following definition that accommodates the technology transfer activities of a wide variety of federal agencies and their R&D laboratories and centers:

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

In some cases, however, technology transfer also can occur between federal agencies, although the primary emphasis is on transfers to all types of nonfederal organizations. In addition, federal technology transfer activities are not always ***from*** a federal laboratory to another party. There are occasions when technology transfer mechanisms can be used by a federal laboratory to bring in from the outside technologies or knowledge that can assist the laboratory in achieving its mission goals. This might, in fact, be a lower-cost alternative to developing a technology or expertise entirely within the laboratory.

Forms of Technology Transfer

The technology transfer process can be very simple or it can be quite complex; but basically, it involves a technical resource involved in R&D (e.g., a federal laboratory), a user of that technology (e.g., a small business), and an interface that connects the two and facilitates movement of the technology from one organization to the other. Some examples of this process include:

- Transfer of technology developed primarily for nongovernment applications
- Secondary applications of technology originally developed for specific government applications
- Mission-related technology transfer between government organizations
- *Ad hoc* technical assistance
- Collaborative R&D between government and nongovernment technical activities and user communities
- Commercial technology transferred for use in government applications.

The forms technology transfer may take include:

- **Commercial transfer—**Refers primarily to the transfer of knowledge or technology from the government to commercial organizations that can realize the potential of new or improved technologies.
- **Exporting resources—**Occurs when federal personnel provide expertise to outside organizations, e.g., through collaborative agreements or volunteer services.
- **Importing resources—**Occurs when a federal laboratory or agency engages in a cooperative effort that brings outside technology into the agency to enhance the agency's efforts.
- **Dual use—**Involves the development of technologies, products, or families of products that have both commercial and federal

government applications. The goal of dual-use technology is the closer integration of federal government and commercial technology and manufacturing.

- **Scientific dissemination—**Includes the traditional methods of publication, conference papers, working papers circulated among colleagues, etc. The sharing is multidirectional and involves government, industry, and academia.

Dynamics of Technology Transfer

The dynamics of the technology transfer effort can be described as market pull or technology push. Technology transfer occurs as a result of market pull when a need or problem causes companies to seek federal technology (e.g., to improve safety, curtail costs, or modify existing products). Technology push occurs when innovations or inventions are used to create new markets or consumer needs. In both cases, the strategic objective is to get federally supported R&D into the marketplace more efficiently and to bring industry into the federal R&D pipeline as early as possible.

To facilitate the success of technology transfer, several changes in federal law and administrative policy have been implemented since 1980. To accelerate the development cycle, technology transfer laws have encouraged the use of innovative collaboration and cooperation mechanisms, such as the Cooperative Research and Development Agreement (CRADA), that can be developed and implemented much more rapidly than traditional contracts and procurements. The federal strategy also includes legal protection for licensing specified intellectual property and sharing licensing income.

In addition, the federal government's commitment to technology transfer has enabled it to achieve greater harmony with commercial practices and standards and to foster partnerships with the private sector.

Goals for Technology Transfer

In a global economy, the economic wealth of one nation is directly affected by its relationships with other nations. A major long-term goal of the federal government is sustained U.S. economic growth, and one of the foundations of sustained economic growth is the development and commercialization of new technologies. To that end, the federal investment in technology research and development is seen as a major contribution to economic growth. Thus,

federal technology transfer programs are intended to make the most of the R&D budget and the expertise of both government and nongovernment scientists and engineers, increasing the return on investment of the federal R&D budget and helping federal agencies meet mission requirements while enhancing U.S. competitiveness in the world economy.

Leveraging R&D Budget Dollars

According to the most recent data available from the National Science Foundation (NSF),[1] U.S. R&D from all sources was approximately $312 billion in 2004, an increase of 4.7% from 2003. Industry provided 64% ($199 billion) of the total R&D funding in 2004, either on internal R&D projects or for contracted R&D activities. Federal government R&D spending also increased in 2003 and 2004, with the federal government providing 30% ($93.4 billion) of R&D funding. However, unlike the business sector, the majority of federal R&D dollars financed R&D in other sectors, with only 40% ($37.4 million) of federal R&D funds actually financing federal agencies/ laboratories and federally funded R&D centers. The other sectors of the economy (e.g., state governments, universities and colleges, and nonprofit institutions) contributed the remaining 6% ($20 billion).[2]

Clearly, federal laboratories can foster and maintain advanced technical capabilities by establishing closer ties among themselves and the commercial and academic sectors. For example, through collaborative efforts federal laboratories can use commercially developed technology, and commercial organizations can capitalize on the laboratories' R&D. The commercial success of technology sharing will ensure that the technologies will be supported and improved through marketplace demand. The commercial viability of products and processes required for the federal government will not only support the commitment to advanced technical capability, but also support the general economic security and prosperity of the U.S.

The benefits of technology transfer efforts include:

- **Lower cost—**Greater competition and higher volume commercial production efficiencies mean that products cost considerably less than products developed for federal government use only.
- **Increased industrial capacity and responsiveness—**An industrial base that is stronger and more responsive to surge demands.

[1] "U.S. R&D Continues to Rebound in 2004," National Science Foundation, January 2006; available on the web at www.nsf.gov/statistics/.

[2] In terms of R&D performance, the NSF reported that federal agencies/laboratories and federally funded R&D centers performed 12% of total U.S. R&D in 2004.

- **Decreased development time**—Products transition from an initial idea to a fielded system in less time than exclusively federal government products.
- **Increased innovation potential—**Because technologies are increasingly developed in the commercial sector, technology transfer will increase the opportunity for incorporating leading-edge commercial technology into federal government products.
- **Increased U.S. competitiveness—**Technology transfer increases economies of scale and strengthens the national industrial base. The overall result is to strengthen the competitiveness of the U.S. in the global economy.

1.2 LEGISLATIVE HISTORY OF TECHNOLOGY TRANSFER

Technology Transfer Legislation

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 Orders is to encourage the pooling of resources when developing potential commercial technologies.

The sharing among federal laboratories, private industry, and academia includes not only technologies, but personnel, facilities, methods, expertise, and technical information in general.

The following chronological outline of the history of technology transfer provides a summary of the major technology transfer legislation and related Executive Orders, as well as other legislation that has a less direct impact on the technology transfer effort. (The major items of legislation are identified by bold-face type.) *A more detailed discussion of this legislation is provided in the Appendix.*

- **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 (1950)**—Established federal policy that all rights to inventions made by government employees within the scope of their employment are assigned to the government.
- **Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480)**—Seminal technology transfer law required federal laboratories to actively participate in and budget for technology transfer activities.
- **Bayh-Dole Act of 1980 (P.L. 96-517)**—Amended Stevenson-Wydler Technology Innovation Act, focusing on the use of

intellectual property (i.e., patents and licenses) to implement technology transfer by allowing small businesses, universities, and not-for-profit organizations to obtain title to inventions developed by them under federal funding agreements.

- **Small Business Innovation Development Act of 1982 (P.L. 97-219)**—Established the Small Business Innovation Research (SBIR) program.
- **Patent and Trademark Clarification Act of 1984 (P.L. 98-620)**—Further amended Stevenson-Wydler and Bayh-Dole regarding the use of patents and licenses to implement technology transfer.
- **Federal Technology Transfer Act of 1986 (P.L. 99502)**—Second major piece of technology transfer legislation focusing directly on technology transfer; established the FLC and enabled federal laboratories to enter into Cooperative Research and Development Agreements (CRADAs) and to negotiate licenses for patented inventions made at the laboratory.
- **Executive Order 12591, Facilitating Access to Science and Technology (1987)**—Further expanded federal technology transfer responsibilities in several areas (see Appendix).
- **National Institute of Standards and Technology Authorization Act for FY 1989 (P.L. 100-519)**—Expanded intellectual property rights in CRADAs.
- **National Competitiveness Technology Transfer Act of 1989 (P.L. 101-189)**—Amended the Federal Technology Transfer Act of 1986 to expand the use of CRADAs and increase nondisclosure provisions.
- **Defense Authorization Act for FY 1991 (P.L. 101-510)**—Established model technology transfer programs for Department of Defense (DOD) laboratories.
- **American Technology Preeminence Act of 1991 (P.L. 102-245)**—Extended the mandate of the FLC and modified CRADA requirements.
- **Small Business Research and Development Enhancement Act of 1992 (P.L. 102-564)**—Extended and modified the SBIR program and established the Small Business Technology Transfer (STTR) program.
- **National Defense Authorization Act for FY 1993 (P.L. 102484)**—Extended CRADAs to federally funded R&D centers.
- **National Department of Defense Authorization Act for 1994 (P.L. 103-168)**—Included Department of Energy (DOE) weapons production facilities in the definition of a laboratory.

- **National Technology Transfer and Advancement Act of 1995 (P.L. 104-113)**—Amended Stevenson-Wydler to make CRADAs more attractive to federal laboratories/scientists and private industry; provided the FLC with reliable funding.
- **Technology Transfer Commercialization Act of 2000 (P.L. 106-404)**—Streamlined the statutory licensing process, redefined what could be licensed, and provided authority for government agencies to in-license in order to "bundle" inventions for licensing purposes.
- **United States Court of Appeals for the Federal Circuit**—Established under Article III of the U.S. Constitution in 1982, the U.S. Court of Appeals for the Federal Circuit (CAFC) was formed by the merger of the U.S. Court of Customs and Patent Appeals and the appellate division of the U.S. Court of Claims. The CAFC has nationwide jurisdiction over a variety of areas, including patents and trademarks. Appeals to the Court come from all federal district courts, as well as from the Board of Patent Appeals and Interferences and the Trademark Trial and Appeals Board. The Court's opinions may be obtained on its home page at www.fedcir.gov.

United States Code

All of the preceding laws are embodied in the United States Code (USC), which provides a single source uniting the provisions of each law. The primary section of the USC covering technology transfer is Title 15 (Commerce and Trade), Chapter 63 (Technology Innovation). Other titles and chapters of the USC cover related topics, such as copyrights, patents and intellectual property rights.

15 USC 3701 through 3704 cover 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 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 Offices of Research and Technology Applications (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.

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, Exclusive Licensing. Regulations governing the rights to inventions made by nonprofit organizations and small businesses, when such inventions were the result of federal funding, are found at 37 CFR 401, Exclusive Licensing.

1.3 TOOLS OF TECHNOLOGY TRANSFER

The laws, orders, and regulations that have been written to implement federal technology transfer have created, or encouraged the development of, the tools of technology transfer. These tools include a number of federal, state, and local organizations and programs, as well as a wide variety of mechanisms to implement technology transfer.

Organizations

The ability to connect federal laboratory resources with other federal laboratories, industry, academia, and state and local governments is essential to the success of technology transfer. A number of organizations on national, state, and local levels are available to provide the connections needed to effect technology transfer. The key technology transfer organizations are the ORTAs and the FLC; other organizations include professional societies, and state and local government organizations. The following pages provide details on the roles played by these organizations, the relationships among them, and how you can use their resources to assist with your own technology transfer activities.

Key National Technology Transfer Organizations

Office of Research and Technology Applications

The Stevenson-Wydler Technology Innovation Act of 1980 called for the establishment of an ORTA in each major federal laboratory. As specified in 15 USC 3710, each federal laboratory with 200 or more scientific, engineering, and related technical positions must have an ORTA staffed by at least one full-time person. ORTA staff members are highly competent technical managers who are full participants in the technology transfer process.

According to 15 USC 3710, the specific functions of each ORTA office are to:

- Prepare assessments for selected R&D projects in which the laboratory is engaged which, in the opinion of the laboratory, may have commercial potential
- Provide and disseminate information on federally owned or originated products, processes, and services with potential application to state and local governments and private industry
- Cooperate with the National Technical Information Services (NTIS), the FLC, and other organizations that link the R&D resources of the laboratory to potential users in state and local governments and private industry
- Provide technical assistance to state and local governments
- Participate, where feasible, in local, regional and state programs designed to facilitate or stimulate the transfer of technology.

At many laboratories, the function of the ORTA includes technology assessment; marketing of laboratory resources; the establishment, negotiation and management of cooperative R&D under CRADAs; and the negotiation of licenses for intellectual property. An ORTA is similar to a "high-tech marketing department" that focuses on two types of marketing efforts: technology transfer services and, in conjunction with the technology developer, specific applications to potential collaborators or adopters. The ORTA is the laboratory's focal point for implementing technology transfer and performs the role of a technology "broker," connecting the people and organizations inside and outside the laboratory who are essential to effective technology transfer (see Figure 1-1).

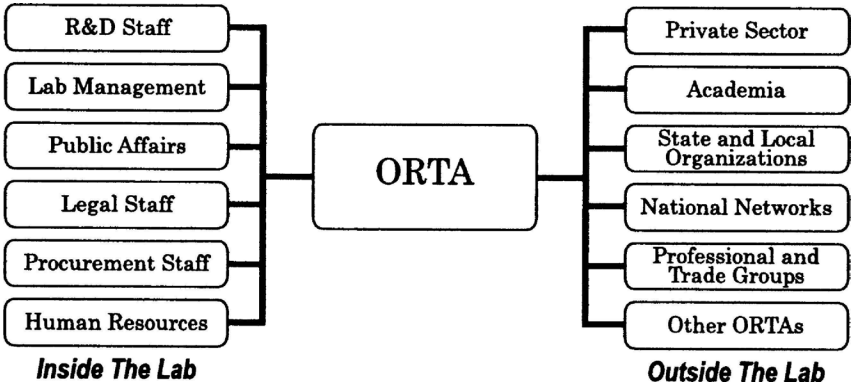


Figure 1-1. The ORTA as a Technology Transfer Broker

Federal Laboratory Consortium for Technology Transfer

Chartered by Congress in 1986, the FLC (www.federallabs.org) is a volunteer organization with a membership consisting of several hundred federal research laboratories and centers representing nearly every federal department and agency dedicated to furthering technology transfer. The mission of the FLC is to promote the rapid movement of federal technology R&D from federal laboratories into the mainstream of the U.S. economy. The FLC offers a wide variety of technology transfer services and resources, including the Technology Locator Service that connects potential partners with appropriate federal resources, a broad range of training courses, high-quality reference materials and publications, a monthly newsletter, national and regional meetings, and a prestigious technology transfer awards program. The FLC website provides information about federal technology transfer, access to member federal laboratories and their resources, the full text of the FLC's publications, and many additional resources for technology transfer practitioners. A detailed discussion of the FLC's mission, history, organization, goals and objectives, and technology transfer services and activities is provided in Section Two, Introduction to the Federal Laboratory Consortium.

Other National Technology Transfer Organizations

Association of University Technology Managers

The Association of University Technology Managers (AUTM) (www.autm.net) is a nonprofit association with a membership of more than 2,700 technology managers and business executives who manage intellectual property. AUTM's roots are in the academic technology transfer community; however, in addition to members from universities, AUTM has members representing institutions, teaching hospitals, industry, legal and financial institutions, and government organizations.

AUTM offers an annual licensing survey and results of other research activities, annual and regional meetings, professional development courses and meetings, AUTM publications, and public education.

Licensing Executives Society

The Licensing Executives Society (LES) (www.usa-canada.les.org) is a professional organization of over 5,000 members who are involved in the transfer, use, development, manufacture, and marketing of intellectual property. LES membership includes

professionals in the fields of law, academia, and science, from both the government and the private sector. The society focuses on networking and training to keep members up-to-date on developments in licensing practices, law, regulation, and current issues relevant to licensing; and publishes numerous books, pamphlets and other educational materials relating to licensing issues.

State Science & Technology Institute

The State Science & Technology Institute (SSTI) (www.ssti.org) is a national nonprofit organization dedicated to improving government-industry programs that encourage economic growth through the application of science and technology. SSTI, which has developed a nationwide network of practitioners and policy makers, assists states and communities with building technology-based economies, conducts research on best practices and trends in technology-based economic development, encourages cooperation among and between state and federal programs, and disseminates information about technology-based economic development.

Technology Transfer Society

Founded in 1975, the Technology Transfer Society (T2S) (www.t2society.org) is a not-for-profit professional organization dedicated to sharing methods, opportunities, and approaches with the technology transfer community. T2S provides resources of information and contacts through:

- Technology transfer programs
- Publications, including the *Journal of Technology Transfer,* a bi-monthly newsletter, and the *Annual Proceedings of the Technology Transfer Society*
- Forums
- Annual conferences.

State and Local Organizations

Technology transfer is actively supported at state and local levels by a variety of organizations, centers, and commissions. These resources can:

- Preview technical assistance requests from businesses to ensure that assistance is not competing with private enterprise
- Provide existing networks to leverage resources leading to more small, disadvantaged business contracts
- Match laboratory/facilities technology to industry
- Provide input regarding industry needs

- Ensure that laws do not impede technology transfer
- Provide a matching grant approach to consortia of university and private research teams
- Start venture capital or commercialization programs
- Provide incentives for adopting more productive technologies.

By their very nature, state and local programs designed to promote business interests in the various states will differ. In general, however, the business service providers in a particular state or region will be some of the most effective intermediaries between the laboratory and the needs of business and industry in that state/region.

For example, local Chambers of Commerce are very closely tied to the needs of local business and industry and will most likely know most of the existing small businesses and economic development organizations in the state. Working through a local Chamber of Commerce can result in cooperative relationships with local civic and business leaders as well as members of organizations who provide a variety of services to business and industry.

Most state and local postsecondary academic institutions work closely with state business and industry through collaborative research, consulting, provision of information services, and continuing education. Many academic institutions provide market research, innovation centers, and patenting and licensing services. Making area academic institutions aware of the resources in a local laboratory can help these institutions connect business and industry to resources in the laboratory and may stimulate the academic institution to become involved in collaborative research with the laboratory in areas of mutual interest.

The Association of Small Business Development Centers (ASBDC) (www.asbdc-us.org) provides confidential assistance, counseling, and advice to small business owners and those who want to start their own business. ASBDC strives to promote growth, expansion, innovation, increased productivity, and managerial excellence for small and medium businesses to help grow local, state, and national economies.

Other state and local resources that can provide information pertaining to the needs of local industry include:

- Local business organizations, such as state bankers' or realtors' associations
- Local chapters of professional organizations
- Other area federal laboratories and agencies

- State agencies
- Local incubators
- Service Corps of Retired Executives (SCORE)
- State Association of Counties
- National Conference of State Legislatures
- Council of State Governments
- American Legislative Exchange Council
- National Association of State Energy Officials
- National Congress of American Indians.

Programs

The various laws mandating technology transfer activities have also established a number of programs to provide money in the form of grants or other monetary awards to business and academic participants in technology transfer.

The primary programs that provide such funding include the following.

Small Business Innovation Research (SBIR)

The SBIR Program (www.sba.gov/sbir) was originally authorized in 1982 and reauthorized through 2008 by the Small Business Research and Development Enhancement Act of 2000. SBIR is a highly competitive program designed to encourage the commercialization of products and processes developed by small businesses through federal funds. Each year 11 federal departments and agencies are required to reserve a portion of their R&D budgets for SBIR awards:

- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Department of Energy
- Department of Health and Human Services
- Department of Homeland Security
- Department of Transportation
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation.

These agencies designate SBIR R&D topics and accept proposals.

SBIR awards or grants are awarded competitively to small U.S.-owned businesses (commercial businesses with less than 500 employees) that submit proposals addressing topics published by the agencies. How an agency selects a published topic varies from agency to agency. In some cases, the agencies select the topics and the businesses submitting the proposals may have no other knowledge of the topic and no contact with anyone at the agency. In other cases, small businesses with ongoing relationships with an agency may actually suggest a given topic and, when the topic is published for open competition, may be the most knowledgeable applicant.

Following submission of proposals, agencies make SBIR awards based on small business qualification, degree of innovation, technical merit, and future market potential. Small businesses that receive awards or grants then begin a three-phase program:

- Phase I is the startup phase. Awards of up to $100,000 for approximately 6 months support exploration of the technical merit or feasibility of an idea or technology.
- Phase II awards of up to $750,000, for as many as 2 years, expand Phase I results. During this time, the R&D work is performed and the developer evaluates commercialization potential. Only Phase I award winners are considered for Phase II. (Note: The SBA has determined that an agency may provide Phase II funding to another agency's Phase I awardee and that agencies may jointly fund Phase II awards.)
- Phase III is the period during which Phase II innovation moves from the laboratory to the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR federal agency funding.

For more information on the SBIR program, visit the Small Business Administration's (SBA) SBIR/STTR website at www.sba.gov/sbir or contact the SBA Office of Technology at (202) 205-6450.

Small Business Technology Transfer (STTR)

Authorized in 1992, the STTR program is a three-phase program similar to the SBIR program in many ways (see above). The key difference is that STTR funding is available only from the DOD, DOE, HHS, NASA, and NSF, and award applicants must be collaborative partnerships involving a small business and a U.S.-located college or university, nonprofit research organization, or federally funded research center. The designated agencies select R&D topics and accept proposals, and award grants for a three-

phase program that mirrors the SBIR Program described above. 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. A small business and a research organization team together for a cost-shared STTR grant. The small business is the dominant partner in that it is responsible for managing and controlling the budget.

For more information about the STTR Program, visit the SBA SBIR/STTR website (www.sba.gov/sbir) or call the SBA Office of Technology at (202) 205-6450.

Mechanisms

The following paragraphs describe a number of mechanisms that facilitate technology transfer efforts from federal laboratories to the private sector. Models/samples of many of these mechanisms are available in the FLC Technology Transfer Mechanisms Database at www.federallabs.org/t2mechanisms.

Cooperative Research

Cooperative research fosters the leveraging of resources. When a laboratory and a private-sector party or parties share mutual research interests, it creates a "win-win" situation. A widely used formal cooperative research mechanism is the Cooperative Research and Development Agreement (CRADA), which is a written agreement (not a procurement contract or a grant) between one or more federal laboratories and one or more nonfederal parties. CRADAs are more fully covered in Section Three. See the FLC T2 Mechanisms Database (www.federallabs.org/t2mechanisms) for model CRADAs from various federal agencies.

Intellectual Property (IP)

Another major technology transfer mechanism is the use of intellectual property resulting from R&D activities at federal laboratories—encouraging scientists and engineers to disclose their

inventions, and government laboratories to license inventions to companies that will commercialize them.

By using patents and licensing agreements, the government facilitates the transfer of federally funded R&D to the private sector for commercialization of the technology. Intellectual property issues relating to CRADAs are fully discussed in Section 3. A complete discussion of the various forms of intellectual property and how it is used to achieve the goals of technology transfer is provided in Section 4. (Go to www.federallabs.org/t2mechanisms for various patent and software license agreements.)

Incubators

An incubator is a multi-tenant business development facility for startup companies. The idea is that startup companies will benefit from being in close proximity to other startups and to relevant technical facilities as well as technical and business expertise. During the time the startup company is physically located in the incubator facilities, the sponsor (i.e., state or local business community) can assist the company with technical and managerial aspects. After a certain length of time, though, the company is expected to move to a new location where it can function on its own.

Informational Materials

Successful accomplishment of technology transfer depends largely upon the active involvement of both laboratory personnel and potential partners in the private sector, academia, and other government agencies. Various mechanisms are used to implement technology transfer awareness among both parties, such as:

- Presentations
- Newsletters
- Brochures and pamphlets
- Electronic and collateral materials
- Internet websites.

Examples of these types of informational materials are available on the FLC website (www.federallabs.org).

Personnel Exchanges

Exchanges of laboratory personnel to the private sector and private-sector personnel to the laboratory to exchange expertise and information can enhance the knowledge, expertise, and research

of both parties. Personnel exchanges are excellent first steps toward long-term alliances between federal R&D facilities and U.S. industry. Personnel exchanges can also foster collaborative research. Generally, no proprietary data are exchanged, the cost is paid by the organization sending the personnel, and the programs are short-term (usually one year).

Technical Assistance

Technical assistance allows the laboratory or facility to provide knowledge, specialized equipment, and facilities to be used for promoting U.S. competitiveness. These agreements allow government scientists and engineers to provide assistance, with or without a fee, to nonfederal parties. Generally, technical assistance is provided at the request of the nonfederal party to solve a problem for which the laboratory scientist or engineer has specialized expertise. This assistance may be as simple as providing information over the phone or as involved as spending a few days onsite.

Collegial Interchange, Conferences, and Publications

Collegial interchange is the informal and free exchange of information among colleagues; it is a basic mechanism for technology transfer. Presentations at professional and technical conferences concerning the results of R&D or discussions of work in progress are considered mechanisms of technology transfer. In addition, government R&D results are often published in professional journals to share information with others. However, caution should be taken not to disclose information prematurely if the results of the research may result in a patent application or if proprietary data are involved.

Grants and Cooperative Agreements (Assistance Instruments)

Grants and cooperative agreements are entered into by the government with a recipient to transfer money or property to the recipient to support or stimulate research. Educational grants are provided to awardees to pursue educational interests, generally in areas of interest to the government. If the award is for an educational grant, the government does not retain use rights to inventions made by the awardee. For all other grants, the provisions of the Bayh-Dole Act apply. Grants are used when the goal is to stimulate R&D with little government involvement. Cooperative agreements are used like grants, except they are characterized by substantial government technical involvement.

Use of Facilities

Laboratory facilities contain unique, complex, experimental scientific equipment and expertise that are not readily available in the private sector. The government allows the use of user facilities by the technical community, universities, industry, and other federal laboratories and centers. The research may be proprietary or nonproprietary in nature, and intellectual property provisions must be detailed in the agreement.

Memorandum of Understanding (MOU) and Memorandum of Agreement (MOA)

An MOU or MOA is an agreement between two government, academic, or private-sector partners (e.g., government, university, or private sector, including nonprofits). In a number of cases, MOUs have been used to establish the organizational links in technology transfer efforts.

Partnership Intermediaries

Affiliated with a state or local government, a partnership intermediary assists companies in utilizing federal technology, provides assistance to ORTAs, and serves as a technology broker. A partnership intermediary relationship is normally implemented via a MOU.

Alliances

Informal tools that allow a federal laboratory to enter into a MOU with other organizations to pursue common technology interests. Alliances enhance the technical capabilities of partners and facilities and are implemented by a nonbinding document that outlines the principles of the alliance.

Miscellaneous Mechanisms

A number of federal agencies utilize various miscellaneous types of technology transfer mechanisms that are specific to the legislation and regulations affecting their agencies. For example, the DOD uses a vehicle known as Other Transactions, which are flexible agreements that are limited to use by DOD laboratories and that are not subject to the statutes and regulations that apply to contracts, grants, and cooperative agreements. Under Other Transactions, patent and data rights are negotiable, and cost-shared government funds are not to exceed the total amount of funding provided by the nongovernment parties.

Other Resources

In addition to the major organizations and programs for technology transfer, there is a variety of other resources, including other federal agencies, state organizations, and various databases of technical information, that are themselves part of the technology transfer process.

National Technical Information Service

As the largest central resource for government-funded scientific, technical, engineering, and business-related information, NTIS (www.ntis.gov) actively disseminates scientific and technical information generated by federally funded research and development in over 350 subject areas from over 200 federal agencies. As part of the overall technology transfer effort, 15 USC 3704b-2 requires that each federal agency transfer unclassified scientific, technical and engineering information to NTIS for dissemination. Such information includes technical reports, computer software, technology transfer application assessments, and information regarding training technologies.

Defense Technical Information Center

DTIC (www.dtic.mil) provides a central point within the DOD for acquiring, storing, retrieving and disseminating scientific and technical information. DTIC maintains a variety of technical information databases and provides online access to these databases as well as gateways to other government and commercial databases.

In support of technology transfer, DTIC has organized a list of 22 technology transfer topics (e.g., domestic technology transfer, dual-use technology transfer, manufacturing technology transfer, technology assessments, etc.) and provides sample lists of citations to encourage access to the referenced reports.

A new online system, the Cooperative Programs for Reinvestment (CPR), has recently been established to provide Internet access to information on more than 300 consortia and federal programs. The CPR service provides, among other things, access to TRP announcements, SBIR announcements, and the technology transfer programs of individual federal laboratories. There are also plans to add information regarding active CRADAs to the system.

Technical Information Databases

In addition to the above resources, many other technology and intellectual property databases, information centers, clearinghouses, electronic bulletin boards, and directories are available to

participants in technology transfer. (For more information concerning many of these, contact the FLC at (856) 667-7727 or visit the FLC website at www.federallabs.org.

1.4 TYPES OF FEDERAL LABORATORIES

It should be noted that the federal laboratory system comprises both government-owned and government-operated (GOGO) laboratories and government-owned and contractor-operated (GOCO) laboratories, and that the type of laboratory affects the intellectual property protection available to the laboratory's employees.

A GOGO laboratory is usually owned or leased by the federal government, and is predominantly staffed by federal employees and supported by nonfederal contract employees. Individual contract employees may be considered "work-for-hire" employees, while staff provided by a firm providing support staff to the laboratory may be covered by the intellectual property rights bestowed on the contracting firm under the provisions of the Bayh-Dole Act or Executive Order 12591. A major difference between federal and nonfederal employees can be found in 17 USC 105, **Subject matter of copyright: United States Government works, "Copyright protection under this title is not available for any work of the United States Government**…**"**

Thus, any work of authorship by a federal employee is considered to be "public" information; and, although protectable as classified, information relating to an invention, or commercially valuable information generated under or brought into a CRADA, therefore may not be copyrighted.

A GOCO laboratory is one at which the facilities and equipment are owned by the federal government, but the employees are not civil servants but employees of a private or public contractor that operates the laboratory under a contract with the federal government under the authority of the Bayh-Dole Act or (for large business contractors) Executive Order 12591. As nonfederal employees, all of the works of authorship by the employees are born copyrighted. Generally, the employees of the contractor have entered into employment contracts where intellectual property rights are assigned to the contractor. All other provisions of the Stevenson-Wydler and Bayh-Dole Acts are essentially the same as those covering GOGO laboratories, except that GOCO laboratories must obtain approval from their respective federal agency for the Joint Work Statement and the CRADA to which it applies prior to commencing work.

1.5 SUMMARY: THE BENEFITS OF INVOLVEMENT IN TECHNOLOGY TRANSFER

Benefits to the Government

For the government, benefits can be derived from technology moving out of the laboratories as well as technical expertise coming into the laboratories. Technology transfer activities can be used to assist in accomplishing mission-oriented R&D, for example, when academic or industrial researchers provide needed expertise on collaborative efforts. In the other direction, the government as a whole benefits when technology moves out of the laboratories because federally funded R&D is being put to new or expanded uses. The government and the individual laboratories also benefit financially to the extent that the technology transfer involves 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.

Benefits to Industry

For industry, involvement in technology transfer projects can provide an increased 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 the relevant R&D that has already been done in the federal laboratories. Business partners may also benefit by using government facilities (e.g., for product testing) rather than building new facilities and making use of the expertise of the federal scientists and engineers.

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

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 the close contact with leading technologists in both government and industry. And, ongoing technology-oriented projects provide a

useful incentive for student involvement and can provide students with valuable experience and contacts when entering the job market later.

Benefits to Technology Transfer Professionals

For the individual scientist or technologist in a federal laboratory, benefits include possible financial gain from awards and royalty payments, in addition to the personal satisfaction 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 will provide the knowledge that one is a strong contributor to government-mandated technology transfer processes.

Technology Innovation—The Results of Innovative Partnerships

Technology transfer has had a dramatic impact on fostering mutually beneficial technology partnerships between industry and federal laboratories. These innovative partnerships have significantly contributed to the mission accomplishment by 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. A few brief examples of successful, innovative technology transfer partnerships illustrate the benefits of technology transfer for the government, the laboratory, and industry.

- Emergency response personnel confronting homeland security challenges, natural disasters, accidents, and other calamities are finding a reliable ally in software developed in a federal laboratory. From the aftermath of the 2004 Florida hurricanes to the Utah Winter Olympics to the Atlanta Millennium Super Bowl, the software has provided crucial logistical assistance to emergency preparedness decision makers in readily understandable visual formats. The software, developed by federal researchers, stores and organizes massive amounts of critical data about a location or special event before an incident happens. During crises, users are armed with total on-scene situational awareness. The software provides detailed forecasts of casualties, necessary command-level responses, specific time-phased resource requirements, and online access to personnel and resource shortfall information. Its predictive models also change as a situation unfolds. According to one Medical Disaster Conference report, the software could reduce human and economic loss by as much as 50% in a biohazard event.

- Federal researchers, in collaboration with a private food-processing company, developed a process for making a sunflower butter product that resembles the flavor, texture, and appearance of commercially available peanut butter. Sunflower seed is consumed in large amounts in Europe and other parts of the world, but U.S. consumption is limited because prices are below the profitability range for U.S. farmers. As a result, the U.S. is losing a major market for its sunflower seeds. This development could reverse that trend. The laboratory's partner created a company dedicated to commercializing the sunflower product, which is currently being sold to large food manufacturers and supermarkets throughout the country. In January 2004, the sunflower butter product, which is a peanut alternative for people with allergies, was made an entitlement item and added to the official list of available commodities in the school lunch program nationwide, which has accounted for the large boost in sales experienced by the company.
- A federal laboratory researcher developed software that provides a new approach to image analysis that significantly improves medical imaging for the diagnosis of medical conditions and dental research. The software system was developed over 20 years for use in the laboratory's remote-sensing applications. The software is capable of much more, however, as it greatly improves analytical capabilities for both image and nonimage data in applications as diverse as facial recognition, drug development, and data mining. In 2002, the laboratory licensed the software to a medical imaging company that has since developed an advanced biological imaging unit that has enabled them to successfully analyze and extract meaningful and significant features from grayscale data previously indistinguishable by the human eye. The software offers selectable levels of detail that increase accuracy for two-dimensional (and potentially three-dimensional) images. The software is broadly applicable for a wide range of uses, including medical diagnosis imaging, manufacturing quality control, homeland security, military reconnaissance, and monitoring of agricultural crops. In 2003, a university dental medicine school purchased an imaging device to advance its understanding of tooth decay and periodontal disease.
- While working at a federal laboratory, an immunologist made a profound discovery—the key to a hypothesized second signal in T-cell stimulation. This discovery of the function of the CD28 molecule in that second pathway has led to major advances in the search for safe and effective therapies for autoimmune disorders. The immune system is coordinated by T-cells that become activated when they encounter a foreign substance, or antigen.

Activated T-cells fight off infection in the body by attacking the foreign antigen. However, T-cells sometimes mistake the body's own antigens for invading antigens and mount an attack, which can lead to the development of an autoimmune disease. Academic and industrial collaborations centering on fundamental discovery by this federal scientist has resulted in revolutionary new methods for treating autoimmune diseases such as rheumatoid arthritis, lupus, multiple sclerosis, and scleroderma. A patent for this method has been licensed exclusively to a private biotech company. Working in collaboration with the company's scientists under a CRADA, the federal researcher tested a soluble form of the CTLA4 molecule in an animal model of multiple sclerosis and found that this treatment was able not only to block the onset of the disease, but also prevent it from progressing.

Details about these and other successful technology transfer efforts are provided in *Federal Technology Transfer 2005: Transferring Federally Developed Research and Technology to the Marketplace*, which is available for download from the FLC website at www.federallabs.org.

Section Two
THE ROLE OF THE FLC IN TECHNOLOGY TRANSFER

2.1 WHAT IS THE FEDERAL LABORATORY CONSORTIUM?

The Federal Laboratory Consortium for Technology Transfer (FLC)—organized in 1974 and formally chartered by Congress in 1986 by the Federal Technology Transfer Act (PL. 99-502) to promote and strengthen technology transfer throughout the U.S.—is the nationwide network of federal laboratories that provides the forum to educate federal technology transfer professionals and link technologies with laboratory missions in the marketplace. In accordance with 15 USC 3710, all major federal laboratories and R&D centers and their parent agencies are members of the FLC. The FLC, by providing opportunities for its member laboratories to collaborate with the private and public sectors, is one of the significant contributors to the fulfillment of this national goal for technology transfer.

The FLC Mission

In accordance with its legislative mandate, the FLC's mission is to assist federal agencies, laboratories, and their partners to accomplish the rapid integration of R&D resources within the mainstream of the U.S. economy. Since its inception, the FLC has followed three basic operating principles that support this mission:

- A need to make broader use of the technologies and expertise developed in federal laboratories
- A focus on communication and interagency/interlaboratory interaction
- An emphasis on technology transfer through person-to-person mechanisms.

The FLC's approach, which incorporates these operating principles, comprises a coordinated program that meets the needs of FLC member laboratories, agencies, and their potential technology transfer partners. Activities authorized by the Federal Technology Transfer Act of 1986 and codified in 15 USC 3710 are:

- Develop and administer technology transfer techniques, training courses, and materials to increase the awareness of federal laboratory employees regarding the commercial potential of laboratory technology and innovations.

- Provide advice and assistance to federal agencies and laboratories for use in their technology transfer programs.
- Provide a clearinghouse for requests for technical assistance from state and local governments, business, industrial development organizations, not-for-profit organizations, including universities, federal agencies and laboratories, and other persons.
- Facilitate communication and coordination between ORTAs at federal laboratories.
- Utilize the expertise and services of the National Science Foundation, the Department of Commerce, NASA, and other federal agencies as necessary.
- Facilitate the use of appropriate technology transfer mechanisms.
- Assist laboratories with establishing programs using technical volunteers to provide technical assistance to local communities.
- Facilitate communication and cooperation between federal laboratory ORTAs and regional, state, and local technology transfer organizations.
- Assist colleges or universities, businesses, nonprofit organizations, state or local governments, or regional organizations with establishing programs to stimulate research and to encourage technology transfer in such areas as:
  - Technology program development
  - Curriculum design
  - Long-term research planning
  - Personnel needs projections
  - Productivity assessments.
- Seek advice in each FLC region from representatives of state and local governments, large and small businesses, universities, and other appropriate persons concerning the effectiveness of the technology transfer program.
- Work with the director of the National Institute on Disability and Rehabilitation Research to compile a compendium of current and projected federal laboratory technologies and projects with an impact on assistive technology for individuals with disabilities.

The FLC's Goals and Objectives

In order to accomplish its mission, the FLC developed a Strategic Plan in FY2005 comprising 3 overarching strategic goals and 12 objectives to accomplish those goals. The FLC's strategic goals and objectives are designed to provide the necessary environment, organization, and technology transfer mechanisms that will

facilitate the fullest possible use of federally sponsored R&D by potential users in both the public and private sectors. These goals and objectives are identified in Table 2-1.

Table 2-1. FLC Strategic Goals and Objectives

FLC Strategic Goals	FLC Strategic Objectives
Develop FLC members to be leaders in technology transfer	Provide and promote networking opportunities among members and with external organizations
	Provide technology transfer education and training opportunities
	Provide an awards program recognizing all levels of technology transfer professionals
	Provide membership and communications program optimizing FLC and technology transfer awareness
Foster the environment for technology transfer	Enhance access to federal technologies and facilities
	Maintain a comprehensive system of communications
	Assist state and local governments, regional organizations and academia to encourage technology transfer
	Identify potential alliances
	Improve organizational structure
	Improve management processes and communication
Enhance the professional organizational structure	Increase FLC membership and participation
	Plan for leadership development
	Improve organizational structure
	Improve management processes and communication

The FLC Membership

The FLC comprises several hundred federal government R&D laboratories and centers that represent the following federal departments and agencies:

Departments

- Agriculture
- Commerce
- Defense
  - Army
  - Navy
  - Air Force
- Education
- Energy
- Health and Human Services
- Homeland Security
- Interior
- Justice
- Transportation
- Veterans Affairs

Agencies

- Central Intelligence Agency
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation
- Smithsonian Institution
- Tennessee Valley Authority

2.2 HISTORY OF THE FLC

The evolution of the FLC—from informal to formal operation and finally to a fully chartered organization—began in 1971 when the Department of Defense (DOD) formed the DOD Laboratory Consortium to improve interlaboratory communication and find civilian uses for technical knowledge that had originally been developed for military purposes. By 1974, the DOD Laboratory Consortium had grown from 11 to 34 R&D laboratories and centers, changed its name to the Federal Laboratory Consortium for Technology Transfer, and invited all federal agencies to participate.

In 1980, the passage of the Stevenson-Wydler Technology Innovation Act (P.L. 96-480)[1] provided increased stimulus to the FLC's development and growth. This law required that each federal laboratory make technology transfer part of its mission by establishing an Office of Research and Technology Applications (ORTA); assessing laboratory R&D projects for potential applications; disseminating information concerning products, processes and services; cooperating with the National Technical Information Service (NTIS) and other organizations; and providing technical assistance upon request.

The FLC was formally established and provided with a charter and defined roles and responsibilities by the Federal Technology Transfer Act of 1986 (P.L. 99-502). (The FLC's legislative mandates were codified in 15 USC 3710.) The Federal Technology Transfer Act of 1986 also required federal agencies with member R&D laboratories to provide a percentage of their R&D budget for the purpose of operating the FLC.

In order to implement the Act, the FLC and the National Bureau of Standards (now the National Institute for Standards and Technology [NIST]) signed a Memorandum of Understanding in 1987. NIST collects from the agencies the funds (0.008% of each agency's R&D budget as determined by the NSF) mandated to be provided to the FLC by the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113), which amended the Stevenson-Wydler Technology Innovation Act of 1980 and the Federal Technology Transfer Act of 1986 (see 15 USC 3710 (c)(6)). An historical overview of the FLC, highlighting federal legislation with a direct impact on the Consortium, is provided below:

- 1971—DOD Laboratory Consortium formed
- 1974—DOD Laboratory Consortium changes name to Federal Laboratory Consortium for Technology Transfer
- 1980—Stevenson-Wydler Technology Innovation Act of 1980 establishes ORTAs at federal labs
- 1986—FLC formally established and chartered by an Act of Congress (Federal Technology Transfer Act of 1986), which also required agencies with federal R&D labs to provide percentage of R&D budget to operate the FLC
- 1987—FLC and NIST sign MOU to administratively implement the Federal Technology Transfer Act of 1986

[1] For a full examination of technology transfer legislation and its impact on the FLC, see Section One.

- 1995—National Technology Transfer and Advancement Act of 1995 provided the FLC with a reliable source of funding from the agencies.

Throughout its history, the FLC has evolved into a strong and viable network that provides valuable assistance to federal laboratories in their efforts to make their scientific and professional resources more available to other organizations both inside and outside the federal laboratory system.

Membership

The membership of the FLC consists of federal R&D laboratories and centers and the departments and agencies they represent. Each member agency and laboratory appoints a representative to represent it in the Consortium and to cast votes in Consortium balloting. Other organizations with the primary purpose of promoting technology transfer may request admission as Affiliate Members; members or employees of Affiliate Members may participate in FLC activities, but may not vote in FLC elections.

Governance

The FLC is governed by the Executive Board and the Executive Committee. The Executive Committee consists of the officers (e.g., Chair, Vice-Chair, Finance Officer, and Recording Secretary), six Regional Coordinators who represent the geographic regions by which the FLC is organized, and the designated representative of NIST, the FLC's host agency. The Executive Board consists of members of the Executive Committee, plus six at-large representatives and the chairs of the FLC's committees. The duties and responsibilities of the Executive Board and of each member of the Executive Board, as well as the authority of the Board, are described in the FLC Bylaws, which can be found on the FLC website (www.federallabs.org).

Committees

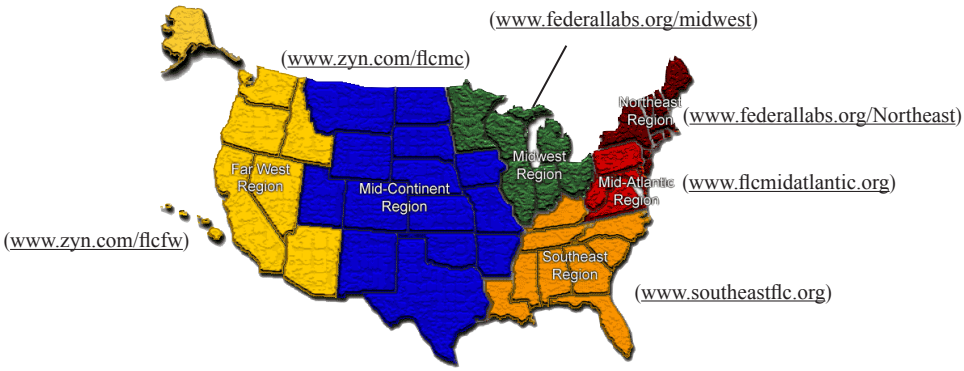
FLC committees are responsible for assuring prudent management of the Consortium; providing services to member laboratories; coordinating issues and policies common to member laboratories; advertising, promotion, and public relations regarding the FLC's technology transfer activities; education and training of user communities; and development and testing of appropriate technology transfer processes. With the exception of the Financial

Management Committee, whose members are appointed by the Finance Officer in consultation with the Consortium Chair, ***FLC members are strongly encouraged to participate in at least one of the following committees***:

- **Awards**—Plans and executes the FLC national awards program.
- **Communications**—Integrates, coordinates, and initiates activities that market and promote the services of the FLC and the resources of its members.
- **Education and Training**—Develops and implements basic, intermediate, and advanced training and education programs; implements and oversees activities that assure the awareness and availability of technology and technical assistance resources of FLC members to the benefit of educational institutions at all levels.
- **Financial Management**—Advises and assists the Executive Board with the collection, management, and disbursement of FLC funds.
- **Legal Issues**—Provides a forum for the discussion of legal concerns in the conduct of effective technology transfer programs by FLC members.
- **Planning and Policy**—Responsible for making recommendations to the Executive Board regarding plans, goals, policies and positions to support the FLC's Strategic Plan.
- **Program**—Develops and implements programs to support the needs of members, including planning and execution of national FLC meetings, seminars, and other programs.
- **State and Local Government**—Implements and oversees activities that assure the awareness and availability of technology and technical assistance resources of FLC members to the benefit of state and local governments.

FLC Regions

The FLC membership is divided into six geographical regions—Northeast, Mid-Atlantic, Southeast, Midwest, Mid-Continent, and Far West (see Figure 2-1). These regional entities provide improved communication and accessibility to laboratories within the regions. Each region has its own website (see Figure 2-1), as well as a regional newsletter. In addition, each region holds an annual meeting for its members.



Far West Region
Alaska
Arizona
California
Hawaii
Idaho
Nevada
Oregon
Washington

Mid-Continent Region
Arkansas
Colorado
Iowa
Kansas
Missouri
Montana
New Mexico
Nebraska
North Dakota
Oklahoma
South Dakota
Texas
Utah
Wyoming

Midwest Region
Illinois
Indiana
Michigan
Minnesota
Ohio

Mid-Atlantic Region
Delaware
District of Columbia
Maryland
Pennsylvania
Virginia
West Virginia

Northeast Region
Connecticut
Maine
Massachusetts
New Hampshire
New Jersey
New York
Puerto Rico
Rhode Island
Vermont

Southeast Region
Alabama
Florida
Georgia
Kentucky
Louisiana
Mississippi
North Carolina
South Carolina
Tennessee

Figure 2-1. FLC Regions and Regional Websites

Each region elects a Regional Coordinator and Deputy Regional Coordinator. Regional Coordinators function as primary links between the FLC and potential users of federal technology in their regions and the organizers of special regional and state projects. They are also focal points for the laboratories and other organizations in their regions. In addition to representing their own laboratories, Regional Coordinators maintain contact with other research institutions, as well as federal, public, and private agencies. The Regional Coordinators are significant links in the entire FLC system, assisting the laboratories they represent in a variety of activities. Regional Coordinators also represent the region as members of the FLC Executive Committee.

2.3 FLC TECHNOLOGY TRANSFER ACTIVITIES AND SERVICES

Technology transfer is accomplished by individual laboratories and centers; however, the FLC provides these laboratories and centers with technology transfer activities and technical assistance services that are essential to an effective domestic technology transfer program. These activities and services include a national interagency network of member laboratories and centers, an electronic communication system that links laboratory representatives as well as potential users to the FLC, a Technology Locator Service that puts potential partners in direct contact with laboratory expertise and technology, national and regional meetings, training, demonstration projects, a national newsletter, media and conference support, and awards.

National Technology Transfer Network

Through its member laboratories and centers, the FLC provides a national interagency network that is essential to an effective technology transfer program. Independently, each laboratory is limited to its own resources or those of its parent agency. However, within the FLC network, laboratories can identify problems and issues and resolve them using the combined resources of all members. The network facilitates FLC outreach, extends the awareness of each member facility's technology and expertise, and significantly improves public and private access to federal technology by potential users. Potential users can access the FLC network through individual FLC representatives, Regional Coordinators, the Technology Locator Service, or officers. The network is able to put the potential user in contact with the person at a federal laboratory who has expertise in the user's specific area of interest. Once the contact is made through the network, the transfer proceeds between the user and the laboratory.

Electronic Communications

The FLC maintains an up-to-date website (see Figure 2-2) at www.federallabs.org. This site provides FLC members and potential partners with:

- Information about the FLC, including
  - Bylaws
  - Strategic Plan

  - Contact information for FLC executives, Regional Coordinators, committee chairs, representatives, members, etc.
  - FLC technology transfer awards program
  - Links to hundreds of federal laboratory and technology transfer websites
  - Searchable databases of member laboratory resources and technologies
  - FLC annual report
  - Links to the websites of the FLC regions
- Access to the Technology Locator Service
- News and information about technology transfer activities, including meetings and other events
- Education and training resources, including
  - Technology Transfer (T2) Mechanisms Database
  - Technology Transfer Training Resources Database (T2 TRDB)
  - *Technology Transfer Desk Reference* (downloadable)
  - *Federal Technology Transfer Legislation and Policy* (the *Green Book*) (downloadable)
- Current and archived copies of *FLC NewsLink* (monthly technology transfer newsletter) and other FLC publications

Figure 2-2. The FLC Website Home Page

Technology Locator Service

The Technology Locator Service provides a centralized service for reviewing and routing requests from potential partners to the appropriate resource (i.e., laboratory or center). The primary function of the Locator Service is to broker requests and direct inquiries from potential partners as well as referrals from FLC Representatives. The Locator Service also serves as a point of entry, responds to requests, records and coordinates responses, provides user feedback, and reports on the level of activity. For industry and other technology seekers, the FLC Technology Locator Service serves as a point of entry to federal laboratory expertise and technology. The Locator Service puts a potential partner in contact with a federal laboratory that has expertise and capability in a specific area of interest. Once the Locator Service identifies the contact, all arrangements for the technical exchange are between the user and the laboratory. The Locator Service functions best when the user makes the request as specific as possible and identifies considerations such as technical need, constraints, and intended use.

To contact the FLC Technology Locator Service or to submit a technology request, go to the FLC website (www.federallabs.org) or call (856) 667-7727.

Meetings

National

The FLC holds one national meeting annually, providing a forum for formal and informal exchanges of information among representatives of member laboratories, parent agencies, state and local government, industry, and academia. These national meetings address the needs of the member laboratories and agencies, the FLC as an organization, technology transfer issues, and provide fundamental, intermediate, and advanced training in technology transfer. These meetings strengthen the FLC network by focusing on issues, subjects, training, and methodologies of interest to the FLC community. However, the meetings are also of interest to those outside the FLC who are interested in learning about the Consortium and federal technology transfer.

Regional

Annual meetings are held by the six FLC regions, focusing on the needs of laboratories within each region.

Training

One of the FLC's primary goals is to provide technology transfer education and training. To accomplish this, the FLC develops and administers training courses and materials that are needed by federal laboratory employees to carry out their technology transfer roles and responsibilities.

Training Courses

The major venue for training is the national meeting, at which the Consortium offers full-day training courses at fundamental, intermediate, and advanced levels. University-certified continuing education units (CEUs) are available for all three courses.

- **Technology Transfer Fundamentals Training**—Designed to introduce newcomers to the field of technology transfer and to serve as a refresher course for technology transfer veterans, Fundamentals training provides a basic foundation in the background, concepts, and practical knowledge required to transfer federally funded technologies from the laboratory to the marketplace. The course includes an introduction to the role of the FLC, an overview of technology transfer, the Cooperative Research and Development Agreement (CRADA), and an introduction to intellectual property issues.
- **Technology Transfer Intermediate Training**—Designed for technology transfer professionals who have a basic foundation in the background, concepts and processes of technology transfer or who have completed the Technology Transfer Fundamentals Training course, this intermediate-level course includes a detailed examination of how to establish and manage a T2 office, how to conduct a technology survey of a laboratory to identify transfer and commercialization candidates, a detailed examination of intellectual property protection, and a discussion of technology transfer partnerships with the private sector.
- **Technology Transfer Advanced Training**—A course for federal technology transfer specialists focusing on intellectual property management, licensing, and negotiating, with in-depth coverage of CRADAs, licensing and international intellectual property, licensing and export control, advanced licensing, and licensing negotiation.

In addition, many of the FLC regions provide significant in-depth training programs at their annual regional meetings. CEUs are also available for many of the regional training courses.

Other Training Resources

The FLC's technology transfer education and training program includes several publications and online resources, including:

- *Technology Transfer Desk Reference* is a publication that provides a comprehensive introduction to technology transfer and the background, concepts, and practical knowledge required for technology transfer practitioners, whether in government or the private sector, to facilitate the transfer of federally funded technologies from the laboratory to the marketplace. The *Desk Reference* can be viewed and downloaded at the FLC website; a printed copy is available free of charge to FLC members and may be purchased by non-members.
- *Federal Technology Transfer Legislation and Policy* (the *Green Book*) is a publication that provides the principal statutory and presidential executive order policies that constitute the framework of the federal technology transfer program. The publication is intended to assist policy makers and technology transfer practitioners in the government by serving as a legal reference source and is designed to help non-government technology transfer professionals acquire a fundamental understanding of the legal framework for technology transfer. The *Green Book* can be viewed and downloaded at the FLC website; a printed copy is available free of charge to FLC members and may be purchased by non-members.
- Technology Transfer Mechanisms Database provides detailed information about and samples/models of a wide variety of technology transfer mechanisms used by federal agencies. The database can be accessed on the FLC website.
- Technology Transfer Training Resources Database (T2 TRDB) provides education and training resources available for federal laboratory personnel and others in the field of technology transfer. Resources include lectures, courses, seminars, workshops, conferences, online courses, and publications. The database can be accessed on the FLC website.

Communication

In addition to the *Technology Transfer Desk Reference* and the *Green Book*, the FLC prepares and distributes a number of high-quality publications to ensure that the efforts of federal scientists and engineers are widely communicated. These publications include:

- ***FLC NewsLink***—A monthly newsletter that focuses on federal research and technology transfer and is distributed to all FLC representatives and other interested individuals and organizations. (The current and archived issues are also available on the FLC website.) With newsletter items provided by member laboratories and agencies, *FLC NewsLink* covers technology transfer activities; provides summaries of available laboratory technologies; and highlights ongoing laboratory research, recently licensed technologies, cooperative agreements, and technology transfer meetings, conferences, and symposiums. *FLC NewsLink* also features updates on FLC activities, tips to enhance job performance, and news from the FLC community, as well as reports on educational outreach efforts of the laboratories and information on educational programs and resources in technology transfer and technology management at universities and federal laboratories.
- ***Federal Technology Transfer Highlights***—Booklet, updated annually, that highlights some of the innovative technologies that have recently been transferred successfully from federal laboratories to the marketplace. The most current version of this booklet is available online at the FLC website.
- **Other publications**—In addition to *FLC NewsLink* and *Federal Technology Transfer Highlights*, a variety of FLC publications, including the *ORTA Handbook*; brochures; articles; exhibits; and presentations is available to members and interested potential partners to help member laboratories and potential users of federal technology learn how best to use the FLC.

Awards

The FLC encourages participation in the technology transfer process by bestowing awards upon individuals who have contributed to the transfer of technology. Information about the FLC awards program, award winners, and award-winning projects and laboratories from 1984 to the present are available on the FLC website. Three types of awards are presented to persons who have contributed to the transfer of technology through the FLC process:

- **Awards for Excellence in Technology Transfer**—Presented annually to recognize individuals (other than FLC Representatives) in federal laboratories who have successfully transferred federally developed technologies. Evaluated by a panel of technology transfer experts from industry, academia, state and local governments, and federal laboratories, as many as 30 Awards for Excellence can be presented each year.

- **Service Awards—**Presented each year to the laboratory representative who has contributed significantly to both technology transfer and the FLC, a nonmember who has actively supported the concept of technology transfer and the FLC, and a representative who has contributed service to the FLC. Service award recipients are chosen by the FLC's Executive Board.
- **Laboratory Director of the Year—**Recognizes federal laboratory directors who actively encourage and support technology transfer within their laboratories. These awards are sponsored by the FLC's National Advisory Council.

Each region also recognizes individuals and organizations that make a significant contribution to regional activities through the FLC's regional award programs.

Trade Shows

The FLC exhibits at a number of major national and regional trade shows each year, providing laboratories an opportunity to showcase their technologies and offering the private sector a "one-stop shopping" opportunity for federal laboratory technologies and services. The FLC maintains a traveling exhibit that can be shipped to meetings and trade shows as needed; tabletop exhibits are also available, and topical exhibits are developed as required. These exhibits can be used to support laboratories or agencies that wish to participate in trade shows.

Demonstration Projects

The FLC regions administer model projects that demonstrate effective techniques for moving technology from federal laboratories to the public and private sectors. The purpose of the projects is to develop innovative techniques for technology transfer and to define mechanisms for utilizing those methods in other locations and environments. The objective is to contribute to local, state, and national economic development and to make U.S. industry more competitive in world markets.

Current FLC demonstration project initiatives include:

- **Fire Fighting Task Force (FFTF) Initiative—**An ongoing outreach initiative to enhance firefighter safety by responding to end-user requirements for technological advances. The FFTF has been effective in locating federal technology to support the real-life needs of fire personnel through needs assessments and real-life evaluation of prototype technologies, including communications in high-noise environments, enhanced vision through

smoke, personnel locating and monitoring systems, improved fire apparatus design and performance, and wildland fires.

- **Assistive Technology Initiative—**This initiative identifies technologies from federal labs that can be adapted to the special needs of the disabled community and includes advocating legislative support for federal R&D in this area. The FLC has developed partnerships with academic institutions and federal agencies, actively soliciting technologies in specific needs areas and linking them with appropriate companies in the assistive technology community. This initiative included funding the first survey of the assistive technology industry, a wheeled mobility initiative, a communication enhancement initiative, and a hearing enhancement initiative to commercialize technologies to improve the lives of people with hearing disabilities.

Additional information on these initiatives can be found on the FLC website.

Section Three
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

The Cooperative Research and Development Agreement (CRADA) is one of the principal mechanisms used by federal laboratories to engage in collaborative efforts with non-federal partners to achieve the goals of technology transfer. The CRADA, which is not an acquisition or procurement vehicle, is designed to be a relatively easy mechanism to implement, requiring less time and effort to initiate than previous methods for working with non-government organizations. The CRADA is also intended to take into account the needs and desires of private industry when commercializing a product.

Because each agency and laboratory is free to develop its own CRADA model, technology transfer personnel must ensure that they utilize their agency's specific wording and format for CRADAs. Table 3-1 provides links to the CRADA information page of a wide variety of federal agencies and laboratories where users of this *Desk Reference* can find information about developing a CRADA specific to their agency and laboratory, as well as agency/laboratory-specific model CRADAs. In addition, the FLC's T2 Mechanisms Database includes models of CRADAs (as well as other technology transfer mechanisms) utilized by various federal agencies and laboratories. The T2 Mechanisms Database can be accessed on the FLC website at www.federallabs.org/t2mechanisms. Although the T2 Mechanisms Database identifies the agency that utilizes a specific mechanism, the documents are provided for information purposes only and practitioners should consult their agency's or laboratory's Technology Transfer Office to determine the specific agreements and format/verbiage available for use.

Table 3-1. Some Links to Laboratory/Agency CRADA Websites

Agency/Laboratory	Technology Transfer/CRADA Website
National Institute of Standards and Technology (NIST)	www.nist.gov/partnerships
U.S. Air Force	www.rl.af.mil/div/IFB/techtrans/crada/
Argonne National Laboratory (Dept. of Energy)	www.anl.gov/techtransfer/Information_for_Industry/CRADA/index.html
Naval Air Warfare Center, Aircraft Division (U.S. Navy)	www.nawcad.navy.mil/crada/
U.S. Department of Agriculture, Agricultural Research Service (ARS)	www.ars.usda.gov/business

3.1 LEGISLATIVE AUTHORITY

The CRADA mechanism was created by the Federal Technology Transfer Act of 1986 (P.L. 99-502) and modified or extended by later legislation (see Section One and Appendix A) to provide federal laboratories with an extremely flexible vehicle for addressing a wide variety of relationship opportunities. Later legislation extended the use of CRADAs to federal research centers and to government-owned, contractor-operated (GOCO) laboratories. In addition, many "nontraditional" types of CRADAs are implemented by agencies and laboratories; these include agreements designed to facilitate equipment loans, material transfers, calibration, clinical trials, and many others.

As currently written into law, the stipulations and requirements for a CRADA are contained in the United States Code, Title 15 (Commerce and Trade), Section 3710a. The text of this section describes:

- The authority of laboratory directors to enter into CRADAs and to negotiate licensing agreements
- The authority for a federal laboratory to accept funds, personnel, services, or property and to provide personnel, services, or property
- The time requirements for approving CRADAs
- The protection of trade secrets and confidential information.

3.2 PURPOSE OF CRADAs

The primary purpose of the CRADA legislation is to provide government laboratories with the authority and mechanisms to enter into collaborative agreements with technology transfer partners, including industry; units of state or local government; industrial organizations; public and private foundations; nonprofit organizations, including universities; and others, including individuals who are licensees of government-owned inventions. These agreements provide agencies with a means to offer intellectual property rights and other federal resources that would otherwise not be available to a non-federal technology transfer partner.

CRADAs provide the means for a laboratory to leverage its R&D efforts in a manner consistent with the laboratory's mission. (Note: The federal researcher must always be aware that a CRADA must serve the purpose of furthering the mission of the laboratory or agency.) Through a CRADA, for example, a laboratory may gain

access to outside expertise and facilities (and in some cases, funds) that can be used to further the mission goals of the laboratory.

Another aspect of the broader purpose of CRADAs is that they encourage the creation of teams to solve technological and industrial problems for the greater benefit of the country. These teams may be partnerships between federal laboratories and commercial organizations, or between federal laboratories and universities, or just about any combination of federal and non-federal organizations.

3.3 CHARACTERISTICS OF A CRADA

One of the chief characteristics of the CRADA is that the government may contribute a wide variety of resources, but no funds. Unlike procurement contracts, the CRADA may not involve "funds out," that is, laboratory funds leaving the laboratory. The government may contribute personnel, services, facilities, equipment, intellectual property, or other resources. The non-federal partner may contribute those same resources, as well as funds, to the collaborative effort.

A second major characteristic of the CRADA is that it is not a procurement contract or grant and should not be viewed as an alternative to normal procurement procedures. Because the CRADA is not subject to the terms of procurement contracts, Federal Acquisition Regulations are not applicable.

In the selection of partners, the language of the CRADA legislation and regulations gives special consideration to small businesses, to consortia involving small businesses, and to businesses located in the United States that agree to manufacture products resulting from the CRADA substantially within the United States. In the case of CRADAs with individuals or organizations subject to foreign control, a consideration in forming the CRADA should be reciprocity; that is, does the foreign government permit U.S. companies to enter into cooperative research and development agreements and licensing arrangements with its own organizations?

With regard to licensing, CRADAs can incorporate a wide variety of arrangements. In addition, CRADAs are sensitive to the needs of business organizations to protect commercially valuable information. Trade secrets or confidential information supplied by a partner shall not be disclosed. Information developed in whole or in part by government employees during the course of a CRADA can be protected from disclosure for up to five years.

3.4 CRADAs AND INTELLECTUAL PROPERTY

The provisions to protect intellectual property developed through CRADAs reassure industry and encourage federal researchers to participate. In this way, both government and industry can see economic benefits to collaborative research. (Note: A complete discussion of intellectual property as it applies to technology transfer is provided in Section Four.)

Starting in the mid-1970s and continuing through the 1980s, several federal laws were enacted to allow government contractors to retain proprietary interest in their inventions. Before these changes, the intellectual property, including copyrights of documents, stayed with the government sponsor. The CRADA emphasizes the negotiation of these rights so the industry partner can benefit from the project. In addition, industry partners need assurances that "trade secrets" and other commercial "know-how" they bring with them will be protected from their competitors. Therefore, any commercially valuable information (i.e., any information affecting competitive advantage) developed jointly under a CRADA may be treated as proprietary for up to five years. In addition, since 1986 the federal laboratories and their inventors have shared royalties from patent licenses for inventions made by government employees, including inventions done under a CRADA.

Section Four
INTELLECTUAL PROPERTY ISSUES

Intellectual property can be a major issue in technology transfer. This section addresses intellectual property, with special attention to the patent process—from applying for a patent to licensing a patented product. The subject of intellectual property—and patents, copyrights, and licensing in particular—is immense and requires considerable legal expertise to cover thoroughly. Clearly, this section cannot cover all of the details of intellectual property, but it does provide a basic introduction so that you can seek appropriate legal advice when the need arises.

The main topics in this section are:

- Definition of intellectual property
- Summary of government policy on the use of intellectual property
- Methods of protecting intellectual property
- Procedures for applying for a patent
- Patent licensing issues
- Income from licenses.

4.1 WHAT IS INTELLECTUAL PROPERTY?

Intellectual, or intangible, assets include any 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 intellectual property. Intellectual property is that subset of intellectual assets that can be legally protected, and includes patents, plant variety protection certificates, copyrights, trademarks and trade secrets. Just as our legal system provides rights and protection for owners of real property such as real estate, it also provides rights and protection to owners of intellectual property (intangible property). The intangible right to intellectual property can be bought, sold, leased, rented, or otherwise transferred between parties. The transfer of intellectual property rights can affect the marketability of a product, as well as the selection of a producer or manufacturer of a product; therefore, the right to intellectual property often involves considerable discussion among the parties in a technology transfer endeavor.

4.2 WHY INTELLECTUAL PROPERTY IS IMPORTANT

A system that provides for intellectual property rights and protections also establishes a method to protect personal recognition for important creative and inventive contributions. The possibility of being recognized for an important contribution, and its accompanying prestige, often act 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.

On the macro level, intellectual property plays a tremendously important role in our modern, industrialized world. Continuation of our high standard of living depends to no small degree upon scientific and technical advances. Systems that protect intellectual property rights (particularly patents) help incentivize investment in the inventive and creative activities that lead to those scientific and technical advances becoming commercialized. How does that happen?

The path from inception to the commercialization of new technology generally requires the investment of significant monetary, time, research, development, manufacturing, and marketing resources. Each step on this path holds 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.

The patent system gives the patent holder an advantage against competitors by excluding them from certain technological avenues of competition for a limited period of time. Knowing that the 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 intellectual property of a company becomes one of its top assets.

4.3 FORMS OF PROTECTION

Intellectual property is essentially 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. The next several sections will discuss these forms, with most of the emphasis placed on patents because

government employees cannot receive copyright protection for work performed as part of their duties.

Patents

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 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, or selling the invention for the life of the patent. Patents are issued by the United States Patent and Trademark Office (USPTO) and are valid throughout the United States. 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 U.S.

As written documents, patents have a distinctive style. 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, that constitute what is covered by the patent.

The level of detail required 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.

Provisional Patent Application

U.S. law permits filing for provisional patent applications (35 USC 111(b) and 119 (e)). Filing a provisional patent application in the U.S. permits the establishment of an initial "effective, or priority, filing date," which does not serve as the basis for measuring the 20-year term of patent protection. Provisional patent applications serve several purposes. First, they can protect an invention against a conflicting patent by establishing an earlier filing date, that is, against a claim that "prior art" bars the invention from being patented. Second, because the rest of the world's patent systems bar patents for inventions that have been previously disclosed publicly, a provisional patent application allows the inventors to publish or give presentations on their inventions without a threat of losing patentability.

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 patent application—does not have to contain claims, an oath, or 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 patent application that references the provisional application the inventor wishes to rely on for the "effective filing date." An inventor may convert an existing patent application into a provisional application within 12 months of filing the regular patent application, but then must file another regular application, also within the 12-month period, before the examination can proceed. However, the 20-year life of the patent begins from the filing date of the regular patent application—not the provisional application.

Types of Patents

There are three types of nonprovisional U.S. patents, as follows:

- Utility—The most common kind, they cover virtually any inventions that are useful.
- Design—Cover the unique shape or ornamental appearance of an object, such as hockey uniforms, ladies' dresses, computer housings, automobile bodies, buildings, shoes, game boards, etc.
- Plant—Cover 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 such as potatoes. The owner of a Plant Variety Protection Certificate (PVPC) 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.

What to Patent

The patent statutes (35 USC 101) 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 or technical process or method
- Machine
- 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
- Business methods
- Biological materials.

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

- Printed matter
- Purely scientific or mathematical principles
- Physical phenomena (e.g., electricity or magnetism)
- Abstract ideas
- Laws of nature.

There is a special category for patent applications on classified inventions that are held secret until declassified. As times and technology change, the range of things that can be patented can also change. The question of patentability is constantly being reinterpreted by the courts.

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 must have utility. As stated in 35 USC 102-103, a patent cannot be obtained if:

- The invention was previously known; or
- The invention does not have utility; or
- The invention was described in print or patented anywhere, or was in public use or on sale in the U.S. more than a year before the date of a provisional application; or
- The invention had previously been made in the U.S. 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 as a whole would have been obvious at the time to a person having ordinary skill in the art.

Who Can Apply

In the United States, a patent application can be filed only by the inventor or on behalf of the inventor, who must be an individual or a group of individuals (co-inventors). The inventor cannot be a corporation, partnership, joint venture, or other business entity. In other words, a patent can only be granted to a real person. An inventor may, however, assign his or her rights in the patent to other individuals or to legal entities such as corporations or the government. Even though the inventor sells or assigns the patent rights to someone else, such as an employer, the application must still be filed in the name of the individual inventor(s). 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 he or she is the true inventor.

Protection Provided by Patents

A patent gives the owner the right to prevent others from making, using, or selling the invention. If an individual or corporation is making, using or selling an invention (or an essential part of it) without the patent owner's permission, the patent owner may file a lawsuit. For government-owned patents, it is up to the Department of Justice to enforce the government's rights. However, the right of enforcement may be granted to licensees [35 USC 207(a)(2)]. The patent owner may obtain an injunction against the infringer of the patent, ordering the infringer not to make, use, or sell the invention for the life of the patent. The patent owner may also be awarded monetary damages. A joint owner of a U.S. patent may make, use, or sell 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 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/she can sue the government for reasonable compensation (28 USC 1498).

Patent Application Timing

Timing is critical when filing a patent application. In the U.S., 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 grace period in the U.S., premature public disclosure of an invention should be avoided. Patent review should be obtained from legal counsel or the Technology Transfer Office to protect the invention before it is publicly disclosed.

The time required to receive a patent is at least two years in the U.S. 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 agrees not to foreign file. The priority date is the earliest filing date of a patent application or the filing date of a provisional application (see above) upon which the actual patent application is based. In any case, after the patent is issued, the USPTO publishes the specifications and accompanying drawings. Summaries of every patent are published each week in the Official Gazette of the USPTO. Online searches for issued patents and published patent applications can be conducted on the USPTO website at www.uspto.gov/patft.

Foreign Patents

The value of filing a foreign patent application for an invention can be a difficult issue. Foreign patents may be valuable if the international markets for a given technology are large. On the other hand, the cost and efforts to secure foreign patents can be greater than the eventual returns (i.e., royalties or license fees) 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.

A United States patent is only effective in the United States, its territories and possessions. Therefore, in order to acquire protection in other countries, patent applications must be filed directly in those countries or under regional patent application systems that include those countries. Those regional arrangements include the European Patent Convention (EPC), covering most but not all European countries, the African Regional Industrial Property Organization (ARIPO), the African Intellectual Property Organization (OAPI),

and Eurasian Patent Convention (EA). Furthermore, a Patent Cooperation Treaty Application (PCTA) may be filed to delay the actual patent filing in a foreign country or region and therefore substantially delay the costs associated with foreign filing. However, the patent owner or inventor must still file national stage applications with the countries from which patent protection is sought.

In addition, the Patent Cooperation Treaty (PCT) provides an applicant the ability to file a consolidated patent application effective in a substantial number of countries by a single application (in English) and later converted into a national patent application.

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 time of 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, by agreement with foreign defense agencies, DOD-owned inventions 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.

Copyrights

Copyrights provide legal protection for products of the mind that are produced in tangible expressions, such as writings, paintings, movies, music, sculpture, and computer software. The work must contain some original expression, which can exist in the form and arrangement of the material.

Copyright categories include:

- 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.
- Sound recordings.

Unlike a patent, a copyright protects the form of expression rather than the subject matter of the work.

Copyright protection is initiated with the creation of a work, without 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, one copy of an unpublished work or two copies of a published work, along with the appropriate filing fee, to the Copyright Office (Library of Congress).

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

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

Copyright protection for individuals extends for the author's lifetime plus 70 years. For a jointly developed work, the protection is for the length 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.

Current copyright law 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.

Other Forms of Intellectual Property

In addition to patents, PVPCs and copyrights, there are other forms of intellectual property, including mask works, trademarks, and trade secrets. However, it should be noted that government employees are required to protect any proprietary information owned by others.

Mask Works

Mask works are patterns used in fabricating integrated circuits on semiconductor chips. In establishing separate protection for mask works, the Act provided 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
- Importing or distributing a semiconductor chip product in which the mask work is embodied.

A mask work is protected for ten years after registration or its first commercial exploitation, whichever occurs first.

Trademarks

Trademark protection can be obtained for any word, symbol, or combination thereof that is used on goods to indicate their source. 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 ten years. State trademarks have various terms and also require renewal.

Trade Secrets

A trade secret is any commercial formula, device, pattern, process, or information that affords its owner a 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 well-suited to nongovernmental licensing programs and often can be 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 and limiting access to the documents, and informing individuals with access to trade secrets about the need for security.

Trade secrets are protected by federal (i.e., the Trade Secrets Act (18 USC 1905) and the Economic Espionage Act (18 USC 90)) as well

as state laws. (In contrast, patents and copyrights are protected by federal laws only.) 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; however, under CRADAs, 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 by the CRADA partner, it must be protected from disclosure; and there are severe penalties for government employees who release trade secrets.

4.4 HOW TO PATENT AN INVENTION

Overview of Inventor's Responsibilities

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 a primary requirement. 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 application.

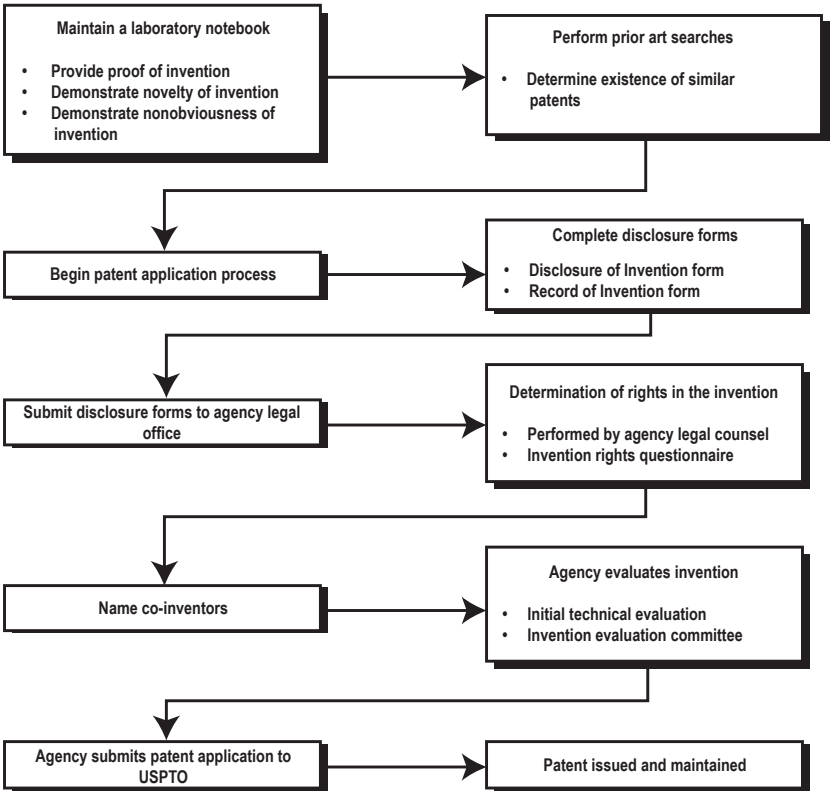


Figure 4-1. Patent Process Overview

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 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 the first 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).
- Alert patent attorneys to potential statutory problems (e.g., meeting the deadline to file an application within one year of a public disclosure).

How to Keep a Laboratory Notebook

There is no specific format for the laboratory notebook; however, it is preferred that the notebook be bound and contain prenumbered pages. When using your 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 your entries in ink to avoid any suspicion of alterations.
- Use pages in numeric order.
- Keep your 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 you affix material 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. (The practice of 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 your 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 a caption saying "performance observed and understood by."
- Witnesses who have observed and understood an experiment or test should sign and date the notebook page under the caption saying "performance observed and understood by."
- For anything new or unexpected that is likely to lead to a patentable invention, you should promptly prepare an invention disclosure.

Prior Art Searches

An understanding of prior art, including similar patents for related inventions, can help you better understand the position of your proposed invention with respect to its prospects for obtaining a patent, and may even trigger ideas for technical improvements in your own work. In some cases, where the inventor is so familiar with an industry or technical field, or is at the threshold of an emerging technology, it may not be necessary to conduct a formal prior art search through the existing patent database. (Online searches may be conducted at www.uspto.gov/patft.)

Disclosure Forms

Once you determine that you would like to begin the process of seeking a patent, you should promptly complete the appropriate disclosure forms and submit them to the appropriate agency/laboratory office, which can also provide the forms.

Procedures vary in each agency, but you will usually need to complete at least two forms:

- Disclosure of Invention Form—Provides a detailed description of the invention; you should include enough information to ensure that reviewers have a clear understanding of what the invention entails.
- Record of Invention Form—Basically provides the inventor's name(s) and dates and is primarily concerned with documenting the history of the invention.

Detailed instructions for completing these forms are provided with the forms.

Copies of pertinent laboratory notebook pages, if available, should be provided with the invention disclosure forms.

Invention Rights

Whenever an invention is made by a government employee, the rights of the government and the inventor depend upon the facts under which the invention is made. Depending upon such facts, there are three possible outcomes:

- The government will be entitled to all rights and the inventor to none, and the inventor assigns the patent rights to the government.
- The government may be entitled to a license to use or practice the invention, and the inventor signs 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.

The allocation of rights is based on the following (see 37 CFR 501):

- 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.

However, even under any of these criteria, the inventor may be entitled to retail all rights, if the government's contribution is insufficient equitably to justify a requirement of assignment, or the government determines not to pursue patenting or otherwise to promote commercialization of the invention, except that retention of these rights by the inventor is subject to the government's right to freely use the invention for governmental purposes and in accordance to government employee conflict of interest statutes, regulations, and policies.

If asked to complete a form pertaining to your invention rights, you may want to obtain assistance from the agency legal counsel before completing the form.

Naming Co-Inventors

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 made a contribution to the conception at least one allowed claim of a patent application. Prior to issuance of the patent, the actual naming of inventors should be reviewed based upon 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. 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. 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 or sell 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 stating otherwise. If the invention is assigned to the government, the government owns the patent. Those inventors assigning to the government are entitled to a share of the license income if the invention is licensed by the government.

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 be forwarded to a technical evaluator or evaluation committee with knowledge of the subject area identified in the patent disclosure forms. The invention is then evaluated to determine its significance.

Invention Evaluation Committee

The final step, which will determine whether or not 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 usually consists of three or more technical experts with some perspective of the related commercial environment, along with a patent counsel and a technology transfer expert as either committee members or advisors. The reasons for selection include the desire to minimize liability for patent infringement for government-developed material, to encourage 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
- Scientific or technical merit
- Whether patent protection is likely to be necessary for the commercial use of the invention
- Whether the invention's primary use is as a research tool.

Upon a vote by the committee, either a patent application is pursued, 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 in the invention and pursue a patent application at his or her own expense if no conflict of interest would arise (see 15 USC 3710d) (However, see 15 USC 3710a (c)(3)(A).)

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(s), as required.

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. Usually, within 18 months, the examiner will begin the examination process, which includes a study of the prior art and additional information filed with the application and conduct an independent search of the patent and technical literature to determine if the invention is novel and nonobvious. The examiner also determines if 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.

Most claims are rejected or objected to in the first office action. The patent attorney handling the application must respond to the USPTO within a specified amount of 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 a clear issue 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 and Interferences. Further appeals to the federal courts are possible but rarely pursued because of the expense involved. In the case of a final objection, the matter may be petitioned to the Commissioner.

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. Overall, a patent is typically issued within 30 to 36 months of filing. Patent protection begins when the patent is issued and is for a term of 20 years from the original filing date.

Patent Maintenance

Initially, a patent is active for four years. Keeping the patent active thereafter requires the payment of annual 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 one-half of those paid by large organizations, including the government.

4.5 LICENSING AN INVENTION

A license is a contract between a licensor (e.g., the holder of a patent) and a licensee (e.g., an industry partner) that ensures the licensee that the licensor will not sue the licensee for patent infringement. In other words, the government agrees not to sue the industry partner for infringing the government's patent.

It is the federal government's technology transfer policy to promote the utilization and commercialization of inventions that arise from agency-supported R&D. The licensing of government-owned patents is one of the tools to achieve this goal.

For CRADAs, patent license agreements may be incorporated within the CRADAs and handled according to CRADA guidelines.

License Policy

In granting a license to a government patent, the industry partner must satisfy a number of conditions. The company must supply the

government with a satisfactory development or marketing plan, as well as information about its ability to implement the plan. The company must commercialize the invention within a specified period of time and must continue to make the benefits of the invention reasonably accessible to the public. The company must report its utilization of the patent periodically to the government agency holding the patent. The government always retains an irrevocable royalty-free right to practice the invention. Normally, licenses will be granted only to companies that agree that any products developed through the use of the invention will be manufactured substantially in the U.S.

Types of Licenses

The government may grant nonexclusive, partially exclusive, or exclusive licenses. Nonexclusive licenses are granted when participation by several companies offers better opportunities for the broad development and use of an invention or when an invention has already been substantially developed for commercial sale. Nonexclusive licenses may be granted without the publication of any notice, as is required for exclusive licenses (see below).

An exclusive or partially exclusive license (e.g., limited to a field of use or geographic area) (see 35 USC 209 and 37 CFR 404) can be granted if the following conditions are met:

- A notice is published in the *Federal Register* of the invention's availability three months prior to the grant, or without such notice where the federal agency, laboratory director, or designee determines that expeditious granting of such a license will best serve the federal government and the public interest.
- An identification of the invention and the prospective licensee has been published in the *Federal Register* within at least a 15-day period for written objections to be filed.
- After objections have been considered, the laboratory director determines that the license is still in the public interest, the desired application will not be readily achieved under a nonexclusive license, the license is a reasonable incentive to attract the investment of risk capital or otherwise promote the utilization of the invention, and the terms of the license are no more than reasonably necessary.
- No determination has been made that the license will substantially lessen competition, result in any undue concentration in any section of the country in a line of commerce, or create a situation inconsistent with antitrust laws.

- First preference is given to small business firms that are capable of bringing invention to practical application.
- The government retains an irrevocable royalty-free right to practice the invention or to have it practiced on its behalf.
- The federal agency, laboratory director, or designee reserves the right to require the licensee to grant sublicenses when necessary to fulfill health or safety needs.

The licensing of inventions arising under a CRADA must follow CRADA guidelines on licensing.

Terminating a License

All licenses include the right of the federal agency, laboratory director, or designee to either partially or fully terminate a license agreement. Termination may occur if the laboratory director determines that the licensee is not executing the plan submitted with the license request and cannot demonstrate that it is able to achieve practical application of the invention within a reasonable time.

Other reasons for termination include public use requirements that might be stipulated in any subsequent federal legislation, or the licensee willfully made a false statement (or omitted a material fact) in the license application, or commits a substantial breach of the agreement contained in the license.

4.6 ROYALTY AND PAYMENT ISSUES

Royalties and Fees

Licensing fees or royalties are determined based on the type of license awarded and its value to the development of the commercial product. They represent compensation for the use of intellectual property.

In arriving at a reasonable compensation figure, criteria to consider include the type of license being granted, the investment of the government and the licensee, the associated risks, the markets to be exploited, and the value of the potential products.

Licensing fees can include upfront fees, maintenance fees, milestone payments, royalties, or any combination of these.

Upfront fees represent one-time earnest money and reimbursement for the expenses involved in consummating the license. Royalties are payments based upon sales or turnover of licensed products that may or may not include an annual minimum amount.

Royalty Rates

Royalty rates are generally established by negotiation between the federal laboratory and the private sector licensee, and they vary considerably depending on the invention that is being licensed. Royalties can be based upon net sales of licensed products, the number of units of licensed products sold, or any other basis that is appropriate for a particular invention and that is acceptable to both parties. The specific royalty rate is most often based upon the projected market value of the licensed products. Historical studies of royalty rates have shown that there are normal ranges for each industry sector and that these ranges correlate well with the expected gross profit margin of similar products sold in a specific industry sector.

The government policy on royalty rate negotiation basically involves arriving at a reasonable compensation that will best accomplish the success of the transferred product or process in the marketplace, using the best commercial licensing practice. If the rate is too high, it will serve as a disincentive for the private sector licensee to make the investments necessary for product development and technology transfer. On the other hand, the intellectual property owner is entitled to fair market value for the rights granted, especially if the license is exclusive or partially exclusive. As with other business transactions, fair market value is ordinarily determined as the result of negotiations between a willing buyer and willing seller.

In addition to the projected gross profit margin, many other factors may be weighed by the participants in royalty rate negotiations, including the value of the invention (e.g., is the invention a major breakthrough that will confer substantial marketplace advantages), the costs to bring the invention to the marketplace, the market potential of the invention, alternative methods that could be employed without using the invention, the need for post-sales support of the product, whether or not a long-term market exists, and the perceived effects of the terms and conditions of the license.

Fixed Payment Fees

In some cases, royalty rates may be difficult to establish because of the nature of the invention, and fixed fees or payments may be more appropriate. For example, if the invention is a process or method, or is used internally by a licensee, there may be no direct link between the sales price of individual items and the invention. In these cases, it may be possible to negotiate a fixed amount to be paid, regardless of sales volume or any other variable measure.

Distribution of Income

As required by federal technology transfer legislation, specific incentives are in place to encourage government employees to participate in the technology transfer process. Specifically, government employees who invent are entitled to a share of license revenues received by the federal agency from licensing their invention.

According to 15 USC 3710c, a federal agency must pay the first $2,000 per year in license income and a minimum of 15 percent of the yearly income thereafter from all inventions to the inventors, and within this guideline each agency is permitted to enact its own sharing scheme. However, the maximum that a single inventor can receive per year is $150,000. Any residual funds are usually distributed to the activity where the intellectual property was developed. A laboratory or R&D center that receives income from technology transfer activities must use it to further research or technology transfer.

Incentive Awards

Federal technology transfer legislation contains provisions for awards to government employees who actively participate in technology transfer, e.g., through the creation of intellectual property that can be used by the private sector. The government recognizes that the requirements to cooperate with the private sector and provide help to nonfederal agencies represent a change in culture for most federal R&D activities. To facilitate this change, many agencies provide invention awards for accomplishments in domestic technology transfer and technical assistance. These are often cash incentive awards that are granted in recognition of an employee's invention that resulted in the filing of a patent application, the grant of a U.S. patent, or the licensing of a patent application or patent.

4.7 ROLE OF INTELLECTUAL PROPERTY IN TECHNOLOGY TRANSFER

To obtain the maximum benefits from the federal R&D investment, Congress has determined that a significant portion of federally owned or originated R&D technology should be transferred to private industry, state and local governments, and 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 intellectual property resulting from R&D

activities at federal agencies by encouraging employees to patent their inventions, seeking potential licensing partners who will commercialize these inventions, and developing CRADAs with private industry, universities, and state or local governments.

Intellectual Property and CRADAs

The U.S. Code provides guidelines for the treatment of intellectual property within a CRADA. The allocation of intellectual property rights should be structured to achieve the goal of transferring technology from the laboratory to the private sector. That goal is most likely to be achieved when intellectual property 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 of time and for specified fields of use or market segments.

In the case of inventions, there may be background patents, as well as patents that arise from the CRADA effort. For background patents, that is, patents that existed before the creation of the CRADA, the guiding principle is to promote technology transfer. If the background patents are owned by the government, the patents may be licensed to the partner, perhaps on an exclusive basis subject to 35 USC 209. If the background patents are owned by the partner, government use for the purpose of procurement or research on a royalty-free basis should be negotiated.

For patents and other intellectual property arising from the CRADA effort, there are three cases to consider: government employees as inventors, the partner's employees as inventors, and jointly invented intellectual property. When a government employee is the inventor, the guiding principle is that invention rights should be made available to the partner on reasonable terms and conditions, and the government should retain some control over future development. Therefore, even though the federal laboratory may license, assign or waive rights, the preferred method is exclusive licensing. When the partner is the inventor, the government should not be required to pay royalties for use, and generally the partner should be able to retain all other rights for patents, copyrights, and technical data that its employees invent within the CRADA. In addition, 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.

4.8 SUMMARY OF PATENT/LICENSE BENEFITS

Benefits for the Government

Through successful patent and licensing agreements, the government achieves one of the primary goals of technology transfer—transfer of federally funded R&D to the private sector for the purpose of commercializing the technology. The intention is to promote economic growth and improve U.S. global competitiveness.

To the extent that the government receives royalties or other payments from patent licenses, there is an increased return on R&D investment that would not exist if the technology had not become commercially successful. Given the regulations for sharing of royalties and other income, this return on investment reaches the laboratory or R&D center directly responsible for developing the technology.

Finally, as a part of a license agreement, the government always retains the right to use the invention or to have the invention used on its behalf for government purposes. The government thus gets the use of a product that has been commercialized with private funding without paying licensing fees to the company that bore the commercialization costs.

Benefits for Industry

Businesses that license government inventions or patent inventions developed through CRADAs save themselves the cost of conducting R&D that has already been done, or will be done, by the government. Businesses that receive exclusive or partially exclusive licenses may obtain a competitive edge, or a perceived competitive edge, in the marketplace.

To the extent that patent license agreements are part of a CRADA, the patent/licensing process encourages cooperative R&D with the federal government. Such cooperation can directly benefit the industry partner by increased access to federal technology and indirectly by stimulating its own personnel to conduct R&D resulting in patentable inventions. This, in turn, helps to promote economic growth.

Benefits for the Government Inventor

To the extent that the invention generates license income, the individual government inventor will receive a share of that income. In addition, creating a novel nonobvious product or process that is

published through a patent may enhance the inventor's professional standing. Whether or not the inventor ever receives substantial financial benefits, the invention may someday be the basis for something that significantly improves the public health and welfare, or it could gain wide recognition in the marketplace, thereby increasing both the inventor's self-esteem and sense of satisfaction with his or her work.

Appendix
OVERVIEW OF TECHNOLOGY TRANSFER LEGISLATION AND RELEVANT EXECUTIVE ORDERS

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, was promulgated to established federal policy so 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 the employee; but 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 Office of Research and Technology Applications (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 (P.L. 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 title to inventions developed with federal funds. Government owned and government operated (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.

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 Federal Laboratory Consortium (FLC) for Technology Transfer. In addition, the law enabled government-owned and government-operated (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, and 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 (1987), was written to require 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 commercialization of federally funded inventions by requiring that, to the extent permitted by law, laboratories grant to 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 non-government 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 GOCOs 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) nuclear weapons 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 not permitted at present). 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 extended the SBIR program to the year 2000, increased the percentage of an agency's budget to be devoted to SBIR and similar programs, and increased the amounts of the awards. The Act also established the Small Business Technology Transfer (STTR) program. (The STTR program is similar to the SBIR program.)

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 federal laboratories and scientists and to private industry. 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 prenegotiated 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 make a commitment to achieve a practical application of the invention within a reasonable period of time; however, the Act exempts from these requirements the licensing of any inventions made under a CRADA. The Act also redefined what could be licensed, and provided authority for government agencies to "in-license" in order to "bundle" inventions for licensing purposes

United States Court of Appeals for the Federal Circuit (established 1982)

Established in 1982 under Article III of the U.S. Constitution, the U.S. Court of Appeals for the Federal Circuit (CAFC) was formed by the merger of the U.S. Court of Customs and Patent Appeals and the appellate division of the U.S. Court of Claims. The CAFC has nationwide jurisdiction over a variety of areas, including patents and trademarks. Appeals to the Court come from all federal district courts, as well as from the Board of Patent Appeals and Interferences and the Trademark Trial and Appeals Board. Appeals are heard by panels comprised of three judges who are randomly selected for assignment to the panels. Losing parties may seek review of a decision of the CACF in the U.S. Supreme Court. The Court's opinions may be obtained on its home page at www.fedcir.gov.

Other Legislation

Other laws that are part of the technology transfer effort, although perhaps not quite as directly as the previously discussed legislation, include:

- The Cooperative Research Act of 1984 (P.L. 98-462) established several R&D consortia (e.g., Semiconductor Research Corporation and Microelectronics and Computer Technology Corporation) 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. 99382) improved the availability of Japanese science and engineering literature in the U.S.
- 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 suc-

cessful 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 federally Funded Research and Development Centers (FFRDCs) not owned by the government.