

Introduction to Federal Technology Transfer Law

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1. Federal Research Laboratories: An \$81 Billion Per Year Enterprise

The Federal government develops new technologies at Federal research and development laboratories controlled by various Federal agencies. The research done at each of these laboratories is part of the mission of the agency that runs each laboratory. There are over

600 Federal research and development laboratories in existence.¹ Each year, the Federal government spends approximately \$81 billion on research activities. For example, in fiscal year 2001, the Federal government spent \$19.4 billion for research performed by Federal employees and \$62.2 billion for research conducted under contracts and grants.² This research takes place, fundamentally, to help each agency accomplish its mission. Still, with this level of expenditure of public funds taking place, Congress has decided that, whenever possible, the technology developed by Federal research laboratories should be “commercialized” and put to practical use for the benefit of the public. This is the key philosophy that drives the Federal technology transfer process.

2. Federal Technology Transfer Defined

There are thousands entities throughout the world, governmental, nonprofit, and commercial, involved in technology transfer activities. Each entity defines “technology transfer” in a slightly different way. A generic definition of technology transfer is thus hard to formulate. Still, the definition provided below, developed by the Government of Canada for its “GeoConnections” program, provides a reasonably useful and generic starting point. According to this definition, technology transfer is

the process of moving an unexploited body of knowledge or know-how from a source organization, where it has been created or enhanced, to another organization where it will be reduced to practice and exploited commercially.

You can view this definition at the Government of Canada GeoConnections web site: <http://www.geoconnections.org/CGDI.cfm/fuseaction/policySupporting.seeFile/id/95/gcs.cfmrce>.

The above definition is a good generic starting point. Generally, however, we think of technology transfer more narrowly, as a transfer of technology from a government entity to a private entity. The government entity, usually a research and development laboratory, has developed the technology in question. The private entity, usually a commercial firm of some sort, wishes to exploit and commercialize the technology. When the government entity in question is the U.S. Government, we have our definition of Federal technology transfer:

1 Source: U.S. Department of Transportation:
<http://www.volpe.dot.gov/infosrc/strtplns/nstc/ppp2/appa.html>.

2 See U.S. General Accounting Office report, “Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology,” GAO-03-47 (October 2002). Available on-line at: <http://www.federalabs.org/ContentObjects/Legislation/gao-d0347.pdf>.

the process of moving an unexploited body of knowledge or know-how from a Federal government research laboratory, where it has been created or enhanced, to a private sector entity where it will be reduced to practice and exploited commercially.

It should be noted that the Federal government is not the only government entity that transfers technology to the private sector. State governments (particularly, state universities) and local governments also transfer technology to the private sector. This paper, however, is about Federal technology transfer. Accordingly, we will not discuss state and local governmental technology transfer in detail.

In addition, it should be noted that our definition of technology transfer does not require that the licensing of a patented invention take place. While technology transfer often does involve the licensing of an invention, technology transfer can take place without such licensing. For example, a private company and a Federal government research laboratory can engage in the technology transfer activities of sharing information, people, facilities, and “know-how” without ever engaging in intellectual property licensing.

Finally, it should be noted that our definition of Federal technology transfer oversimplifies a bit concerning the process by which the technology is created and the direction of the transfer. In our definition, the Federal government has already created the technology and the direction is from the Federal government to the private sector entity. These two assumptions are not always true. For example, some of the technology that is transferred is often created jointly by the Federal government and a private entity partner working together under a “Cooperative Research and Development Agreement.” In addition, it is possible in rare cases for the transfer of technology to go the other way, from a private entity to the Federal government.

3. Why Learn About Federal Technology Transfer Law?

If you are an attorney in government practice, you may need to know about Federal technology transfer law in order to advise your government clients in this area.

If you are in private practice, either as an attorney in a law firm or as in-house counsel to a company, you may need to know about Federal technology transfer law in order to effectively advise your clients who are engaging in technology transfer activities with Federal government research laboratories.

Attorneys in Colorado are more likely than attorneys in some other states to encounter technology transfer law issues. This is because Colorado is home to a large number of Federal agencies and employees.³ This large Federal presence means that technology

³ As of December 2002, Colorado was home to 52,431 Federal employees working for dozens of Federal

partnering opportunities with the Federal government probably will present themselves to your clients more frequently than if you practiced in some other states.

In particular, Colorado is home to two major Federal research laboratories: The National Renewable Energy Laboratory (NREL) in Golden and the National Center for Atmospheric Research (NCAR) in Boulder. NREL is part of the Department of Energy (DOE) and NCAR is part of the National Oceanographic and Atmospheric Administration (NOAA). NOAA is an agency of the Department of Commerce (DOC). These two laboratories by themselves present your technology-oriented clients with some exciting research and development business opportunities. The DOC also runs the National Institute of Standards and Technology (NIST) which has a major facility located in Boulder. NIST is a major licensor of Federally-developed technology and also makes outright grants to private entities to encourage high-technology research.

4. Origins of Federal Technology Transfer Law

Federal technology transfer has been taking place at a significant rate since the 1950's. In particular, the Department of Defense (DOD) and the DOE have been licensing technology developed in DOD and DOE research laboratories since the 1950's. These early licenses were offered on a non-exclusive, royalty-free basis.

In general, however, Federal technology transfer in the early days was more the exception than the rule. Federal technology transfer occurred haphazardly until Congress passed key legislation in 1980 and 1986. Before 1980, technology transfer was an after thought for Federal research laboratories because it was not part of each research laboratory's core mission. The following three Federal statutes are the "seminal" Federal technology transfer laws. As updated and amended, these three statutes form the core of Federal technology transfer law as we know it today.

- **Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480).** This law ushered in a new era in Federal technology transfer. This statute, signed into law by President Carter on October 21, 1980, made it the responsibility of each Federal research laboratory, and each research laboratory employee, to facilitate the transfer of laboratory-developed technology to state and local governments and to the private sector. The statute created an "Office of Research and Technology Applications" (ORTA) in each Federal research laboratory having 200 or more full-time employees. The function of a laboratory's ORTA is to facilitate the transfer of technology from the research laboratory to state and local governments and to the private sector whenever possible. The Stevenson-Wydler Act has been codified at 15 U.S.C. §§ 3701-3715.

agencies. Source: U.S. Office of Personnel Management:
<http://www.opm.gov/feddata/geograph/2002/table3.asp>.

- **Bayh-Dole Act of 1980 (P.L. 96-517).** The second foundational Federal technology transfer statute was also enacted in 1980. On December 12, 1980, President Carter signed into law a statute commonly referred to as the “Bayh-Dole Act of 1980.” This statute amended the patent laws (including licensing provisions) of the United States to enable the more rapid and plentiful transfer of technology from the Federal government to state, local, non-profit, and commercial entities. In particular, the Act allowed state and local government entities, as well as non-profit, university, and small business entities, to obtain title to inventions that were developed with Federal funds. The portions of the Bayh-Dole Act that are pertinent to technology transfer have been codified at 35 U.S.C. §§ 200-209.

- **Federal Technology Transfer Act of 1986 (P.L. 99-502).** This law amended the Stevenson-Wydler Act, adding the “Cooperative Research and Development Agreement” (CRADA) as a legal mechanism for transferring Federal technology from research laboratories to the private sector. CRADA's are one of the most popular technology transfer mechanisms because they
 1. Provide research flexibility, generous licensing terms, and proprietary information disclosure protection to the private entity collaborator;
 2. Allow the Federal research laboratory access to the unique resources and knowledge base of the private entity collaborator; and,
 3. Encourage the commercialization of Federally- developed technology by allowing the negotiation of exclusive patent licensing for inventions that may result from planned cooperative research.

5. Why Do Federal Research Laboratories Engage in Technology Transfer?

Congress has mandated that it is the policy of the Federal government to facilitate the transfer of Federally-developed technology to state and local governments and to private industry. As stated by Congress at 15 U.S.C. 3710:

(a) Policy

- (1) It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development. To this end the Federal government shall strive where appropriate to transfer federally owned or originated technology to State and local governments and to the

private sector.

(2) Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional.

(3) Each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory.

As we can see from the above, Congress has recognized a need for the Federal government to be proactive in identifying technology developed in Federal research laboratories that has commercial potential. Congress has required Federal research laboratories to put this Federally-developed technology into the hands of private industry whenever possible. The Federal government requires private entities that receive Federally-developed technology to “commercialize” it and put it into practical use for the benefit of the public. This is fair: The the public does, after all, pay for the Federal government's technology research by way of taxes. Congress has even made success in technology transfer a rating factor in the job performance of Federal research laboratory staff.

But even without such a Congressional mandate, Federal research laboratory personnel are interested in technology transfer for the very human reasons of prestige and recognition. The mission of each these laboratories is to create new breakthroughs in the fields in which the laboratory staff work. When a technology that is created in a Federal research laboratory is successfully commercialized and put to practical use, this is powerful evidence of the value of the research being done by the laboratory.

6. Statutory Sources of Federal Technology Transfer Law

Below is a list containing some of the principal statutory sources of Federal technology transfer law. Please note that this list is not complete. It includes only those statutes deemed most significant.⁴

- **Stevenson-Wydler Technology Innovation Act (P.L. 96-480) (1980).** This statute required Federal laboratories to facilitate the transfer of federally owned and originated technology to state and local governments and the private sector.

⁴ Adapted from National Science Board, “Science & Engineering Indicators – 1998”; Arlington, VA; National Science Foundation, 1998 (NSB 98-1). See table 4-8 on page 4-29. This document is available for viewing and download at <http://www.nsf.gov/sbe/srs/seind98>.

- **Bayh-Dole University and Small Business Patent Act (P.L. 96-517) (1980).** This statute, usually referred to simply as the “Bayh-Dole Act,” permitted government grantees and contractors to retain title to Federally funded inventions and encouraged universities to license inventions to industry. The act is designed to foster interactions between academia and the business community.
- **Small Business Innovation Development Act (P.L. 97-219) (1982).** This statute established the Small Business Innovation Research (SBIR) program within the major Federal research and development agencies to increase government funding of research that has commercialization potential within small high-technology companies.
- **National Cooperative Research Act (P.L. 98-462) (1984).** This statute encouraged U.S. firms to collaborate on generic, precompetitive research by establishing a rule of reason for evaluating the antitrust implications of research joint ventures. The act was amended in 1993 by the National Cooperative Research and Production Act (NCRPA), which allowed companies collaborate on production activities as well as research activities.
- **Federal Technology Transfer Act (P.L. 99-502) (1986).** This statute amended the Stevenson-Wydler Technology Innovation Act to authorize “Cooperative Research and Development Agreements” between Federal laboratories and other entities, including state agencies.
- **Omnibus Trade and Competitiveness Act (P.L. 100-418) (1988).** This statute established the Competitiveness Policy Council to develop recommendations for national strategies and specific policies to enhance industrial competitiveness. The act created the Advanced Technology Program and the Manufacturing Technology Centers within the National Institute for Standards and Technology to help U.S. companies become more competitive.
- **National Competitiveness Technology Transfer Act (P.L. 101-189) (1989).** This statute amended the Stevenson-Wydler Act to allow government-owned, contractor-operated (GOCO) laboratories to enter into CRADA's.
- **National Cooperative Research and Production Act (P.L. 103-42) (1993).** This statute relaxed restrictions on cooperative production activities, enabling research joint venture participants to work together in the application of technologies they jointly acquire.
- **Technology Transfer Commercialization Act (P.L. 106-404) (2000).** This statute amended the Stevenson-Wydler Act and the Bayh-Dole Act to improve the ability of government agencies to monitor and license federally owned inventions.

7. Mini-Review of Patent Law and Patent Rights Licensing

As noted in Section 2, technology transfer can take place without the licensing of “patented” inventions. Licensing of patented inventions, however, is still very important in the area of Federal technology transfer. If you don't practice regularly in this area, the following quick review of some of the basic concepts in patent law and patent licensing may be helpful.⁵

7.1. Patent Laws in the U.S. Code:

The patent laws of the United States are found in title 35 of the U.S. Code. The patentability of “inventions” (including a discussion of the sorts of things that can and cannot be patented), is explained in 35 U.S.C. §§ 101-105. Patent rights to inventions made with Government assistance are discussed at 35 U.S.C. §§ 200-212.

7.2. Things That Can Be Patented (35 U.S.C. § 101)

Any new and useful

- Process
- Machine
- Manufacture
- Composition of Matter

In addition, any new and useful improvement to a process, machine, manufacture, or composition of matter may also be patented.

7.3. Examples of Patentable Things

Industrial or consumer machinery, technical or industrial processes, manufactured things, new chemical compounds, and any improvements to these things.

⁵ For purposes of simplicity, we will limit our discussion in this paper to “utility” patents. For a discussion of “design” patents and “plant” patents, see the FLC's “Technology Transfer Desk Reference” at section “4.” A copy of the Technology Transfer Desk Reference can be found on-line at: http://www.federalallabs.org/ContentObjects/Publications/T2_Desk_Reference.pdf.

7.4. What Sorts of Things Cannot Be Patented?

- **Abstract Ideas.** These include scientific and mathematical principles. If you can take the abstract idea and reduce it to a new and useful application, however, such as a machine based on an scientific principle, you can patent the application of that idea.
- **Laws of Nature.** Although you might be the first to discover the existence of a law of nature, you can't "invent" it. For example, you cannot patent the law of gravity. Again, you can patent the new and useful processes, machines, manufactures, and compositions of matter that make use of a particular law of nature.
- **Physical Things that Occur Naturally.** Ordinary things that occur naturally in our world are not patentable. New and useful processes, machines, manufactures, and compositions of matter utilizing physical things are patentable. For example, you cannot patent the chemical element, "carbon." Carbon is a naturally occurring chemical element. On the other hand, if you invent a new, low-cost process for extracting the carbon allotrope, "diamond," from discarded charcoal briquets, you can patent the process for doing so.
- **Literary Works (including music, written works, and works of art).** A literary work is really just the expression of an idea. You cannot patent the expression of an idea just as you cannot patent the idea itself. (Expressions of ideas, however, can be subject to copyright protection.) You can, of course, patent any new and useful process, machine, manufacture, or composition of matter that is based on an idea. If you come up with a new idea and you want to patent it, the idea cannot remain abstract. You must define it and present it as a process, machine, manufacture or composition of matter. It has to be new and useful, too.
- **Things Which are Not New or Useful.**

7.5. Inventions and Inventors

Patentable things are generically referred to as "inventions." The people who invent inventions are generally referred to as "inventors."

7.6. What Rights Do You Get When You Obtain a Patent?

You get the exclusive right to “practice” your invention for 20 years. In the patent laws, this right is stated in the negative: You have the right to prevent others from practicing your invention for a period of 20 years. See 35 U.S.C § 271.

What does it mean to “practice” an invention? You practice an invention when you “make, use, offer to sell, or sell” your invention. See 35 U.S.C § 271. If your invention is patented and the time period for the patent has not expired, absent a license, no one but you may legally make, use, offer to sell, or sell your invention. If someone does practice your invention without permission, the person or entity is liable for patent “infringement.”

7.7. Patent Licenses

So what is a patent “license”? You may give someone permission to “practice” some or all of your rights under your patent. This permission is a patent “license.” Patent licenses usually take the form of contractual agreements with conditions. Generally, but not always, one of the conditions is the payment of money, termed a “royalty,” for the right to practice your invention. A license that requires the payment of a royalty is “royalty-bearing.” A license that does not require the payment of a royalty is “royalty-free.”

Patent licenses can be “exclusive,” “non-exclusive,” or “partially exclusive.” In addition, a patent license can be limited by “field of use” or “territory” (geographical area).

A full discussion of the nature of “exclusivity” in patent licensing is beyond the scope of this paper. The following simplified definitions provide a brief outline of license exclusivity issues:

- **Exclusive License.** An exclusive license gives the licensee, and only the licensee, the right to practice the invention within a certain field of use or territory or both. Maximum “exclusivity” would give the licensee a license for all fields of use and in all territories and would prevent even the licensor itself from competing against the licensee. An exclusive license is a very powerful grant of permission because it limits the licensee's competition. Under an exclusive license, the licensor gives up the right to grant licenses to other parties (and perhaps even the right to practice the invention itself) for a certain field of use, territory, or both, for the rights granted under the license.
- **Non-exclusive License.** A non-exclusive license gives the licensee the right to practice the invention within a certain field of use or territory or both, but does not prevent the licensor from licensing the same rights to other parties. Again, the fields of use and the territories can be as large as “all fields” and “all territories.” Under a non-exclusive license, however, licensor is free to grant licenses to other parties for the same field of use, territory or both. There is far

less incentive to enter into a non-exclusive license because the prospective licensee is not guaranteed some level of freedom from competition.

- **Partially Exclusive License:** This is a hybrid type of license and is subject to varying interpretations of what “partially” exclusive means. Generally, however, a partially exclusive license is still “exclusive” in that it gives the licensee the exclusive right to practice the invention within a certain field of use or territory. This exclusive grant, however, is limited in some way. There may be a known set of “co-exclusive” licenses that are granted where more than one, but not an infinite number, of licensees are granted licenses. Sometimes the “partially exclusive” license is exclusive in one field of use or territory but specifically non-exclusive in others. Sometimes the license is truly exclusive, but only for a certain length of time (e.g., after a specified length of time, the license converts to a nonexclusive license for the remainder of the patent's duration).

7.8. Patent License Fields of Use and Territories

A “field of use,” as the name implies, is an industry, market, scientific field, set of specific purposes, etcetera, in which the invention can be practiced. A field of use for a new drug, for example, could be limited to “medical treatment of human cancers.” The field of use would thus not include “medical treatment of animal cancers.” Similarly, the field of use for a new computer display screen technology might be “military aircraft heads-up displays” as opposed to a wider field of use that would also include “video arcade game screens.”

A “territory” is just that, a geographical area. A license can be granted for only a specific territory, such as “China,” “the United Kingdom and its possessions,” or “North America,” or it can be granted for all territories. Specifying a territory allows one licensee to practice the invention exclusively in one “territory” while allowing another licensee to practice the invention exclusively in another “territory.”

8. Key Provisions of the Federal Technology Transfer Laws

A complete review of each section in the U.S. Code relevant to technology transfer is not possible within the scope of this paper. In order to give the reader a framework for understanding the core ideas embodied in the technology transfer laws, however, I provide synopses of some of the key provisions in these laws, especially those provisions which are important from a legal and intellectual property standpoint. I intentionally omit

some administrative details such as the creation of various offices and roles as well as funding and reporting mechanisms.

- **15 U.S.C. § 3706:** Authorizes the Secretary of Commerce is to enter into “grants” and “cooperative agreements” to enable Federal technology transfer. The total amount of the grants and cooperative agreements awarded cannot exceed 75 percent of the cost of the program under which they are awarded. The grants and cooperative agreements can be with governmental, non-profit, or commercial entities. Note that the arrangement is termed a “grant” generally when there is a minimum of technical assistance from the Federal government. Where the Government plays a more active role in assisting technically with the research, as well as providing funding, the arrangement is generally termed a “cooperative agreement.” We must distinguish a cooperative agreement from a “Cooperative Research and Development Agreement” that is provided for at 15 U.S.C. § 3710a. The Federal government may not provide funds under a “Cooperative Research and Development Agreement” - it may only provide personnel, facilities, intellectual property, and other non-monetary assistance.
- **15 U.S.C. § 3710(a):** Makes it a core job function of each Federal research laboratory, and each Federal research laboratory employee, to look for and implement technology transfer to state and local government and to the private sector.
- **15 U.S.C. § 3710(b):** Creates an “Office of Research and Technology Applications” (ORTA) in each Federal research laboratory having 200 or more full-time employees.
- **15 U.S.C. § 3710(c):** Requires each ORTA to enable Federal technology by performing 5 core functions (see subsections 1 – 5). These functions include sizing up various Federally-developed technologies for their commercial potential; disseminating information about transferable technology; cooperating with state and local governments on technology transfer issues; providing technical assistance to state and local governments; and, participating in regional technology transfer programs.
- **15 U.S.C. § 3710(e):** Charters the Federal Laboratory Consortium for Technology Transfer (FLC) as a clearinghouse of information and assistance for Federal research laboratories. The FLC had actually been in existence before the formal charter was granted by Congress, but was now given the official mission of assisting all of the Federal research laboratories in their technology transfer efforts. Funding for the FLC is mandatory and comes from the budgets of the Federal research laboratories. The FLC helps the member research laboratories by allowing them to pool their technology transfer resources. The FLC is an excellent source of information and education for third-parties who want to engage in technology transfer activities with Federal research laboratories.
- **15 U.S.C. § 3710a(a):** Creates the important “Cooperative Research and Development Agreement” technology transfer legal mechanism. This important portion of the Federal technology transfer laws was added by P.L. 99-502, the Federal

Technology Transfer Act, in 1986. This is the third most important Federal technology transfer statute second in importance only to the seminal Stevenson-Wydler Act and Bayh-Dole Act. CRADA's are agreements by which a Federal research laboratory may enter into an agreement with a third party to jointly develop new technology. A model CRADA can be found in the FLC's "Technology Transfer Desk Reference" document in Appendix "C." A section-by-section analysis of a typical CRADA can be found in the same document in Appendix "D."⁶

Subsection "2" of 15 U.S.C. § 3710a(a) specifically authorizes the licensing of Federally-owned inventions under 35 U.S.C. § 207.⁷

- **15 U.S.C. § 3710a(b)(1):** Specifically provides that the Federal government may agree (including agree in advance) in a CRADA to license to the cooperating entity any new invention that results from the research conducted under the CRADA. It also provides that any Federally-created invention which existed before before the signing of the CRADA can be licensed as well, subject to the conditions on Federal licensing imposed by 35 U.S.C. § 209.

In addition, the Federal laboratory is required to provide the option of an exclusive license for a pre-negotiated field of use. This is a very powerful incentive to enter into a CRADA with a Federal research laboratory: If you enter into a CRADA with a Federal research laboratory, you are guaranteed an exclusive license for any invention created under the CRADA (albeit, for a pre-negotiated field of use) if you want it.

- **15 U.S.C. § 3710a(b)(1)(A):** This section provides the Government's reserved rights in the inventions that are licensed. In exchange for granting a license under a CRADA, the Federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license to the invention. This allows the Government to practice the invention (or have it practiced on the Government's behalf) throughout the world, for the Government's purposes. The Government does not want the granting of the license under the CRADA to stop the Government from continuing its research on and deployment of any inventions created under the CRADA.

In practicing the invention, however, the Government agrees to not disclose trade secrets and other confidential information it has received from the collaborator.

- **15 U.S.C. § 3710a(b)(1)(B):** The collaborator under the CRADA has to grant an exclusive, nonexclusive, or partially exclusive license to the invention to a responsible

⁶ The FLC's "Technology Transfer Desk Reference" document can be viewed and downloaded from the FLC at this web page:
http://www.federal labs.org/ContentObjects/Publications/T2_Desk_Reference.pdf.

⁷ Note that this section is numbered "3710a," with a lowercase "a" immediately following "3710." This section should be distinguished from section "3710(a)," which indicates subsection "a" of the prior section, "3710."

applicant under reasonable terms should another party wish to license the invention in the collaborator's field of use. If the the collaborator does not do so, the Government has the right to grant such a license. This provision allows the Government to promote the dissemination of the useful technology from entity to entity, thus making it more valuable to the public, while still compensating the party that originally collaborated under the CRADA.

- **15 U.S.C. § 3710a(b)(1)(C):** This provides that the Government will not use its right under subsection “B” except in exceptional circumstances (three separate exceptional circumstances are enumerated). This subsection ensures that the Government will only invoke its right under subsection (B), to force the re-licensing of the technology, when the licensee is failing to fully put the invention to practical use (or for the Government's own health and safety needs). Thus, subsection “B” is a “stick,” but one the Government cannot use, per subsection “C,” until the licensee has had a fair opportunity to fulfill its obligations under the license.
- **15 U.S.C. § 3710a(b)(2):** If an invention is created solely by the CRADA collaborator's employees, not by the Government's employees or a joint team, the collaborating party retains the rights to the invention. The collaborating party must still provide the government with a nonexclusive, nontransferable, irrevocable, paid-up license to the invention.
- **15 U.S.C. § 3710a(c)(4)(A):** Special consideration is to be given to small businesses that wish to enter into CRADA's.
- **15 U.S.C. § 3710a(c)(4)(B):** Preference is to be given to U.S. Entities when entering into a CRADA. In addition, preference is to be given to entities who agree to manufacture products developed under the CRADA substantially in the United States. Finally, if a foreign firm wishes to enter into a CRADA, take into account whether the foreign government in question allows the U.S. entities to enter into similar agreements (i.e., does the foreign government give “reciprocity” for CRADA-style agreements).
- **15 U.S.C. § 3710a(c)(5)(C):** Federal laboratories that are owned by the Government but are operated by a contractor may also enter into CRADA's. These “Government owned, contractor operated” (GOCO) laboratories must follow the procedures and receive the approvals provided for in this subsection in order to enter into a CRADA.
- **15 U.S.C. § 3710a(c)(7)(A):** This section provides that no trade secrets or other confidential information received from CRADA collaborating parties may be disclosed. This provides important protection for proprietary data and know-how that must be revealed to the Government employees in the course of the research and development under the CRADA.
- **15 U.S.C. § 3710a(c)(7)(B):** Any information that is created as a result of the research

done under a CRADA that constitutes a trade secret or confidential information may be protected by the Government from disclosure for up to 5 years. Note how the Government does not have to put this protection in the CRADA – it is discretionary. Most Government research laboratories want to disclose the results of their research efforts. It is part of their public mission to disseminate the knowledge they are creating. Accordingly, the Government does not have to protect this information and, even if it does so, that protection lasts for no more than 5 years.

Note that this section specifically provides protection from disclosure under “subchapter II of chapter 5 of title 5” (5 U.S.C. §§ 551-559). This is a specific exemption from the requirement to disclose Government information under the “Freedom of Information Act” (5 U.S.C. § 552) and other Federal “government in the sunshine” laws.

- **15 U.S.C. § 3710a(d)(1):** Under a CRADA, the Government may provide personnel, services, facilities, equipment, intellectual property, and other resources but it may not provide funding. This is key to a CRADA: The Government is forbidden to provide monetary funding. The collaborating party under a CRADA may provide funding if the CRADA so provides. (These funds are sometimes collected by way of “facility use” fees charged by the Government.) The Government can provide funding in a “cooperative agreement” situation, as opposed to a CRADA. See 15 U.S.C. § 3706, referenced above, for the statutory basis for cooperative agreements. A “cooperative agreement,” unlike a CRADA, is essentially a Federal funding grant that also includes significant Federal technical assistance.
- **15 U.S.C. § 3710c(a)(1)(A):** This provision provides an incentive to encourage Federal research laboratories and their employees to invent and to license Federally-developed technology to the private sector. Under this provision, when a Federal research laboratory licenses an invention developed under a CRADA, or simply licenses an existing invention per 35 U.S.C. § 207, it is allowed to negotiate for and collect royalties for the licensed invention. In any year in which such royalties are collected, the first \$2,000 and at least 15 percent of the remaining royalties collected are paid to the inventors of the technology at the laboratory. This is a direct monetary incentive to the laboratory's staff. Even if the laboratory staff are not the “inventors” of the technology, they may still be paid appropriate incentives out of the royalties if they “increased the technical value” of a licensed invention.
- **15 U.S.C. § 3710c(a)(1)(B):** In addition to the incentives above, the remaining royalties collected are transferred by the agency to its research laboratories. A majority of the royalties must go to the laboratory where the invention occurred.
- **15 U.S.C. § 3710c(a)(3):** Payments made under 15 U.S.C. § 3710c may not exceed \$150,000 per year for any one employee.
- **35 U.S.C. § 200:** This section establishes that it is the policy and objective of

Congress to use the patent system to “promote the utilization of inventions arising from federally supported research or development.” This section of the U.S. Code corresponds to section 6(a) of P.L. 96-517 (the Bayh-Dole Act).

- **35 U.S.C. § 207(a):** This provision authorizes each Federal agency to obtain domestic and foreign patents for the inventions created by or assigned to the agency. It also authorizes each Federal agency to grant royalty-bearing and royalty-free licenses to Federally-owned inventions and to take all other necessary steps to protect and administer the rights in Federally-owned inventions.
- **35 U.S.C. § 207(b):** This provision designates the Secretary of Commerce as the focal point for managing Federally-owned inventions. It specifically authorizes the Secretary of Commerce to help Federal agencies identify areas of research and development having commercial potential.
- **35 U.S.C. § 208:** This section authorizes the Secretary of Commerce to promulgate regulations specifying the terms and conditions of licenses to Federally-owned inventions. These regulations have been promulgated and can be found at 37 C.F.R. §§ 404.1 – 404.14.
- **35 U.S.C. § 209(a):** This provision authorizes each Federal agency to grant exclusive and partially exclusive (as opposed to non-exclusive) licenses but sets conditions on when exclusive and partially exclusive licenses can be granted. In particular, exclusive and partially exclusive licenses can only be granted when they are a reasonable and necessary incentive to “call forth the investment capital and expenditures needed to bring forth the invention to practical application” (see subsection (a)(1)(A)). Exclusive and non-exclusive licenses can also be granted if they are a necessary incentive to “promote the invention's utilization by the public.”

In essence, Congress is saying in this section that exclusive and partially exclusive licenses can be used, but only when offering a non-exclusive license would not generate any interest in the licensing of the technology.

- **35 U.S.C. § 209(b):** This portion of section 209 is quite significant. It provides that any products embodying or produced through the use of a Federally-licensed invention should be manufactured in the United States.
- **35 U.S.C. § 209(c):** This portion of section 209 gives preference to small businesses who apply for licenses to Federally-owned inventions.
- **35 U.S.C. § 209(d):** This portion of section 209 sets the mandatory terms and conditions on licenses granted to Federally-owned inventions. In particular, subsection (d)(1) requires the Federal government to retain a “nontransferrable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government....”

- **35 U.S.C. § 209(e):** When the Federal government intends to grant an exclusive or partially exclusive license for a Federally-owned invention, it must first publish notice of this intent in an “appropriate manner” 15 days before the license is granted. (Per the Department of Commerce's regulations, the notice required is published in the Federal Register. See 37 C.F.R. § 404.7.)
- **35 U.S.C. § 209(f):** Before the Federal government can grant any license (exclusive, partially exclusive, or nonexclusive), the prospective licensee must submit a plan showing how it will develop and market the invention. The plan is treated as proprietary information and is not to be disclosed under 5 U.S.C. § 552 (the Freedom of Information Act).

9. Federal Regulations That Address Technology Transfer

Technology transfer issues are addressed at several places in the Code of Federal Regulations. The most important of these are the Department of Commerce's regulations at 37 C.F.R. §§ 404.1 – 404.14. These regulations specify the parameters of and conditions on licensing of Federally-owned inventions. Of particular importance are 37 C.F.R. § 404.5 and § 404.7, which specify the mandatory restrictions and conditions on the licenses for Federally-owned inventions. For example, 37 C.F.R. § 404.5(a)(2) specifies that the licensee must agree to manufacture the invention in question substantially in the United States. This is in accordance with 35 U.S.C. § 209(b). In this age of off-shoring production to very low-cost production facilities outside the United States, this is not a minor consideration.