

Introduction to Federal Technology Transfer Law

Addendum

by Brock Wood

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1. Legal Mechanisms Used in Technology Transfer

Technology transfer can occur formally and informally. In a formal sense, however, transfer does not take place unless a legal mechanism for doing so has been entered into by the Federal government and by the party receiving the technology. The legal mechanisms you should be familiar with are:

- Grant Agreements
- Cooperative Agreements
- Cooperative Research and Development Agreements (CRADA's)
- Patent Licenses

1.1. Grant Agreements

Grants agreements are authorized at 31 U.S.C. § 6304. As noted by Congress in this section, grants, including grants to commercial entities, are permitted when a law authorizes the public purpose of support or stimulation (as opposed to a need for procurement) by the Government. As noted by Congress in 31 U.S.C. § 6304(b), extensive involvement by the Federal government is not expected under a grant agreement. For that situation, agencies generally use a cooperative agreement or a Cooperative Research and Development Agreement (CRADA).

If an invention that is patentable results from research conducted under a grant agreement, and the recipient of the grant is a small business or non-profit institution, the non-profit or small business entity may elect to retain the rights to the invention pursuant to 35 U.S.C. § 202.

Grants are generally available only as part of an established agency program under which they are awarded. For information on a particular agency's grant opportunities, contact the agency in question.

1.2. Cooperative Agreements

Cooperative agreements are provided for at 31 U.S.C. § 6305. This section is worded very similarly to 31 U.S.C. § 6304 concerning grants. As noted by Congress in this section, cooperative agreements, including cooperative agreements with commercial

entities, are permitted when a law authorizes the public purpose of support or stimulation (as opposed to a need for procurement) by the Government. As noted by Congress in 31 U.S.C. § 6305(b), extensive involvement by the Federal government is expected under a cooperative agreement. (Compare this expectation of involvement to the expectation of lack of involvement in a grant situation.)

In the case of a cooperative agreement, the Federal agency in question will probably provide substantial technical assistance in addition to funding. Contrast this with a CRADA where technical cooperation and assistance are provided but no Federal monetary funding is permitted.

If an invention that is patentable results from research conducted under a cooperative agreement, and the cooperative agreement was entered into with a small business or non-profit institution, the non-profit or small business entity may elect to retain the rights to the invention pursuant to 35 U.S.C. § 202.

Cooperative agreements generally are available only as part of an established agency program. For information on a particular agency's cooperative agreement opportunities, contact the agency in question.

1.3. Cooperative Research and Development Agreements

As previously discussed, CRADA's are flexible and useful tools by which Federally-developed technology can be transferred to a private entity. CRADA's are authorized by 15 U.S.C. § 3710a.

CRADA's have some unique characteristics that set them apart from other technology transfer mechanisms:

- CRADA's can be entered into on an ad hoc basis – no established agency program (such as a grant program) need exist to enter into a CRADA. The Federal research laboratory or the collaborating entity can initiate the CRADA.
- Several aspects of a CRADA are, such as the details of the statement of work and the licensing terms of inventions created as a result of the research, are negotiable.
- CRADA's can be entered into in a relatively short length of time compared to other transfer mechanisms.
- CRADA's allow for the pre-negotiation of invention licensing terms before an invention is actually created.

- CRADA's are not considered procurements or grants. As a result, neither the Federal Acquisition Regulations nor the Contract Disputes Act applies to a CRADA.
- CRADA's allow Federal inventions to be licensed exclusively and partially exclusively without notice.
- CRADA's allow access to Federal research and development resources (including human talent and knowledge) that may be unique to the laboratory and may be hard to duplicate at the collaborating firm simply by using Federal funds.

Information on entering into a CRADA can be obtained by contacting the Federal research laboratory in question. If the laboratory is a Government-owned, government-operated (GOGO) laboratory that has 200 or more full-time employees, the laboratory should have an “Office of Research and Technology Applications” that is specifically authorized to work with collaborating entities on CRADA's and other partnerships. Most Federal agencies have developed CRADA “guidelines” or “policies” that are posted for public viewing. Knowing in advance the agency's approach will tell you what to expect when negotiating a CRADA. For example, see the Department of Veterans Affairs CRADA guidelines at this web site:

<http://www.vard.org/tts/crada/guide.htm>

1.4. Patent Licenses

A license to a Federally-owned invention, or a license to an invention that results from research done under a Federal grant, cooperative agreement, or CRADA, is a great way to transfer technology from the Federal government to the private sector. A license can be associated with the other three technology transfer mechanisms when an invention results from the research done under the mechanism. In addition, a license can be negotiated and obtained as a “stand-alone” transfer mechanism for an invention the Government has already created.

Patent licenses offered by the Government are similar to patent licenses offered by private entities. There are some unique aspects to Government patent licenses that were explained in the section explaining the key provisions of Federal technology transfer law.

In addition, it should be noted that the Government is required to provide 15 days notice and solicit public comment before it may grant an exclusive or partially exclusive license. This requirement is found at 35 U.S.C. § 209(e). The exception to this requirement is for

patent licenses for inventions that result from the research conducted under a CRADA. See 35 U.S.C. § 209(e). Licenses for any inventions that may result from CRADA research are “pre-negotiated” when the CRADA is agreed to. The license is said to be “pre-negotiated” because the invention is not yet in existence when the CRADA is signed. In addition, under a CRADA, the Government is required to offer an exclusive license to the collaborating party if the research results in an invention. See 15 U.S.C. § 3710a(b)(1). This being the case, the exception to the public notice and comment provision of 35 U.S.C. § 209(e) for licenses to inventions created through CRADA research makes sense.

2. CRADA Process Walk-through

An excellent walk-through of the process of entering into a CRADA has been created by Mr. Kelly McGuire, Chief of the ORTA, U.S. Army Aviation and Missile Command, Research and Development Engineering Center, Huntsville, AL. Mr. McGuire's walk-through is in slide-show format. The presentation can be found on-line at this web site:

http://www.federallabs.org/sandiego/proceedings/Monday/fundamentals/5_SDMOD4_CRDA.pdf

3. Example CRADA

See instructor handout.

4. Example Federal Patent Licenses (Exclusive and Non-exclusive)

See instructor handout.

5. Suggestions for Negotiating CRADA's and Government Patent Licenses

5.1. Know Which Items are Negotiable and Which are Not

Most of the items in a CRADA and in a patent license are “boilerplate” standard clauses that the Government is either not authorized to vary or is unwilling to vary. For example, the Government's retention of a royalty-free license to practice an invention for the Government's purposes, the requirement of a preference for small businesses, and the requirement for U.S. manufacture are found in the authorizing statutes and are generally not negotiable.

CRADA Clauses That Usually are Negotiable:

- The statement of work itself, including all of the parameters of the research to be done, resources to be provided, etc.
- Any funding from the collaborating party, and how that funding will be collected
- Any pre-negotiated licenses, and the type (exclusive, non-exclusive, or partially exclusive)

Patent License Clauses that Usually are Negotiable:

- License type (exclusive, non-exclusive, or partially exclusive)
- Amount of royalty payments (if any)
- Timing of royalty payments (if any)
- Schedule for and details of the plan to achieve practical application of the invention
- Maximum length of time allowed to achieve practical application of the invention

5.2. Key to the Negotiation: Understanding the Government's Motivation

The key in any negotiation is to understand the other's party's goal in the negotiation. Unlike a typical licensing agreement between two private entities, the goal of a Federal research laboratory in entering into a CRADA and/or a patent license is not to achieve the largest amount of monetary compensation possible. While obtaining a reasonable payment for its assistance under a CRADA or a reasonable royalty payment for a license is certainly a factor for a Federal research laboratory, the laboratory's main objective is to successfully commercialize and put into practical use the technology that has or will be developed. Showing the laboratory that the technology in question has a high probability of being successfully commercialized is the key to convincing the laboratory to enter into the agreement or license. It is also key to getting the laboratory to be flexible regarding license's terms.

5.3. A Suggested Way to Structure Royalty Payments in an Exclusive or Partially Exclusive Government Patent License

If the Government is offering an exclusive or partially exclusive license to the collaborating party, the Government will likely ask for some sort of royalty payment in return. The Government will probably be flexible in the way it structures the payment of the royalty. Remember that the Government's goal is not to achieve the largest possible royalty payment but to successfully transfer the technology to the private sector and benefit the public. Accordingly, the following suggested royalty proposal may be appealing to the Government:

- Base the royalty payment on a percentage of gross sales of the product that incorporates or is produced through the use of the licensed invention.
- Set the royalty rate between 1 and 7 percent of the gross sales price. When setting the percentage, adjust according to the factors affecting the license, such as amount and type of exclusivity in the license and the nature of and commercial market for the invention, in order to make this rate reasonable for both parties.
- Guarantee to the Government a minimum yearly payment regardless of gross sales.
- Schedule the minimum yearly payments to begin after a certain amount of time has elapsed.

Why might this proposal be appealing to the Government?

- The amount of the royalty is easy to calculate (it is a percentage of gross sales).
- The royalty rate is “in the ballpark” to begin with and is adjusted based on factors that are rationally related to the license and the invention in question.
- The Government gets to “keep the licensee's feet to the fire” with the minimum yearly payments provision. This satisfies the Government's desire to have an inducement on the licensee that makes the licensee work hard to commercialize the invention. The Government doesn't want the guaranteed payment for the money it provides: The Government wants the guaranteed payment because it motivates the licensee. If the licensee has to make a minimum yearly payment

regardless of the income from the licensed invention, that obligation is an inducement to the licensee to commercialize the invention and make it “pay off.” This, of course, is the Government's ultimate goal in licensing the invention.

- Scheduling the yearly payments to begin some time in the future, rather than immediately, is a reasonable accommodation to the licensee. The Government does not want to hamper commercialization by putting the licensee into a financial bind early in the commercialization process.

This suggested proposal is based on concepts developed by Attorney Jesse Erlich of Perkins, Smith & Cohen, LLP, in his essay, “The Federal Technology Transfer Process – Licenses and Cooperative Research and Development Agreements.” See The FLC's “Technology Transfer Desk Reference” at Section “D”.¹

6. Federal Government “Venture Capital” for High-risk, High-return Technology Research and Development

The National Institute of Standards and Technology (NIST) provides Federal “venture capital” to small businesses with plans for high-risk, high-return R&D. The “Advanced Technology Program” (ATP) at NIST is authorized under 15 U.S.C. § 278n.

Some key features of a grant of funding under the ATP:

- Designed to provide funding when traditional venture capital firms will not take the risk
- Award recipient directs the research goals
- NIST shares in the risk of longer-range, higher-payoff research
- NIST commits approximately \$1,000,000 per year per project
- U.S. for-profit companies keep the rights to intellectual property created under ATP-funded projects
- NIST monitors the progress of research efforts

Conditions on the award if a single company is the award recipient:

- Project has a 3-year time limit
- The award cap is set at \$2,000,000
- Award recipient pays indirect costs of project
- If large company selected, the company pays at least 60% of the total project

¹ The FLC's “Technology Transfer Desk Reference” document can be viewed and downloaded from the FLC at this web page:
http://www.federalallabs.org/ContentObjects/Publications/T2_Desk_Reference.pdf

cost

Conditions on the award if a joint venture is the award recipient:

- 5-year time limit
- No limit on award amount (other than availability of funds)
- Joint venture shares 50% of the total project cost

The downside: No funding was authorized by Congress for new awards for Fiscal Year 2005 (funding was authorized to make payments on previous awards). Fiscal Year 2006 funding is not yet determined.

For more information, visit the NIST ATP web site: <http://www.atp.nist.gov>.

7. Three Favorite On-line Sources of Federal Technology Transfer Information

- **Federal Laboratory Consortium for Technology Transfer (FLC)**
Contains great educational resources, including the FLC's "Technology Transfer Desk Reference"
URL: <http://www.federallabs.org>
- **National Institutes of Health Office of Technology**
Great introduction to Federal technology transfer as well as downloadable sample documents.
URL: <http://ott.od.nih.gov>
- **National Institute of Standards - Technology Partnerships Home Page**
Another great introduction to Federal technology transfer. Contains detailed information on partnerships available and how to enter into them.
URL: <http://patapsco.nist.gov/ts/220/external/index.htm>