**Collaborator License Options to Laboratory Inventions Made under CRADAs**

What are a Collaborator’s options for obtaining rights to government laboratory employee “subject inventions” made (i.e., conceived or first actually reduced to practice) under a Cooperative Research and Development Agreement (CRADA)? Laboratory subject inventions are inventions made solely by government employees or jointly with Collaborator employees during the performance of a CRADA.

The statutory basis for this discussion can be found at 15 USC §3710a (b)(1), which states in pertinent part that,

"Under an agreement [CRADA] entered into pursuant to subsection (a)(1), the laboratory may grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, for reasonable compensation when appropriate. The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement.”

A prevalent practice at many government laboratories has been to interpret the statutory language “[t]he laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use” to mean that a pre-negotiated field of use must always be specified at the time of CRADA execution. Interestingly, this practice almost always leaves open for future negotiation other exclusive licensing terms. Other licensing terms include, but are not limited to, royalties or other reasonable compensation, time to achieve practical application, right of patent enforcement, license duration, transferability, meeting milestone achievements, etc.

Another common practice at many laboratories has been not to pre-negotiate a specific field of use but, rather, to grant CRADA Collaborators other licensing options. The first sentence in §3710a (b)(1) states that a laboratory “may grant . . . patent licenses or assignments, or options thereto.” Other patent licenses can include nonexclusive licenses, field of use nonexclusive licenses, and totally exclusive licenses. For instance, a Collaborator could ask for a pre-negotiated nonexclusive license and defer negotiating a field of use exclusive license if and when a laboratory subject invention is actually made. Moreover, in lieu of license rights, a Collaborator could ask to obtain an assignment of title ownership in laboratory employee subject inventions.

Is the practice to pre-negotiate field of use licenses required under the statue? For reasons that will become evident, Congress intended that the pre-negotiated field of use exclusive license option to be the “minimum rights” licensing option that a Collaborator may request from a laboratory at the time of CRADA formation. This option was mandated by Congress to provide a Collaborator with the assurance that it could walk away at the end of the CRADA with a field of use license acceptable for its needs. However, a Collaborator may decline this option if it determines other license or ownership rights better meet its objectives. A Collaborator may choose to defer negotiating license rights until after a laboratory subject invention is actually made under the collaboration so it can better identify the fields of use at that time.

Reviewing the House Report 104-390 from December 7, 1995, and the House Committee on Science views, can enlighten the reader for understanding Congress’s intent and requirements behind the exclusive licensing language as enacted in theNational Technology Transfer and Advancement Act of 1995 (Public Law 104-113)

<https://www.gpo.gov/fdsys/pkg/CRPT-104hrpt390/html/CRPT-104hrpt390.htm>Included below are pertinent sections taken from the House Report found at the link above. My commentary is provided, shown in bold and within brackets, interspersed within the excerpts from the House Report.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start of Excerpts from House Report \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**II. Purpose of the Bill**

H.R. 2196, as reported, amends the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480) and the Federal Technology Transfer Act of 1986 (P.L. 99-502), among other provisions. The bill seeks to provide the following objectives:

(1) To promote prompt deployment by United States industry of discoveries created in a collaborative agreement with federal laboratories by guaranteeing the industry partner sufficient intellectual property rights to the invention;

**III. Background and Need for the Legislation**

Despite the success of the CRADA legislation, there are existing impediments to private companies entering into CRADAs. The law was originally designed to provide a great deal of flexibility in the negotiation of intellectual property rights to both the private sector partner and the federal laboratory; however, it provides, little guidance to either party on the adequacy of those rights a private sector partner should receive in a CRADA.

Agencies are given broad discretion in the determination of intellectual property rights under CRADA legislation. This has often resulted in laborious negotiations of patent rights for certain laboratories and their partners each time they discuss a new CRADA. With options ranging from assigning the company full patent title to providing the company with only a nonexclusive license for a narrow field of use, both sides must undergo this negotiation on the range of intellectual property rights for each CRADA.

This uncertainty of intellectual property rights, coupled with the time and effort required in negotiation, may now be hindering collaboration by the private sector with federal laboratories. This, in essence, has become a barrier to technology transfer. Companies are reluctant to enter into CRADAs, or equally important, to commit substantial investments to commercialize CRADA inventions, unless they have some assurance they will control important intellectual property rights.

H.R. 2196, the National Technology Transfer and Advancement Act of 1995, seeks to enhance the possibility of commercialization of technology and industrial innovation in the United States by providing assurances that sufficient rights to intellectual property will be granted to the private sector partner with a federal laboratory. The Act guarantees to the private sector partner the option, at minimum, of selecting an exclusive license in a field of use for a new invention created jointly or solely by the government laboratory in a CRADA. The company would then have the right to use the new invention in exchange for reasonable compensation to the laboratory. The Act also assures the collaborator that it may take title to an invention it makes under the CRADA.

**VII. Committee Views**

Section 4. Title to intellectual property arising from cooperative research and development agreements.

The section provides clear guidelines that simplify the negotiation of a Cooperative Research and Development Agreement (CRADA)--addressing a major concern of private sector companies--and, in the process, gives companies greater assurance they will share in the benefits of the research they fund. The Committee believes the Act will result in a reduction of negotiation time and effort required to implement a CRADA and an alleviation of the uncertainty that can deter companies from working with the government. This will lead to quicker transfer and commercialization of laboratory technology.

**[So, it was Congressional intent to assure that private sector companies would know up front that they would be able to walk away with the intellectual property rights necessary to commercialize technology developed under a CRADA. The Act “guaranteed” a minimum exclusive field of use license, as negotiated, and permitted a laboratory to offer other rights including total exclusive license rights or even title ownership. Interestingly, Congress expressed its intent to simplify negotiations based on the premise that companies were funding the research. Historically, Collaborators would use their own funding to perform their obligations under a CRADA and would often reimburse the laboratory for its participation. More recently, situations are occurring where a laboratory funds its own efforts and Collaborators are even utilizing federally funding from another agency to support its responsibilities under a CRADA. I do not think Congress contemplated Collaborators walking away with field of use exclusive license options to government employee inventions when they do not have any of their own money in the game.]**

Each private sector partner entering into a CRADA with a federal laboratory has the ability to require that the CRADA provides exclusive intellectual property rights for a pre-negotiated field of use for any invention occurring under the agreement, regardless of whether the invention is made by a laboratory employee, a company employee, or a combination thereof. Thus, the industrial partner receives, at minimum, the option of an exclusive license in a field of use selected by the company. The important factor is that industry selects which option makes the most sense under the CRADA.

**[The committee’s comments above on what the statute was written to do adds clarity to how the statute should be interpreted and put into practice. They state that, “[e]ach private sector partner entering into a CRADA with a federal laboratory has the ability to require that the CRADA provides exclusive intellectual property rights for a pre-negotiated field of use for any invention occurring under the agreement.” The committee states further that, “[t]he important factor is that industry selects which option makes the most sense under the CRADA.” So, whenever a prospective Collaborator asks for a pre-negotiated exclusive field of use license a laboratory must entertain their request. A Collaborator receiving federal funding from another agency to perform its obligations under the CRADA does not change this requirement. Thus, regardless of the funding equities, a Collaborator may ask a laboratory to pre-negotiate a field-of-use exclusive license. However, what often makes more sense for a Collaborator is to wait and identify fields of use at the time a laboratory subject invention is actually made rather than at the time of CRADA formation due to the uncertainty of the fields of use needed. In addition to pre-negotiated exclusive license rights laboratories can, and often do, also offer nonexclusive licenses to laboratory inventions.]**

A company will now have the knowledge that they are assured of having no less than an exclusive license in an application area of its choosing. The Committee believes these statutory guidelines give companies real assurance that they will receive important intellectual property out of any CRADA they fund. Knowing they have an exclusive claim to the invention will, consequently, give a company both an extra incentive to enter into a CRADA and the knowledge that they can safely invest further in the commercialization of that invention.

**[What happens if a "pre-negotiated field of use" is specified but a Collaborator reconsiders the pre-negotiated field of use as being too limiting, or additional fields of use are desired, after an invention is actually made? Is a laboratory precluded from re-negotiating the field of use under the CRADA because it is no longer a “pre-negotiated” field of use license? Having such a restriction on laboratory subject inventions would create a chilling effect on these collaborations. Maybe it actually depends on whether the laboratory is willing to re-negotiate the field of use or add fields of use based on the CRADA collaborator’s ability to bring the invention to practical application in the newly identified fields.]**

Although a collaborating party is given a statutory option to choose an exclusive license for a field of use, agencies may still assign full patent title to the company. Agencies consulted by the Committee felt they needed to retain that flexibility for inventions made by government employees and the Act allows them to do so.

**[So, in lieu of the “option to choose an exclusive license for a field of use,” a Collaborator may request an assignment of full patent title. If a laboratory agrees that it will assign ownership to laboratory employee made inventions there is obviously no need to pre-negotiate a field of use. An agreement to assign ownership provides an even stronger intellectual property position than a pre-negotiated field-of-use exclusive field of use license.]**

The Committee fully expects that the private sector partner enters into a CRADA in order to advance a specific research agenda and that the company intends to aggressively pursue, whenever appropriate, full commercial opportunities for any new discoveries resulting from the CRADA. Should a private sector partner, for their own reasons, choose not to commercialize a resulting invention while another company is interested in pursuing its commercial opportunities, the Committee expects that the CRADA partner would license the invention rights to the other company.

It is generally contemplated that companies and agencies will work together to convert that company's specific research agenda into a document stating a particular field of use, for which the company is entitled to exclusive intellectual property rights. If more than one company is involved, the Committee expects each of their research interests be taken into consideration in defining the field of use, and that in no event will the total rights given to the private sector participants under a CRADA be less than they would be if just one company was participating in the CRADA.

In return for the intellectual property rights, the government may negotiate for royalties as reasonable compensation. The government is always entitled to a non-exclusive, nontransferable, paid-up license to use the invention for its own purposes, since it should not be expected both to pay for the research and then to pay for the use of that research.

**[The prevalent practice at many laboratories is to pre-negotiate a field of use and to leave other exclusive licensing terms open for subsequent negotiation. However, what happens if the parties can’t agree on the royalties or other licensing terms during subsequent negotiations? Doesn’t that mean an initially pre-negotiated field of use can be “held hostage” by the laboratory, preventing the collaborating party from its presumed assurance of exclusive license rights? If so, shouldn’t royalties and other common licensing terms also be pre-negotiated?]**

**­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­** End of Excerpts from House Report \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What are a Collaborator’s options under the statute? When a Collaborator decides that it is in its own best interest to pre-negotiate a field of use exclusive license to laboratory inventions a laboratory is statutorily obligated to engage in negotiations. Even in the rare circumstance when a Collaborator wants an exclusive license for a pre-negotiated field of use with all the attendant terms and conditions found in a typical patent license, a laboratory may accommodate their request and make such a license a part of the CRADA. Under this approach, the Collaborator and laboratory merely have to execute the pre-negotiated license once a laboratory subject invention is made and identified as subject to the license.

As the statute provides, and as articulated by the House Committee, pre-negotiating a field of use exclusive license is the “minimum” option that a laboratory must ensure it provides a Collaborator. However, there are a number of possible other options the parties may agree to at the time of CRADA formation. The variety of options expand when multi-party CRADAs are entered into and each party has competing interests. In many situations co-exclusive field of use licenses are acceptable to the parties.

Another common approach taken at the time of CRADA formation, or at the time a CRADA is modified due to the addition of a new joint work statement, is to defer negotiating a field of use exclusive license until such time a subject invention is actually made. The licenses are then negotiated with all the terms and conditions found in a typical patent license, including the field of use. Collaborators with ARL have been agreeable to pursuing collaborations knowing they have the option to negotiate exclusive licenses within negotiated fields of use when subject inventions arise. When this is the case ARL typically uses the following language in its CRADAs.

"ARL agrees to enter into negotiations in good faith with COLLABORATOR for an exclusive license to COLLABORATOR within specified fields of use, at reasonable rate, terms and conditions (including optionally a right of patent enforcement), of ARL-Made or Jointly-Made Subject Inventions."

Another interesting approach has been taken by the Public Health Service (PHS) (i.e., NIH) in their CRADA template. Although the parties don’t pre-negotiate a specific field of use the parties agree to an “upper bound” on whatever field of use is ultimately negotiated. The following was taken from the PHS model CRADA, PHS-CRADA-2012 version.

**“Collaborator’s License Option to CRADA Subject Inventions**. With respect to Government rights to any CRADA Subject Invention made solely by an IC employee(s) or made jointly by an IC employee(s) and a Collaborator employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator anexclusive option to elect an exclusive or nonexclusive commercialization license. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.” (Emphasis added)

The Department of Agriculture takes a similar approach to the PHS and uses the following language which was taken from the Agricultural Research Service CRADA template.

“COOPERATOR is granted an option to negotiate an exclusive license in each Subject Invention owned or co-owned by ARS for one or more field(s) of use encompassed by the Scope of Agreement. This license shall be consistent with the requirements of 35 USC 209(a), 209(b) (manufactured substantially in the U.S.), and 209(f) and other such terms and conditions as may be reasonable under the circumstances, as agreed upon through good faith negotiations between COOPERATOR and ARS.” (Emphasis added)

Both the PHS and Department of Agriculture limit the fields of use for future negotiations by applying a boundary defined by the scope of their research plans under their CRADAs.

The option language in 15 USC 3710a (b)(1) requires an agency to accommodate a prospective Collaborator’s desire to pre-negotiate a field of use for an exclusive license to laboratory inventions made under a CRADA. However, interpreting the statutory language, with explanatory support from the commentary of the House Committee, leads to the reasonable conclusion that alternative license options are meant to be made available at the time of CRADA formation. The Supreme Court has long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer and the principle of deference to administrative interpretations.[[1]](#footnote-1) Thus, a Collaborator can: (1) engage a laboratory to pre-negotiate a field of use exclusive license, with other licensing terms and conditions to be negotiated later; (2) ask to defer negotiating a field of use exclusive license until after an invention is made; (3) ask during CRADA formation to be granted a totally exclusive license with other licensing terms to be negotiated later; (4) ask during CRADA formation to pre-negotiate all exclusive licensing terms found in a typical patent license; (5) ask that ownership of laboratory inventions be assigned in lieu of pre-negotiating a field of use exclusive license; or (6) ask and agree to defer negotiating an exclusive field of use license that will not exceed the scope of the research under a Research Plan or Joint Work Statement. Other options are also possible.

The Government’s Regulations pertaining to contractors that support CRADA activities and contractor rights in inventions also recognize that the negotiation of license rights may be delayed. The standard patent rights clause, 37 CFR §401.14, at paragraph (c) states: “As prescribed in §401.3, replace (b) of the basic [patent] clause with the following paragraphs (1) and (2)”:

(b) “Allocation of principal rights”--

(1) The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause, including (2) below, and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(2) If the Contractor performs services at a Government owned and operated laboratory or at a Government owned and contractor operated laboratory directed by the Government to fulfill the Government's obligations under a Cooperative Research and Development Agreement (CRADA) authorized by 15 U.S.C. 3710a, the Government may require the Contractor to negotiate an agreement with the CRADA collaborating party or parties regarding the allocation of rights to any subject invention the Contractor makes, solely or jointly, under the CRADA. The agreement shall be negotiated prior to the Contractor undertaking the CRADA work or, with the permission of the Government, upon the identification of a subject invention. In the absence of such an agreement, the Contractor agrees to grant the collaborating party or parties an option for a license in its inventions of the same scope and terms set forth in the CRADA for inventions made by the Government.

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, Apr. 2, 2004]

Note that in (b)(2) above an agreement by a government contractor supporting a CRADA, “shall be negotiated prior to the Contractor undertaking the CRADA work or, with the permission of the Government, upon the identification of a subject invention.” Thus, a pre-negotiated field of use exclusive license must be offered, but alternative license rights may be negotiated “upon the identification of a subject invention.”

Of the six options identified above a laboratory must agree to engage in negotiations under option (1) if desired by the Collaborator. Options (2) through (6) may be preferred by a Collaborator in lieu of option (1) but may be granted at the discretion of the laboratory. Other options not described here, such as offering multiple field of use exclusive licenses, may be considered as well. To repeat the House Committee on Science, “[t]he Act guarantees to the private sector partner the option, at minimum, of selecting an exclusive license in a field of use for a new invention created jointly or solely by the government laboratory in a CRADA.” “The important factor is that industry selects which option makes the most sense under the CRADA.”

**Concluding Remarks**

Whether a field of use exclusive license is “pre-negotiated” at the time of CRADA formation, or negotiated at a later time, recognize that there is always a negotiation. There is never any guarantee that a laboratory will agree to the field(s) of use a Collaborator has requested. Just as a government patent licensee must demonstrate it has the capability to bring an invention to practical application under a patent license, a CRADA Collaborator should be able to demonstrate it has the wherewithal to do the same for the field of use identified on any subject inventions made under the CRADA. If the parties fail to reach an agreement at the time of CRADA formation the prospective Collaborator can choose to walk away from the collaboration without expending resources. If a Collaborator agrees to defer negotiations for field of use exclusive licenses until such time a subject invention is actually made, again, there is no guarantee that the parties will agree on the scope and terms of a license. Recall from above that the Public Health Service and Department of Agriculture take the approach of establishing an upper bound on the fields of use based on the scope of research identified in the Joint Work Statement. So, although everything falling under that upper bound is apparently up for grabs, even then, the PHS may not agree to every field of use that falls within those upper bounds. Their approach seems to imply that a request by a Collaborator for a license in a field of use outside the scope of the JWS would require the Collaborator to file an application for a patent license under the government’s licensing regulations just like any other interested party not a party to the CRADA, including the requirement to place a public notice.

Because the statute says that a laboratory, “shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use,” a recommended practice is to affirmatively capture a collaborating party’s decision to decline the pre-negotiated field of use option based on their decision to accept alternative options. To evidence such a decision language could be added to the CRADA that specifically says the Collaborator has declined the pre-negotiated field of use option. Alternatively, correspondence from the Collaborator made part of the record during CRADA negotiations can also remove any uncertainty about the Collaborator’s decision to decline the pre-negotiated field of use option. However, the lack of explicit mention of the Collaborator declining to exercise its option for a pre-negotiated field of use license in the CRADA, or in the record during negotiations, does not mean a laboratory has failed to meet its statutory obligation, making the CRADA subject to challenge as somehow being legally insufficient. A reasonable assumption can be made that a Collaborator knows, or should know, it has the ability to require a laboratory to offer this option but has opted not to do so as is evidenced by whatever alternative license or ownership rights are set forth in the CRADA.

1. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., et al*, 467 U.S. 837 (1984**)** [↑](#footnote-ref-1)