

Intellectual Property And Other Contractual Issues In Cooperative Research And Development Agreements (CRADAs): Part I

By Matthew W. Sagal, Gene Slowinski, Kenneth Freese and Steven Ferguson

The Alliance for Advanced Energy Solutions—Los Alamos and Chevron

From the beginning, the partnership between Los Alamos National Laboratory (LANL) and Chevron Advanced Energy Technology has been unique. Both partners saw numerous ways in which they could work together to help Chevron solve some of the most troublesome and common problems of the oil and gas industry, while addressing U.S. energy security concerns. With an initial project in place in 2003 (LANL's wireless communication technology INFICOMM), the parties agreed to further the relationship with an alliance, the Alliance for Advanced Energy Solutions. Through the Alliance, LANL's Technology Transfer Division found a way to expedite the projects between the parties using an umbrella Cooperative Research and Development Agreement (CRADA). The umbrella CRADA is a particularly effective means to streamline approvals and coordinate large numbers of projects with a single partner. Because the umbrella CRADA sets the overall contractual terms of interaction including protection of proprietary information and rights for licensing of intellectual property, the Alliance is able to focus more effectively on identifying, defining, and executing technical programs. Since the Alliance agreement was signed in 2004, LANL and Chevron have started 15 projects together with more projects in development. For more information on the Alliance see: <http://www.techcommjournal.com/archive.php?articleID=35>.

Developing Velcade® For Treatment of Multiple Myeloma

Collaboration with the National Cancer Institute (NCI) of the National Institutes of Health (NIH) led to the development of the first new treatment for the treatment of multiple myeloma approved by the FDA in over a decade. In 1998, ProScript Inc. and NCI entered into a Cooperative Research and Development Agreement (CRADA) to utilize the expertise and clinical trials networks of the NCI Cancer Therapy Evaluation Program (CTEP) to study ProScript's promising anti-cancer chemical compounds. The key

outcome of the CRADA collaboration was that Dr. Shanker Gupta at the NCI discovered how to protect these boronic compounds by creating a freeze-dry powder formulation. This dry formulation remains effective while exhibiting a dramatically longer and stable shelf life.

NCI carried out multiple clinical trials under the CRADA using its clinical trial networks. The data was crucial for understanding the therapeutic activity of Velcade® and its potential use to treat various cancers. The NIH Office of Technology Transfer exclusively licensed Dr. Gupta's discovery to Millennium Pharmaceuticals (successor in interest to ProScript) to provide an incentive for investment in the continued development of Velcade®. The product was approved by the FDA in 2003. For more information see: <http://www.ott.nih.gov/docs/VelcadeCaseStudy.doc>.

Introduction

This review of Cooperative Research and Development Agreements (CRADAs) is being published in two parts. Part I, presented here, includes an overview of CRADAs, organizational and policy matters, and part of the material on patent

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licensing. Part II, to be published in a future issue, will include the balance of the patent licensing material and discuss financial aspects and confidentiality and trade secrets.

Overview of CRADAs and the Purpose of This Article

The Stevenson-Wydler and Bayh-Dole Acts of 1980 provided the initial enabling legislation that encouraged the private sector to commercialize federally developed and/or funded science and technology. Since that beginning, further legislation and regulations within the federal government have expanded and clarified government-private sector R&D relationships. The rules governing such relationships are intended to create a reasonable balance between the public interest involved in tax-payer funded R&D and the interests of non-governmental organizations, including for-profit firms and non-profits such as universities.

One important type of collaboration between a federal laboratory and a non-governmental organization (typically an industrial laboratory) is a Cooperative Research and Development Agreement (CRADA), in which both parties bring resources to an agreed set of scientific or technological objectives. Those resources may be funding; professional skills; pre-existing (“background”) intellectual property; or capabilities and facilities for laboratory experiments, evaluation, or prototype manufacturing. Typically, a CRADA Research Plan describes the scientific tasks to be done, a timetable, expected deliverables, resources brought by each, and the allocation of work. The CRADA also contains other terms and conditions of the relationship between the parties, such as intellectual property rights. The CRADA sets the stage for subsequent related agreements, most notably a future licensing agreement that describes the rights of the parties to exploit CRADA-related intellectual property and the flow of payments associated with those rights.

As in all R&D relationships involving the federal government, CRADAs have rules of engagement, covering both use of intellectual property and other issues bearing on use of the results of the collaborative work. Those rules are applied in the specific language of each individual CRADA and associated licenses. In a CRADA, the rules reflect the fact that technical work is carried out between a federal laboratory and a non-governmental entity, usually a for-profit firm. That imposes some constraints, based on statutes or government policy. However, the U.S.

government is motivated to provide incentives for private firms to invest efforts in CRADAs and to take the further risks in commercializing CRADA results. Both statutes and policy provide those incentives, and government laboratory managements have some freedom of action in negotiating terms that meet the needs of their commercial CRADA partners.

The purpose of this article is to provide insights to R&D executives on significant contractual issues that typically arise during planning and negotiating CRADAs and associated licenses. As examples, these issues include rights to use inventions (including exclusivity aspects), processes for negotiating royalties and other financial flows, manufacturing rights and obligations, and allowable constraints on publication or other public disclosures.

While CRADA rules on contractual issues are tied to relevant law, there are two aspects that can create complexity and uncertainty from the perspective of a private sector R&D executive planning and negotiating a CRADA with a federal laboratory:

1. Each U.S. Government Agency (such as the Department of Energy or the National Institutes of Health) has the authority, inside broad legislative mandates, to establish its own policies and practices for CRADAs. That means that positions on some contractual matters will vary among federal laboratories.
2. Inside each agency, some contractual matters are not negotiable, being tied directly to federal law or other binding mandates. But other matters are negotiable. The agency’s willingness to agree to the private entity’s wishes on a contractual matter (or reach a mutually acceptable compromise) depends on the reasonableness of the private entity’s position in the specific circumstances of the CRADA. Even allowable deviations from standard practice can require additional approval sign-offs, sometimes delaying a final agreement.

Other Federal-Private Sector Collaborations

In addition to the Cooperative Research and Development Agreements (CRADAs) that are the focus of this article, other federal-private sector relationships include development contracts, Small Business Innovation Research (SBIR) grants, Small Business Technology Transfer agreements, Work-for-Others for non-Federal agencies, and other mechanisms that vary among federal agencies. A complete survey of the types of federal-private R&D relationships and the rules governing each is beyond the scope of this article. There are several sources available to the

interested reader.^{1,2,3,4}

Format

To discuss the complexities within the space constraints of this article, the authors have used the following format:

Authors Sagal and Slowinski developed a list of questions that they have found important in working on CRADAs with private sector consulting clients. Authors Freese and Ferguson then respond to each question from the perspective of their own agency and federal laboratory (Department of Energy and Los Alamos National Laboratory; and National Institutes of Health, respectively). While this format should provide useful background for planning a specific CRADA, the reader should be aware of four important caveats:

1. The answers to some questions are not definitive, as they are situation-dependent even within the relevant agency.
2. Since many practices and policies vary among government agencies, CRADAs with agencies other than the Department of Energy or National Institutes of Health may be handled differently than the answers in this article suggest.
3. Laws and policies can change over time, so answers in the future could be different.
4. An R&D executive contemplating a CRADA or associated licensing agreement should insure the active participation of their legal counsel.

The questions and responses fall into four categories:

- A. Organizational and policy matters
- B. Patent licensing
- C. CRADA and patent licensing financial aspects
- D. Confidentiality and trade secrets

Note that some issues appear in more than one

category.

Some questions refer to the following documents, available online:

The NIH Model CRADA, NIH Model Materials CRADA, NIH Model Clinical Research CRADA and NIH Model Patent License Agreement –Exclusive:

http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.html

A Model CRADA for LANL:

<http://www.lanl.gov/orgs/tt/pdf/partnering/crada.pdf>

The Federal Laboratory Consortium for Technology Transfer Desk Reference:

http://www.federallabs.org/pdf/T2_Desk_Reference.pdf

The Federal Laboratory Consortium for Technology Transfer Green Book (Legislation and Policy):

<http://www.federallabs.org/store/greenbook/>

A: Organizational and Policy Matters

Question A1

The Federal Laboratory Consortium for Technology Transfer (FLC) has 253 federal laboratories as members. The FLC serves as an information source, provides training, presents awards and connects technology seekers with federal laboratories with potential solutions. The FLC has a comprehensive guide to legislation and executive orders: the “Green Book.” How important and visible is the FLC? Is the “Green Book” important for anyone involved in a CRADA?

Freese: FLC was created at the same time as the enabling legislation (Stevenson-Wydler and Bayh Dole Acts of 1980). It is an effective networking and educational organization. FLC has a Washington office that keeps track of pending legislation and regulations and keeps member laboratories informed. The FLC is a valuable networking organization for federal laboratories and is able to present issues and recommendations to the various federal agencies involved with CRADAs. FLC also works with industry and university groups to improve the effectiveness of technology transfer from federal laboratories. FLC has held joint meetings with complementary organizations such as the Department of Energy’s Technology Partnerships Working Group and World’s Best Technologies Conference, co-sponsored with the National Association of Seed and Venture Funds. In the future, FLC plans to hold joint meetings with the Licensing Executives Society (LES), the Association of University Technology Managers (AUTM), and the Industrial Research Institute (IRI).

Ferguson: In addition to Dr. Freese’s comment on the FLC, the “Green Book” is a useful compilation of

1. “Building a Business: Doing Business with the NIH”; Gil Ben-Menachem, Steven M. Ferguson & Krishna Balakrishnan, *Nature Biotechnology*, Volume 24 Number 1 (January 2006).

2. *Report on Technology Transfer and Related Technology Partnering Activities at the National Laboratories and Other Facilities, Fiscal Year 2006*; prepared by the Office of Policy and International Affairs, U.S. Department of Energy, March 2007.

3. “Products, Partners & Public Health: Transfer of Biomedical Technologies from the U.S. Government”; Steven M. Ferguson, *Journal of Biolaw & Business*, Vol. 5, No. 2, 2002.

4. See the Web site of the Federal Laboratory Consortium for Technology Transfer: www.federallabs.org.

information regarding the standard rules for working with any federal laboratory. It is a valuable reference for companies who wish to quickly get “up to speed” with having an understanding as to what federal laboratories can or cannot do with respect to R&D relationships with outside organizations. Most firms will find this to be a pleasant surprise as federal legislation over the years (as highlighted in the “Green Book”) has made it easier and easier for federal labs to foster the collaborations and other relationships that both companies and the labs themselves find mutually beneficial. The FLC newsletter also highlights some of the various licensing and collaboration opportunities available from its members.

Question A2

Every federal laboratory with more than 200 technical employees must have an Office of Research and Technology Applications (ORTA), acting as a “technology broker” between the laboratory and industry. Depending on the laboratory, ORTA serves as information source, contact finder, deal maker, and contract administrator. What are the roles of ORTAs in planning and negotiating CRADAs? Does the initiative and choice of a specific industry partner for a CRADA come from the ORTA, or from individual scientists and line managements? Does the ORTA control CRADA negotiations, or do line managements in the lab determine the lab’s positions in CRADA negotiations?

Freese: The internal name of the ORTA varies within federal laboratories; at LANL it is called the Technology Transfer Division, or more generically, the Technology Transfer Office (TTO). The TTO sees its role as facilitating the CRADA and associated licenses; serving both the laboratory and the firm. The TTO represents the interests of the laboratory during negotiations, and one of those interests is getting laboratory technology commercialized.

Some TTOs are more active than others. At one extreme, the TTO acts as a compliance office, insuring that technology transfer agreements follow law and policies. That is how the LANL TTO started out over 25 years ago. Today the LANL TTO is much more active and innovative, developing strategies and innovative approaches for commercialization of LANL technology. CRADAs and licensing are just two of several tools that LANL uses to implement these strategies. Some CRADAs are driven by LANL researchers to partner with the best in industry to accomplish their research goals; some are driven by a company to accelerate development and commercialization of a technology; and some are catalyzed by the TTO which recognizes an opportunity to commercialize

technology invented at LANL.

Ferguson: At NIH, certain technology transfer functions such as patenting, licensing and policy are centralized in the Office of Technology Transfer (OTT); while other functions fundamental to the conduct of research are handled through Technology Development Coordinators (TDCs) at the various NIH institutes. With respect to CRADAs, this means that the development of individual CRADA programs and their negotiation with prospective partners is handled at the institute level TDC offices; with a centralized review function that includes OTT regarding licensing, patenting and policy issues. Rather than having separate offices conducting CRADA negotiations at each of the 27 NIH institutes, many of the CRADA planning and negotiation functions for smaller institutes are handled by “Competitive Service Centers” operated by the larger NIH offices. Currently, such centers are operated by the National Cancer Institute (NCI), National Heart, Lung and Blood Institute (NHLBI), and the Office of Technology Transfer (OTT).

In all cases, CRADA formation is driven by the desire of a principal investigator(s) to solve an important basic scientific or clinical question. While either party can initiate a CRADA, there must be contributions to the research provided by both. In clinical trial CRADAs and regular CRADAs, there is a joint research plan that is the main focus of the negotiation, with both parties doing portions of the work. In a material CRADA, only the NIH conducts the research. The company contributes unique biological material.

Question A3

The FLC uses the word “alliance” to refer to an informal agreement between a federal lab and a private entity captured in a non-binding agreement. An alliance makes it possible to enter into a Memorandum of Understanding (MOU) or a Memorandum of Agreement (MOA), which presumably includes binding aspects. Are non-binding “alliance agreements” commonly used, and under what circumstances? Are MOUs or MOAs used often, and under what circumstances? What are their purposes? Are there binding aspects to MOUs and MOAs?

Freese: We use the word “alliance” differently. LANL uses “alliance” to mean an overarching strategic agreement with a partner under which individual CRADAs and licenses fit. For example, LANL has such an alliance agreement with Chevron. LANL sometimes uses non-binding MOUs and MOAs, usually at the request of the company to set the

stage for negotiation of a CRADA or other binding contractual agreement.

Ferguson: With 27 individual institutes, overriding alliance-type agreements are not common. However, when there is a major issue that affects multiple research programs at NIH, an intellectual agreement is typically handled centrally by the NIH OTT. Examples are the agreements regarding human embryonic stem cells with several providers, as well as the agreements with DuPont for “oncomouse” and “cre-lox” patents. These examples are significant in that they provide that any NIH-funded non-profit organization will enjoy the terms negotiated by NIH in agreements with these providers.

At NIH, it is common for us to have “collaborations” or “partnerships.” Often collaborations can be informal arrangements—often on a scientist-to-scientist or laboratory-to-laboratory basis, much like in academia. As long as there are no requirements regarding intellectual property rights or payment of funds from one party to another, these collaborations can be done at the scientist level. With the formation of a Public-Private Partnership Office at NIH, partnerships are receiving increased attention. These often involve multi-company, multi-organization pre-clinical research efforts to pool expertise and other scientific resources to work on medical problems (e.g. validating biomarkers) of interest to all participants.

Question A4

Each agency can create its own rules for CRADAs, consistent with law and regulations. Some agencies have created “model CRADAs” and published them on their Web sites. To what extent do CRADA rules and associated patent licensing agreements vary among agencies? How much flexibility does a laboratory have to deviate from the agency’s model CRADA when negotiating with a prospective CRADA partner?

Freese: Most DOE labs are GOCO (government owned, contractor operated). That structure impacts on flexibility on CRADA negotiations and terms. As contractor personnel, LANL managers do not have independent authority to use language beyond the model CRADA that has been customized for each laboratory. Therefore, it may be difficult for the Technology Transfer Office to agree to CRADA language that differs greatly from the DOE model.

Any language outside the terms of the model CRADA must be approved outside LANL, by local DOE site offices or DOE Headquarters in Washington. In those cases, the TTO can find itself in the difficult role as an intermediary between the company and

DOE offices outside LANL. Our experience shows that if the firm’s demands for deviations from the model CRADA are too large, we may not be able to conclude a successful negotiation. For example, we might be unsuccessful if a company wanted to avoid the model CRADA entirely and use “their agreement.”

In contrast to the CRADA, LANL does not have a DOE model patent license. LANL is now operated by Los Alamos National Security, LLC (LANS). LANS has a class waiver in its Operating Contract to elect to retain title to inventions coming from LANL research. Therefore, LANS has much more independence in negotiating licensing terms with private entities working on CRADAs with LANL.

Ferguson: NIH laboratories are largely GOGO (government-owned, government-operated). Since CRADA negotiations are conducted by government employees either within or acting as a Service Center to the NIH Institute that will be signing the agreement, questions or discussion concerning the terms of agreements can be handled directly. The key to a successful negotiation is the development of a well-defined research plan that clearly shows the contribution of each party to the overall program. This negotiation is handled at the institute level by the Technology Development Coordinator working with the Principal Investigator. Key to the approval of CRADAs by NIH is the CRADA sub-committee of the Technology Transfer Policy Board, whose membership includes scientists as well as staff from the Office of Technology Transfer and the Office of General Counsel. Generally the NIH CRADA committees can accept changes to the model CRADA, as long as the changes do not conflict with law or policy. This process works well in practice as NIH CRADA partners have been able to use this process to develop successful products such as Havrix® (hepatitis A vaccine), Taxol® (treatment for breast and ovarian cancer), Occuvites® (vitamin to prevent eye macular degeneration) among others. Knowing that both commercial as well as public health success can be achieved by CRADAs has encouraged flexibility so that the most productive relationships can be achieved in these relationships. Thus the negotiators and various review bodies (example: CRADA Committees in NIH) try to be flexible on some terms, but law or policy is binding. An example is the NIH publication policy. While laboratory CRADA results cannot be withheld from publication, it is possible to delay them for up to 60 days if needed to file a patent application.

Question A5

Is any special consideration for CRADAs given to small businesses? For example, must a government laboratory review alternative firms that are “small business” as potential CRADA partners before agreeing to a CRADA with a large firm?

Freese: Yes, LANL has a special provision in our operating contract with DOE to support regional economic development, and most of that activity involves small businesses. We do offer special consideration to small businesses by waiving some administrative fees on the cost of doing work for small businesses under a CRADA; and for regional small businesses in Northern New Mexico, we offer a reduced overhead rate on the cost of work under at CRADA.

Ferguson: CRADA partners are selected by NIH based upon mutual interest in a given, well-defined research project plus the ability to provide intellectual contribution or unique resources to the research. Unlike research agreements sponsored at academic institutions, CRADAs do not always require funding to be sent to the NIH by the corporate partner. Because of its interest in earlier stage innovative research, NIH has had a number of CRADAs with the biotech industry, nearly all of which are small businesses under the SBA definition.

Question A6

Article 7.2 in the model PHS CRADA refers to an “option” to a patent license, “substantially in the form of the appropriate model PHS license agreement.” Appendix A in the model PHS patent license agreement lists the relevant patents and patent applications, suggesting that the patent license agreement is negotiated after work under the CRADA is completed. Are the CRADA and patent licensing agreement negotiated in parallel, at the start of the CRADA; or is the patent licensing agreement negotiated after the CRADA is underway or after work under the CRADA is completed? If the patent license agreement is negotiated after the CRADA work is underway, what is the default if the government lab and the firm cannot agree on the terms of the patent license agreement?

Freese: DOE CRADAs include an option for an exclusive or non-exclusive license, but the details of the option are contained in a separate Option Agreement. Licensing terms are not negotiated at the start of the CRADA, since at that point we have no idea what the foreground intellectual property or the business outlook will be. If background intellectual property of the laboratory is required to use the results of the CRADA, the CRADA will contain a notice that a background intellectual property license may be

required. If the background intellectual property is encumbered (example: a prior license has been granted), that will also be noted in the CRADA. We do this to provide full disclosure of the IP landscape before decisions are made to enter the CRADA. As for what happens if we cannot agree to licensing terms after we have started the CRADA: That has never happened to my knowledge. LANL is motivated to make the license happen. Sometimes the Option Agreement may include a range of possible royalties for the eventual license, if the technology and business opportunity are well understood at the start of the CRADA. We try to be flexible and do what makes sense based on the facts of each case.

Ferguson: Like the LANL, the licensing terms for an invention coming from a CRADA would be negotiated after the invention was made. This is done for the same reason that Dr. Freese mentioned – it is extremely difficult to provide a reasonable valuation for invention when you don’t know what it is or what market it may serve. Also the company may not need a license to the technology if they turn out to be a co-inventor of the new invention made during of the collaboration.

NIH CRADA partners have an option to either a non-exclusive license or an exclusive license. When the invention coming from the CRADA is a new research tool, the company typically will take a non-exclusive license since they will be able to use it internally without further development. Also like DOE, the NIH is motivated to make the license agreement happen since a CRADA partner already has experience with the technology and thus is a prime candidate to commercialize the invention.

Question A7

What is the organizational split of responsibilities between negotiating a CRADA and negotiating the terms of a patent license?

Freese: At LANL, both the CRADA and its associated licensing agreements are negotiated by the Technology Transfer Office (TTO). We find that it is more effective to have all the agreements negotiated by the same team. It speeds the process and provides more consistent communications throughout the process.

Ferguson: At NIH, CRADAs and licenses are nego-

tiated by different groups. CRADAs are negotiated by or on behalf of the TDC in each of 27 Institutes, while patent licenses are negotiated centrally in the Office of Technology Transfer. With this separation of CRADA and licensing responsibilities, the for-profit firm and the NIH officers are still able to work closely together to ensure that the terms of the CRADA and the terms of the license both support development of the underlying technology. For example, the research conducted under the CRADA can be used by the company to help meet its milestones and diligence requirements under the license agreement.

B: Patent Licensing

Question B1

We understand that an Invention Evaluation Committee (IEC) makes the judgment as to whether an invention by a federal scientist should be the subject of a patent application. How does the IEC work in a CRADA? Suppose the firm and the IEC differ on the potential commercial value of an invention under a CRADA. Can the private entity make those decisions for foreground inventions regardless of the identity of the inventor? Can these decision rules be negotiated as part of a CRADA?

Freese: Inventions made under a CRADA are called "Subject Inventions" under the definitions of the CRADA. The terms of the CRADA are clear about ownership of title to Subject Inventions and how decisions are made on prosecuting patents. Each party has the first option to retain title, or ownership, to Subject Inventions made by its employees. If a party does not choose to exercise that option, the other party has second option to elect title in such inventions. If a CRADA partner wishes to prosecute a patent for one of our inventions, we generally agree and allow them to do so if they pay the prosecution costs. For inventions made jointly by both parties, the Subject Invention is jointly owned. If neither party wishes to retain title a Subject Invention, DOE has the right to take title to that invention for the U.S. Government.

Ferguson: Our procedures concerning this matter err on the side of filing, especially if requested by the CRADA partner. The private firm will generally be expected to pay for prosecution either as co-inventor or licensee. Having the patent rights is important since it is the only way that the NIH can provide exclusivity to the results of the CRADA research. We are unable to license "know-how" or keep our discoveries as a trade secret. Additionally, royalty income to reward government inventors and

laboratories for their inventive contribution can only come from licensing of patent rights or unpatented biological materials.

Question B2

Broadly, how much flexibility is there in the terms of licenses to the firm for CRADA related intellectual property? More specific questions are below, but how much freedom does a federal laboratory have when negotiating an intellectual property license under a CRADA?

Freese: A "right of first refusal" for an exclusive or non-exclusive license to the CRADA partner is built into the CRADA. Exclusive licensing terms can be quite flexible depending on the needs of the licensee. However, some of the terms are required by statute, such as requirement for substantial U.S. manufacturing for sales within the U.S., government march-in rights, reserved government rights, and indemnity of the U.S. Government.

Ferguson: At NIH, the situation is again very similar to that described above for the LANL. We also try to structure the agreement and its terms to reflect the specific circumstances and plans of the licensee, especially when dealing with smaller firms. We also keep in mind that both NIH and its parent agency HHS are healthcare organizations. This means that our agreements tend to favor things that benefit public health (such as development of orphan disease indications) over strict economic returns. We also seek to achieve "non-economic" returns in our agreements by encouraging licensees to include the final commercialized product in indigent access programs in the U.S., or to have the product distributed in developing countries.

Question B3

In the FLC Desk Register (4-19), an exclusive license to a government owned invention may be granted to a company only after publication of the intent in the Federal Register and the public is given an opportunity to object. The laboratory director makes the decision based on government and public interest. Is this public comment a normal requirement in a CRADA or patent license? What is the practical effect of this requirement?

Freese: The Federal Register public disclosure requirement for government owned, government operated (GOGO) laboratories is real. However, for DOE labs, which are government owned, contractor operated (GOCO), that requirement does not apply. Under the Prime Contract for each DOE GOCO Laboratory, the contractor operator has a right to retain title to inventions made at the Laboratory.

But DOE labs do have a “fairness of opportunity” policy, which is satisfied by publication of the licensing opportunity on the LANL Web site. When we do publish federal notices of opportunities, we no longer use the Federal Register but rather Federal Business Opportunities (FedBizOps) at www.FedBizOpps.gov. We increasingly rely on use of our Web site to announce licensing opportunities to meet our public notice requirements.

Ferguson: For inventions that did not arise from a CRADA (i.e. are not CRADA Subject Inventions), we publish a notice in the Federal Register for a sixty day comment period, identifying the technology and the company who has applied for an exclusive license. It is uncommon that we receive any comments or objections to these notices, but it is an additional means for us to be sure that we are making the correct decision about granting an exclusive license. If an objecting party files a competing license application, we give careful consideration as to how to grant licenses to both parties either through non-exclusive licensing, co-exclusive licensing or splitting the license Field of Use between the applicants. If we (or the applicants themselves) are not able to resolve this, we will then pick one company for the exclusive license based upon what is in the best interest of public health. Licensing opportunities for NIH and FDA technologies can be found at: http://www.ott.nih.gov/licensing_royalties/techabs.html

Question B4

The model CRADA Article 6.1 vests invention ownership in the inventing party, with joint inventions jointly owned. The model patent license agreement speaks to inventions made by government scientists, apparently “solely,” and does not discuss joint inventions.

Are patent licenses to the firm from the government limited to patents where government scientists are sole inventors? Does the government have rights to sole inventions of the firm? Can both independently exploit joint inventions without accounting to the other? Further, the implication is that inventorship must be carefully monitored in a CRADA, for commercial reasons as well as conforming to patent law. This is a vital issue in R&D alliance agreements between private firms. Please clarify the impacts on both the commercial aspects of CRADAs and the licensing agreements, and on working relationships between the government laboratory and the firm.

Freese: Yes, both parties have equal rights to exploit a jointly owned invention without account-

ing to each other. But this could lead to confusion and competing development of the invention. The CRADA partner does not need a license for its own inventions, including jointly owned inventions. However, for joint inventions, LANL is willing to grant the firm an exclusive license to our interest in the invention for appropriate consideration, since the Laboratory is foregoing its right to independently license the joint invention. The right of the firm to negotiate an exclusive license to joint inventions is included in the CRADA Option Agreement. The ownership of sole inventions by lab scientists cannot be negotiated away; so there must always be a license if the CRADA partner wants to practice the invention. Therefore, people must always be conscious of “who invented.”

Ferguson: We would echo the DOE comments. The ownership of any new invention must follow inventorship under patent law. That cannot be negotiated away. We fully expect that in many circumstances that new inventions will be jointly owned with the CRADA partners due to co-inventorship. This is a result of the collaborative nature of CRADA research. As noted before, this means that the company has complete freedom to operate under the invention without taking a license. They may still want to license the NIH rights in order to secure venture funding or otherwise protect their investment in commercializing the invention, but this is not required. If the company wants to sublicense rather than commercialize the patent rights, permission (or a license agreement) with the co-owner is required in certain European jurisdictions but not in the United States.

The balance of the questions on patent licensing will be in Part II.

Acknowledgements

The authors wish to thank the Department of Commerce EDA University Center program, Rutgers University, National Institute of Health and the Department of Energy for their support of this project.

This manuscript has been authored by Los Alamos National Security under Contract No. DE-RP52-05NA25396 with the U.S. Department of Energy. The publisher, by accepting the article for publication, acknowledges that the United States Government retains a non-exclusive, paid-up, irrevocable, world-wide license to publish or reproduce the published form of this manuscript, or allow others to do so, for United States Government purposes. ■