

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

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Introduction

This review of Cooperative Research and Development Agreements (CRADAs) is being published in two parts. Part I, which included an overview of CRADAs, organizational and policy matters, and part of the material on patent licensing; was published in the March 2009 issue. Part II, presented here, completes the patent licensing material and covers financial aspects and confidentiality and trade secrets.

An explanation of the “Q&A” formatting and some caveats are in Part I.

B: Patent Licensing

The first four patent licensing questions were in Part I.

Question B5

The model CRADA Article 7.3 describes a formal process for the firm to exercise its option to a patent license for a specific patent. Article 7.3 reads like a “one patent at a time” patent license negotiation process, with the firm declaring its intent to exercise its option to a patent license at a fixed time after a specific patent application is filed. In contrast, the model patent license lists multiple patents, suggesting that the patent license covers multiple patents for work under a CRADA. Please clarify. This question is tied to a previous question on the timing of the CRADA and the patent license agreement. As a practical matter, the financial value of a patent (and thus the terms of payments from the firm to the government) is tied to the entire suite of patents and non-patent trade secrets developed during the course of the CRADA.

Freese: When a LANL scientist makes an invention, the CRADA partner announces its intent to exercise its option for a license by a letter. This is just normal communications. If patents are generated early in a CRADA, the patent license negotiation might start before the CRADA is over. For that to occur, the business opportunity must be well enough defined so that the terms can be negotiated. If more laboratory patents subsequently arise, the license will be amended and the license terms adjusted accordingly. The Option Agreement is valid for some

time after the CRADA is over (usually six months). So the licensing process depends on the individual firm’s commercial strategy and circumstances.

Ferguson: Like for LANL, when negotiating a license agreement with NIH it is possible to include CRADA inventions as well as other relevant intellectual property in the same document. This process can start as soon as the patent application is filed and the company is ready to proceed—there is no need to wait until the CRADA research has been completed. As new patent rights of interest emerge over time from the CRADA research or other NIH research programs, it is possible to add them into the existing agreement by amendment. Amending license agreements to add in new patent rights should not be considered a negative—in fact it is a good indicator of the importance of the underlying technology and its commercial importance. For example, the NIH have agreements regarding HIV diagnostic technology that have been amended as many as seven times during the last twenty years. The products (and the companies) continue to enjoy considerable success.

Question B6

The FLC Desk Reference refers to requirements that the firm must meet, and continue to meet, for a continuing exclusive license to CRADA related inventions by the government laboratory. A Laboratory Director can terminate a license to a government owned patent if the Director determines that the company is not properly executing its commercialization plan or the firm cannot project commercialization in a reasonable period. The model license agreement spells out these requirements. The firm must agree to a commercialization plan and benchmarks, which are described in the license agreement (see Article 9 of the model license agreement). The firm must report to the government on its commercialization progress, with detailed status reports and reasons for any slippage or changes. The government must approve any changes. These requirements continue for the life of the license to the firm.

How burdensome are these commercialization performance requirements, and how carefully does

the government laboratory critique them? How aggressively does the government laboratory enforce the commercialization performance requirements? What is the track record of CRADA-related licenses being terminated because the government is dissatisfied with the firm's performance and terminates the license over the firm's objections?

Freese: We enforce these requirements. However, the commercialization requirements are re-negotiated if circumstances change the business conditions. LANL has terminated licenses, but only after unsuccessfully working with the firm to re-negotiate the commercialization plan. Termination occurs if the licensee is in default and lab believes that the firm is no longer capable of commercializing the technology. Sometimes a firm will voluntarily surrender the license when they cannot meet their commercialization objectives, since there are ongoing payments or minimum royalties.

Ferguson: The Monitoring and Enforcement Branch has been set up in our office to work on these requirements with licensees. Technology licensed from NIH is usually very early stage, and the commercialization path may be unclear and subject to severe regulatory uncertainties. The NIH tries to be reasonable both in the initial development plan requirements and later revisions. We work with the firm to make reasonable allowance for commercialization realities. However, diligence is important for a public health agency. The NIH must be convinced that the firm is doing everything it can reasonably do under the specific circumstances in order to retain its license.

Question B7

Article 5.2 of the model license agreement provides that products shall be "manufactured substantially in the U.S. unless a written waiver is obtained in advance from the government." What is the practical impact of this? How difficult is it for the firm to negotiate a waiver, and does a waiver necessarily still require some specific value added in the U.S.? Can a waiver be successfully negotiated downstream as the firm's commercialization and manufacturing plan evolves? For example, suppose the firm decides, after the work under the CRADA is completed, to move to offshore manufacturing? If a firm does not have a waiver or exceeds the non-U.S. manufacture spelled out in the waiver, what is the track record of enforcement (termination of a license) by the government?

Freese: The U.S. manufacture requirement for sales of licensed products in the U.S. is enforced, and this can be a dealkiller for foreign based companies. The intent is to generate a "net benefit to the U.S.

economy," because the invention was funded, at least in part, by U.S. taxpayers. We have not seen this requirement waived by the DOE. Sometimes the specific situation can make this difficult. An example would be a new technology for TV sets, since there are no TVs made in the U.S. "Net benefit" could be conducting R&D in the U.S., or allowing subsystems to be made abroad if the overall system is made in the U.S. The worst-case situation is manufacturing outside the U.S. and importing the product for sale in the U.S. Neither LANL nor DOE would agree to this. Multinational U.S. firms are wary of the U.S. manufacturing requirement, since the obligation is for the life of the patent license and impacts on freedom to operate. Sometimes a foreign firm will partner with a U.S. firm and create a 3-way CRADA with manufacturing or other benefit to the U.S. economy. If a U.S. firm is sold to a foreign firm, LANL must approve the license transfer because of export control and the U.S. manufacturing requirement. LANL tracks this by required reports, and the laboratory has an audit right for manufacturing location.

Ferguson: It is important to realize that statute requires U.S. manufacturing only for products to be sold in the U.S. In the biomedical area, this means that the FDA has to approve the manufacturing site whether it is located in the United States or not. Often small, early stage firms do not know where they are going to manufacture. Or a large firm may have unique manufacturing facilities in other countries; and it would be impractical to duplicate that capability in the U.S. We will consider waivers of this requirement based upon lack of available manufacturing capacity in the U.S. or economic hardship for the company involved. A related factor for NIH as a healthcare agency is to insure that U.S. citizens can get drugs and other medical advances arising from NIH research. So NIH

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and the firm must attempt to find creative solutions that will meet those objectives. In one situation, for example, a firm with a single FDA-approved site in Europe was given a waiver but agreed to build its next manufacturing plant for U.S. product sales in the U.S. FDA-approved manufacturing sites are costly to establish but are considered to be the “gold standard” for these types of products across the world and are not readily duplicated.

Question B8

The model CRADA Articles 7.4 and 7.5 speak to royalty-free government rights to have a CRADA invention practiced “by or on behalf of the government” worldwide. That government right seems to be independent of inventor in the CRADA, although the language is slightly different depending on inventor. The same government right is in Article 5.1 of the model license agreement. Note that Article 5.1 does prevent the government from disclosing trade secrets of the firm in exercising this government right.

What does “by or on behalf of government” mean, and what are the limits of that right? For example, suppose the commercialized output is a prescription drug. Can the government have a third party make the drug (royalty-free) for sale through Medicare or to the V.A. (i.e. on behalf of government)? To what extent is this government right negotiable? What are the practical impacts of this right, and what is the track record of government exercising this right in the CRADA environment?

Freese: The Government’s Reserved Rights and March-In Rights are non-negotiable. They are intended to provide the Government with the ability to use Government supported technology for its own purposes and meet a critical national emergency need that cannot be met by the licensee of a patent. It is not intended to create an independent commercial venture to compete with the licensee.

Ferguson: We agree with LANL. From a practical perspective, the most common use of these rights would be that the government is free to continue its research, as it would typically prefer to buy a finished product from a commercial source rather than establish its own manufacturing operation.

Question B10

The FLC Desk Reference says that, in a CRADA, background patents of the government may be licensed to the company on an exclusive basis for a “reasonable period of time” and for specified fields of use or market segments. But Article 3.2 of the model patent license agreement excludes dominant background patents of the government from the patent license to the firm. Article 7.1 of the CRADA calls for a license to government background inventions only to carry out CRADA R&D. The three documents seem inconsistent on this matter. Suppose the firm needs a license to government background inventions in order to commercially exploit the firm’s license to CRADA inventions, or to carry out the firm’s own R&D outside the work under the CRADA. What are the constraints on licensing terms for government background patents, if any? How does the firm acquire rights to those government background patents? For example, can rights to government background patents be included in the patent license agreement? Commercialization may cover a lengthy period. Can the “period of time” for exclusive background rights be negotiated as (for example) to be the same as the exclusivity period for foreground rights?

Freese: In an Appendix to a CRADA, we list possible LANL background intellectual property that may be required to practice foreground inventions expected to be made under the CRADA. We indicate if any of the background intellectual property is encumbered. The partner may also list such background intellectual property in the Appendix. The CRADA does not grant any rights to the background intellectual property of the other party. Licenses to background intellectual property required to practice foreground intellectual

property would have to be negotiated separately. We have no limitation of the term of exclusivity for either background or foreground patents, up to the life of the patent.

Ferguson: Our experience here is similar to the LANL. Our CRADAs include lists of relevant background patents of the NIH and of the company, but no background licenses are granted to either party. Practically speaking, a firm would never be sued by NIH for using the patents solely for work under a CRADA. Sometimes a firm's attorneys will ask for a background license while the CRADA is underway—which the NIH would be willing to give, but in a separate agreement. As for time scale, sometimes the firm requests a short term “evaluation” or “internal use” license, perhaps for the length of the CRADA. For commercialization (right to sell), the background license can be exclusive and have the same term as the license to a CRADA subject invention for up to the length of the patent life. But an important difference is that public notice is required for an exclusive background license.

Question B11

Article 4 of the license agreement allows the firm to sub-license after review by the government laboratory, with approval “not unreasonably withheld.” The sublicenses are tied to the rights of the government to terminate the license for many reasons, including all of the Article 13 requirements such as achieving benchmarks and fulfilling the commercialization plan. As a practical matter, do these government termination rights create a barrier to satisfactory sub-licensing by the firm to third parties; with those third parties being aware of this termination possibility by the government?

Freese: LANL wants to encourage sub-licensing, for wide commercial use of laboratory patents. While we do not require approval of sublicenses, we do require in the original license that Government rights and legal obligations in the license flow down to all sublicensees. While these requirements do not generally discourage sub-licensing, a sub-licensee must understand that they must comply with all requirements including U.S. manufacturing, government march-in rights, indemnity, etc.

Ferguson: Since many of NIH's licensees are early-stage biotech companies, we fully expect to see sublicensing of our technology as it goes through development, especially when it comes time to do very costly Phase III clinical trials. NIH does require approval of the sublicense before it can be granted,

though this is done to be sure that the sublicensee is aware of their obligations and responsibilities to the NIH and to determine what share of the sublicensing financial proceeds will be paid to the NIH. In order to protect the sublicensee, we also want the sublicense to be convertible to a direct license with the NIH should our original agreement be terminated for any reason.

Question B12

The model patent license, in Article 5.4a, gives the government a right to provide a research license to third parties to encourage basic research, including commercial entities, even if the cooperating firm under the CRADA has an exclusive license. The only limitation is that the government must consult with the firm before granting such a license to a commercial entity. How common is that government grant of a “research license,” and what are the practical impacts on the firm? In the “consultation” can the firm as a practical matter prevent or limit the government from doing that? Do the terms of the “research license” actually inhibit the third party from using the license to enable competitive actions? Is there clear distinction between the “research license” in 5.4a and the “exceptional circumstances” commercial license in 5.4b?

Freese: All of our licenses include a reserved government right to use the technology for government purposes. This includes a right for LANL to use the licensed technology for our own R&D, including working in partnerships with others. LANL has never granted independent “research licenses” of the type described in the question.

Ferguson: A research license is to “make and use,” not to “sell” the underlying technology. NIH needs to encourage medical research wherever conducted; so we need to ensure that needed research licenses are available. Even where the CRADA partner obtains an exclusive commercialization license, we do not let them block future research. But there are limitations on a research license, in addition to a prohibition on the “right-to-sell.” For example, NIH cannot license materials owned by the CRADA partner to a third party, even for research purposes. Additionally the NIH would deny or terminate a research license if the third party was violating the intent of that license, such as selling the materials. The CRADA partner would have no obligation to provide its own materials to an NIH research licensee. Financial terms of NIH research licenses of all types have been collected at a public Web site: <http://www.research-tool.info/english/index.html>.

Question B13

The model CRADA, Article 8.2(b), states that CRADA materials (i.e. biological materials) made jointly can be provided freely by NIH to third parties for further research, although the parties may agree to hold back materials if a patent application or patent is pending. Does that mean that materials that were made (for example) in part in the government lab, with the firm's input, may be provided to third parties regardless of the firm's wishes?

Freese: This does not apply to LANL.

Ferguson: Materials made by NIH personnel are NIH property and must be provided to other researchers under the terms of Material Transfer Agreements or research licenses. This is in contrast with materials made by the CRADA partner. If the NIH received requests for materials owned by the CRADA partner, it would refer such requests directly to them.

Question B14

In the model CRADA, Article 10.3, either party may unilaterally terminate the CRADA on 60 days notice, apparently "for convenience." The model patent license agreement does not have a provision allowing for unilateral termination of the license. The model CRADA does not address intellectual property rights after termination. How are real agreements crafted to deal with this problem? Please clarify the CRADA firm's patent license rights in the event of termination for convenience, as negotiated in a real CRADA and patent license agreement.

Freese: CRADA terminations are always no-fault. The notice period for terminating a CRADA is negotiated but we typically require 90 days notice. The only reason why LANL would terminate a CRADA is lack of funding, either at LANL or at the firm. All work under CRADAs at the Laboratory is done with full cost recovery, whether it is supported by the government or the CRADA partner. Therefore the cost of the work performed cannot be negotiated by LANL, but the scope and schedule of work is negotiable. CRADA partners have terminated CRADAs because of business strategy changes. There have been a few occasions over the years that multiple CRADAs have been cancelled because of large budget cutbacks from DOE for DOE supported work done under the CRADA. However, a senior LANL manager would not terminate a CRADA simply because he or she thought that LANL scientists had something better to do. But if government programs require use of staff or facilities that are being used under a CRADA, the government use would take priority. This could delay work under a CRADA. In any event, the laboratory

cannot terminate options for licenses to inventions already made.

Regarding termination of licenses, the laboratory requires licensees to meet minimum royalty payments or milestones. Failure to meet these requirements is cause for termination or renegotiation of the license terms. Licensees may terminate licenses subject to the termination terms of the individual license, which may include liquidated damages for premature termination.

Ferguson: Generally the company may terminate its CRADA or license agreements with 60 days notice. There does not have to be a specific cause; though typically when this happens it is due to a change in business development strategy at the firm, financial problems at the company or unanticipated scientific or regulatory hurdles for the technology. However, the CRADA and license agreement are not linked—a firm can keep one but drop the other as long as it continues to meet its obligations under the term of the remaining agreement.

Before the NIH would terminate a license agreement or CRADA it would first seek to try to discuss the situation with the company to try to come to some mutually satisfactory solution to the problem.

C: CRADA and Patent License Financial Aspects

Question C1

The FLC Desk Reference discussion of royalty rates says that payments from the company to the government for government owned intellectual property is determined through negotiation between the government and the company. The discussion of factors governing the negotiation does not suggest any special rules that would constrain that negotiation. In the model CRADA, Article 7.2, the terms of the license to the firm will include such matters as relative contributions, the plan for development and marketing, risks to be incurred by the firm, and the firm's subsequent R&D costs. Also, the field of use will not exceed the scope of the Research Plan. In a CRADA, are payments from the firm to the government "as negotiated" at the time the CRADA is signed? Are those negotiated later as part of the patent license agreement? This is related to the question above on timing of the CRADA and the patent license agreement.

Freese: The CRADA and patent license are separate agreements. Funding to the laboratory under a CRADA is to support the collaborative R&D. Fees and royalties under a license are paid according to the terms of the license agreement. It is common to

negotiate licenses for field of use that are necessary for the partner's business markets.

Ferguson: The situation at the NIH is similar. Not all CRADAs at NIH require funding by the company, as there are other resources than cash that the NIH finds useful for CRADA projects. It is important to prepare a realistic research plan with a corresponding budget and list of resources early in the CRADA negotiation process.

The financial terms of the NIH license agreements are negotiated separately though we can consider activities and payments made by CRADA partner to be part of their diligence and performance under the license agreement.

Question C2

The model patent licensing agreement allows for an upfront payment, annual minimum royalties, royalties on sales, benchmark payments, and sub-licensing royalties. Are there any rules that a government laboratory must follow when negotiating royalty rates, upfront payments, minimum royalties, or benchmark payments? In practice, what is the usual financial structure? Do firms often make upfront payments when entering into a patent license agreement? How about minimums and benchmark payments? Are government negotiators familiar with NPV techniques in negotiating payments, and do they agree to the use of such methods?

Freese: We usually have minimums or benchmark payments to encourage the licensee to vigorously exploit the technology. We try to be flexible and customize the terms to meet the needs of both parties and arrive at a total package that recognized fair value for the license. For example, with a startup firm, upfront payments may be small and downstream royalties or equity shares larger. A larger firm that can afford bigger upfront payments may prefer that in order to pay smaller royalties during commercialization. LANL is familiar with NPV techniques, and so are most of the firms; we use these techniques as tools in negotiating the financial structure of the license.

Ferguson: At NIH we would also try to match up the financial terms of the license agreement with the scope and commercial market to be addressed. There is considerable flexibility in the terms of the final package similar to what the LANL does. We do not take equity in start-up firms, although we can structure equity-like benchmark payments to conserve cash for the company in its initial phases. We are also familiar with NPV techniques but don't always find them useful for early-stage, high risk technologies. Instead we place more reliance on comparables since

we are doing about 250-300 agreements per year. For financial terms for research licenses we have placed more than 15 years worth of data on the Web at <http://www.research-tool.info/english/index.html>. This includes agreements for re-sale of materials as reagents or internal use agreements.

Question C3

The rules governing CRADAs are clear that a government laboratory may contribute a variety of resources, but no funds. These resources can be people's skills and time, equipment, background intellectual property, or services; but never money. On the other hand, the firm may contribute funds to support the government laboratory's work under a CRADA. Does a government laboratory typically expect a firm to contribute funds to support the laboratory's work? How common is that practice? If the firm does contribute funds, what is the range and average of the firm's funding, as a fraction of the government laboratory's total costs for work under a CRADA?

Freese: As a general rule, LANL will contribute no more than 50 percent of total value of all resources, including funding of people, equipment, and services such as testing. In contrast, a firm may contribute up to 100 percent of the costs of LANL's participation in the CRADA, if no government funding is available to support the laboratory's share of the R&D.

Ferguson: Some funds are typically provided by the company, but that is not a strict requirement. Funds supplied by the company might be used to hire a post-doctoral researcher, for example, if the NIH lab didn't have adequate funds in its own budget for such work on the CRADA. However, the NIH looks primarily for intellectual contributions by the firm: background intellectual property, unique biological materials or efforts by the firm's scientific staff. The firm may also bring equipment, unique testing ability, or other valuable resources to the collaboration.

Question C4

The model patent license agreement covers only patents, and the payments from the firm to the government are tied only to patents. Can the government laboratory expect payments from the firm for the values of non-patent information (to be held as trade secrets) developed by government scientists? How commonly are such payments built into CRADAs or license agreements?

Freese: The financial aspects of the license agreements can only address the values of patents, software copyrights, and trademarks. That is because technical information created at the government laboratory under a CRADA cannot be held indefinitely

as “trade secrets” and disclosed only to the firm for its exclusive use. Our CRADAs provide for Protected CRADA Information, a special class of information generated under the CRADA that is commercially valuable and which can be withheld from public disclosure for a limited period of time, typically five years. However, all technical information must ultimately be disclosed to the public, unless classified. In the short term, technical information created by the government laboratory can be withheld from public disclosure for limited times, usually to permit adequate planning and filing for patent protection.

It is important to recognize that patents are published, and copyright protection does not limit viewing the software, just using or reproducing it or preparing derivative works. So ultimately knowledge created at a government laboratory is disseminated; but the rights to practice it for commercial purposes can be restricted by patents or copyright, and are licensable.

Ferguson: The situation at NIH is similar to that at LANL except that by statute government employees cannot hold copyrights. Technical information owned by the NIH must be ultimately disclosed to the public, by statute or through publication. For that reason, trade secrets cannot be considered in the financial negotiations for a license.

One other related consideration here is biological materials. Since these materials are often very difficult or costly to duplicate they often can be licensed without patent protection since the “real” value is having rapid access to them. The NIH has done extensive licensing of unpatented materials and has model agreements (for both commercialization and internal use) posted on its Web site.

Question C5

Federal employees are entitled to a specific share (with a minimum of 15 percent) of royalty income from patents licensed to companies, with an annual maximum and perhaps other rules. How does this work in a CRADA? For example, if a government scientist and a company scientist co-invent, does the government scientist get 15 percent of the royalty paid by the company? Would the company scientist get only what the company provides (perhaps a plaque and a handshake)? Is this a problem in CRADAs, in working relationships between government and company scientists?

Freese: The entitlement to a share of royalties is based on Federal statutes and contracts to operate the government laboratories. Of course, private sector employees may receive stock options, bonuses,

and other performance incentives that federal employees do not receive. LANL staff are employees of Los Alamos National Security (LANS) LLC, who is the current operator of the Laboratory. LANS policy is to share 35 percent of patent royalties with employees or contractors who are the inventors. LANS does not share royalties with co-inventors who are employees of the commercial partner.

Ferguson: Since 1986, 15 percent has been the historical minimum payout of royalties to government inventors up to a cap for each inventor that is set by statute. At NIH, the actual inventor payout is now higher for each license agreement. Specifically it is for each year: 100 percent of the first \$2,000 received; 15 percent of the next \$48,000 received; and 25 percent of anything above \$50,000 received with a cap of \$150,000 for each inventor across all or his or her inventions. The payout is made only to inventors who have the obligation to assign their rights to the government. If the company or other party assigns their rights in a joint NIH invention to the government, the NIH shares royalties with company co-inventors as if they were an NIH employee.

Question C6

The model CRADA, Article 6.4, states that the firm must pay patent costs for government inventions that are licensed to the firm. The firm pays all costs if license is exclusive and a pro-rated share (among all licensees) for non-exclusive licenses. Is it commonly done that way? Is this allocation of patent costs negotiable?

Freese: This is our general licensing policy and not limited to CRADA partners. As a practical matter, LANL pays for initial patent prosecution of its own inventions and joint inventions and then expects reimbursement from the licensee in the license terms. The licensee is also expected to pay for foreign filing and maintenance costs. It is very common for exclusive licensees to pay for the full patent prosecution and maintenance costs; pro-rating of costs among non-exclusive licensees is difficult to allocate fairly when the total number of licensees may not be known in advance. In those cases we set a uniform licensing fee for all licensees.

Ferguson: The situation is similar at NIH, although a joint invention may be filed directly by the company. In an exclusive license agreement we would require full payment of all back patent costs but would consider a payment plan if the sum is substantial. The licensee can provide input direction regarding future patent expenses though careful selection of national jurisdictions at National Phase or EPO Grant stages.

D: Confidentiality and Trade Secrets

Question D1

The FLC Desk Reference (3.3) states that trade secrets disclosed by a partner firm shall not be disclosed. But the definition of “Confidential Information” in the model CRADA does not clearly distinguish between (a) trade secrets of the firm, developed independently of work under the CRADA, that is revealed to the government laboratory; and (b) non-patent and non-public technical information that is developed by either or both jointly in the course of work under the CRADA. The model patent license agreement does not define or address Confidential Information. That raises questions on the obligation of the government laboratory to maintain trade secrets in confidence.

The Desk Reference states that intellectual property rights for trade secrets are negotiable in a CRADA. As an example, intellectual property disclosed by a private entity can be protected from competitors. Commercially valuable trade secrets developed jointly under a CRADA can be held in confidence for up to 5 years, even though most intellectual property generated at federal laboratories cannot be held in confidence. The Model CRADA Article 8.6 states that confidential information is maintained for 3 years after end of the CRADA, although the firm may “request an extension” if products are not yet commercialized.” That suggests that the government lab may reveal the firm’s confidential information at that time, even if the firm wishes to hold such information as trade secrets.

The startup of significant commercialization can take much longer than five years, and the commercial value of trade secrets can persist for a much longer time. Can a CRADA provide for a longer (than 5 years) confidentiality period for foreground trade secrets developed under a CRADA, including trade secrets developed solely or jointly by a government scientist?

Can a CRADA require the government to maintain the firm’s trade secrets (a) above in confidence for substantially longer periods (example: in perpetuity) than for trade secrets under (b) subject to the usual exclusion such as independent invention, public disclosure by others, etc.? Why the lack of clarity in the model CRADA, and do actual CRADAs draw this distinction more carefully?

Freese: LANL will not reveal the firm’s trade secrets that the firm developed independent of the CRADA. The CRADA specifies that trade secret in-

formation developed at private expense and provided by the partner under the CRADA may be returned to the partner at the end of the CRADA. With respect to technical information developed solely by the firm’s scientists under a CRADA: if that information qualifies as Protected CRADA Information, the period during which such information will be kept confidential is typically five years. The confidentiality period can be extended if the CRADA firm has a good reason. As I commented earlier in the context of the financial terms of the license, there are no perpetual secrets from the government’s own work (unless classified). The results of LANL work may be kept confidential for very limited times, consistent with patent prosecution requirements.

DOE has the charter to broadly disseminate its work, unless classified, and LANL staff, like academics, are evaluated in part on their record of publications. The CRADA partner is asked to cooperate in allowing LANL people to publish promptly as much information as possible, consistent with the restrictions for Protected CRADA Information.

Ferguson: The situation at NIH is similar to that of LANL for information generated by the company or by our own employees. The NIH, of course, also has an academic orientation with peer and institutional expectations that scientific staff will publish their work. As was commented on earlier, technical information can be held back for short times for the patent filing process. There are some nuances, however. For example, there can be extra protection for clinical trial data to be used in regulatory filings. Raw data can be held as proprietary to the CRADA partner, although clinical trial results would be published. ■

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