

TECHNOLOGY TRANSFER QUESTIONS..txt

From: Bob Fien [rfien@campbellap.com]
Sent: Monday, January 26, 2009 5:34 PM
To: GC-62
Subject: TECHNOLOGY TRANSFER QUESTIONS.

Sensitivity: Confidential

To Whom It May Concern,

Campbell Applied Physics, Inc has been working with several DOE labs (e.g., Oak Ridge, Pacific Northwest, Laurence Livermore, Sandia) on various commercialization projects and, has been asked to submit answers to the questions presented in 72036 Federal Register / Vol. 73, No. 229 concerning our experiences. Please accept the following as our response to that request.

1. Existing and Other Agreements (4sub questions):

The DOE labs currently offer CRADAs, WFO Agreements, and User Agreements, all briefly referenced below. The DOE Orders and model agreements for CRADAs, WFO and User Agreements can be found at http://www.gc.doe.gov/lab_partnering.htm.

Questions for Comment:

(i) What improvements to the existing transactions (e.g. CRADAs, WFOs, User Agreements, etc.) would you suggest that DOE consider?

Answer: As a long time participant in the DOE GIPP program and member of the US Industry Coalition, CAP is aware that small entrepreneurial technology companies are major contributors to the program. To assist them in becoming familiar with DOE procedures, easily accessible and widely publicized "Sponsor Training Materials" might be useful, not only in helping demystify the process once it has begun, but in encouraging small companies to engage in the process in the first place. The relative complexity of DOE contracts and regulations, combined with language and processes unique to government and not intuitively understood by those with purely private sector experience may intimidate small entrepreneurial companies and cause them to avoid participation.

(ii) Are there terms and conditions that are troublesome and what steps might DOE take to streamline these agreements?

Answer: Some legal words and phrases used in the private sector have slightly different meanings in DOE contracts. Conversely, some words and phrases unique to DOE contracts have definitions identical to other words and phrases in common usage in the private sector. Terms which immediately come to mind are "Background IP", "Foreground IP" and "Results". This may make DOE contracts difficult to understand and follow for those unfamiliar with their nuisances.

(iii) Are there other types of research agreements or mechanisms that should be offered at DOE labs?

Answer: Not that I can think of.

(iv) How would such new agreement types or mechanisms be an improvement on or augment the existing Agreements?

Answer: NA

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2. Best Practices (2 sub questions):

DOE is interested in improving the ways the laboratories collaborate, and improving the transfer and deployment of laboratory technologies into the marketplace.

Questions for Comment:

(i) Are there other agency, industry, nonprofit or university technology transfer 'best practices' DOE should consider adopting?

Answer: I have no knowledge of any "Best Practices" published by DOE. However, I have found the "Code of Practice for the Management and Commercialization of Intellectual Property from Public-Private Collaborative Research" published by the Advisory Council for Science, Technology and Innovation of the Irish Government to be a useful tool.

(ii) What are they and how would they improve DOE's current technology transfer program?

Answer: An easily understood and heavily promoted Code of Practice (Best Practice Guide) would be helpful.

3. U.S. Competitiveness: (6 subquestions)

Under Cooperative Research and Development Agreements (CRADAs) with DOE labs and under license agreements to lab inventions, the relevant statutes require that a 'preference' be given to companies who agree to manufacture new inventions made under those agreements substantially in the U.S. As a matter of DOE policy, DOE has imposed a stricter standard than that required by statute under which every partner must agree to manufacture new technology substantially in the U.S. or make a legally binding commitment to provide an 'alternate net benefit to the U.S. economy.' The DOE policy is more fully described in the DOE model CRADA at Article XXII and the guidance provided for that Article. This standard is also more stringent than the standard imposed under 35 U.S.C. Sec.200 et seq. ('Bayh-Dole') for funding agreements with Federal agencies. Bayh-Dole recipients may take ownership of new technologies without limitation on their own manufacture, but must agree not to assign or exclusively license those new technologies to other parties who do not agree to substantially manufacture in the U.S. DOE maintains its commitment to the U.S. economy, but is open to streamlining negotiation of the U.S. Competitiveness issue in view of the practical realities of a global economy.

Questions for Comment:

(i) What alternate approaches to addressing U.S. competitiveness would you suggest DOE consider?

Answer: Rather than "requirements" DOE might consider "incentives" such as a sliding scale royalty for licensing DOE Background, Foreground and/or Project Results based on US content (value added). Such an incentive would seem to promote both the competitiveness of the United States and the competitiveness of the technologies commercialized through DOE.

(ii) How would these alternatives help transactions/interface with DOE facilities? Background:

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For example, one possible way to streamline this process is to forego a legally binding commitment from any partner that has a "substantial presence" in the U.S. This could be accomplished in a number of ways, such as where a partner indicates in writing that it or its intended suppliers will make best efforts to manufacture products resulting from the agreement in the U.S., and provides factually supported statements that it satisfies at least two of the following three factors:

- (1) The partner has or plans to have manufacturing facility in the U.S. where its products resulting from the agreement will be manufactured;
- (2) more than half of the partner's assets are located in the U.S. or it derives more than half of its revenue or profits from the U.S.; and
- (3) significant design and development (other than the CRADA) will be done in the U.S. in an existing U.S. research facility.

Another alternative would be to limit the legally binding commitment for substantially manufacturing in the U.S. to a specified number of years, e.g., 5 years. That would give the U.S. manufacturing facility a head start on sales (and setting up supply chains) before manufacturing might be moved offshore, as well provide some certain benefit to U.S. competitiveness.

Answer: Limiting the legally binding commitment for substantially manufacturing in the U.S. to a specified number of years would be helpful to Industry Partners who are concerned with maintaining the global competitiveness of the commercialized technology over a period of years (e.g., after the "IP Based Competitive Advantage" has begun to deteriorate).

As to the first alternative (2 of 3 = Safe Harbor), this may provide some marginal improvement in the process.

(iii) would any of these three be a useful approach to industry to better streamline the process of the U.S. Competitiveness negotiation process?

Answer: The second alternative (Term of Years) would be most beneficial in streamlining the process (i.e., it's a lot easier and quicker to accept terms and conditions that carry incalculable risks [e.g., loss of price competitiveness] if those terms have a sunset point). The first alternative (Safe Harbor) should also streamline the process at least to the extent that Safe Harbors generally streamline planning and negotiation.

(iv) Does DOE's current implementation of U.S. Competitiveness have a negative impact on technology transfer? How?

Answer: No. NA.

(v) would approaches taken by other Federal Agencies with regard to U.S. Competitiveness in CRADAs be useful? If so,

Answer: As of this date we have not dealt with other agencies in a CRADA context and thus have no basis for answering

(vi) what are those approaches and how are they implemented?

Answer: NA

4. The Intellectual Property Rights disposition in work For Others (WFO) Agreements: (4 sub questions):

Under WFO Agreements with DOE labs, the sponsor may access highly specialized or

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unique DOE facilities, services, or technical expertise. The sponsor pays the full cost of the research with nonfederal funds, and, with very limited exceptions may elect ownership in any new inventions by lab employees. Those new inventions are subject to a Government use license, March-InRights, and U.S. preference provisions in licensing of the patent rights. In addition, at many laboratories the sponsor may mark all newly generated data as proprietary. The current DOE model provides that the sponsor retains title to lab inventions because the sponsor pays full cost and bears all of the risk. On the other hand, one might argue that the laboratory contractor should own the IP it develops because it would allow the laboratory to better ensure full utilization of the intellectual property for the benefit of the public and provide additional benefits to inventors through laboratory royalty sharing policies. If the laboratory owns such inventions, as is the norm under sponsored research at most universities, it could also provide free use of the inventions to non-profit research organizations and universities. As a matter of general policy, the latter position is reflected in the provisions in Bayh-Dole when government funding is involved. One proposal aimed at satisfying both sides of the issue is to modify the terms and conditions of DOE's WFO Agreements so that the labs may retain title to lab employee inventions but grant the sponsor a nonexclusive, royalty-free, non-transferrable, non-sublicensable worldwide license in a field of use with no requirements concerning U.S. manufacture, no Government use license where the Government is not a likely user of the technology, and no March-In Rights. In addition, the sponsor would be offered the opportunity to negotiate an exclusive license in a field of use for reasonable compensation and consideration of U.S. competitiveness.

Questions for Comment:

(i) How would these proposed changes affect the attractiveness of WFO Agreements?

Answer: The proposed changes (in which labs retain title to their employee inventions but grant the sponsor a non-exclusive, royalty-free, non-transferrable, non-sub-licensable worldwide license in a field of use with the opportunity to negotiate an exclusive license), appear to make WFOs indistinguishable from CRADAs, thereby decreasing the attractiveness of the WFO as a vehicle.

(ii) What other options do you recommend for DOE to consider?

Answer: None other than discussed above.

(iii) What is the desirable disposition of IP rights that would stimulate working with a DOE laboratory or facility?

Answer: The private sector prefers exclusive IP rights with pre-established royalties and minimal (well defined and objective) contingencies under which exclusivity might be lost or royalties raised. Agreements whereby money is spent and IP rights and royalties are negotiated later or, where the Step-in Rights are subjective make it difficult for the for-profit private sector to analyze and fund.

(iv) Do the Government reserved license in Sponsor inventions, March-In Rights, and U.S. preference clauses pose any problems for a successful project?

Answer: Not particularly except as discussed above.

5. Negotiable or Non-negotiable User Agreements: (3 sub questions):

DOE labs also offer User Facility Agreements under which parties may gain access to designated unique lab equipment and facilities to perform their own experiments. Under the Non-proprietary User Agreement, which is aimed primarily at

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non-commercial, basic science research, a user may access lab equipment/facilities and may collaborate with lab scientists in carrying out its research. The user and the lab share the costs of the research by each absorbing their own costs, the lab and the user may elect to retain ownership of their respective new inventions, and the research data is made publicly available. The Proprietary User Agreement permits the sponsor to conduct proprietary research using unique lab equipment/facilities. In this case, the user pays the full cost of the research, and the user retains ownership of research data and inventions. User Agreements have been used successfully at labs for over 25years. Typically User Agreements have relatively short durations, their terms and conditions are non-negotiable, and labs are authorized to enter into the agreements without additional DOE approval. As such, execution takes relatively little time. The most recent changes to these agreements permits some terms and conditions to be negotiable, but changes require DOE approval. These new Interim User

Agreements and the class patent waivers to which they are attached can be found at <http://www.gc.doe.gov/1002.htm>. Comments are solicited on the terms of these agreements.

Questions for Comment:

(i) Do you think these new DOE-wide standardized User Agreement formats which allow for some negotiation will promote more timely placement of User Agreements?

Answer: Yes

(ii) Should DOE allow some negotiability of the terms or utilize agreements that are non-negotiable?

Answer: User Agreements may be the only agreements simple and straightforward enough to utilize non-negotiable forms.

(iii) Please describe the pros and cons of each approach?

Answer: Non-negotiable Contract Forms can be executed with minimal review and thus can be implemented quickly. Negotiable contract forms allow for flexibility of the contracting terms to fit specific situations at the cost of rapid implementation. However, I'm not sure that situations appropriate for Use Agreements have many "variables" that would warrant negotiation.

(iv) Are there any other issues, concerns, or experiences that could make working with DOE laboratories and facilities more effective and efficient?

Answer: Our experience thus far working with several national laboratories has been very satisfying. ORNL in particular stands out. We have found the ORNL technical staffs and contracting staffs to be patient, entrepreneurial, appreciative of our commercial imperatives and very helpful in guiding us through the process. Whatever unique CRADA/WFO training ORNL employs might be shared with other labs and/or used in preparation of a "Best Practices Guide".

I hope you find our responses helpful. If you have any follow-up questions or if we can be of any further assistance please feel free to call or write anytime.

Sincerely;
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