From: Michael Bauer [MBauer@FoundationCap.com]
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To: GC-62
Subject: Fed Register comments

Dear Sir or Lady,

Per Wendolyn Holland's request, here are my comments:

(i) What improvements to the existing transactions (e.g. CRADAs, WFOs, User Agreements, etc.) would you suggest that DOE consider? Most obvious problem is cost of resources at national labs, which is much higher than at universities and other institutions due to imputed overhead. These costs should be reviewed to find whether they're a) really reflective of real costs at the labs, b)whether they truly reflect unique capabilities that justify the higher cost vs. comparable institutions.
It's telling that many of the labs themselves tend to outsource certain research tasks, while the capabilities are available at the labs, people there themselves feel they get better value for money with 3rd party providers. Therefore, something seems to be broken.

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

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

(iv) How would such new agreement types or mechanisms be an improvement on or augment the existing agreements? N/A

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. Question for Comment:
(i) Are there other agency, industry, nonprofit or university technology transfer ''best practices'' DOE should consider adopting? The clear missing piece is more maturation funding, and maturation projects guided by interested commercialization parties. In other words, many projects are considered completed from a research perspective a long time before a commercializable prototype has been created.
One way to handle this differently is to find interested commercialization parties for certain early technologies; get their guidance on when they'd be ready to license the technology, in terms of performance parameters reached within certain timeframes; and then commit maturation $ towards reaching these objectives. The commercialization partner could even be asked for a hard contractual commitment to license the technology if the lab can develop it to the identified degree of maturity within the agreed upon timeframe.
(ii) What are they and how would they improve DOE's current technology transfer program?? See above

3. U.S. Competitiveness: (6 sub questions) 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? A time based commitment would make the most sense. As with any new technology, as it matures and becomes more commoditized, lower cost overseas manufacturing becomes more of a factor in overall competitiveness. If licensees were required to manufacture in the U.S. for 5 years, or until a certain sales volume is reached (technology and market dependent), and after that had the flexibility to move offshore, this would enhance the licensee's long term competitive position.
(ii) How would these alternatives help transactions/interface with DOE facilities?
(iii) background: 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 a 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.
(iii) Would any of these three be a useful approach to industry to better streamline the process of the U.S. Competitiveness negotiation process?
(iv) Does DOE's current implementation of U.S. Competitiveness have a negative impact on technology transfer? How? New technologies that, while technically superior to older ones, would result in a higher cost product due to the U.S. manufacturing requirement compared to off-shore products manufactured using older technology, will not get licensed.
(v) Would approaches taken by other Federal Agencies with regard to U.S. Competitiveness in CRADAs be useful? If so, N/A
(vi) what are those approaches and how are they implemented? N/A

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 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-In Rights, 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, nontransferrable, 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. Question for Comment
(i) How would these proposed changes affect the attractiveness of WFO Agreements? Probably reduce it because a) markets fear complexity and b) nobody will conduct company-essential research at a facility where IP can't be owned outright (since that complicates any acquisition of the company). It would probably lead to more companies doing the math & trying to hire DOE research talent out of the lab and recreate the facility at a lower cost (only in a few cases are the research tools available at the labs more important than the scientists' brains). That's already a consideration at current WFO rates - if a full time researcher at the lab costs me $300k a year with WFO, but she makes only $150k a year, would she be interested in continuing her work outside the lab for $250k/year? Probably yes.
(ii) What other options do you recommend for DOE to consider? Identify the labs' truly unique and not easily replicable capabilities and offer research using these with a WFO etc. agreement that contains the proposed changes. For all other WFO work, offer a more streamlined WFO agreement, ideally at a lower cost and without any IP ownership gotchas.
(iii) What is the desirable disposition of IP rights that would stimulate working with a DOE laboratory or facility? If I fully pay for it, I own it.
(iv) Do the Government reserved license in Sponsor inventions, March-In Rights, and U.S. preference clauses pose any problems for a successful project? Substantially lower the commercial value of the created IP (probably by 30-70%).

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 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 25 years. 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 permit 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. Question for Comments:
(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? N/A
(ii) Should DOE allow some negotiability of the terms or utilize agreements that are non-negotiable? N/A
(iii) Please describe the pros and cons of each approach. N/A

6. Are there any other issues, concerns, or experiences that could make working with DOE laboratories and facilities more effective and efficient. Any offered arrangements should be structured to make it easy (i.e. as un-complex as possible) and quick (i.e. no lengthy approval cycles) as possible - companies competing in the marketplace don't have the time to wait around.
Overall, timeframes bureaucratic delays at the labs seem way too long. In a recent project, a strong candidate technology for licensing was identified by a commercial partner, and brought to the lab's commercialization department's attention. That department then took 6 weeks to secure approval for the required validation/maturation funds; that actually was faster than expected. However, after that it took over four months for the funds to become available to the 3rd party contractor the lab had selected to perform the work; it is unclear why that was the

case. That contractor then ran into difficulties performing against the timeline they agreed to, and at this time, it looks as if the commercialization may fail due to these combined delays. Had the bureaucratic delay of getting the funding to the contractor been 4 weeks instead of 4 months, the contractor would have had ample time to get his work done in time.

Best regards,
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