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Dear Brian:

We would like to thank you once again for the excellent briefing you gave to the Bayh-Dole Coalition on the recent determination of exceptional circumstances (DEC) by the Department of Energy intended to promote the domestic development of DOE funded inventions.

That action raised many concerns when it suddenly began appearing in funding agreements with little explanation. In the future, it would be better to engage the stakeholder community well in advance when similar policy concerns first arise. We are always happy to work with the funding agencies to find the best possible solutions while still maintaining the provisions of Bayh-Dole, which are so essential to our national health and wealth.

While your briefing was very illustrative, we have subsequently heard concerns from several of our members that the additional requirements of the DEC may make licensing and securing critical investment in inventions made with DOE funding more difficult. To help alleviate the situation, it would be useful to have the guidance you provided in writing so it could be shared with potential licensees with concerns about the precise meaning and intent of the DEC.

Towards that end, it might be helpful to start by addressing the questions raised by our academic and industry members that you graciously addressed in our call. They were:

- The Bayh-Dole Act requires patent owners to receive a case-by-case waiver from the funding agency if they are unable to find a licensee to manufacture resulting technologies substantially in the United States. The agency can deny the request without appeal. Why isn't this authority sufficient to encourage domestic manufacturing whenever possible?
- It appears that DOE plans to review any merger or acquisition of the patent owner or licensee before such actions can go forward. Is that accurate? If so, it may seriously jeopardize the opportunities, if any, for investment in developing these technologies as it is standard and accepted practice of the past four decades for licensees and industry partners to require the freedom to seek acquisition and investment opportunities without need for consent of the licensor or funding agency.
- Will this language be applied retroactively to grants and contracts in force before the DEC was issued? If so, will patents already licensed be subjected to review?
- Does DOE intend to review every exclusive and non-exclusive license, even if the patent owner secured a commitment that the resulting product will be substantially manufactured in the United States?

The provisions of the DEC regarding changes in ownership of the contractor or licensee are concerning to many of our members. Of particular concern is the statement in Attachment A that should a contractor or other entity receiving invention rights undergo a change in ownership amounting to a controlling interest *or sell, assign, or otherwise transfer title or exclusive rights in the invention(s), then the assignment, license, or other transfer of rights in the subject invention(s) is/are suspended until approved in writing by DOE* (emphasis added). Breach may lead to forfeiture of title.

As we discussed, the implication is that any exclusive license to a DOE-funded invention must be approved by DOE before it is effective. The result is significant uncertainty about the ability of our institutions to commercialize DOE-funded technologies. Few companies will agree to negotiate licenses with a requirement for prior government approval, especially given uncertainties about timely approval of such licenses with the

resulting burdens on DOE. A further implication of the provision is that any merger or acquisition involving a licensee must be approved by DOE. The result is potential government micromanagement of business decisions, which will not be acceptable to most private businesses. This would be most damaging to small companies, which as noted previously, are a significant focus of the Bayh-Dole Act.

We understand and share DOE's concern about the off-shoring of emerging energy technologies of strategic importance to U.S. national security. However, the ability of our member institutions to transfer such technologies to the private sector for further commercial development may be seriously impeded, if not eliminated, by these requirements. Ironically rather than enhancing U.S. competitiveness, the unintended effect could be to undermine it, keeping these inventions on the shelves while private domestic industry seeks technologies from international institutions, which they are free to do.

In our discussion, you indicated that DOE does not intend to routinely review licenses. You also indicated that DOE does not plan to review mergers or acquisitions except in unusual cases.

Issuance of clarifying guidance to confirm these understandings would be most helpful. The guidance also should spell out circumstances where DOE review and approval of transactions pursuant to the Competitiveness provision might occur. This would greatly aid our institutions in reassuring prospective licensees of DOE's intent and help avoid the more severe implications of the provision. Such guidance also should confirm that should submission of legal documents such as license agreements be required, DOE will protect them to the maximum extent possible under FOIA. We also suggest that applications for waivers where a domestic manufacturer cannot be found will automatically be granted unless the agency notifies the contractor to the contrary within ninety (90) days.

As you know, Congress intended for the exceptional circumstances provision to be used rarely, and only if its use would further the policies and objectives of the law. The primary goals as stated in the statute are "to use the patent system to promote the utilization of inventions arising from federally supported research and development; to encourage maximum participation of small business firms in federally supported research and development efforts...". Bayh-Dole was one of the first laws to include strong provisions encouraging that resulting inventions be manufactured in the United States whenever possible. Our member organizations take these responsibilities very seriously.

We understand DOE's concern about the scenarios that DOE has experienced that led to the development of the DEC. We also are aware of Administration and Congressional concerns about the need to secure critical supply chains. However, we must ensure that while attempting to address these legitimate concerns, we don't inadvertently undermine Bayh-Dole by again inserting Washington micro-management into the system.

We look forward to working with DOE to address these concerns in ways that will not be counterproductive and deleteriously affect the ability to commercialize technologies crucial to our future national and economic security.

Thank you again for your willingness to work with us.

Sincerely,

Joseph P. Allen
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