Dear Brian:

Thank you for your recent note. The Bayh-Dole Coalition is pleased to see that the Department has dropped its requirement that owners and licensees of DOE inventions must get approval from the agency before they change ownership in order to retain their rights to inventions made with agency funding. That requirement had no statutory basis in the Bayh-Dole Act and was counterproductive to its goal of “encouraging maximum participation of small businesses firms in federally supported research and development” as these are the very firms most likely to trigger the clause.

While removing that provision is an improvement, the Coalition remains concerned that the remaining provision threatens the fundamental goal of Bayh-Dole. That is spelled out in the very first sentence in the report of the Senate Judiciary Committee describing the purpose of the bill as “to establish a uniform Federal patent procedure for small businesses and nonprofit organizations...”

The report goes onto to describe how the proliferation of agency policies before the law harmed innovation:

Presently there are at least 24 different patent policies in effect in the Federal agencies. These are frequently contradictory from agency to agency (and even sometimes within the same agency) and have proven to be formidable barriers to organizations interested in participation in Government work. The mere complexity of these policies constitutes a very real hurdle to universities, nonprofit
organizations and small businesses who do not have large legal staffs to negotiate through this policy maze.

Thus, creating uniform policies across all agencies is a central tenet of the law. The “exceptional circumstances” clause of Bayh-Dole is not a loophole for undermining that goal.

Bayh-Dole was one of the first statutes to promote domestic manufacturing, which it did in the case of products arising from exclusive licenses that are sold in the United States. In your note and in the Department’s “Frequently Asked Questions” paper explaining the DEC, the Department contends that this language is now antiquated because it does not include products made from non-exclusive licenses or for those intended for foreign sale. Both your note and the FAQ state that “case examples” underscore this point, but no specific cases are presented, only general statements. There is certainly no evidence to support an inference that academic institutions are intentionally using non-exclusive licenses in order to avoid triggering Bayh-Dole’s domestic manufacturing preference.

We do agree that the problem of increasing U.S. manufacturing is “complex and multi-dimensional.” The crux of the problem is that too many times it is impossible to find a domestic firm with the capability to competitively produce a product.

However, putting an additional burden on academic institutions to find a domestic manufacturer for non-exclusive licenses and requiring case-by-case waivers from DOE when that proves impossible is highly unlikely to have much effect on our domestic manufacturing capability. The only thing it is likely to increase is government micro-management—the very thing Bayh-Dole was enacted to prevent.

It’s also striking that rather than identifying specific DOE programs where a justification for increased domestic manufacturing can be made based on the availability of firms that can do the job, the DEC applies department-wide. We are concerned that it could set a precedent for other agencies to also establish their own domestic manufacturing policy. And that is exactly how a uniform patent policy ends.

It would have been more productive for the Department to have discussed its concerns with those who know most about the realities of licensing under the Bayh-Dole Act, the
academic institutions and small companies which own and license inventions under the law, than to have the government impose requirements not sanctioned under the law in its funding agreements with no warning.

We would be happy to facilitate a dialogue on this or any other point of concern between the Department and Bayh-Dole stakeholders in the public and private sectors. In the meantime, we urge the Department to rescind the remaining provisions of the DEC.

Thank you for your consideration.

Joseph P. Allen
Executive Director
Bayh-Dole Coalition