

May 13, 2024

The Honorable Maria Cantwell
Chair
Senate Commerce, Science, and Transportation Committee
254 Russell Senate Building
Washington DC, 20510

The Honorable Ted Cruz
Ranking Member
Senate Commerce, Science, and Transportation Committee
254 Russell Senate Building
Washington DC, 20510

Dear Chair Cantwell and Ranking Member Cruz:

The [Bayh-Dole Coalition](#) is a diverse group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act.

The Economist Technology Quarterly appropriately called Bayh-Dole: “Possibly the most inspired piece of legislation to be enacted in America over the past half century... More than anything, this single policy measure helped reverse America’s precipitous slide into industrial irrelevancy.”

Bayh-Dole was one of the first pieces of legislation emphasizing the importance of domestically manufacturing federally funded inventions whenever possible. When globalization was in vogue, this requirement was considered naive by some. Now that the impact of the loss of America’s manufacturing base has become apparent, it is clear Bayh-Dole was prescient.

While the law emphasized domestic manufacturing of applicable inventions, the authors rightly felt that the worst case scenario was that a technology would waste away on a shelf if it could not be made here. That’s why the law allows universities and small companies to file waivers with the agency funding the research so products could still be commercialized when they cannot be produced domestically.

The Bayh-Dole Coalition appreciates the Senate Commerce, Science and Transportation Committee’s legitimate concern that whenever possible, federally funded inventions should be made in the United States. However, it’s also important that we recognize the crux of the problem -- too many times it is not possible to find a domestic manufacturer.

For that reason, we must oppose the pending “Invent It Here, Make It Here” legislation before your committee. Rather than addressing the core problem, it puts additional burdens on the small companies which drive American innovation and license approximately 70% of academic patent licenses.

Another contribution of Bayh-Dole was attracting innovative small companies to take government grants and contracts, which is the foundation of the Small Business Innovation Research (SBIR) program. But the pending bill harms these patent owners by making it harder for them to license their inventions to gain

access to foreign markets necessary for their economic success. The bill would create additional complexity and barriers by requiring companies -- even small companies -- to find a U.S. manufacturer for a product that is solely intended to be sold abroad. If it's hard to find a manufacturer for the domestic market, imagine the challenges for a small company to require an exclusive licensee that could sell their product in Bolivia to find a U.S. manufacturer. The likely outcome is those products will simply not be made.

Further, the definition of "Manufactured Substantially in the United States" which adds factors such as "mining" to the list of requirements that must be met is so restrictive that finding a domestic manufacturer would become even harder.

The fact is, the current agency waiver procedure provided under Bayh-Dole is already broken. Universities have found that in the vast majority of cases, agencies never respond at all. It's not hard to imagine the impact of such neglect on a small company licensee which has tried in good faith to find a U.S. manufacturer but cannot. Time is money to these businesses and it's unconscionable for them to wait months or even years on an unresponsive bureaucracy. The pending bill makes the waiver process even more cumbersome.

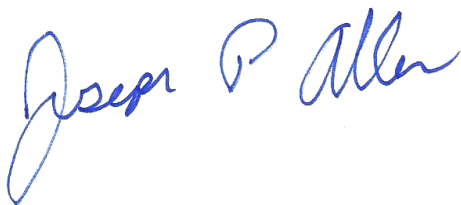
Finally, it should be pointed out that the Committee is attempting to amend the Bayh-Dole Act, which was specifically written to fall under the jurisdiction of the Senate Judiciary Committee. The bill shifts oversight of the law's 44-year-old domestic manufacturing provision to your committee. That seems highly problematic.

Rather than making it harder to license federally funded inventions, what the Committee could do to help is direct the Department of Commerce to develop a comprehensive database of U.S. manufacturers and their capabilities. The Manufacturing Extension Program seems like a good place to start. Rather than putting the burden on a university technology transfer office and a small company licensee, the database could be searched looking for a match. If a good faith effort had been made and documented showing a domestic manufacturer cannot be found, the funding agency could be given 60 days to respond. If they don't, the waiver would be automatically granted.

The worst of all worlds is to condemn promising technologies to waste away if they can't be made here. That benefits no one. Rather than sitting on the sidelines, the government needs to assist the process, not make it harder.

The Bayh-Dole Coalition would be delighted to work with you to effectively address this serious issue. While well intended, the "Make It Here, Invent It Here" bill does not address the real problem and risks undermining the effectiveness of the Bayh-Dole Act. That is something this nation cannot afford to do.

Sincerely



Joseph P. Allen
Executive Director
Bayh-Dole Coalition