Executive Summary

- The Senate Commerce Committee will likely mark up on May 16 the Invent Here, Make Here Act of 2023, a bill designed to limit the ability of agencies to allow federally funded inventions to be manufactured outside of the United States.
- The bill would expand strict waiver requirements currently in place for federally funded inventions licensed by the Department of Homeland Security to all federal agencies and would prohibit waivers for license applications that intend to manufacture in a country of concern.
- The bill may impose unnecessary barriers to the deployment of new technologies because it adds a strict definition of “manufactured substantially in the United States” and allows the secretary of the Department of Commerce to prohibit licensees from manufacturing in countries it determines to be a risk to national security.

Introduction

On May 16, the Senate Commerce Committee is scheduled to hold a markup on the Invent Here, Make Here Act of 2023 (the Act), a bill designed to make it extremely difficult for agencies to waive requirements that federally funded inventions be manufactured in the United States. Currently, the Bayh-Dole Act generally allows private institutions and firms to obtain control of licenses for federally funded inventions, but it imposes a domestic manufacturing requirement. Only if an agency waives this requirement can a business manufacture the invention outside of the United States.

The Act would add strict requirements to the waiver process. Congress included a provision in the 2023 National Defense Authorization Act that added an additional layer of review for waivers granted by the Department of Homeland Security (DHS) and prohibited waivers for companies that would manufacture in countries of concern. The Act would expand these requirements to all agencies, not just DHS.

Unfortunately, this bill could do more harm than good. The Bayh-Dole Act was designed to bring U.S. inventions into the market, and overly restrictive rules on where firms can manufacture could limit the incentive to license the technology in the first place. Moreover, the existing waiver requirements are already fairly restrictive, so it is unclear why additional restrictions are necessary.

Bayh Dole and Make in America Requirements

Congress passed the Bayh-Dole Act to promote innovation and commercialization of federally funded research. By granting firms and universities the ownership of the patents on inventions they create with the help of federal funding, they can obtain a return on their research and development investments. At the time of the law’s passage, only 5 percent of patents were used in the private sector, largely because the government maintained
ownership of the patent. After Bayh-Dole was passed, which granted firms and universities the ownership of those patents, commercialization of research largely increased.

Congress didn’t fully give up federal control of these inventions, however. The Bayh-Dole Act prohibits the manufacture of federally funded inventions outside of the United States barring a waiver from an agency in cases where “reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States” or “under the circumstances domestic manufacture is not commercially feasible.”

Currently, the waiver process is underused and could benefit from improvement. A recent survey of universities’ technology transfer offices found that waiver decisions took over a year on average, and that doesn’t account for the almost half of institutions that reported they never received a response. Unsurprisingly, only 25 percent of institutions in the survey even sought a waiver within the past five years. The Biden Administration did take steps to improve the process, issuing an executive order in 2023 that encouraged agencies to develop timely and transparent processes and tasked the National Institute of Standards and Technology (NIST) with developing guidance on what factors agencies should consider when determining whether domestic manufacturing is not commercially feasible.

**Invent Here, Make Here Act**

The Act has two main components. First, the bill would increase coordination among NIST, Manufacturing USA Network, the administrator of the Small Business Administration, and the director of the Made in America Office at the Office of Management and Budget (OMB) to identify domestic inventors and manufacturers that can develop commercial products based on the federally funded research.

Second, the bill adds additional process requirements on granting waivers for foreign manufacturing. Most notable, the bill would add a definition to the term “manufactured substantially in the United States” that includes “all articles, materials, or supplies mined, produced, or manufactured in the United States.” In addition, it would prohibit waivers for manufacture in countries of concern, very similar to the provisions that currently apply to DHS. Finally, it would require OMB approval prior to an agency granting a waiver.

Taken together, these provisions strongly encourage domestic manufacturing of federally funded inventions. There may be cases where foreign manufacturing can spur the development of these inventions, however.

**Risks to the Innovation and Deployment of New Technologies**

While the Biden Administration clearly has made American manufacturing a key priority, forcing firms to manufacture in the United States comes with trade-offs that could likewise harm U.S. universities, businesses, and consumers.

For example, completely prohibiting waivers to manufacture in countries of concern may make sense for DHS, where the federally funded inventions have a higher chance of affecting national security, but a blanket ban may prevent cases where the manufacture of the invention poses no security risk, economic or otherwise, and foreign manufacturing could drastically save costs and make the invention commercially viable. Worse, the bill would also allow the secretary of the Department of Commerce to prohibit waivers for manufacturing in any country the secretary determines is engaged in conduct detrimental to the national security of the United States.
This is problematic in isolation, but by expanding the definition of “manufactured substantially in the United States,” the bill would effectively prohibit firms from manufacturing the inventions if even a small portion of the materials was obtained in foreign jurisdictions. For example, the new definition includes provisions that materials must be mined in the United States for the product to be “manufactured substantially in the United States,” even if that material is not widely mined in the United States already. This would necessarily increase costs and make it more difficult for the development of federally funded inventions.

Finally, often firms manufacture products close to the market they wish to operate in to lower costs and increase efficiencies. If the purpose of the Bayh-Dole Act is to commercialize federally funded inventions, further limiting production to just the United States could limit potential profits and add risk to investments. Instead, federal policy should minimize risks to private firms that take the risk of developing federally funded inventions, especially when these inventions could include priorities for the White House such as green energy or semiconductor production.

This doesn’t mean every waiver should be granted. But current processes already disincentivize institutions from even requesting waivers. Congress should consider potential reforms to the bill to incentivize waivers when requiring manufacturing in the United States would prevent the development of the invention.

**Conclusion**

Congress passed the Bayh-Dole Act to incentivize the commercialization and development of federally funded inventions. While one could certainly argue that such inventions should be manufactured in the United States if possible, the Invent Here, Make Here Act would add unnecessary barriers to an already difficult waiver process, potentially jeopardizing innovation and development of American inventions.