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Is Bayh-Dole the Next Lever in the Push to Onshore Pharma Manufacturing?

WRITTEN BY

Melinda Rudolph | Deborah L. Spranger | Nile Delso

The U.S. government is pushing to redomesticate the manufacturing of pharmaceutical, biotech, gene therapy, and medical device products, both to bolster U.S. manufacturing generally and to address continuing shortages of these life-saving drugs and devices. While much attention has been given to the pending tariffs on pharmaceutical products, particularly active pharmaceutical ingredients (API), the federal government has other tools at its disposal, including the Bayh-Dole Act (the act).

Many commercial drugs, biologics, and devices were developed using federal funds, whether through federally funded research labs at U.S. colleges and universities or through the receipt of federal grants, including from the National Institutes of Health (NIH), the U.S. Small Business Administration (SBA), or the U.S. Department of Defense (DOD).

These drugs, biologics, and devices are considered federally funded "inventions" under the act, and are subject to certain federal government use, supervision, and reporting obligations. Specifically, the act requires that a federally funded invention must be "manufactured substantially in the U.S." Failure to meet this requirement can lead to a number of consequences, including the government exercising so-called "march-in rights" and taking title to the invention. The government also has the right to force a license to a third party, granting them rights to commercialize the invention.

Until now, the interpretation and enforcement of the "manufactured substantially" requirement has been left to the various federal funding agencies. But with the Trump administration's renewed focus on domestic manufacturing, life sciences organizations should prepare for the possibility of an overhaul to the current administration's approach and be ready to pivot.

What Is "Manufactured Substantially in the U.S."?

The meaning of "manufactured substantially in the U.S." is not a defined term under the act, nor is there significant guidance as to its meaning. Furthermore, enforcement of the manufacturing requirement —which has been minimal — is generally within the purview of the funding agency, creating potential policy inconsistencies across agencies.

However, the requirement is on lawmakers' radar. In 2023, the Senate introduced the bipartisan bill Invent Here, Make Here Act of 2024, which proposed defining "manufactured substantially" to mean "manufactured substantially from all articles, materials, or supplies mined, produced, or manufactured in the United States."

The definition was ultimately struck from the bill before it died in Congress, but it could have significantly impacted organizations that rely on certain materials produced outside the U.S. Therefore, if the bill is reintroduced once again, this more detailed definition could create additional challenges for universities and life sciences organizations that are developing and commercializing federally funded inventions.

Reporting Requirements and Government Visibility

On July 28, 2023, the Biden administration issued Executive Order 14104, which tasked agencies with requiring funding recipients to report the names of licensees and manufacturing locations of the applicable subject inventions on an annual basis (a new, government-wide requirement). Reports for unclassified inventions are generally made in the iEdison system, which is operated and overseen by the National Institute of Standards and Technology (NIST) and accessible to funding agencies. Under the order, agencies must transition all unclassified invention reporting to iEdison by December 31, 2025. Classified subject inventions will continue to be reported through agency-specific secure channels.

These reports inevitably increase potential visibility of manufacturing compliance, but it remains to be seen whether the administration's focus on domestic manufacturing will result in increased scrutiny. Much of the auditing functions under the act are performed by the grantor agencies, not NIST, meaning agency resources will potentially be a factor in enforcement. With many agencies experiencing extensive layoffs and budget cuts, staff resources may be spread thin and enforcement may depend largely on agency priorities.

Manufacturing Waiver

While subject inventions must be substantially manufactured in the U.S., it is important to note that there is an exemption available in circumstances where domestic manufacture is not commercially feasible or when reasonable (but unsuccessful) efforts have been made to grant licenses on similar terms to potential licensees likely to manufacture substantially in the U.S.

Once again, uncertainty surrounding the manufacturing requirement and eligibility for the waiver may make pursuing a waiver more challenging in the current political climate. However, Executive Order 14104 called upon agencies to improve and streamline the waiver process, in addition to requesting that the NIST develop additional guidance for agencies to consider when assessing whether domestic manufacturing is commercially infeasible and develop common waiver-application questions for all agencies. To date, the draft interagency waiver-request form is available for comment, while the detailed guidance on "commercial feasibility" has not yet been issued.

Potential pharmaceutical tariffs complicate the determination, as both foreign and domestic manufacturing operations could arguably become commercially infeasible, depending on the particular circumstances. For example, on the current version of the Interagency Domestic Manufacturing Waiver Request Form, factors considered include the cost of foreign manufacture and how long it would take to make U.S. commercial manufacturing feasible. While potential pharmaceutical tariffs could act as a catalyst to make domestic production more attractive, it would require significant time and investment. Companies (both the owner of the drug, biologic, or device and the contract manufacturers) would need to allocate substantial resources to build or upgrade facilities, train workforce, and navigate regulatory requirements — all of which could extend the timeline for achieving substantial U.S. manufacturing capabilities.

Conclusion and Recommendations

Universities and licensees of federally funded inventions should have an action plan in place to prepare for increased scrutiny of the act's manufacturing requirements. This includes assessing whether there are any aspects of the current manufacturing process that have a foreign component, in addition to evaluating and documenting whether the invention can meet the current conditions for a waiver.

For organizations licensing or acquiring technology and inventions, it's also essential to conduct robust diligence and contract for necessary warranties and indemnities to prepare for potential legal uncertainties with respect to any nondomestic aspect of the manufacturing process.

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