

NOW & NEXT

Intellectual Property Alert

AUGUST 21, 2023

Recent executive order prioritizes domestic innovation and manufacturing

By Seth D. Levy, Freddy R. Lopez, and Vincent C. Capati

Seeking to “invent it here, make it here,” POTUS signed an executive order emphasizing the significance of the innovation ecosystem in the United States and, in turn, prioritizing domestic manufacturing.



What's the Impact?

- / The executive order outlines actions, restrictions, and deadlines in connection with commercializing federally funded inventions to foster domestic economic growth, enhance domestic manufacturing, and support national security objectives.
- / Universities and research institutions must align their technology transfer strategies to preserve their intellectual property rights and ensure continued funding.
- / Small businesses participating in SBIR and STTR programs need to carefully consider their strategies for manufacturing products developed using federal funds.

Industry in the United States regularly offshores manufacturing, exporting technical know-how where foreign jurisdictions enjoy technology transfer paid for by U.S. taxpayers and developed with the ingenuity of world-class universities and research institutions. Although the offshoring

of manufacturing is often a practical necessity to effectively bring technological innovations to market, some argue that it both intensifies the United States's deficit in domestic manufacturing expertise (and capital) and creates weaknesses in the economy and [national security as to the foreign manufacture of sensitive technologies](#).

This tension is a particular challenge for academic institutions, which rely heavily on federal funding to support a wide range of research programs. Through their technology transfer offices (TTOs), these institutions protect the resulting intellectual property and seek commercial licensees to translate the results into products and services that benefit the public. Because academic institutions aren't in a position to manufacture products for commercial sale themselves, they rely on companies to do so. Across industries, most companies manufacture their products overseas. Thus, academic institutions' licensing options may be unduly limited if domestic manufacturing requirements tied to the licensing of federally funded innovations are made too stringent. In fact, existing domestic manufacturing requirements have already presented challenges for some of these institutions.

A related issue arises for small businesses that take advantage of federal funding to support their research and development activities, such as through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. As these companies plan to commercialize their products, they frequently engage with or create overseas manufacturing capabilities for economic, regulatory, or other reasons. Strengthening the requirements for domestic manufacture of these companies' products can significantly impact their path to market or, in some cases, undermine their viability as businesses altogether.

On July 28, 2023, the Biden administration issued the "[Executive Order on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs](#)" to bolster domestic investment in innovative technologies developed using federal funds by enhancing the requirements for domestic manufacturing. The administration issued [several objectives and mandates](#) directly affecting academic TTOs nationwide as well as the many small businesses that receive federal funding, such as through the SBIR and STTR programs. Here, we highlight how universities, research institutions, and impacted small businesses can prepare to address these changes:

Emphasis on manufacturing new inventions in the United States and, particularly, in critical industries

Consideration of domestic manufacturing in funding agreements

Heads of federal agencies are to consider, in federal funding agreement solicitations, domestic manufacturing, such as domestic job creation, domestic economic market presence, and observance of United States national security interests. Agencies are also to consider expanding domestic manufacturing requirements, especially for critical and emerging technologies, when awarding funds to support supply chain resilience and economic security. Guidelines are to be available by April 23, 2024. **Federal funding recipients should consider how these issues will be addressed in grant applications when seeking federal funds and in their licensing and**

commercialization activities when identifying commercial opportunities to leverage the resulting intellectual property.

Reduce barriers to participation

The Small Business Administration and agencies participating in the SBIR and STTR programs are to reduce barriers to program participation, streamline access to funding opportunities, and encourage the production of new technologies in the United States. **Companies exploring the possibility of federal funding through SBIR and STTR programs should benefit from improvements in these processes while being mindful of changes in domestic manufacturing requirements and reporting obligations.**

Evaluate “exceptional circumstances”

Heads of federal agencies are to consider whether “exceptional circumstances” exist to extend the “substantially in the United States” manufacturing requirement (i) to non-exclusive licensees of subject inventions and (ii) for use or sale of subject inventions outside the United States, with respect to critical technologies—such as energy storage, quantum information science, artificial intelligence and machine learning, semiconductors and microelectronics, and advanced manufacturing—while also encouraging small businesses and nonprofit research organizations to participate in the creation of these technologies. **TTOs and companies receiving federal funding should watch for updates on these issues, particularly in the critical technology fields specifically identified in the executive order, as they will directly impact licensing and commercialization plans.**

Improve transparency, cut red tape, and streamline reporting requirements to better track progress toward domestic manufacturing goals

iEdison requirement

All funding agencies will move to the [iEdison](#) online system to report subject inventions and related information to the federal funding agency by 2025. **This should streamline and simplify the internal operations of TTOs.**

Monitor manufacturing locations

Federal funding recipients will need to monitor and update the awarding agency on the location in which subject inventions are manufactured, including the names of licensees and their manufacturing location for the applicable subject inventions. **TTOs should consider updating their license agreements to request this additional information from licensees, both in their initial commercialization plans and periodic reporting on exploitation of licensed intellectual property rights. TTOs and companies receiving federal funding should align the confidentiality obligations in their various agreements with the anticipated need to share this information with the federal government.**

Utilization reporting

Federal funding recipients should expect additional manufacturing-related utilization questions from funding agencies by May 1, 2024, for all subject inventions to which the recipient elected to retain title on or after July 28, 2023. ***TTOs and companies receiving federal funding should plan to have relevant information readily available in order to address anticipated questions.***

Award terms and conditions

Expect award terms and conditions for reporting requirements to be developed and implemented by each awarding agency by September 26, 2023. ***TTOs and companies receiving federal funding should watch for communications from funding agencies about these issues and prepare to respond in a timely manner.***

Make the domestic manufacturing waiver process clearer, timelier, and more consistent

Waiver applications

Heads of federal agencies must acknowledge receipt of waiver applications within ten business days, and have decisions, along with necessary negotiations, finalized as soon as possible. The Secretary of Commerce will develop common waiver application questions for all agencies by October 26, 2023. ***Speeding up this process and making it more consistent should be a welcome change for TTOs and companies receiving federal funding, as the timing and substance of these review processes have often been unpredictable or unclear.***

Waiver granting process

Heads of agencies are to outline a waiver granting process that avoids placing the waiver application burden on the federal fund recipient. By October 26, 2023, the Secretary of Commerce will provide guidance (for notice and comment) on the factors that should be weighed when determining whether domestic manufacturing is not commercially feasible. ***Clarifying guidance should be helpful for TTOs, companies, and the federal agencies alike. TTOs and companies should watch for this new guidance.***

Looking ahead

While the federal agencies continue to develop and finalize the procedures and materials noted above, TTOs and companies receiving federal funding should begin assessing their current operations, planning for anticipated changes, and evaluating the manufacturing strategies being developed and implemented for their subject inventions.

As always, Nixon Peabody LLP is continuing to monitor these developments and can provide practical counsel to universities, research institutions, and other federal funding recipients navigating these technology transfer, intellectual property, and commercialization issues.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

Seth D. Levy

213.629.6161

slevy@nixonpeabody.com

Freddy R. Lopez

213.629.6038

flopez@nixonpeabody.com

Vincent C. Capati

213.629.6091

vcapati@nixonpeabody.com