



August 2, 2023

RE: COGR Analysis on Executive Order 14104 “*Federal Research and Development in Support of Domestic Manufacturing and U.S. Jobs*”

On July 28 the Administration released an Executive Order (EO 14104) on [*Federal Research and Development In Support of Domestic Manufacturing and U.S. Jobs*](#). The EO seeks to ensure the commercialization of federally funded inventions by U.S. manufacturers. It has substantial implications for research institutions’ technology transfer operations.

The EO directs DOD, Ag, Commerce, HHS, DOE, DOT, DHS, NSF and NASA to encourage domestic manufacturing in their R&D solicitations and funding agreements, including OTA’s and SBIR/STTR programs. The agencies also are encouraged to enhance their technology transfer and commercialization capabilities.

The EO sets forth a number of new reporting requirements. R&D funding agreements from the named agencies will require annual reports on licensees and manufacturing locations of subject inventions. NIST is to develop award terms and conditions within 60 days. NIST also is to develop an action plan to transition all the above agencies to the iEdison invention reporting system. The action plan is due in a year. The agencies are directed to complete this transition by the end of calendar year 2025. Common invention utilization questions including production locations are to be developed by NIST within 180 days, for use by the agencies by May 1, 2024. Agencies are to submit annual utilization reports to the Made in America Office Director starting in two years.

Agencies are also directed to consider within 90 days whether exceptional circumstances exist under the Bayh-Dole Act warranting restriction of title to inventions or extension of the Bayh-Dole “substantial U.S. manufacturing” requirement to non-exclusive licenses or sales of inventions outside the U.S. This includes consideration of certain critical and emerging technologies and other measures to promote domestic manufacturing. Agencies are to submit implementation reports to OMB/OSTP within two years and annually thereafter for five years.

Finally, agencies are to develop a process for waivers of the domestic manufacturing requirement with the concurrence of the Made in America Director. NIST is to develop guidance for the agencies on factors and considerations in determining whether domestic manufacturing is not commercially feasible, consistent with Bayh-Dole Act requirements. The guidance is to be available within 90 days. NIST is to develop common waiver application questions that address a number of criteria. Agencies must acknowledge receipt of waiver applications within 10 business days. They also must develop guidelines for waiver negotiations. Waivers should be limited to applicants that commit to manufacturing in locations that maintain a market economy. Summaries of the action on each waiver application are to be provided to Commerce annually beginning in 2024. Commerce will publish periodic summaries.

In COGR's view the EO is something of a mixed bag. On the positive side, we long have advocated standardization of invention reporting and use of iEdison by all agencies. However, reporting challenges and burdens will increase, particularly with the new requirement to report manufacturing locations. In addition, the EO does not set forth timelines for agency actions on waiver requests. While the discussion of exceptional circumstances essentially restates existing Bayh-Dole authorities, it may encourage agencies to make greater use of the authority to restrict title to inventions or expand the domestic manufacturing requirement. Finally, responsibility for implementation of the EO seems diffuse and unclear. The EO does not mention the Bayh-Dole regulations at 37 CFR 401, which would seem to be the logical mechanism for effective implementation.

If you have any questions concerning this EO or the information in this document, please contact Robert Hardy, Director of Research Security and Compliance at rhardy@cogr.edu.

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