A Proposal Regarding The Domestic Manufacturing Requirement Of The Bayh-Dole Act

By Gillian M. Fenton

This article summarizes, from a practical perspective, difficulties in defining and analyzing the Domestic Manufacturing Requirement of the Bayh-Dole Act as applied to products that are based on or utilize an invention arising from U.S. federal funding.

- The key terms *manufacturing* and *substantially* are not defined in the Act or its implementing regulations, raising uncertainty for licensees of funded inventions.
- The current process for issuance of waivers of the Domestic Manufacturing Requirement is unduly lengthy and restrictive.
- The Bayh-Dole Act has not been substantially amended since its enactment in 1980, a time before the current knowledge economy and the advent of complex products and global supply chains.
- The Bayh-Dole Act rests on a policy of prioritizing American manufacturing jobs. This could be beneficially expanded to include other highly skilled job types and to consider other benefits to U.S. national security.

In the United States, a unique statutory framework governs the transfer of technology and inventions made through the use of federal funding from the government and academia to the private sector. This framework is set out in The University and Small Business Patent Procedures Act of 1980,[1] commonly known as the Bayh-Dole Act. The purpose of the Bayh-Dole Act is to capture the value of public investment in research and development by enabling private-sector entities to develop and commercialize products and services based on funded inventions. Accordingly, the Act sets out a framework for licensing patent rights in such inventions for public benefit. This framework includes a number of incentives for licensees, as well as protections for licensors and the government, and specifies various license requirements designed to achieve the policy goals of the Act. Importantly, the Act sets out a preference for U.S. industry in the form of a requirement that, unless waived by the government, licensees agree to manufacture licensed products substantially in the United States: this is known as the Domestic Manufacturing Requirement or DMR.[2] The Act also sets out a unique penalty for failure to comply with the DMR: the government has the power to cause the licensor to grant a new license, even if the original license was exclusive, to another party deemed more likely to abide by key requirements of the Act, including the DMR. This power, known as "march-in rights," may also be exercised if the licensee fails to pursue commercialization, or fails to supply licensed products to meet a public health or safety need, or to comply with a government regulation or standard that calls for the use of products based on the funded invention.[3]

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In the 44 years since its enactment, Bayh-Dole has achieved remarkable success in facilitating the transfer of technologies across all industries, making the United States a global leader in innovation. Licenses promulgated under the Act have led to the formation of thousands of technology-based startup companies and have generated tens of thousands of new jobs, expanding and modernizing the U.S. manufacturing base and technology workforce.[4]

An understanding of the Bayh-Dole Act of 1980 is essential to the success of business collaborations, especially intellectual property license agreements, at the interface between the private sector and U.S. universities, research institutions, and government entities. Recently, the Biden Administration drew at-

1. Public Law 96-517 (as amended), now codified at 35 U.S.C. 200 *et seq.*

2. 35 U.S.C. 204.

3. 35 U.S.C. 203.

4. An analogous statute, 15 U.S.C. 3701 *et seq.*, known as the Stevenson-Wilder Act, covers the establishment of a technology transfer function within the federal laboratories system and the legal authority for federal laboratories to collaborate with private-sector entities through cooperative research and development agreements or CRADAs (Section 3710a). CRADAs similarly include a domestic manufacturing requirement (Section 3710a(c)(4)(B)) and framework for march-in rights (Sections 3710a(b)(1)(B) and (C)).

tention to the use of the Bayh-Dole Act and its implementing regulations[5] to advance the U.S. innovation economy by emphasizing domestic manufacture of cutting-edge technologies and products developed with U.S. government support. Biden's policy is described in Executive Order 14104,[6] which lays out a sweeping array of circumstances in which agencies are directed to prioritize domestic manufacture and to improve reporting and oversight of private sector parties engaged in the development and commercialization of products arising from inventions made through the use of U.S. federal funding. While the recent U.S. presidential election signals many significant changes in administration policy, the Trump Administration is likely to maintain a focus on advancing innovation—including through prioritizing U.S. manufacture of innovative products and technologies.

I have had occasion to analyze the Bayh-Dole Act's DMR[7] as applied to complex biologic products developed from federally funded technology. This project ultimately resulted in two publications—one analyzing the nature and scope of the DMR, and the other focusing on grounds and procedures for securing a waiver of the DMR.[8] The decision to publish was motivated by findings that the Bayh-Dole Act—which has not been amended since its original enactment over 40 years ago—is not sufficiently robust or clear to be applied easily to today's complex technologies and equally complex resulting products. The Act provides that certain products based on or embodying an invention that was made through the use of federal funding must be "manufactured substantially in the United States" unless a waiver of this requirement is secured from the cognizant federal funding agency. However, very little guidance exists in the law itself, its implementing regulations, legislative history, or court or administrative agency interpretations, for what is meant by the terms "substantially" or "manufactured." No particular threshold, methodology, or metric is provided or recommended. Thus, depending on the nature of the supply chain for a complex product incorporating a mix of U.S. and global suppliers, or a geographically dispersed multi-step manufacturing process, it may not even be clear whether the DMR is satisfied or not. This uncertainty raises significant risk for innovative businesses in many industries, including biotechnology and pharmaceuticals (collectively, biopharma), given the high level of investment capital required for commercial-scale manufacturing operations and the difficulty of moving operations once established. This is particularly true for products based on inventions made by universities through federal funding of biomedical research: the intellectual property arises from an invention that is frequently licensed to a private-sector company long before the eventual product is identified through development work performed by the company.

The Act does provide that funding agencies have discretion to grant waivers of the DMR. Waivers may be granted on either of two grounds: (1) that the licensor of the technology (*i.e.*, the party who received U.S. government funding) has been unable to secure a licensee willing to commit to manufacturing licensed products in the U.S., even after a reasonable effort to identify such a licensee, or (2) that it would be commercially unfeasible for the licensee to manufacture licensed products in the U.S.[9] However, across much of the U.S. government, the process for securing such waivers is broken—it either takes an unrealistic length of time for a waiver to be granted (12 months or more), or government agencies may never even respond to acknowledge submission of a waiver application.[10] Waivers that have been granted historically have been of narrow and rigid scope, often specifying by name the permitted manufacturing facilities.[11] Such granularity does not reflect the pragmatic necessity for manufacturers to continuously optimize the utilization of their resources, and it provides no recourse if the use of a named facility must be temporarily suspended to address findings made during an inspection by the U.S. Food and Drug Administration (FDA). This difficulty is exacerbated by the fact that the DMR attaches to the licensed product for the product's entire commercial lifetime—even after patents have expired.

The Bayh-Dole Act provides that the DMR must be satisfied by the product—considered as a whole—that is commercially developed on the basis of an invention arising from federal funding and licensed to a private-sector licensee for commercialization. This is the case even if the funded invention relates only to a single step of the process, or a single component of the product, requiring a wide-ranging analysis. As noted above, the eventual product may not even be identified

5. 37 C.F.R. Parts 401 and 404.

6. 88 F.R. Vol. 51203 (Aug. 2, 2023).

7. 35 U.S.C. 204.

8. Fenton and Bouquet, *les Nouvelles* Vol. LIX, No. 2, pp. 50-58 and pp. 59-66 (June 2024).

9. 37 C.F.R § 401.14(g); 37 C.F.R. § 404.5

10. *https://autm.net/AUTM/media/Events/Images/AUTM-US-Manufacturing-Waiver-Survey-Results_VF.pdf.*

11. This practice is endorsed in the Public Health Service Technology Transfer Policy Manual, see Chapter 604A. The PHS Tech Transfer Policy Manual is utilized by major biomedical R&D funders including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

when a license is entered into by the federal funding recipient and a licensee willing to take on the risks and rewards of developing a product based on the funded invention. The Act is silent as to where the analysis of the product's compliance with the DMR should begin: with conventional ingredients or components that can be purchased commercially, or need one trace back to the raw ingredients arising from primary extractive industries such as agriculture, forestry or mining? The latter approach is taken in some significant statutes in the field of U.S. federal procurement law,[12] but it is unclear whether the policies behind federal procurement laws are the same or similar to the policies undergirding the Bayh-Dole Act.

Executive Order 14104 seeks to address some of the issues highlighted above by instituting a uniform process and e-filing portal (iEdison) for funding agencies to use when reviewing applications for DMR waivers. The new intake form is quite granular, seemingly going beyond the requirements of either the Act itself or its implementing regulations to address such issues as fair labor practices in the facilities where manufacturing would take place.

In a separate development, in late 2023, Senators Baldwin and Vance proposed the "Invent Here, Make Here" Act[13] (the IHMH bill) which has been reported out of the Senate Judiciary Committee but lacks a counterpart bill in the House, making its future uncertain. In its original form, the IHMH bill called for amending 35 U.S.C. 204 to specify that "manufactured substantially in the United States" meant "manufactured substantially from all articles, materials, or supplies mined, produced, or manufactured in the United States." By introducing the word *all* and specifying that the analysis for country of manufacture should begin with raw ingredients derived from primary extractive industries, the original IHMH bill would have doubled down on the difficulties pointed out above. The original bill also called for shifting the review of waiver applications from the cognizant funding agencies to the Made in America Office,[14] and set uniform standards for review of all waivers of statutory domestic manufacturing preferences, lumping the Bayh-Dole Act in with federal procurement laws. The IHMH bill was amended upon being reported out of committee and, as presently constituted, omits the original text defining *manufactured substantially in the United States.* The amended bill also preserves the current status quo for reviews of waiver requests by the cognizant federal funding agencies. However, the amended bill would address the issue of processing time for waiver applications, by setting a deadline of 90 days after receipt of the corresponding application for issue of DMR waivers, unless grant of the waiver would raise a national security risk.[15]

Neither of the foregoing recent initiatives addresses the fundamental issue of the broad terminology in which the DMR is defined in the Bayh-Dole Act, namely the terms "manufactured" and "substantially." The only current source of guidance for construing these terms is in the legislative history of the Bayh-Dole Act, which states that the DMR is "designed to maximize the probability that the jobs created through the commercialization of new products and technologies based on Government supported inventions will benefit American workers."[16] It is an open question how applicants should connect this expressed policy with any specific threshold, methodology, or metrics for measuring the "substantiality" of "manufacture" in the U.S. or any foreign country.

This brief survey of difficulties encountered when making analyses required for compliance with the DMR of the Bayh-Dole Act illustrates several issues that could be beneficially addressed. It does not appear to be necessary to amend the Act itself: a proper rulemaking process that guides how to interpret the Act would be helpful, and perhaps even a new guidance framework under existing rules would be sufficient if developed with a pragmatic understanding of the challenges faced by licensees in the course of commercial development.[17] Accordingly, I propose the following initiatives:

1. **A threshold should be defined for the statutory term "substantially."** The threshold should reflect how the funded invention relates to the final product. For example, a product should be deemed "substantially manufactured in the United States" if a simple majority (more than 50

12. *E.g.*, the Trade Agreements Act, 19 U.S.C. § 2518(4)(B), and the Buy American Act, 41 U.S.C. § 8302.

13. S.1956 (2023-2024).

14. Established under Section 70923(b)(2) of Publ. Law 117-58 (135 Stat. 1309) (15 Nov. 2021).

15. If the grant of a waiver would result in manufacture in a "country of concern" the waiver will not be granted unless upon written authorization of the President or a designee of the President. The "countries of concern" include North Korea, China, Russia, and Iran.

16. Senate Judiciary Report on S.414, available at *https://bayhdolecoalition.org/wp-content/uploads/2023/05/S-414-Senate-Judiciary-Commmittee-Report.pdf.*

17. Although the recent Supreme Court decision overturning the Chevron Deference doctrine may undermine an approach of merely promulgating a guidance framework or even of confining clarifications to the level of rule amendments. See *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___; 144 S. Ct. 2244 (June 28, 2024).

percent) of the product components (assessed by their cost or value) are sourced within the U.S. This analysis need not extend all the way back to raw products of primary extractive industries. Because the focus is on innovation, an inventory of the sources of commercially available off-the-shelf (COTS) components should be sufficient, since such components lack a nexus with the value of the funded invention. Alternatively, if key high-value steps/components, *i.e.*, those having a nexus to the funded invention, are sourced within the U.S., a lower threshold should be acceptable for U.S. components overall. The rationale for this is that the licensee has taken steps to assure that the value of the invention—which relates most closely to U.S. leadership in innovation—is preserved within the United States.

2. **The statutory term "manufacturing" should be defined.** Implementing regulations and administrative decisions under the Trade Agreements Act[18] and the Buy American Act[19] have addressed the question of what is meant by "manufacturing" in the context of federal procurement law. While helpful, there is not a clear logical connection between the term as utilized in federal procurement laws versus in the Bayh-Dole Act. "Manufacturing" is a broad concept involving the transformation of source materials or intermediates into a finished product; given the breadth of innovative industries relevant to the Bayh-Dole Act, a broad view of "manufacturing" is warranted. However, in light of the policy of advancing job opportunities for American workers, there should be a clearer connection between "manufacturing" and the funded invention: if multiple transformative steps are required to create the final product, a premium should be placed on assuring that the step or steps most closely related to the funded invention take place in the U.S. Correspondingly, there should be less emphasis on where transformations take place that involve only conventional skills and known technologies.

3. **The focus on manufacturing jobs as the acme of innovation leadership should be re-examined.** The U.S. economy and job market structure were very different in 1980 than each is today. In 1980, a strong emphasis was rightfully placed on manufacturing and the production of tangible products. Today, the U.S. has progressed to a knowledge-based economy. While manufacturing remains important, there are other types of highly skilled, high-wage-earning jobs that should be considered, and novel products and services have been developed that may not even have a clear tangible component, such as the large and diverse e-commerce ecosystem, or the manifold uses of artificial intelligence that are still being explored. The underlying policy of advancing American jobs remains relevant, but the focus for evaluating what is being achieved by the DMR and the waiver process should be expanded to include other types of highly skilled jobs with high economic value—perhaps including software engineers, database or web portal technicians, AI developers, R&D experts, and others. For virtual products and services, the geographic location of servers or server farms could become relevant to the DMR. As a practical matter, given the vast diversity of new innovations falling under the Bayh-Dole Act, the burden should be on the licensee/applicant to explain the value of U.S. jobs other than traditional manufacturing and how the grant of a waiver of the DMR would nonetheless benefit the U.S. economy and U.S. leadership in innovation globally.

4. **Benefits to the U.S. beyond American jobs should be considered.** At its best, the Bayh-Dole Act nurtures and supports an ever-advancing innovation economy in the U.S. At its worst, the Act is rigidly isolationist and protectionist, disadvantaging any involvement of imported products, components, or raw materials even from nations sharing the U.S. worldview of free and open democracies, rule of law, and functioning free markets. Global supply chains have arisen over the course of many years of international diplomatic and business relationships, and will not be undone quickly, easily, or without risk of substantial negative repercussions. At the same time, policy leaders in the U.S. have recognized key connections between innovation leadership and national security. In the field of global public health, for example, the recent COVID-19 pandemic has taught us that a novel infectious disease can emerge anywhere on the planet and present a threat even to nations thousands of miles away from the disease's point of origin. Social and economic strains caused and revealed by the pandemic underscore the importance of U.S. national security interests in supporting the well-being of allied countries, and capacity building in vulnerable economies. The permitted grounds for a waiver of the DMR should be liberalized to include an analysis of whether a waiver would serve an important U.S. national

18. 19 U.S.C 2518(4)(B).

19. 41 U.S.C. 8302.

security interest. This could include strengthening ties with key U.S. economic allies or building manufacturing capacity in developing countries that could be deployed to rapidly address emerging public health threats. Many other scenarios can be envisioned where the Bayh-Dole Act could support U.S. diplomacy through strengthening the economies of U.S. allies.

5. **The government should adopt a unified process for waiver processing across all funding agencies.** The harmonized process proposed in Executive Order 14104, utilizing the iEdison portal, should be adopted uniformly by all agencies that provide R&D funding from which new inventions can arise. Each agency should designate an office or official having familiarity with industry and with the dynamics of innovation and product development to lead the review of waiver applications. As the designated lead agency for implementation and rulemaking under the Bayh-Dole Act, agencies should notify NIST of all waiver requests and enable NIST to develop an understanding of the volume of waivers requested, processing time, decisions to grant or deny waivers, and trends developing over time or across industry sectors. As a science and technology agency, NIST is better situated to coordinate the waiver process and to assist any agencies that require assistance in using the iEdison portal or in reviewing the waivers, than is the Made in America Office, as proposed in the IHMH bill.

The foregoing suggestions are offered as potential improvements to the administration of the Bayh-Dole Act and would, if implemented, enhance compliance by licensees with the Act's Domestic Manufacturing Requirement while assuring that the underlying policy objectives of the Act remain in place and are even strengthened. These suggestions reflect a pragmatic understanding of how innovative businesses operate in our modern, interconnected, knowledge-based innovation economy. I urge rulemaking bodies within the United States government to consider these suggestions.[20] ■

20. The author would like to thank Hon. Walter Copan for a constructive critique of this manuscript.