Waivers Of The U.S. Domestic Manufacturing Requirement Of The Bayh-Dole Act To Support Global Supply Chains

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Abstract

The Bayh-Dole Act ("Bayh-Dole" or the "Act") [1] *governs the licensing of federally funded and federally owned inventions. A key requirement, referred to as the "Domestic Manufacturing Requirement" is that licenses of such inventions to private sector entities should benefit U.S. industry, specifically by requiring manufacture of products that embody or are made through such inventions "substantially in the United States." If an invention will not be "manufactured substantially in the United States," a waiver must be sought. The Act and its implementing regulations provide two grounds for agencies to grant waivers: (1) if the applicant demonstrates that "reasonable but unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States," or (2) "if domestic manufacture is not commercially feasible." Waiver requests must granularly address the grounds for the waiver, why a waiver is necessary under the specific circumstances, and why the grant of a waiver would advance the agency's mission and the policy behind the Act.*

1. Introduction

This is the second of two articles concerning the Domestic Manufacturing Requirement, codified at 35 U.S.C. § 204. In the first article, we presented an analytical approach to interpreting § 204 and whether it applies to a given invention that arose from U.S. federal funding of research or other activities. In this article, we present a practical approach to securing waivers of the requirement from the cognizant U.S. federal funding agency, including the process, current framework, and practice tips. As with our first article, the topic of this article is of particular concern to recipients of U.S. government funding for inventive activities and their licensee partners. Indeed, the availability of a waiver of the requirement will drive strategic decisions on how to structure manufacturing operations and supply chains for the resulting products for years after the receipt and utilization of the U.S. research funding from which the innovative product arose.

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2. Background

We previously summarized Bayh-Dole and explained how it addressed the prior obstacles to development and commercialization of products based on inventions made by either U.S. government employees or by private sector organizations in the performance of work under grants and other types of government agreements. The Act and its implementing regulations gave recipients of federal grants or contracts (Awardees) a path to securing title to the inventions they made (referred to herein as "Federally Funded Inventions").[2] The Act also imposed certain requirements on the licensing of inventions made by government-employed scientists and engineers or Federally Funded Inventions to which the government has obtained title because the Awardees either did not elect to retain title to their inventions, discontinued patenting activities for such inventions, or otherwise failed to comply with the standard patent rights clauses set out in 37 C.F.R. § 401.14 (referred to herein as "Federally Owned Inventions"). For convenience, where the Act imposes consistent requirements on both Federally Funded and Federally Owned Inventions, we will refer to them collectively as Federal Inventions.

The Domestic Manufacturing Requirement, also referred to herein as the "DMR," is the provision in the Act that most clearly reflects the Act's original policy

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1. The University and Small Business Patent Procedures Act of 1980, Public Law 96-517 (as amended), codified at title 35 of the United States Code (U.S.C) 200 *et seq.*; see also implementing regulations at 37 C.F.R. Parts 401 and 404.

2. These are referred to as "Subject Inventions" in the regulations.

objective to promote innovation in the United States. It requires that all Federal Inventions that are licensed to private-sector entities should benefit U.S. industry by requiring that products based thereon be manufactured substantially in the United States. This requirement attaches to licenses of the *exclusive* right to sell or use a Federally Funded Invention in the United States,[3] and to all license grants (non-exclusive and partially exclusive as well as exclusive) of commercial rights in Federally Owned Inventions.[4] The DMR attaches to products "embodying" the *invention* or "produced through the use of" the *invention* and remains applicable through all tiers of licensing and sublicensing or other transfer of license rights, for the commercial lifetime of the corresponding products.

Enforcement of Bayh-Dole, specifically including the DMR, has been utilized by the Biden Administration as a tool to advance national policy priorities.[5] In addition, much public attention has focused on recently proposed changes to the "march-in" rights provisions of the Act, which are largely outside of the focus of this article.[6] There is, however, a connection between the two: exercise of a march-in right through modification or revocation of a license to Federal Inventions embodied in or utilized in making a product is the exclusive remedy for failure to comply with the DMR or for breach of a granted waiver of the DMR.[7] For these and other reasons we discuss below, readers should expect further policy developments and a focus on promotion of U.S. manufacturing for at least the remainder of the Biden Administration.

This article is intended as a practical guide for licensees of Federal Inventions who have determined that the Domestic Manufacturing Requirement applies to them and that a waiver is required in order to effectively commercialize their in-licensed products. We believe that an increasing number of licensees will face this situation, especially when commercializing highly complex technologies in our current, globally interconnected economy, for which the United States remains a leading commercial marketplace. Thankfully, the Act and its implementing regulations provide that the DMR may be waived in certain circumstances.[8] We turn now to the process for securing waivers, as well as what to expect in a waiver grant. In the 40-plus-year history of the Act so far, it is clear that the burdens imposed on those engaged in the development and commercialization of Federal Inventions are sufficiently offset by the benefits of private-sector access to these taxpayer-funded inventions, producing a strong history of flourishing innovation in the United States across multiple industries.

3. Waivers of the Act's Domestic Manufacturing Requirement

If an exclusive licensee-developer of a Federally Funded Invention or any licensee of a Federally Owned Invention concludes that a Federal Invention will not be "manufactured substantially in the United States,"[9] and the Bayh-Dole Act's Domestic Manufacturing Requirement applies, a waiver must be sought. The Act and its implementing regulations provide two grounds for agencies to grant waivers: (1) if the applicant demonstrates that "reasonable but unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States," or (2) "if domestic manufacture is not commercially feasible."[10] We will now examine in more depth the two eligible grounds for granting waivers, and the paths for applying for waivers of Federally Funded versus Federally Owned Inventions.

a. Process for Applying for Waivers

(1) Federally Funded Inventions

The government-wide regulations on Federally Funded Inventions obligate the original Awardees and certain sub-Awardees[11] to apply for waivers of the Domestic Manufacturing Requirement. However, these regulations do not specify the process that applicants must follow to obtain such waivers. Fortunately, the guidance issued by the National Institutes of Standards and Technology ("NIST") for its "interagency Edison"

3. 35 U.S.C. 204.

4. 35 U.S.C. 209.

5. Executive Order No. 14104, issued July 28, 2023. See Executive Order on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs | The White House.

6. See Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (88 F.R. 85593) published by the National Institute of Standards and Technology ("NIST") on December 8, 2023, which received over 50,000 comments.

7. 35 U.S.C. 203(a)(4) and 37 C.F.R. § 401.14.

8. This article focuses on the normal framework of the Act with respect to the DMR. However, the Act also authorizes federal agencies to make "determinations of exceptional circumstances" ("DEC") that justify variations from the normal framework; see 35 U.S.C. 201 *et. seq.* and 37 C.F.R. Part 401. For example, DECs have been issued by the Department of Energy that significantly broaden the scope of the DMR for Federally Funded Inventions. See *https://www.energy.gov/gc/determination-exceptional-circumstances-decs.*

9. The analysis leading to such a conclusion is the focus of the first article in this two-part series.

10. 37 C.F.R. § 401.14.(i); 37 C.F.R. § 404.5

11. Under 37 C.F.R. § 401.14(g), Awardees must flow-down the clause to sub-Awardees who will perform research and development activities. The clause provides that the "mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the federal agency with respect to the matters covered by the clause."

(or "iEdison") portal sets forth such a process for Awardees with agreements with agencies that use the portal.[12] iEdison is an online, relational database designed to enable Awardees to meet all the reporting requirements of the Bayh-Dole Act and its implementing regulations. The system is also used by the funding agencies to receive and review the information and documentation submitted. The guidance requires Awardees to (i) request waivers of the DMR for each Federally Funded Invention; (ii) specify the grounds for the waiver and (iii) to upload supporting documentation providing the rationale for the request.[13] iEdison automatically routes the request to the designated agency official. If approved by that official, the system sends a notice of the approval, with an official approval document that includes terms and conditions of the approval, including any limitations of the waiver to specific time frames, fields of use, countries, etc. If the request is denied, the applicant receives a notification indicating the denial. The decision, reason(s) for the denial, and decision date will be displayed in iEdison next to the request in the Invention Report.

Awardees doing business with agencies that do not participate in iEdison have a more challenging route: the Awardee has to contact the point of contact in the award document to get instructions for filing waiver requests. In many cases, the award document will have a designated contact for patent matters. If there is no such contact, the Awardee will have to contact the individual designated as responsible for the administration of the agreement (*e.g.*, for procurement contracts, the Contracting Officer). Then, the Awardee will have to validate information that is provided concerning the process and the addressee for the request, submit the request, confirm receipt, and follow-up until a decision is communicated. Unfortunately, given the consequences of proceeding without a required waiver, the burden is on the applicant to ensure the request is timely processed.

After submission, applicants should expect that agency review may take as little as two to four months or, more commonly, a year or longer until a decision is rendered and communicated to the applicant; however, the Act does not impose any timelines for agency consideration.[14] It is important to note also that the decision to grant or deny a waiver is within the discretion of the cognizable federal agency. The agency may also, in its discretion, impose conditions on the grant of a waiver. Waivers may be structured to advance the goals of the Bayh-Dole Act, and/or the mission of the agency (in the case of the Public Health Services ("PHS"), for example, to advance public health in the United States or globally).

As mentioned, the original Awardee must file a request for a waiver of the DMR for any of its exclusive licensees who propose not to manufacture products based on a Federally Funded Invention substantially in the United States. Since the exclusive licensee is not the party directly facing the U.S. government, the licensee must rely upon the licensor (the Awardee, often a university or research institute technology transfer officer) to represent the licensee's interests. The license agreement between the Awardee/licensor and the exclusive licensee should therefore include a covenant for the licensor to cooperate with the licensee in submitting and timely prosecuting the waiver application.

(2) Federally Owned Inventions

As with Federally Funded Inventions, there are no government-wide regulations that specify the process for obtaining waivers of the Domestic Manufacturing Requirement for Federally Owned Inventions. However, based on our experiences, a waiver that is sought as part of the technology licensing process (*i.e.*, an upfront waiver) is handled by the lead agency negotiating the license. For example, in the case of PHS, the lead agency could be a National Institutes of Health ("NIH") Institute or Center (*e.g.*, the National Institute of Allergies and Infectious Diseases). In these circumstances, the prospective licensee will raise its desire to secure a waiver during the course of negotiations, and the license document will contain the resulting waiver, if granted. If a waiver is sought subsequent to execution of a license agreement, application must be made to the agency body responsible for license compliance (in the case of NIH, this would be the central NIH Office of Technology Transfer). Thus, different agency officials may be reviewing waiver applications depending on the circumstances.

As with Federally Funded Inventions, the Act and its implementing regulations do not set any firm time period by which the cognizant federal agency must complete its review. If and when granted, the waiver will be documented in a separate letter or notice to the applicant (who in the case of Federally Owned Inventions, is the licensee). Each waiver grant should be reviewed carefully to confirm that it is of the requested duration (it should be coterminous with the license grant of rights to make, use, offer for sale, sell, and import licensed products) and has an acceptable scope (as

12. For a list of these agencies, see *https://www.nist.gov/iedison/agency-contact-list.*

13. *https://www.nist.gov/iedison/iedison-organization-user-guide/invention-reports/submitting-domestic-manufacturing-waiver.*

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

mentioned above, agencies may have a practice of limiting waiver terms to specific geographies, even specific facilities).

b. Substance and Rationales for Waivers

As with the waiver process requirements for applicants, there are no government-wide regulations governing the substance and rationales for granting waivers. However, the NIH provides helpful guidance in its *Public Health Service Technology Transfer Manual* (Ch. 604 and 604A)(the "PHS Manual") concerning the information of most interest to agency officials reviewing applications for waivers of the Domestic Manufacturing Requirement. While NIH is not the lead agency responsible for promulgating regulations under the Act, the PHS Manual provides a useful example of how agencies approach the review process. Waiver requests submitted to NIH must include "sufficient and detailed supporting information" that granularly addresses why a waiver is necessary under the specific circumstances, and why the grant of a waiver would advance the agency's mission and the policy behind the Act (in the case of NIH, these factors center on public health both in the U.S. and globally). It is critical for applicants to provide specific facts in support of the arguments made, which are described more fully below. Finally, applicants should understand that, while applicability of the Act is triggered by the presence of a Federal Invention, federal agencies such as NIH will review the entire manufacturing process for the product—not just for the active pharmaceutical ingredient ("API") or key elements that correspond to patentable or patented subject matter. Overall, applications to NIH or other agencies must include a "robust basis" justifying grant of a waiver.

Each of the two grounds for granting waivers will now be examined in more detail.

(1) Reasonable Effort to find a U.S. Licensee

The first acceptable ground, namely that the applicant has made reasonable but unsuccessful effort to secure a licensee willing to manufacture products embodying the Federal Invention substantially on U.S. soil, is usually only made by applicants with licensing programs—*i.e.*, by universities and research institutes. It may also be applicable to Awardees such as start-up and small biotechnology companies who engage in partnering in order to leverage the capabilities of larger organizations in order to access markets that the Awardee cannot serve itself. The licensing argument must be presented with fully developed, relevant and sufficient facts.[15] Following is the guidance from the PHS Manual concerning the information of most interest to the agencies in deciding waivers based on this ground:

a. The nature of the particular market for the subject invention would suggest whether a probable range of companies interested in a license is large or small (*e.g.*, a large range would require greater marketing efforts to be "reasonable"). Potentially relevant information might include: the significance of the technology, the availability of alternative products, size and location of intended patient populations, and the degree of regulatory review needed to bring the product to the U.S. market.

b. Good faith efforts for marketing the technology to companies willing to manufacture in the United States were unsuccessful. Potentially relevant information might include: (i) number of companies contacted; (ii) methods used for marketing and contacting companies; (iii) types of licenses and terms offered to potential licensees; (iv) comparison of terms offered to potential exclusive licensees that will manufacture substantially in the United States versus to licensees that will not; and, (v) responses of companies to marketing efforts.

The facts concerning the nature of the market will provide the required context for the argument on reasonableness of the applicant's prior unsuccessful efforts to secure a licensee willing to comply with the Domestic Manufacturing Requirement. For example, if the pool of potential licensees is small, the technology has a high significance, there are few or no alternatives to the technology that are available, the market is large and regulatory review complicated, it will be more reasonable for an applicant to have only solicited a limited number of potential licensees. The facts setting out a history of the licensing effort will provide specific support for the arguments that the prior efforts were reasonable.

(2) Not Commercially Feasible to Manufacture on U.S. Soil

The second acceptable ground for a waiver of the Domestic Manufacturing Requirement is that manufacture on U.S. soil is not commercially feasible. In the case of Federally Funded Inventions, the licensee will typically take the lead on developing this argument and should expect to collaborate with the Awardee (usually a university or research institute, acting through their technology transfer office) who will be the government-facing party responsible for submitting the application and reporting the outcome to the manufacturer. The commercial infeasibility argument is highly dependent on the specific circumstances[16] and must be supported by robust facts illustrating a

15. *PHS Technology Transfer Policy Manual*, Ch. 604A.

16. *Id.*

wide range of potential factors. Following is the guidance from the PHS Manual concerning the information of most interest to the agencies in deciding waivers based on this ground:

a. The circumstances that make foreign manufacture necessary;
b. The state of the U.S. market for the potential product, including what companies, if any, make the same or similar products and where such products are manufactured;
c. Whether requiring U.S. manufacture will delay entry of the product into the U.S. market, and the effect such delay may have on the public health;
d. The part or percentage of products arising from the invention that would be manufactured outside the United States;
e. The U.S. manufacturing capabilities of the Awardee's licensee and the efforts made by the licensee to locate, develop, or subcontract for such U.S. manufacturing capabilities;
f. The factors making domestic manufacture not commercially feasible, including the relative costs of U.S. and foreign manufacturing, the alternative products or therapies available, and the size of the intended patient population;
g. The value or benefit to the United States of permitting foreign manufacture of the technology. Relevant facts may include: (i) the direct or indirect investment in U.S. plants or equipment resulting from foreign manufacturing; (ii) the creation of new or higher quality U.S.-based jobs; (iii) the enhancement of the U.S. skills base in the technology of the subject invention; (iv) the further development within the United States of the technology enabled by foreign manufacture; (v) a positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts; and (vi) other provisions in the exclusive license that will ensure a correlative benefit to the United States (*e.g.*, U.S. manufacture of another product).

As discussed in Part 1 of this two-part series, a supply chain map and/or manufacturing flow diagram is an important aid to developing these points of argument and sharpening the focus on the specific factors that make U.S. manufacture not commercially feasible. Inputs may be required from a range of functions, including marketing, competitive intelligence, medical affairs and regulatory affairs (in the case of biomedical products), finance and product development, as well as supply chain and manufacturing experts.

Throughout, the waiver argument should emphasize the potential value or benefit to the United States of permitting foreign manufacture. This may include an assessment of whether the U.S. will realize a public health benefit more quickly because foreign manufacture enabled a faster path to licensure of the product. Alternatively, permitting foreign manufacture of products based on the Federal Invention may enable the developer to invest in other U.S.-based plants, facilities or equipment—for other products or product lines of greater strategic or other potential value. Every waiver argument should address a central policy of the Bayh-Dole Act: would granting the waiver result in the creation of new or higher quality U.S. jobs (*e.g.*, by allowing the contractor to focus on creating more jobs in its core business)? Overall, would the waiver result in an enhancement of the U.S. workforce skills base in the technology (*e.g.*, through collaboration with the experts in the foreign plant)? Finally, if relevant, applicants should describe what effect the waiver would have on the United States balance of trade (*e.g.*, would it enable increased exports of products or services, or yield enhanced licensing revenues coming into the U.S.?).[17]

If feasible, the waiver rationales and other supporting documents that an applicant uploads to iEdison or otherwise provides to the agency should assert both grounds for a waiver.[18] This should increase the likelihood that the agency will approve the waiver. Finally, the applicant should include a brief discussion of any prior waivers granted to it since a reviewer may find such precedent to be helpful in supporting a new waiver grant.

c. What to Expect from the Waiver Application Review Process—Insights from the "Tuesday Licensing Forum"

Since one of the largest funders of research in the United States is the National Institutes of Health, we focus on NIH policy and practices concerning review of applications for waivers of the Bayh-Dole Act Domestic Manufacturing Requirement, as these are germane to Federal Inventions in the field of biomedical research. As noted above, other U.S. agencies may follow different practices; counsel should investigate available information concerning the practices of specific agencies. For NIH, valuable guidance is set out in the *PHS Technology Transfer Manual*, and additional insights summarized below have been gleaned from topics discussed during meetings of the Tuesday Licensing Forum, a venue for peer-to-peer education of technology transfer professionals hosted by the Federal Laboratories Consortium (FLC | Home (*federallabs.org*)).[19]

17. For a good overview of waiver arguments, see "Applying for a Waiver from U.S. Manufacturing Requirements for Federally Funded Intellectual Property," Gadhia *et al.*, "Life Sciences Law & Industry Report," 09 *LSLR* 980, 08/21/2015, available from Bloomberg BNA.

18. *Id.*

19. Based upon notes of the Tuesday Licensing Forum discussions of 2 August 2022 and 10 January 2023.

(1) General

- A waiver application will not be considered until sufficient information, as determined by the reviewing agency, is provided by the applicant.
- Specifics of the manufacturing process and the supply chain should be included.
- The agency may defer consideration until the site of proposed manufacture for the U.S. commercial market is known: NIH will not grant a general or blanket waiver.
- Applicants should expect an NIH waiver to specify the exact facility in which manufacture will take place; in the case of a complex supply chain, it is important to cover all facilities in which manufacturing operations will be carried out.
- One factor critical to success of a waiver application is whether the facility or facilities under consideration have been inspected by the U.S. Food and Drug Administration ("FDA") and have been approved for the manufacture of human pharmaceutical products.
- Another influential factor is whether the facility is owned by the developer or a contract manufacturing organization ("CMO"). In the case of a CMO, the applicant should expect to explain what makes an ex-U.S. CMO necessary—is there no CMO on U.S. soil that can provide appropriate manufacturing services? An existing, ex-U.S., developer-owned facility may be considered more favorably than an ex-U.S. CMO, especially if the waiver application describes the circumstances and worker skill sets that make that facility well-suited to serving the U.S. market for the product, assuming of course that the facility is FDA-approved.
- The country in which a facility is situated will also have an influence on whether a waiver is granted; for example, the Department of Energy currently disfavors the grant of waivers for manufacture in China.

(2) Review of Grounds for a Waiver Based on Reasonable but Unsuccessful Efforts to License to a U.S. Manufacturer

For submissions based on the first ground, *i.e.*, that reasonable efforts were expended to secure a licensee willing to manufacture on U.S. soil, but these efforts were unsuccessful, applicants should expect to meet a high threshold of evidence. The agency will evaluate reasonableness of the effort made, including whether inducements or more favorable terms were offered to U.S.-based manufacturers. Documentation should be provided showing the number of potential licensees who were contacted, over what period of time, the level of interest expressed by potential licensees, an explanation of any special inducements or more favorable terms offered to U.S.-based licensees, and any other factors showing futility of continuing efforts to identify a developer willing to manufacture on U.S. soil.

(3) Review of Grounds for a Waiver Based on Commercial Infeasibility

Waivers applications based on the second ground, *i.e.*, that manufacture in the United States is not commercially feasible, may be reviewed more favorably where the licensee/developer would have to invest in building new manufacturing capacity, but has an appropriate existing facility abroad. NIH reviewers understand the magnitude of investment required for constructing a new biopharmaceutical manufacturing plant and securing FDA and other approvals for operational readiness, including hiring and training of the necessary skilled manufacturing work force. This factor will be weighed against the benefit of an earlier product introduction into the U.S. market, with corresponding benefits to public health, if the waiver is granted. The same is not necessarily true for an applicant who plans to out-source manufacturing to a CMO: expect to show that the entire U.S. industry of CMOs lacks the capacity and/or functionality required for manufacture of the product. An argument solely based on cost-effectiveness of ex-U.S. manufacture by a CMO may not be well received.

In all applications—involving either or both of the eligible grounds for issue of a waiver - the application must address the question of how and to what extent granting the waiver will enhance U.S. jobs and/or job quality, since this is a key policy driver of the Bayh-Dole Act. As discussed above, the benefit may arise directly from the product that embodies the Federal Invention, or it may be a collateral benefit arising from investments in other products or other capabilities that entail creation of skilled jobs (preferably but not necessarily in manufacturing) in the United States.

In summary, a waiver of the DMR is likely to be restricted to the sites and activities set out in the application and should run for the commercial lifetime of the product. It is important to bear in mind there is no well-established process for updating, correcting, or amending a waiver that has been granted. If a supplemental waiver is required, for example, to cover an alternate manufacturing site (such as a contingent or backup site, a second site, or a successor site), applicants should expect that a more stringent review process will apply, since the reviewing agency may question why any new site could not have been planned and constructed in the United States, especially if several years have passed since an original waiver was granted.

Finally, developers of Federal Inventions, including waiver recipients (and as applicable, their licensee-developer partners) should understand that the Act re-

quires ongoing government oversight. The portal on iEdison includes a template for submission of annual invention utilization reports; it is worth browsing this to understand what information is collected concerning compliance with the DMR.[20]

d. What if a Waiver is Denied?

The grant or denial of a manufacturing waiver is within the discretion of the reviewing federal agency. While the Bayh-Dole Act and its implementing regulations do not address the circumstance where an agency simply does not respond to a waiver application, the implementing regulations do provide some guidance for applicants whose waiver applications are denied. In particular, the regulations provide that each agency must establish and publish procedures under which denial of a waiver application "may be appealed to the head of the agency or designee."[21] While there appear to be no known publicly available examples, a further appeal from an adverse decision of the agency head might proceed via a claim filed against the federal agency under the Administrative Procedures Act ("APA").[22] Not all federal agency actions can be appealed under the APA, so the availability of this remedy requires careful analysis. If available, this path would require that the denied applicant file suit against the reviewing agency in a federal district court of competent jurisdiction. The claim would be reviewed for whether the agency acted in a manner that was arbitrary, capricious, or otherwise constituted an abuse of its discretion. Under the APA, the reviewing court must "(1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in [certain cases] or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court."[23]

e. Penalty for Failure to Comply

Concerning products embodying Federally Funded Inventions, 35 U.S.C. 203 provides the applicable penalty for failure to comply with the Bayh-Dole Act's Domestic Manufacturing Requirement: the federal agency may exercise its march-in rights. More specifically, Section 203 provides that the cognizant federal agency shall have the right to require the contractor, assignee, or exclusive licensee to grant a license to a responsible applicant, upon terms that are reasonable under the circumstances, and if the contractor refuses to grant such license itself, the agency may do so if it determines that such action is necessary because a waiver has not been obtained, or the developer is in breach of its waiver. Implementing regulations are found at 37 C.F.R. 401.14(j). Concerning products embodying Federally Owned Inventions, 35 U.S.C. 209 provides for renovation of the license for failure to comply with the DMR. Implementing regulations are found at 37 C.F.R. 404.5. The Act and its implementing regulations (cited above) robustly address the appeals process for an exercise of march-in rights.[24] While the exercise, or even attempted exercise, of march-in rights does not directly entail the imposition of a financial penalty on the developer, it can critically impair the developer's financial and commercial outlook for the affected product and perhaps for its overall business viability.

There are, however, other potential consequences of failure to secure a manufacturing waiver, or for breach of an existing waiver—and these include potential exposure to significant fines and money damages. For example, the False Claims Act[25] ("FCA") provides that each invoice submitted by a contractor to the government is an implied certification that the submitting party has complied with all applicable material federal government laws and regulatory requirements.[26] In the case of a contractor seeking payment by the government for products that embody a Federal Invention, this would include certification that the purchased product was manufactured in compliance with all requirements of the Bayh-Dole Act, including the DMR. Each such

20. *https://www.nist.gov/iedison/iedison-organization-user-guide/utilization-reports/creating-utilization-report.* The template includes specific questions on whether exclusive licenses include a clause stating the Domestic Manufacturing Requirement, and whether all products commercialized under such licenses comply with the DMR. These appear to reflect implementation of the Executive Order issued on July 28, 2023 (*https://www.whitehouse.gov/briefing-room/presidential-actions/2023/07/28/executive-order-on-federal-research-and-development-in-support-of-domestic-manufacturing-and-united-states-jobs/*).

21. 37 C.F.R. 401.11(b). Detailed review of jurisdictional and procedural issues involved with such appeals is beyond the scope of this article.

22. For further discussion of the APA, see Congressional Research Service Report No. LSB10558.

23. 5 U.S.C. § 706.

24. See 37 C.F.R. 401.6.

25. 31 U.S.C. § 3729 – False Claims. See also *https://www.law.cornell.edu/wex/false_claims_act* and *https://www.justice.gov/civil/false-claims-act.*

26. See *Universal Health Servs. v. United States*, 579 U.S. 176, 190 (2016).

invoice could represent a separate FCA violation. It is important for counsel advising business executives to explain fully the risk environment in which decisions are made concerning compliance with the DMR.

4. Conclusion

Compliance with the Domestic Manufacturing Requirement of the Bayh-Dole Act is an important requirement affecting licenses of inventions made through the investment of U.S. taxpayer funds, throughout the licensing process from due diligence to ongoing compliance with the parties' obligations, lasting throughout the commercial lifetime of the corresponding products. It is critical that counsel as well as business negotiators understand the implications of the DMR for consequential investments in the relevant products, including the construction and/or enhancement of manufacturing facilities in the United States and globally. This is also the case in mergers and acquisitions of businesses that have acquired license rights to Federal Inventions. The investigation of whether a waiver of the DMR is required is a highly fact-specific endeavor that must be undertaken with a wholistic view of the entire supply chain and manufacturing process for products that embody or are made through the use of Federal Inventions. If a decision is made to pursue a waiver, the applicant should develop and submit granular and robust grounds for the request. We expect continued government scrutiny and focus on strategies to promote U.S. manufacturing competencies and capabilities as an important aspect of national security and U.S. strategic leadership in innovative industries. ■

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