The U.S. Domestic Manufacturing Requirement Of The Bayh-Dole Act: An Interpretative Approach And Analysis

*By Gillian M. Fenton and Christopher C. Bouquet**

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 the licensing 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." Unfortunately, the plain language of the Act and its implementing regulations does not provide any definition or other guidance on what if any threshold should be exceeded in order for manufacturing to be deemed "substantially in the United States." Further, the legislative history is only minimally helpful in the interpretation of the language and, as of the writing of this article, there are no published decisions providing guidance on the proper interpretation of this language. This article proposes that, in the absence of a specific binding statutory regulatory or judicial definition, it is appropriate to look to analogous U.S. government acquisition statutes and their implementing regulations for a workable definition.

1. Introduction

This is the first of two articles concerning the "Domestic Manufacturing Requirement," which is codified at 35 U.S.C. § 204. Here we present 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. While the analysis given below is applicable generally across diverse fields of research and industry, we use federal funding of biomedical research and the development of a novel vaccine or biopharmaceutical as a relevant example. In our second article, we will present the process, current framework, and practice tips for seeking a waiver of the Domestic Manufacturing Requirement from the cognizant U.S. federal funding agency.

Both topics that we address are of particular concern to funding recipients and their licensee partners, who need to understand how the requirement may affect strategic decisions on how to structure their manufacturing operations and supply chains for innovative products years after the receipt and utilization of U.S. research funding. These decisions in turn may implicate very significant investments made by licensees and the risk environment in which such decisions are made. The complications and impacts have grown more significant over the 40-plus years since Bayh-Dole was enacted, as the global economy has emerged and become increasingly interconnected and interdependent.

■ Gillian M. Fenton, Special Counsel, Innovation and Government Collaborations, Vaccines Legal Operations, GSK Vaccines, Rockville Center for Vaccine Research, Rockville, MD USA
E-mail: gillian@gillianfenton.com

■ Christopher C. Bouquet, Managing Member, Law Office of Christopher C. Bouquet, PLLC, Alexandria, VA USA
E-mail: cbouquet@bouquetlawoffice.com

2. Background

Prior to 1980, the U.S. government took title to inventions made by the government or by private-sector organizations in the performance of work under grants and other types of government agreements ("Subject Inventions"). Thus, awardees of these agreements ("Awardees") did not have the right to commercialize the inventions made during the course of their work. However, the government was not effective in out-licensing these inventions to industry. Prior to the enactment of Bayh-Dole less than 4 percent of inventions made by government employees or made by the private sector through the use of government funding were licensed to industry for commercial use.[2] As a result, while the government had full use of these inventions for its purposes, their potential to benefit the commercial marketplace and society in general was woefully under realized: the taxpayers were not getting the most "bang for their bucks" invested in federal research and

**The views expressed in this article are those of the author alone and do not reflect the positions or policies of GSK. This article is for education purposes only and does not constitute legal advice.*

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. Payne, Eric. 2023. "The Critical Importance of the Bayh-Dole Act in the U.S. Energy Transition." *les Nouvelles*. September 2023.

development. Without a clear path to securing commercialization rights, innovative organizations were reluctant to incur the opportunity costs associated with accepting government funding. The enactment of Bayh-Dole in 1980 redressed these deficiencies. Understanding the Act and its implications is therefore essential to development and commercialization of products based on government owned or funded inventions.

Bayh-Dole and its implementing regulations gave Awardees a path to securing title to Subject Inventions made by the Awardees in the course of performing work under their agreements with the government (*e.g.*, for research, development, procurement, and/or services). For convenience, we will refer to this type of invention hereafter as a "Federally Funded Invention." In order to retain title to a Federally Funded Invention, the Awardee must timely disclose the invention to the government, formally elect to retain title, file a patent application strictly in accordance with the detailed procedures and deadlines set forth in a standardized clause, and subsequently report any decisions not to continue with patent prosecutions in the United States and around the world.[3] Failure to comply with these procedures and deadlines can lead the Awardee to lose title to the invention, which then reverts to the government. These requirements attach for the life of the patent rights, even after performance is completed under the grant or other government agreement. An important point in due diligence investigations for transactions involving Federally Funded Inventions is therefore to verify that the Awardee has timely and properly secured title and remains in compliance with the requirements.

Bayh-Dole and its implementing regulations also include provisions outlining a clear path for the out-licensing of inventions made by government employees in the course of their work (such as investigators at the National Institutes of Health), or Subject Inventions to which the government has obtained title because the Awardee elected not to retain title or due to error or omission of an Awardee to properly elect to retain title. For convenience, we will refer to this type of invention as "Federally Owned Inventions." Upon making a determination that licensing a Federally Owned Invention is in the public interest and obtaining the prospective licensee's commitment to achieve practical application of the invention within a reasonable time, the government may enter into non-exclusive, exclusive or partially exclusive licenses for such inventions under specified terms and conditions. For convenience, where the Act imposes consistent restrictions or requirements on the licensing and commercial development of both Federally Funded and Federally Owned Inventions, we will refer to them collectively as Federal Inventions. We will also point out where the Act and/or its implementing regulations distinguish between these two categories.[4]

One of the required conditions for licensing Federal Inventions is that the Bayh-Dole Act bestows on the government a nonexclusive, nontransferable, irrevocable, paid-up license to practice any Federal Invention or to have it practiced for or on behalf of the United States. This so-called government use license runs with the technology and binds any original or successor licensee throughout the commercial life cycle of products and/or services based on the Federal Invention.[5] All transactions in the nature of licenses or asset transfers, even those that are otherwise of exclusive rights, are subject to the ongoing, irrevocable rights of the government.[6] The Act does not define the intended scope of the government use license, but it is generally understood to embrace government research, development, education, manufacture, procurement of products and services, and in some instances incorporation into standards or other requirements of the government. It does not extend to uses for commercial purposes.[7]

Another requirement, which reflects Bayh-Dole's original policy objective to promote innovation in the United States, is that all Federal Inventions that are licensed to private sector entities should benefit U.S. industry, specifically by being 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,[8] and to *all* license grants (non-exclusive and partially exclusive as well as exclusive) of commercial rights in Federally Owned Inventions.[9] In particular, the Act requires that such licenses provide that any products "embodying" the invention or "produced through the use of" the invention "will be manufactured substantially in the United States."[10] These manufacturing provisions of the

3. 37 C.F.R. § 401.14, Standard Patent Rights Clauses.

4. At least one funding agency, the U.S. National Institutes of Health (NIH) refers to Federally Funded Inventions as "extramural inventions" and Federally Owned Inventions as "intramural inventions." Other agencies may use different nomenclature.

5. *University of South Florida Board of Trustees v. United States*, 2024 WL 500636 (Fed. Cir. February 9, 2024) (establishing that the government may assert the government use license as a defense to patent infringement suits).

6. *Ibid.* This government right and exception to licensing exclusivity needs to be understood by licensees and their legal advisors.

7. See Susan B. Cassidy, Alexander B. Hastings, and Jennifer L. Plitsch, "What Every Company Should Know about IP Rights When Selling to the U.S. Government," 9 *Landslide* 6 (July/August 2017).

8. 35 U.S.C. 204.

9. 35 U.S.C. 209.

10. 35 U.S.C. 204 and 209.

Act, which remain applicable through all tiers of sublicensing or transfer of license rights for the commercial lifetime of the corresponding products, are referred to collectively as the "Domestic Manufacturing Requirement" ("DMR") and will be the primary focus of this article. Recently, the DMR has taken on a renewed prominence in national policy priorities, as reflected in the issue of an Executive Order by President Biden in mid-2023.[11] Readers should expect further developments and a focus on promotion of U.S. manufacturing for at least the remainder of the Biden Administration.

Bayh-Dole empowers the government with certain rights to enforce compliance with the DMR. For Federally Owned Inventions, the government may modify or revoke a license if its licensee (or the exclusive licensee of an Awardee) breaches the DMR.[12] For Federally Funded Inventions, failure to comply with this requirement is one of four reasons set out in the Act for which the government may exercise so-called march-in rights.[13] In a march-in situation, the government may direct an Awardee or licensee to grant a license to the invention to a third party, or may itself grant such a third party license, notwithstanding the Awardee's ownership or the existence of prior license rights.[14] The potential jeopardy to commercial licensing transactions, coupled with the complexity and expense of manufacturing on an industrial scale, underscore the importance for licensees to understand and comply with the Act's Domestic Manufacturing Requirement.[15]

This article, along with our companion article, collectively provide a guide to navigating the obligations and mitigation strategies for the Domestic Manufacturing Requirement. This requirement, originally conceived more than 40 years ago, can be a challenge for organizations engaged in commercializing highly complex technologies in our current, globally interconnected economy. It is not uncommon that a global supply chain is required to commercialize a Federal Invention. Thankfully, the Act and its implementing regulations also provide that the DMR may be waived in certain circumstances.[16] In this article, we will analyze the meaning and applicability of the DMR. Our second article will focus on the requirements for securing waivers, as well as what to expect in a waiver grant. We turn now to the question of how to interpret the DMR.

3. How to Determine Whether a Waiver is Necessary

a. The Meaning of "Manufactured Substantially in the United States"

The first step in analyzing the requirements for compliance with the Domestic Manufacturing Requirement is to determine whether the invention will be "manufactured substantially in the United States." If so, then a waiver is not necessary. If not, then a waiver is necessary if the invention is a Federally Funded Invention that will be exclusively licensed in the U.S. or if the invention is a Federally Owned Invention. If the invention is a Federally Funded Invention that will be manufactured by the Awardee and/or not exclusively licensed in the U.S., no waiver is necessary. This is an easy question to answer if the "manufacturing" takes place in a single facility—it is either in the U.S. or it is not. It is an entirely different and more complex question if instead the "manufacturing" requires multiple processes that are carried out at multiple facilities located in different geographies across the world—that is, a global supply chain.

11. See "Executive Order No. 14104 on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs | The White House," 88 Fed. Reg. 51203 (July 23, 2023). The E.O. is being implemented in part through the development of a new Common Form for applications for a waiver of the DMR; see "Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Domestic Manufacturing Waiver Request Form" 88 Fed. Reg. 85243 (December 7, 2023). Practitioners should monitor the Federal Register and their cognizant funding agencies for additional implementing actions.

12. 37 C.F.R. § 404.5.

13. The four sets of circumstances in which "march-in" may occur are: (1) the Awardee has not taken effective steps to achieve practical application of the Subject Invention within a reasonable time; (2) such action is necessary to meet health and safety needs that the Awardee is not meeting; (3) such action is necessary to meet applicable requirements for public use that the Awardee is not meeting; and (4) the Awardee has not bound its exclusive licensee to manufacture products based on the Subject Invention substantially in the United States, or the exclusive licensee is in breach of this requirement. On December 8, 2023, the National Institute of Standards and Technology (NIST) published a Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (88 F.R. 85593). For purposes of this article, we will address the RFI only as it relates to the Domestic Manufacturing Requirement.

14. A license granted or directed to be granted pursuant to march-in is of course separate from and in addition to the government use license, see note 7.

15. 37 C.F.R. § 401.14. Note, the exercise of march-in rights is the exclusive remedy available to the government to enforce compliance with the DMR.

16. Our focus is 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" or "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.*

To assess the more complex questions, we need to interpret the statute. The first step in construing any statute is to determine whether its language has a plain and unambiguous meaning.[17] Unfortunately, neither the Act, the main implementing regulations promulgated by the National Institute of Standards and Technology (NIST), nor agency-specific regulations[18] define what is meant by "manufactured substantially in the United States." The focus of analysis is on the word "substantially"—for which the ordinary meaning is "considerable in importance, value, degree, amount or extent."[19] However, the plain English definition of this term lacks the precision needed to support business and legal decisions as consequential as whether a waiver of the Domestic Manufacturing Requirement is needed for a specific Federal Invention under consideration. Indeed, the language of the Act does not indicate whether this analysis should be based on the number or geographic location of components, manufacturing steps, or another metric, such as cost or value. Similarly, the Act does not provide any definition or other guidance on what if any threshold should be exceeded in order for manufacturing to be deemed "substantially in the United States." If the plain English meaning as specified in dictionaries is insufficient to interpret a statute, it becomes necessary to look at its legislative history.[20] Hence we next review the legislative history of the Bayh-Dole Act.

(1) Legislative History

The legislative history of the Act provides some limited insight into Congress's intent in enacting it. The Senate Judiciary Report on the requirements for Federally Funded Inventions states as follows:

> Section 205. Preference for United States Industry.
>
> Section 205 provides that persons receiving an exclusive license to use or sell a subject invention in the United States must agree to manufacture any products embodying the invention substantially in the United States. Agency approval is required to dispense with this requirement. This section 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.[21]

Based on this history, it appears that Congress wanted agencies to interpret the Domestic Manufacturing Requirement in a manner that maximizes the probability of creating American jobs through the commercialization of the inventions. Thus, the interpretation of "manufactured substantially in the United States" that creates the most United States jobs should be favored over alternative interpretations. It is also clear that the Act prioritizes manufacturing jobs over other types of jobs, such as research and development, distribution, and sales, etc. While this provides some limited help in assessing different approaches, it does not provide much help in fleshing-out a specific workable definition of the term "substantially."[22] Nor have any court decisions construing this term in the Bayh-Dole Act been issued as of this writing. In the absence of a specific binding statutory regulatory or judicial definition, it is appropriate to look to analogous U.S. government acquisition statutes and their implementing regulations for guidance. We have identified two such acquisition statutes, discussed below.

(2) Analogous Acquisition Provisions

Trade Agreements Act Clause. The first analogous acquisition provision is found in the regulations that implement the Trade Agreements Act (TAA)[23] on federal acquisitions. The TAA authorizes the president to waive discriminatory purchasing requirements with respect to countries that (i) become parties to the World Trade Organization Government Procurement Agreement (WTO GPA) and (ii) provide appropriate reciprocal competitive government procurement opportunities to U.S. end products and suppliers of such products.[24] Under the definitions set forth in the TAA, for purposes of determining whether an end product is made in a country that is a signatory to the WTO GPA, an article is considered an end product of a country if (i) "it is wholly the growth, product, or manufacture of that country" or (ii) in the case of an article that consists in whole or in part of materials from another country, it has been substantially transformed in that country

17. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997).

18. NASA previously had a definition at 14 C.F.R. § 1274.911 but it was removed from the Code of Federal Regulations. See 85 Fed. Reg. 72919-01 (November 20, 2020).

19. American Heritage Dictionary, at *https://www.ahdictionary.com/word/search.html?q=substantial* (accessed on January 18, 2024).

20. *Connecticut National Bank v. Germain*, 503 U.S. 249, 253-254 (1992).

21. Senate Judiciary Report on S.414, accessed on September 5, 2023 at *https://bayhdolecoalition.org/wp-content/uploads/2023/05/S-414-Senate-Judiciary-Committee-Report.pdf.*

22. This issue is also not addressed in the recent related NIST Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, see 88 F.R. 85593 (December 8, 2023).

23. 19 U.S.C. § 2518(4)(B).

24. Office of the United States Trade Representative, "Government Procurement," accessed on November 28, 2023 at *https://ustr.gov/issue-areas/government-procurement#:~:text=The%20Trade%20Agreements%20Act%20of,appropriate%20reciprocal%20competitive%20government%20procurement.*

into a new and different article of commerce.[25] Federal Acquisition Regulation (FAR) 52.225-5, Trade Agreements, implements this statute. It requires that, in certain acquisitions the contractor may deliver either "U.S. made" or "designated country end products." However, whereas under the statute, a U.S. made end product has to be "wholly" made or substantially transformed in the U.S., under the FAR a "U.S.-made end product" means an "article that is [1]…manufactured in the United States or [2] that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed."[26] There is no requirement that the article be "wholly" manufactured in the U.S. This is referred to as the "FAR TAA Test." The regulatory history makes clear that "U.S.-made end products" are "products that are manufactured or substantially transformed in the United States, *regardless of the source of the components*" (emphasis added).[27]

The case of *Acetris Health, LLC v. United States*[28] involved an offer submitted in response to a Department of Veteran's Affairs (DVA) solicitation for pharmaceutical tablets to treat hepatitis B. While the active pharmaceutical ingredient (API) for the offered tablets was made in India, the weighing, mixing, and compounding involved in formulating the API into final tablet form was performed in New Jersey. The DVA ruled that the offeror was ineligible for award of a contract because the manufacturing process for the tablets did not meet the FAR TAA Test and the offeror appealed. On appeal, the government argued that the FAR TAA Test impermissibly varied from the test in the TAA statute itself.[29] Based on the statutory test, the government argued that the tablets were not U.S.-made end products because they were not wholly manufactured in the U.S. and the offeror's activities in the U.S. (formulating an imported drug into tablets) did not rise to the level of "substantial transformation." However, the court held that the FAR Council[30] had authority to promulgate a test that varied from the statutory test and that, under that test, as long as the end product is "manufactured" in the U.S., regardless of the source of its components, it is a U.S.-made end product. Based on Supreme Court precedent interpreting the meaning of the term "manufacturing" in an old customs statute, the *Acetris* court indicated that a product is "manufactured" for purposes of the FAR TAA Test if "a new article is produced of which the imported material constitutes an ingredient or part." Further, the court held that the formulating activities for the tablets in New Jersey qualified as "manufacturing," regardless of whether these activities rose to the level of "substantial transformation." Finally, the court noted that the "products may very well be [also] substantially transformed in the United States, but we need not decide this question here."

Thus, if the FAR TAA Test were adopted as a definition of "manufactured substantially in the United States" under the Bayh-Dole Act, any products embodying the pertinent invention or produced through the use of the invention would have to be either (1) manufactured in the United States or (2) substantially transformed in the United States into a new and different article of commerce. However, the first prong of the test only assesses whether the product is "manufactured" in the United States to some degree or extent. It does not assess whether or not the manufacture in the United States was "substantial" for purposes of the Bayh-Dole Act DMR—*i.e.*, whether it was "considerable in importance, value, degree, amount or extent"[31] in relation to the total manufacturing process for the tablets. For example, in the *Acetris* case, the first prong does not assess whether, in relation to the manufacturing activities for the imported API abroad, the formulating that was performed in the United States was considerable in importance, value, degree, amount or extent. Turning to the alternative "substantial transformation" prong under the FAR TAA Test, this "does not require some minimum quantum of manufacturing or assembly to be performed"[32] and therefore also fails to assess whether the manufacturing in the United States was substantial. Thus, even if the tablets in *Acetris* were substantially transformed in New Jersey into a new and different article, it would be quite difficult for an agency applying Bayh-Dole to determine whether the U.S. manufacturing processes were substantial in relation to the processes that occurred in India. As such, the FAR TAA Test

25. 19 U.S.C. § 2518(4)(B).

26. FAR 52.225-5, Trade Agreements.

27. Federal Acquisition Regulation; Foreign Acquisition (Part 25 Rewrite), 63 Fed. Reg. 51642 (Sept. 28, 1998) (emphasis added). We note that the word "substantially" also appears in the TAA and in the FAR TAA Test, which underscores ambiguities that must be traversed when faced with a need to determine with precision whether the test is satisfied or not.

28. 949 F.3d 719 (Fed. Cir. 2020).

29. 19 U.S.C. § 2518(4)(B).

30. The Federal Acquisition Regulatory Council provides "direction and coordination of Government-wide procurement policy and Government-wide procurement regulatory activities in the Federal Government." See *https://www.acquisition.gov/far-council.*

31. *American Heritage Dictionary*, at *https://www.ahdictionary.com/word/search.html?q=substantial* (accessed on January 18, 2024).

32. John M. Peterson, "Substantial Transformation—The Worst Rule For Determining Origin Of Goods—Except For All the Rest" at *https://www.cit.uscourts.gov/sites/cit/files/Substantial%20Transformation.pdf.*

fails to provide a workable definition of "manufactured substantially in the United States" for purposes of the Bayh-Dole Act.

Buy American Act Clause. The second analogous legal test, also in the FAR, implements the Buy American Act (BAA), which requires that in certain acquisitions, agencies must procure only items "that have been manufactured in the United States *substantially* all from articles, materials, or supplies mined, produced, or manufactured in the United States," unless the agency grants a waiver (emphasis added).[33] These items are referred to in the FAR implementing regulations as "domestic end products." Under FAR 25.003, the term "end product" means "those articles, materials, and supplies" acquired by the government for public use. Following are applicable definitions of various types of "domestic end products":

- For end products that do not consist wholly or predominately of iron or steel or a combination of both, a domestic end product is "an unmanufactured end product mined or produced in the United States" and certain end products manufactured in the United States. End products manufactured in the United States are domestic end products if the cost of their "components mined, produced, or manufactured in the United States exceeds 65 percent of the cost of all its components."[34]
- For end products that consist wholly or predominately of iron/steel, a domestic end product is an end product [i] manufactured in the United States, if [ii] the cost of foreign iron or steel constitutes less than 5 percent of the cost of all components used in the end product.
- These requirements for the domestic content of the end products are referred to as the "Component Tests."[35]

Thus, the test required by the BAA (the "BAA Test") requires both manufacturing of the end product in the U.S. and the satisfaction of the applicable Component Test. The Comptroller General of the United States has held that, under the BAA, the term "manufacture" means:

[C]ompletion of an article in the form required for use by the government. Manufacturing may include a mechanical operation performed on a foreign product or assembly of separate items, whereby the identity and character of the end item is established and fixed as to its current and future use. Thus, the key in determining whether a process constitutes manufacturing for [BAA] purposes is whether the item being purchased by the government is made suitable for its intended use and its identity established.

Packaging is not considered manufacturing under the BAA.[36]

For the following reasons, unlike the FAR TAA Test, the BAA Test provides a workable definition of the term "manufactured substantially in the United States" under the Bayh-Dole Act:

- The BAA Test precisely defines manufacturing as the place where the product is made suitable for its intended use.
- The Component Test addresses the "substantiality" requirement of the Act's Domestic Manufacturing Requirement. If the cost of components manufactured in the United States do not meet the specified percentage of the total cost of all components, then the product would not be considered as manufactured substantially in the United States.
- The United States component manufacturing requirements of the BAA Test likely would result in the creation of more United States jobs than the FAR TAA Test. Therefore, the BAA Test is aligned with Congressional intent as expressed in the legislative history of the Bayh-Dole Act.

Therefore, under the Bayh-Dole Act, products embodying the Federal Invention or produced through its use should be considered to be "manufactured substantially in the United States" if the products (1) are manufactured in the United States under the Comptroller General's definition (*i.e.*, they are made suitable for their intended use) and (2) meet the applicable Component Test.[37] It should be noted that, while we have expressed a view on how to assess compliance with Bayh-Dole's requirement for manufacture "substantially in the United States," there is still no directly applica-

33. 41 U.S.C. § 8302.

34. FAR 52.225-1, Buy American-Supplies (Oct 2022). The percentage is set at 65% for 2024 through 2028 and escalates to 75% starting in calendar year 2029.

35. For purposes of BAA compliance, all commercial off the shelf ("COTS") items manufactured in the United States that meet the definition in FAR 2.101 are domestic end products regardless of the Component Test. FAR 52.225-1 defines a COTS item as any item of supply that is (i) a "commercial product" as defined in FAR 2.101; (ii) sold in substantial quantities in the commercial marketplace; and (iii) offered to the government without modification in the same form in which it is sold in the commercial marketplace. While compliance with the Component Test is not required for such items in an acquisition context, it could be required for COTS items under Bayh-Dole for the purpose of the DMR, to assess the "substantiality" of manufacture in the U.S. This is a novel question that is not easily answered by the statute, its implementing regulations, or legislative history and in the absence of court decisions.

36. *Dynamerica, Inc.*, B-248237 (Sept. 28, 1992) (citations omitted).

37. The exemption for COTS items under the BAA Test is specific to the BAA and may not apply to determinations of substantial manufacturing under the Bayh-Dole Act.

ble precedent or regulatory or statutory guidance on this topic. In light of the complex technologies and/or complex products that are subject to the Bayh-Dole Act, we believe that it is important to document the details of the approach that is utilized for making this analysis and, if there is any question about whether aspects of the approach comply with the Act or the approach varies from the BAA Test, to proactively address the situation with the agency, especially since different potential approaches can yield different results. This is particularly important where a commercial developer/licensee has reasonably concluded that a product that is subject to the Act is indeed manufactured "substantially in the United States" despite having some imported components and/or some manufacturing steps carried out outside of the U.S., such that a waiver of the Domestic Manufacturing Requirement is not necessary and therefore is not sought from the funding agency. Depending on the degree of uncertainty in the analysis, it may be prudent to apply for a waiver nonetheless so that the funding agency may issue a decision affirming that a waiver is not required.

b. Determining Whether Products Embodying or Produced Through Use of the Federal Invention Will be Substantially Manufactured in the United States

Having established a workable definition of "manufactured substantially in the United States" we now come to the next question—exactly what subject matter is "in scope" of the required analysis of the Domestic Manufacturing Requirement? The Bayh-Dole Act regulates manufacturing activities related to Federal Inventions including both Federally Funded Inventions and Federally Owned Inventions. Conceptually, while the invention is the hook through which the Act becomes applicable, the law requires that the analysis encompass the place(s) of manufacturing of the components and the final manufacturing activities for the end product that "embodies" the invention or is "produced through the use of the invention." It is not a valid approach to isolate the place of manufacturing of the portion of a product that most closely relates to the invention, such as, in the case of a pharmaceutical product, an active pharmaceutical ingredient. Rather, the source materials and place(s) of manufacture of the end product must be considered in a wholistic manner: the entire manufacturing process must be considered end-to-end, starting from raw material inputs and culminating in the finished product ready for end-use.

However, as noted above, for Federally Funded Inventions, the Act's DMR only applies to exclusive licenses to use or sell products based on the inventions in the United States.[38] A threshold question is therefore: is the product covered by a license that includes rights for the U.S. market? And does the license confer exclusive rights to commercialize in the United States? If not, the DMR will not apply. However, given the state of worldwide markets for pharmaceuticals and other advanced technologies, the U.S. is frequently a key market driving the value of biomedical license transactions.

There are also important differences in the timing for when a commercial developer of a product must undertake analysis of the DMR: if, for a Federally Owned Invention, the time horizon from the licensing transaction to commercialization is short, a waiver of the requirement may need to be negotiated for and included up front in the license agreement between the agency and the licensee. As a practical matter, this is only done if the commercial developer can articulate plans to serve the U.S. commercial market at the time the license is negotiated. Alternatively, if the commercialization horizon is long, a waiver may only be sought after the license has been executed and the manufacturing process fully designed, sometimes years later. This situation is actually fairly common in the case of biopharmaceuticals (therapeutics and vaccines), as the path from initiation of development to commercial launch can take from six to seven years to 10 to more than 20 years. Given the rate of candidate failure during this lengthy development period, many developers understandably wait until a biologic product candidate has reached advanced development (Phase II clinical trials) before confronting the business question of how best to tackle commercial manufacture. Unfortunately, the lapse of time and the expertise of those usually involved in this industrial manufacturing decision can create a risk for compliance with the requirements of the Bayh-Dole Act. We recommend that in-house counsel proactively monitor the product's progress through development stage gates and assure that the analysis of whether a waiver of the DMR is required is coordinated with the development of a commercial manufacturing strategy for the U.S. market.

In the case of a complex technology or a complex product, a global supply chain is often required. Modern manufacturing is seldom a single process carried out in a single factory. Given the need, consistent with the BAA Test, to cover the entire transformative process from primary source materials to a finished product ready for end-use, it is important to consult with the corporate functions responsible for pilot, scale-up,

38. In the case of products with a lengthy development path, such as biopharmaceuticals, particularly where the manufacturing process and locations may evolve during development, manufacturers should ensure compliance with the DMR throughout the evolution of the production and manufacturing processes. This is unlike the infringement exception analysis under 35 U.S.C. § 271(e)(1) where a distinction is made between activities during development of products subject to regulatory oversight, versus commercial activities for such products.

Table 1: Component Test		
Component	**Place of Manufacture**	**Percentage of Total Costs of All Components**
Framing	United States	30%
Motor and Propellor Assembly	United States	40%
Inner Workings (*e.g.,* speed control, batteries, receiver, power distribution board, etc).	Malaysia	10%
Landing Equipment	Canada	10%
Transmitter	Taiwan	10%
	Total	**100%**

and commercial manufacturing planning and operations. Ideally, this investigation is carried out early in the planning process so as to guide decision-making for key investments and capability development. A supply chain diagram showing the end-to-end manufacturing process is an invaluable tool to support the compliance analysis as well as decision-making. Counsel should educate manufacturing strategy and logistics executives on the risks and consequences of not complying with the Domestic Manufacturing Requirement or seeking a waiver. As mentioned, failure to do so is one of the four grounds for the U.S. government to exercise march-in rights under the Act. Thus, the licensee developer is at risk of losing exclusivity of its license rights, with potentially grave consequences to its returns on investment and ability to achieve its business goals. And the investment required can be substantial: one current estimate puts the value of a new, industrial scale biologics manufacturing facility at around $150,000,000, and the lead time required from breaking ground to a production-ready, FDA approved, fully staffed facility at around four years.[39]

A well-constructed supply chain diagram will reveal whether and how much of the manufacturing process will be carried out at sites that are on U.S. soil. Then, costs of all starting materials or components can be calculated and allocated as being either U.S.-sourced or imported.[40] For example, assume that, under a research and development contract funded by the U.S. Department of Defense, an engineering firm made a Federally Funded Invention of a next generation aerial drone that will have both military and commercial logistics applications. The contractor then exclusively licenses the invention to a drone manufacturer for use and sale in the United States. As required by the FAR clause implementing the Bayh-Dole Act in government procurement contracts, the contractor includes the Domestic Manufacturing Requirement in the license agreement.[41] Thus, the drone manufacturer will have to make any products embodying the invention substantially in the United States.

The manufacturer has sites in both the United States and Canada in which it can perform the final assembly, integration and testing of the drone. To comply with the DMR, it selects the U.S. site for these operations and reflects that decision on its supply chain diagram. Therefore, as long as the manufacturer does not shift those final manufacturing operations to the Canada site, it will meet the "manufacturing in the United States" prong of the BAA Test. To ensure compliance with the Component Test, the manufacturer plots out on the supply chain diagram the places of manufacture of the components of the drones and prepares a component cost calculation. It shows the following, see Table 1.

As mentioned above, the Component Test is satisfied if the cost of the components of the drones "manufactured in the United States exceeds 65 percent of the cost of all its components." Since the cost of the components of the drones manufactured in the U.S. will be 70 percent of the total costs of the components,[42] the manufacturer has developed a manufacturing plan for the drones that satisfies the Component Test and is compliant with the DMR.

It is also important to understand whether the process being diagrammed and assessed is robust enough to handle future demand for the product: is it sufficient to serve peak markets in the U.S.? Will the same process

39. See, for example, Rathore, A.S., Shereef, F. "The influence of Domestic Manufacturing Capabilities on Biologic Pricing in Emerging Economies." *Nat Biotechnol* 37, 498–501 (2019). *https://doi.org/10.1038/s41587-019-0116-0.* For a more recent specific example, see "Pfizer Acquires Abzena's Biologic Manufacturing Facility" (*pharmanewsintel.com*).

40. This is more easily stated than achieved. Component costs as well as manufacturing costs typically undergo a lengthy period of optimization and are of course subject to efficiencies of scale, preferred supplier agreements, and many other variables.

41. See FAR 52.227-11, Patent Rights-Ownership by the Government.

42. The information in the table is illustrative only and is not based on any actual data.

be utilized for global markets? In what circumstances might it become necessary to outsource any of the manufacturing steps to contract manufacturers? Many multinational businesses regularly revisit and reevaluate their manufacturing and supply chain operations, and the decision of whether to "buy or build" a new facility or enhance an existing one can be quite significant, often reflected prominently in the financials and strategic outlook for the developer.[43] Once a decision is made, it can be quite difficult to alter, even when the consequences of failure to comply with the Act are well articulated and understood. It is therefore particularly important to educate supply chain executives that the DMR attaches for the lifetime of the product and that the manufacturing plan must be robust enough to remain in compliance throughout or, if variations become necessary, that they are implemented in a way that maintains compliance with the DMR. As explained in our companion article, even a waiver of the DMR permitting ex-U.S. manufacture may be phrased narrowly enough to restrict otherwise rational economic choices affecting product supply chains.

4. Conclusion

In this article, we have provided an interpretative analysis of the Domestic Manufacturing Requirement of the Bayh-Dole Act and a framework for analyzing whether the DMR applies to a given Federal Invention, such that a decision can be made on whether a waiver is necessary or desirable. 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 end products that embody or are made through the use of Federal Inventions. 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. Our companion article will focus on the process and practice of securing waivers of the DMR from relevant funding agencies. ■

Acknowledgements

The authors would express their gratitude to Steven M. Ferguson, CLP and Prof. Adam Mossoff for their critical evaluations and comments on the manuscript.

43. See *supra*, note 41.