



U.S. DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 230831-0207]

Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice; Request for Information (RFI).

SUMMARY: The National Institute of Standards and Technology (NIST) seeks comments on the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, which reviews the factors that an agency may consider when deciding whether to exercise march-in rights. NIST requests information from the public on the proposed version of this guidance document to ensure that it is clear, and its application will both fulfill the purpose of march-in rights and uphold the policy and objectives of the Bayh-Dole Act. The information received in response to this RFI will inform NIST and the Interagency Working Group for Bayh-Dole (IAWGBD) in developing a final framework document that may be used by an agency when making a march-in decision. NIST will hold at least one informational webinar explaining the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* and how the public can submit comments. Details about the informational webinar(s), including dates, times and any registration requirements, will be announced at <https://www.nist.gov/tpo/policy-coordination/bayh-dole-act>.

DATES: Comments must be received by 5 PM Eastern time on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to be considered. Written comments in response to the RFI should be submitted according to the instructions below. Submissions received after that date may not be considered.

ADDRESSES: Comments may be submitted by electronic submission via the Federal eRulemaking Portal.

1. Go to www.regulations.gov and enter NIST-2023-0008 in the search field
2. Click the “Comment Now!” icon, complete the required fields
3. Enter or attach your comments.

Please submit comments only and include your name and/or your organization’s name (if any) in your submission. Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials.

All submissions, including attachments and other supporting materials, will be a matter of public record. Relevant comments will generally be available on the Federal eRulemaking Portal at <https://www.Regulations.gov>. NIST will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

FOR FURTHER INFORMATION CONTACT: Mojdeh Bahar, Associate Director for Innovation and Industry Services, National Institute of Standards and Technology, 100

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SUPPLEMENTARY INFORMATION:

I. Background

The Federal Government invests approximately \$115B each year in extramural research and development at universities, non-profits, and small and large businesses.¹ This results in the creation of thousands of inventions annually. 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., commonly known as the “Bayh-Dole Act” or “Bayh-Dole,” governs these inventions made with Federal assistance. The Bayh-Dole Act outlines the rights of persons, nonprofit organizations, and small business firms (“contractors”), and, as set forth in Executive Order 12591, all contractors regardless of size and to the extent permitted by law, in “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement” (“subject invention”) as well as rights retained by the government. One such right is the funding agency’s right to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant a license itself (35 U.S.C. 203). This right, referred to as “march-in,” can only be exercised if the agency determines that:

- (1) action is necessary because the contractor or assignee has not taken,
or is not expected to take within a reasonable time, effective steps to

¹ National Center for Science and Engineering Statistics. *Survey of Federal Funds for Research and Development, 2021*. Available at: <https://nces.nsf.gov/surveys/federal-funds-research-development/2021>.

achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

NIST has been delegated responsibility by the Secretary of Commerce to promulgate regulations concerning the management and licensing of federally funded inventions. On January 4, 2021, NIST published a notice of proposed rulemaking (NPRM) in the *Federal Register* (86 FR 35)² requesting public comments on several proposed changes to the Bayh-Dole regulations at 37 CFR parts 401 and 404, including a provision related to march-in rights which stated that march-in “shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.” In connection with that provision and other proposed changes, NIST received over 81,000 public comments and

² Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 *Federal Register* 35, <https://www.federalregister.gov/d/2020-27581>

was directed through Executive Order 14036 to consider not finalizing the provision on march-in rights and product pricing in the proposed rule. In the Final Rule published in the *Federal Register* (88 FR 17730)³ on March 24, 2023, NIST did not finalize this provision but stated its intent to engage with stakeholders and agencies with the goal of developing a comprehensive framework for agencies considering the use of march-in.

NIST has been working with the IAWGBD which regularly meets to find agency consensus on policy and procedures related to the implementation of the Bayh-Dole regulations, to draft this framework. The objectives for the *Draft Interagency March-In Guidance Framework* are to:

- Provide clear guidance to an agency on the prerequisites for exercising march-in, and, if those prerequisites are met, on facts to be gathered by the agency and factors to consider in determining whether to march-in
- Ensure that decisions to exercise march-in support the policy and objectives of Bayh-Dole
- Encourage the consistent and predictable application of the Bayh-Dole Act's march-in authority
- Balance the need to incentivize industry investment in the development and commercialization of subject inventions with the need to promote public utilization of subject inventions

II. Request for Information

³ Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 88 *Federal Register* 17730, <https://www.federalregister.gov/d/2023-06033>

NIST publishes this notice to seek comments on the *Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights*, included with this RFI as Appendix A.

All responses that comply with the requirements listed in the DATES and ADDRESSES sections of this RFI will be considered.

The following list of topics covers the major areas about which NIST seeks information. The listed areas are not intended to limit the topics that may be addressed by respondents so long as they address the proposed march-in framework, including, but not limited to, sections or questions that are confusing or need additional context or explanation; additional sub-questions that would assist an agency in answering the major questions outlined in the framework; specific challenges posed by the framework as written; and other recommended improvements. Responses may include any topic believed to have implications for decision making related to march-in, regardless of whether the topic is included in this document.

NIST is specifically interested in receiving input from the public pertaining to the following questions:

- 1) After reading through the framework and example scenarios, if needed, how could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?
- 2) The framework contains many terms which have specific meanings under Bayh-Dole or in technology development and commercialization. Are the definitions provided at the beginning of the framework easy to understand? Do they aid in your ability to interpret the framework?
- 3) How could the framework be improved to be easier to follow and comprehend?

- 4) Does this framework sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?
- 5) The framework is not meant to apply to just one type of technology or product or to subject inventions at a specific stage of development. Does the framework ask questions and capture scenarios applicable across all technology sectors and different stages of development? How could any gaps in technology sectors or stages of development be better addressed?

Authority: 35 U.S.C. 203, 206; DOO 30-2A.

Alicia Chambers,
NIST Executive Secretariat.

APPENDIX A

Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

Table of Contents

Definitions	2
Introduction to March-in Rights & Framework	4
Does Bayh-Dole Apply?	8
Ownership and Licensing.....	10
Is a Statutory Criterion Met?	11
Would March-In Support the Policy & Objective of Bayh-Dole, Considering The Specific Case And Broader Context?.....	19
Scenarios & Examples.....	23

Definitions

When used within this framework, including the introduction, the terms listed below should be interpreted as defined below:

Agency – Any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5. For purposes of this framework, and in accordance with 35 U.S.C. 203 “agency” shall refer to the agency or agencies under whose funding agreement the subject invention was made.

Head of Agency – The head of the agency is the Department Secretary or in the case of DOD, the Secretary of that particular military branch. For independent agencies (e.g., NSF, NRC, NASA, etc.) the agency head is the highest-ranking member within the agency, such as the Director or Administrator.

Contractor – “Contractor” is defined under Bayh-Dole as “any person, small business firm, or nonprofit organization that is a party to a funding agreement.” (35 U.S.C 201(c)). Executive Order 12591 expanded this definition to include “any business firm regardless of size.” Throughout this document, unless indicated otherwise, “contractor” may include contractors as well as subcontractors and assignees, including inventor(s) or Third Party Assignees following agency approval of a request to waive rights.

Funding Agreement – Any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

Practical Application – To manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

Product – Consistent with 35 U.S.C. 204, “product” includes “any products embodying the subject invention or produced through the use of the subject invention.” For purposes of this framework, “product” may also include a service when that service requires the use of the subject invention.

Shelving - When an entity holds a patent or has a license to make, use, or sell an invention, but they do not develop, use, or sell that invention (or a product embodying the invention) or seek out third parties to do so for an extended period of time.

Subject Invention – Any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d) [1] of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance. Bayh-Dole governs the rights and obligations surrounding subject inventions; therefore, only subject inventions are subject to march-in under Bayh-Dole.

Other terms used throughout this framework should be read consistent with the definition within the Bayh-Dole statute and regulations (35 U.S.C. 201, 37 CFR 401).

Introduction to March-in Rights & Framework

Under the University and Small Business Patent Procedures Act of 1980, more commonly known as the “Bayh-Dole Act” or “Bayh-Dole,” the government allows recipients of federal research funding to retain rights to inventions conceived or first actually reduced to practice under a federal funding agreement (“subject inventions”). The government, however, retains certain rights and imposes certain obligations on the contractor, including the authority to “march-in.” March-in allows the agency to require the contractor, or an exclusive licensee to grant a license to the subject invention in any field of use to a responsible applicant or applicants. If they refuse, then the agency may itself grant a license. However, the agency can only exercise march-in rights in four specific circumstances, the criteria of which are specified in the statute (35 U.S.C. 203):

- (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

To date, no agency has exercised its right to march-in. Several agencies have considered march-in previously but have either declined to exercise it or worked with the parties to find an alternative solution to achieve the desired objectives. March-in is an important tool for agencies, but that tool is accompanied by potentially significant positive and negative ramifications. Therefore, in addition to the statutory criteria discussed above, the agency should carefully consider all circumstances and consequences and ensure that its march-in decision is consistent with the policy and objectives of Bayh-Dole. The policy and objectives are enumerated in the Bayh-Dole Act at 35 U.S.C. 200:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in

federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

The exercise of march-in rights is just one tool that may be available to the government and use of march-in should be considered in the context of all tools at the agency's disposal to address situations.

Regulatory Procedures for March-In

If the agency has reason to believe that the exercise of march-in rights could be warranted (i.e., one of the four criteria appear to exist and there is reason to believe that the invention in question is subject to Bayh-Dole), then it can initiate the procedures for march-in under 37 CFR 401.6.⁴

First, the agency must notify the contractor in writing of the circumstances it believes warrants march-in and request an informal consultation and information so that the agency and the contractor can understand the nature of the issue and may consider possible alternatives to march-in. At the end of this informal consultation, the agency will provide written notice to the contractor of its decision whether to continue with formal march-in procedures based on the available information.

If the agency decides to move forward with formal march-in proceedings, the contractor is permitted to submit information and an argument opposing use of march-in. If that submission raises a genuine dispute over material facts upon which the march-in is based, the head of the agency or his or her designee will undertake fact-finding or refer fact-finding to another agency official (the "fact-finder"). If the agency proceeds with fact-finding, the agency should permit the contractor to appear with counsel, submit evidence, present witnesses, and confront witnesses or experts presented by the agency.^{5,6} The fact-finder will then prepare or adopt written findings of fact, which will be sent to the contractor. The contractor will be given the opportunity to submit arguments or, if requested, present oral arguments before the agency head or designee makes a decision.

At this point, the head of the agency or designee will make a determination based on the written findings of facts; information and arguments submitted by the contractor; any other information in the administrative record; and the policy and objectives of the Bayh-Dole Act.

Agencies shall develop an appeals procedure pursuant to 37 CFR 401.11(c). It is recommended that the appeal be decided by the head of the agency or by his or her designee who is at a level above the person who made the determination. Additionally, a contractor, inventor, assignee, or exclusive licensee adversely affected by a march-in decision may appeal that decision in the United States Court of Federal Claims (35 U.S.C. 203(b)).

About this Framework

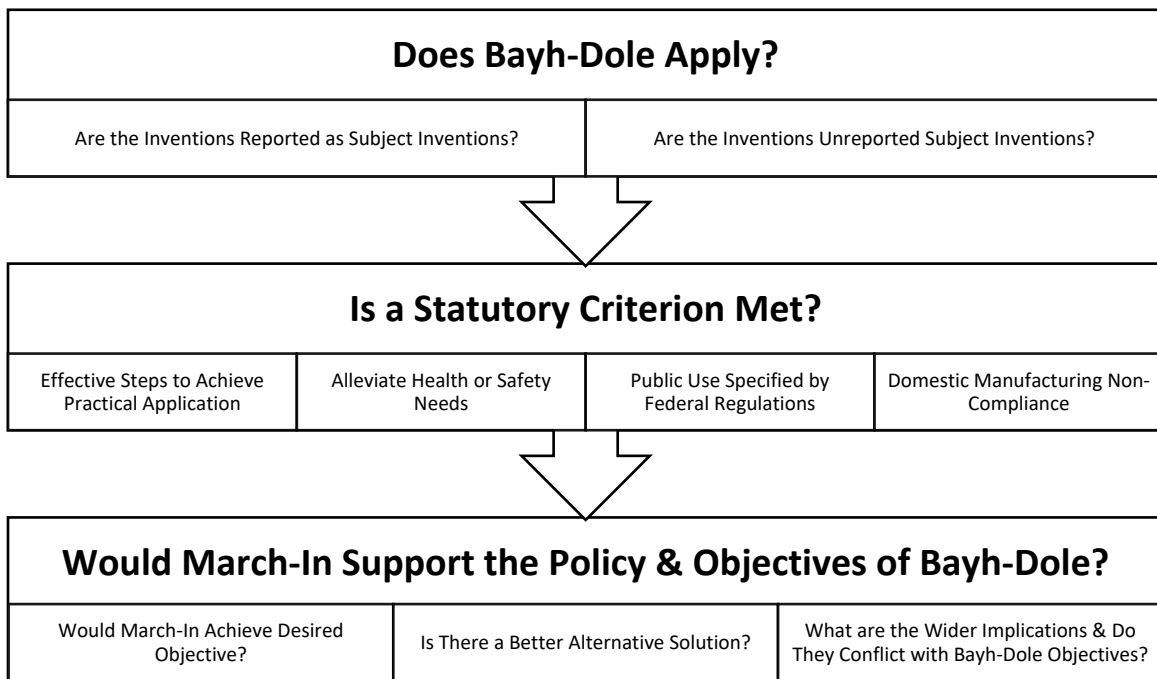
⁴ This represents a summary of the march-in procedures. For a full description, see 37 CFR 401.6.

⁵ A transcript shall be made and available at cost to the contractor, though this requirement can be waived upon agreement by the agency and the contractor.

⁶ All portions of the march-in proceeding are closed to the public and are held confidential (35 U.S.C. § 202(c)(5)).

While the decision to exercise march-in rights lies ultimately with the head of the agency or his or her designee, this framework details facts the agency may seek and the considerations that the agency may use in making these decisions.

When determining whether to exercise march-in rights, the agency may consider a variety of facts but must assess three overarching questions: 1) whether Bayh-Dole applies to the invention(s) at issue; 2) whether any of the statutory criteria for exercising march-in applies under the circumstances; and 3) whether the exercise of march-in rights would support the policy and objectives of Bayh-Dole. This framework will explore each of these topics in more depth and includes some, though not necessarily all, of the questions and factors the agency may weigh when considering march-in.



When reviewing this framework, it is important to remember that march-in considerations are extremely fact-dependent and any decision to exercise march-in will be made based on the totality of all circumstances. Nothing in this framework should be treated as a mandate that an agency exercise its march-in right, as a requirement that an agency collect facts to answer every question posed here, or as a limitation on the facts and questions an agency can consider. Rather, it provides a more comprehensive outline of the factors that an agency may weigh when determining whether to exercise march-in rights.

Information Gathering

Much of the information discussed in this framework may be easily accessible through records maintained by the agency, such as the iEdison system, and agencies should make efforts to compile information from these sources when possible.⁷ However, some information will need

⁷ iEdison is “an interagency online reporting system for recipients of federal funding agreements to report subject inventions to the federal funding agency and complete other reporting as required by the Bayh-Dole Act and its implementing regulations.” Available at <https://www.nist.gov/iedison>.

to be obtained through additional searches (e.g., the United States Patent and Trademark Office (USPTO) or grants and contracts databases), discussions with the contractor, information requested from or through the contractor, or other means. Some information sought in this framework may not be discovered until later steps in the process, and the facts and landscape may shift during march-in proceedings. Therefore, it should be noted that, if at any time during the process, the agency decides that it does not wish to exercise march-in rights, it may terminate the proceedings.

Given that the contractor is responsible for monitoring its licensees and exclusive licensees and that the agency only has direct relationships with its contractors (as opposed to that contractors' licensees, or sub-licensees), the agency will correspond and interact with the contractor as it assesses march-in. When requesting certain information, the contractor is expected to engage with and gather information from its licensees or other outside parties as needed. Some information relevant to this framework may not be available until later in the process, and the facts or underlying circumstances may shift while the agency is assessing a march-in request. If at any time during the process, the agency decides march-in is not warranted, it may terminate the proceedings.

Does Bayh-Dole Apply?

Because Bayh-Dole only governs subject inventions, as a threshold consideration, agencies should determine whether a march-in assessment is directed to a “subject invention.” Under Bayh-Dole, the government cannot march-in and issue licenses to any U.S. patent. Government use of march-in rights is limited to these inventions funded by the government. In many cases, march-in requests are directed to patents that acknowledge government funding, and that acknowledgement can be an indication of a subject invention. However, whether an invention is a subject invention can be a complex and fact-intensive inquiry. For example, some patents that acknowledge government funding will not meet the statutory definition of a “subject invention” (e.g., those under a funding agreement made primarily for educational purposes). Agencies evaluating march-in may consider these questions in assessing government funding for purported subject inventions:

- I. Was the invention(s) in question reported to the government as a subject invention(s)?⁸ If there are products at issue, do they embody a subject invention or are they produced or performed through use of a subject invention?
 - A. What purported subject invention(s) are relevant to this march-in analysis? If available, collect the iEdison Invention Report Number, Date Reported to Agency, Title Election Status, and reported Funding Agreements.⁹
 - B. What patent application(s) and/or patent(s) are associated with the subject invention(s)? All available, associated patent numbers and patent application numbers should be made part of the agency record.
- II. Is this invention an unreported subject invention?
 - A. Do unreported patent applications and/or patents covering the invention acknowledge federal funding?¹⁰
 - B. Do publication(s) exist that cover the invention? If so, does the acknowledgement section(s) reference government funding?¹¹ If so, what funding agreements were listed as supporting the research described in the publication?
 - C. Did the contractor receive any funding agreements related to the invention and conducted by an inventor listed on the invention and/or patents? If available, note all funding agreements for the contractor relevant to the subject matter of the invention and work done by the relevant inventor.

⁸ If an invention is reported to the agency as a subject invention, it will be assumed that it is a subject invention. If a contractor contends an invention is not a subject invention, then they would be given the opportunity to provide evidence to raise this as a “genuine dispute over a material fact” under 37 CFR 401.6(3-5).

⁹ If an invention is funded by multiple agencies, the funding agencies should notify one another and attempt to work together to come to one unified government determination on whether march-in is warranted.

¹⁰ Typically, this can be found near the beginning of the patent application and/or patent in the specification describing the invention.

¹¹ Government funding may be listed in an acknowledgment in a publication but not contribute to the conception or first actual reduction to practice of any invention. (37 CFR 401.1(a)(2)). Further analysis may be warranted to determine if an invention is a subject invention subject to Bayh-Dole, but references to relevant publications can be useful in this analysis.

- D. What are the approved scientific aims under the listed funding agreements?
1. If available, the funding agreement, including the Scope of Work which might relate to the subject invention, should be part of the agency record.

Note that the agency may request input from a program manager, legal counsel, and/or subject matter expert, and analyze publications, patent applications, or issued patents to help identify potential overlaps with the scientific aims of a funding agreement(s).

- E. Based on the information gathered in this section, can the agency confirm whether each invention relevant to the march-in assessment was “conceived or first actually reduced to practice in the performance of work under a funding agreement?”¹²

¹² A contractor or licensee may be given the opportunity to dispute a finding that an invention is an unreported subject invention by raising it as a “genuine dispute over the material facts” under 401.6(3-5).

Ownership and Licensing

To evaluate march-in, agencies should also determine the contractors and licensee(s) that currently have rights to the subject invention and are involved in activities like research and development (R&D) or manufacturing, marketing, and selling products. The march-in assessment will often center on the scope and extent of what these parties are doing in an effort to understand the full scope of efforts undertaken to practice the subject invention. The totality of this information will allow agencies to understand the relevant stakeholders and their current actions.

- I. Which owners are listed for each subject invention, patent application and/or patent relevant to this march-in analysis in USPTO records and other sources?
- II. Which license(s) cover the subject invention, associated patent application(s), and/or patent(s)? If available, note which subject invention(s), patent application(s), and/or patent(s) are covered by each license; whether the license is exclusive or non-exclusive; and the field of use.

Is a Statutory Criterion Met?

The statute only authorizes march-in in four statutorily defined circumstances (35 U.S.C. 203(a)), therefore, agencies must assess whether at least one of these circumstances applies before proceeding. To that end, and depending on the details of a march-in consideration, agencies may consider some of the following questions:

Criterion 1. Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

This criterion focuses on the steps that contractors have taken to develop and achieve practical application of the subject invention. For example, if a contractor or licensee has stopped further work on the subject invention and the contractor and/or licensee has refused to restart work and rejects requests to license the subject inventions, that could suggest limited opportunities to commercialize the subject invention into new products. Stalled product development could be an indication of conflict with the objectives of the Bayh-Dole Act to encourage utilization and commercialization of federally funded inventions. To assess the steps contractors and licensees are taking to commercialize these subject inventions, agencies should assess if the subject invention is licensed and whether there is a product embodying the invention on the market. If the contractor has not licensed the invention, or if no product exists, agencies may need to further assess whether march-in is warranted.

If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted. Whether action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users.

Agencies may also consider the circumstances surrounding the patent status, any licenses and/or offers to license, and the products themselves—however, some of those issues may be better addressed through other statutory march-in criteria, other provisions in the Bayh-Dole Act, or different government authorities.

It should be noted that given the nature of this criterion, the questions the agency asks may vary depending on the stage of development as well as whether the contractor is licensing the technology for development and commercialization or intends to develop and commercialize the resulting product directly.

- I. When determining whether to exercise march-in under this criterion, the agency will first assess which of the following categories best describes the **current** stage of development for the subject inventions and/or products and answer the corresponding questions.
 - A. The subject invention is not licensed, and the contractor has no plans to develop or commercialize, itself. **Complete Section II.**

- B. The subject invention is licensed, or the contractor is developing the subject invention with plans to directly commercialize it. **Complete Section III.**
 - C. The product is commercialized. **Complete Section IV.**
- II. In considering whether this criterion 1 applies to a subject invention that is not licensed and the contractor has no plans to develop or commercialize itself, the agency may assess:
- A. What actions has the contractor taken to license the subject invention (for example, is it evaluating licensing offers, or seeking out interested licensees)?
 - B. Have the contractor and any potential licensee(s) reached mutually agreeable license terms?
 - 1. If yes, then why is the subject invention not licensed?
 - 2. If no, has the contractor offered to license the subject invention under commercially reasonable terms? Are there companies that want to license but the contractor will not agree to terms offered?
 - C. Is there an indication the contractor would decline to license the subject invention even if a potential, responsible license applicant was presented?
 - D. Is there a valid reason (technical, legal, or otherwise) that explains why the contractor has stopped licensing efforts? What is that reason?
 - E. Are there concerns about the contractor shelving the subject invention(s) without justification and not committing to discernable steps on re-engaging in its licensing?
- III. In considering whether this criterion 1 applies to a licensed subject invention or a subject invention that is being developed or commercialized by the contractor, the agency may assess:
- A. What steps are needed to bring the product to market? Is the contractor or the licensee taking these steps or planning to take these steps within a reasonable timeframe?
 - 1. If the invention is licensed but the licensee is not taking steps to bring it to market, has the contractor attempted to address the matter with the licensee? Are there appropriate product development milestones in the License Agreement? Are there unmet milestones the contractor could enforce? If not, are there other steps the contractor can take under the terms of the license to ensure development?
 - 2. What is the degree of investment, time, and regulatory requirements needed to bring the product to market?
 - B. Is regulatory approval needed or pending?
 - 1. If yes, is the contractor and/or licensee seeking regulatory approval? If approval was denied, what were the reasons and will further approval be sought, for example after additional data is collected?
 - C. If the licensee or contractor is not intending to manufacture the product, have they identified manufacturers?

1. If a potential manufacturer(s) has been identified, have the manufacturer and contractor(s)/licensee(s) reached mutually agreeable license terms?
 - a. If yes, when will manufacturing begin?
 - b. If no, has the contractor(s)/licensee(s) offered to license the subject invention for manufacturing under commercially reasonable terms? Are there manufacturers who desire a license, but the contractor(s)/licensee(s) has not agreed to terms offered?
 2. If a potential manufacturer has not been identified, what actions has the contractor(s) or licensee(s) taken to identify potential manufacturers?
- D. Is there a valid reason (technical, legal, or otherwise) that explains why the contractor or licensee has stopped development or commercialization efforts? What is that reason?
- E. Are there concerns about the contractor or licensee shelving the subject invention(s) without justification and not committing to discernable steps on re-engaging in its development?
- VI. In considering whether this criterion 1 applies to a product that is being commercialized, the agency may assess:
- A. Is the contractor or licensee marketing or selling to end-users or consumers in the U.S.? If not, why?
 - B. Has the product utilizing the subject invention been sold or offered for sale in the U.S. using distribution channels (e.g., retailer, wholesaler, through a regulated intermediary, or direct to consumer) used for similar products?
 - C. How does the availability of the product benefit the public, and how is the public harmed by limited availability of the product?
 - D. At what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S?
 - a. Has the contractor or licensee made the product available only to a narrow set of consumers or customers because of high pricing or other extenuating factors? Has the contractor or licensee provided any justification for the product's price or background on any extenuating factors which might be unreasonably limiting availability of the subject invention to consumers or customers?

Criterion 2. Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.

In considering march-in based on criterion 2, agencies will seek a clear picture of the health or safety need that is not being reasonably satisfied. The agencies can also assess what it would take to better or fully meet the need and will evaluate how march-in could address the health or safety need.

- I. What is the health or safety need to be addressed? What is the scope of the health or safety need? How long is the health or safety need anticipated to last?
- II. Has the agency consulted with other agencies resulting in agreement on unmet health or safety needs and/or other necessary actions?
- III. How does the subject invention or the product at issue address the unmet health or safety need?
- IV. What is necessary to resolve the health or safety need?
 - A. Greater quantity or quality of a specific product?
 - B. Different or additional ways to access the product?
 - C. More options to access similar, but not identical, products? (For example, if the contractor manufactures one dosage of a drug but a new use is identified that requires a much lower or higher dosage).
 - D. Greater access through additional uses of another existing product?
- V. Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?
 - A. For example, has the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people's health at risk?

It should be noted that in reviewing this question, the agency is not limited to reviewing price increases; the initial price may also be considered if it appears that the price is extreme, unjustified, and exploitative of a health or safety need.
- VI. How would march-in address the health or safety need? Are there other products, or other potential alternatives to march-in, that would address the health or safety need, in whole or in part?
- VII. Has the contractor been consulted about options, short of march-in, to address the unmet need?

Criterion 3. Action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees.

Under criterion 3, agencies will evaluate whether any Federal regulations relate to the use of products commercialized from the subject invention. They will assess whether the contractor(s) and/or licensee(s) have taken reasonable steps to address any needs related to these Federal regulations, including making the subject invention available to all who require it.

- I. Does a Federal regulation expressly require the subject invention to be used in or in combination with another product (if the subject invention is commercially available)? If a Federal regulation does not expressly require such use, does a Federal regulation in practice effectively require the use of the subject invention in order to satisfy a regulatory requirement?
- II. Is the subject invention already available to those who require it under the regulation?
 - A. If not, is there evidence that the contractor(s) or licensee(s) is restricting access or imposing barriers to access?
- III. How does the subject invention address the need?
- IV. Do other current technologies address the issue? If so, what are those technologies?
- V. Has the contractor contacted the agency that issued the regulation for assistance?
- VI. How much time is required to meet public use requirements by Federal regulation?
- VII. Has the contractor been specifically consulted about addressing the public use requirement?

Criterion 4. Action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

This criterion relates to 35 U.S.C. 204 and requires that exclusive licenses to use or sell in the U.S. include an agreement that products embodying subject inventions be manufactured substantially in the U.S.¹³ The requirement for such an agreement may be waived by the agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. Broadly, agencies will evaluate if § 204 applies, request specific details on where any products are being manufactured, and determine if a manufacturing waiver is required and if a request to waive the preference for U.S. industry has been granted.

- I. Are the prerequisites triggering the agreement required under section 204 present?
 - A. Has the contractor granted an exclusive license to use or sell any subject invention in the United States?
- II. Did the contractor's exclusive license agreement require that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S.?
 - A. If no, can the agreement be amended to incorporate the agreement required by section 204?
 - B. If no, was a request for waiver of the preference for U.S. industry submitted to the agency(ies)? Was the request granted and under what terms?
- III. Are products embodying the subject invention or produced through the use of the subject invention being manufactured under that exclusive license?
 - A. If yes, in what countries are those products being manufactured?
 - B. Taking the manufacturing locations of all components of the product into consideration, would the product be considered to have been manufactured substantially in the U.S.?
- IV. If the answers to II and/or III above are no, was a request for waiver of the preference for U.S. industry submitted to the agency(ies)?
 - A. If yes, was the waiver request granted?

¹³ Pursuant to 35 U.S.C 202(a)(ii) some agencies may have issued Determinations of Exceptional Circumstances (DECs) amending the standard patent rights clauses of their funding agreements to include broader domestic manufacturing obligations than those enumerated in 35 U.S.C. 204. Agencies who have issued such DECs should refer to those DECs to determine the extent of the government's rights when contractors are noncompliant with the manufacturing obligations under the DEC. For example, DOE's "DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES UNDER THE BAYH-DOLE ACT TO FURTHER PROMOTE DOMESTIC MANUFACTURE OF DOE SCIENCE AND ENERGY TECHNOLOGIES" does not specify any government march-in rights, but requires contractors to "convey to DOE, upon written request from DOE, title to any subject invention, upon a breach" of their U.S. Competitiveness provision.

1. If so, what were the terms of the waiver (subject inventions covered, duration, countries or facilities wherein products can be manufactured, field of use, etc.)?
 2. If the waiver request was submitted but denied, why was it denied?
- B. If no, has the agency contacted the contractor under its enforcement authorities of the terms and conditions of the funding agreement to demand that a waiver request be submitted?

Would March-In Support the Policy & Objective of Bayh-Dole, Considering The Specific Case And Broader Context?

The Bayh-Dole regulations under 37 CFR 401.6(a)(6) state that “[t]he consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. The Bayh-Dole Act emphasizes “utilization of inventions arising from federally funded research and development” and the “commercialization and public availability of” those inventions. The foundation of Bayh-Dole’s policies and objectives reflect two themes (among others): promoting the development of new products in the U.S. and their availability to end-users or consumers in the U.S. Accordingly, agencies evaluating march-in should prioritize both policy goals—incentivizing U.S. innovation and promoting access to the fruits of that innovation in the U.S. Determining whether an individual march-in decision would advance or impede these goals may be a complex and fact-specific assessment. Agencies should also weigh how an individual march-in decision could impact the broader policy objectives for U.S. competitiveness and innovation.

- I. Would march-in help achieve practical application, alleviate health or safety needs, meet public use requirements, or meet manufacturing requirements?

This section of the framework is intended to inform the agency’s assessment of the practical value of exercising march-in, specifically in terms of increasing accessibility of the subject invention(s)—what would happen if a contractor, licensee, or the agency issued (or tried to issue) a new license(s) to the subject invention(s)? How likely is it that march-in would solve the problem identified by those seeking it? Could other interested and willing licensees practice the subject invention in sufficient time to address the problem? An absence of other interested licensees could weigh against march-in. Agencies may also need to consider whether there is intellectual property (beyond the subject invention(s)) that could possibly prevent other licensees from making the product or offering the service in question. A complicated intellectual property landscape could reduce the likelihood of successful licensing and weigh against march-in. To that end, agencies reviewing march-in may ask some of these questions:

- A. Is there another willing and able licensee or is it likely that one could be found?
 1. How long would it take another licensee(s) to start producing and marketing the covered product? How long would it take before another licensee(s) could satisfy existing demand for the product? At what price would another licensee(s) be able to make the product available to the public?
 2. What steps, if any, could or should the agency or the existing contractor(s) take to identify other willing licensee(s) under the circumstances?
- B. What intellectual property, in total, is needed to make the product in question? Does making the product or performing the service also require use of intellectual property that was not government funded and is not subject to Bayh-Dole?

1. For example, if only one of several patents necessary to produce a product is subject to march-in, that likely weighs against march-in, since other licensees would need separate permission to use several other patents before they could make the product. On the other hand, if all the intellectual property needed to produce the product is a subject invention(s), that might result in a different licensee being able to produce product quickly or efficiently.
- C. When do the patents subject to the march-in evaluation expire?
1. Will the patents expire before the march-in process is completed and another licensee is able to bring a product to market? Consider the remaining patent life in relation to the timeline for march-in proceedings, federal court appeals, transfer of know-how and build out of product manufacturing capability, and/or any necessary regulatory approvals. If the patent term is likely to end before the march-in process concludes and before a new licensee could bring a product to market, these factors weigh against a decision to exercise march-in rights.
- D. Is the product or service subject to regulatory exclusivity, such as those provided by the FDA? If so, how much time remains in the period of exclusivity?
- E. If march-in is requested in response to an emergency or an urgent public health or safety issue—how long is the emergency or issue expected to last? Consider if the march-in process would take longer than the emergency is expected to last, as that could weigh against march-in.
- F. If march-in is requested based on the criterion of domestic manufacturing—
1. Is the contractor willing to submit a request to waive the preference for U.S. industry? Consider whether the agency would grant a waiver, if requested.
- G. Would a determination to march-in promote utilization of this subject invention? Would it protect the public against non-use or unreasonable use of this subject invention?
1. Would march-in have an impact on public availability of the benefit of the invention in the short and long-term?

The situation and pertinent facts may evolve with time. Agencies may revisit these questions—e.g., whether there is another willing and able licensee—and defer a march-in determination in the event appropriate licensees emerge. Another possible circumstance that could affect march-in analysis includes another product coming to market during the pendency of the march-in process that displaces the market for product that is the subject of march-in.

- II. Are there other ways to address the identified problem, and can those alternatives be pursued instead of or in parallel with any march-in proceedings?

During review of march-in, more expeditious resolutions may be identified, and agencies should weigh viable alternatives when making march-in decisions. However, just because

there may be alternative resolutions to the problem that prompted march-in consideration, that does not mean exercise of march-in rights is inappropriate.

- A. Are there other alternatives available to address the problem identified? How effective are the alternatives (or how likely is it that other alternatives would solve the problem), and how effective are the alternatives in comparison to march-in?
- B. If the subject invention is licensed, what efforts have or can the contractor(s) and/or licensee(s) take to solve the problem?
- C. Are the contractor and its licensee(s) willing to take action to remedy the matter without the agency exercising march-in?
- D. Is there a problem such as anti-trust activity, fraud, or bankruptcy, that would be best addressed by other federal or state governmental authorities?
- E. Is there patent litigation pending or other legal actions or concerns regarding the patents associated with the subject invention? Consider whether other legal processes (e.g., a challenge to the validity of the patent, licenses being revoked) may allow another manufacturer to bring the product to market more quickly, as that could weigh against use of march-in.
- F. Is there another federal agency taking action that would resolve underlying issues without the use of march-in?

III. What are the wider implications of use of march-in?

At its core, the Bayh-Dole Act focuses on U.S. innovation and the commercialization of inventions that arise from federally funded R&D—all with an eye towards advancing the interests of the American public. Prior to exercising march-in, funding agencies should consider both the practical impact and the potential impact on the broader R&D ecosystem. To that end, agencies may consider questions such as:

- A. Would march-in protect the public against nonuse or unreasonable use of subject inventions?
 - 1. Consider ways to ensure that any use of march-in achieves the intended outcomes and does not have broad and unintended consequences on U.S. competitiveness and innovation.
 - 2. Consider whether march-in would send a clear signal to industry so other contractors and licensees can rely on that agency's prior decisions to avoid similar issues in the future.
- B. Consider whether march-in would increase public availability of federally funded inventions and foster support for the federal research enterprise.
- C. Would exercise of march-in rights here promote competition without unduly encumbering future R&D? Would it impact competition and R&D more broadly? For example, would there be a decrease in the number of applicants for federal funding?
- D. Would exercise of march-in impact utilization of subject inventions more broadly?

1. Would march-in have an impact on U.S. competitiveness and innovation?
 2. Would prospective licensees likely avoid future collaborations with federally funded research institutions, organizations, small businesses, and investigators? For example, would there be a decline in the number of collaborations with the federal laboratory? Would an agency's practice result in a decline in the number of collaborations? Agencies may answer both questions post facto, and cannot be predicted. However, if an agency has had a similar effort that had impacted the number or quality of collaborators, they could extrapolate the effect. Agencies should consider the potential chilling effect on the agencies' existing relationships with industry and ability to address Administration priorities.
- E. Consider whether input from other agencies would be helpful to understand the ramifications of a march-in decision, e.g., the State Department, Office of the U.S. Trade Representative, or Department of Commerce as to any diplomatic or trade implications or the United States Patent and Trademark Office as to any intellectual property implications.

Scenarios & Examples

This section of the framework presents a variety of hypothetical scenarios where march-in could emerge. These examples and the subsequent discussion showcase how an agency might apply this framework, considering certain factors and questions, in assessing march-in.

In an actual march-in analysis, an agency would consider the relevant facts and questions, explore the relevant Bayh-Dole statutory march-in criteria, and evaluate any feasible alternatives before making a determination of whether to exercise march-in. However, for clarity and brevity, when discussing these scenarios, please assume the following:

1. The agency establishes or has established that Bayh-Dole applies to the subject invention(s).
2. Only Bayh-Dole subject inventions are needed to successfully manufacture the product (i.e., no additional intellectual property licensing would be needed).
3. Although the agency considers the relevant factors and answers relevant questions within the framework, only one criterion and certain illustrative facts and circumstances may be addressed in the discussion of each scenario.

These scenarios are hypothetical and should not be read or inferred to reference a particular invention, product, contractor, or licensee. Further, nothing in the discussions of these scenarios should be interpreted as an obligation upon the agency to exercise march-in. As stated previously, march-in decisions are extremely fact-dependent and the agency would consider the totality of circumstances in a real-life situation, whereas these scenarios only address select issues.

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Scenario 1

Background: A biotech company has partnered with a U.S. government-funded university to develop treatments for autoimmune skin diseases. The company was granted an exclusive license to a government-funded patent owned by the university. The patent claims a new compound that has shown promise in pre-clinical trials for psoriasis. The company has also separately developed another psoriasis treatment and that second treatment—which recently received FDA approval—was developed solely by the company without any government support. Once the company secured FDA approval for that second treatment, it appears to have stopped all work on the patented compound that was invented by the government-funded university. A second company has approached both parties for a license to the university-owned patent, but its request was denied, so the second company has asked the government funding agency to march-in and require the university to grant it a license to the university patent.

Discussion:

Statutory Criteria - In this scenario, it appears the contractor and licensee may not be taking effective steps to achieve practical application of the subject invention in such field of use (Statutory Criterion 1). Before proceeding, the agency would seek information from the contractor to confirm whether the current licensee has in fact stopped development of the subject invention. If so, the agency would continue this inquiry to determine if the licensee is inappropriately shelving the technology.

To make this determination, the agency would explore the questions detailed in Statutorily Defined March-In Criteria; Criterion 1; Section III. It appears the licensee might have ceased development of the subject invention in favor of another competing technology (Statutorily Defined March-in Criteria, Criterion 1, III, A). The agency would then ask whether there was a valid, technical reason that the licensee stopped development (Section III, B). For example, if the licensee obtained poor results in clinical trials, that could justify halting work and weigh against march-in. However, the fact that there is another interested licensee suggests the subject invention holds clinical promise, and that could weigh in favor of march-in.

The agency would also ask whether the contractor has taken steps to remedy this situation and whether the contractor's agreement with the licensee includes milestones or other diligence provisions that would allow the contractor to terminate the license and "clawback" the technology. If the contractor intends to enforce "clawback" provisions to terminate the license and seek other licensees, or if it intends to enforce milestones within the license to push further development of the university-patented invention, these factors could weigh against march-in. If the license in question did not contain such provisions or the contractor was unwilling to exercise its rights, then these circumstances could weigh in favor of march-in.

Policy & Objectives of Bayh-Dole – As part of this analysis, the agency would also look at whether exercising march-in rights would achieve the desired outcome and support the policy and objectives of Bayh-Dole. First, the agency would consider whether march-in would promote utilization and protect against non-use of this subject invention (Would March-In Support the Policy & Objective of Bayh-Dole; Section I). Here, the agency would analyze whether the second company that sought a license pursuant to march-in was a reasonable applicant (Section I, E). In other words, would that company be capable of bringing the product to market? If a viable and qualified company was interested in restarting development work but being denied the opportunity, that would weigh in favor of march-in. However, if that second company, on its face, lacked any of the experience or resources necessary to bring a new psoriasis treatment to market—and if the agency was unlikely to find another qualified and interested licensee (for example, because the product failed clinical trials)—these factors and circumstances would weigh against march-in. The agency would also look at timing factors, like the remaining patent life compared to the time required to complete march-in proceedings, exhaust appeals, and further develop the technology—as a short remaining patent term could weigh against march-in (Section I, B, 1). Second, the agency would consider whether there are viable alternatives (Section II), like the contractor clawing-back the existing license and issuing one to a new developer. Finally, the agency would assess the wider implications of exercising march-in (Section III). This would depend in large part on further factual development referenced above. But if there is a valid reason why this licensee stopped work, then march-in here seems unlikely to advance the goals of Bayh-Dole. But if this is a case of a licensee impermissibly shelving a subject invention to preserve the market position of a competing product, march-in here could deter similar actions by others in the future.

Scenario 2

Background: An advanced manufacturing startup that received Phase I and Phase II SBIR grants is working on improved 3-D printing technology for construction materials. The startup is regularly attending conferences and showcasing its prototypes and it recently closed a successful Series A funding round with several venture investors who have a history of success in the relevant markets. But it has been several years since the startup launched and it is not yet offering a commercial product or service. The startup also holds a portfolio of five government-funded patents directed to its

technology. A large, established construction company is looking to launch a 3-D printing initiative and it has asked the government funding agency to march-in and grant it a license to the startup's patent portfolio. The established construction company claims the startup is impermissibly shelving the subject invention by not launching a product or service, yet, and the established company contends it has the resources and funding on hand to bring this technology to market quickly—making it a preferred licensee.

Discussion:

Statutory Criteria - In this scenario, it appears the contractor is taking steps to achieve practical application of the subject invention (Statutorily Criterion 1). The agency would likely start its analysis by discussing the contractor's plans to develop or license the invention (Statutorily Defined March-in Criteria, Criterion 1, I-III). Here, the contractor seems to be actively developing the technology and preparing to market it in at least one field of use. It has recently raised additional funds that would support further development and product launch. The mere fact that a potential competitor might be able to bring a subject invention to market more quickly than the contractor does not mean the contractor is impermissibly shelving a subject invention. On the other hand, if there are indications that the startup is delayed because it is devoting all its resources to develop to unrelated technology, that could weigh in favor of march-in. The agency may also monitor the continued progress of the contractor in developing this technology to improve construction material manufacturing.

Policy & Objectives of Bayh-Dole - The first part of this analysis looks at whether march-in would promote utilization and protect against shelving or non-use of this invention (Would March-in Support the Policy & Objective of Bayh-Dole; Section I). Here, it appears the contractor is still actively developing this technology and not shelving it, which would weigh against march-in, even though other licensees might also be able to bring this technology to market. The agency may also consider if there are other steps it, or the contractor, could take to speed development—if that is warranted (Section II). Finally, the agency may consider the wider implications of exercising march-in (Section III). For example, the Bayh-Dole Act includes the objective of "encourage[ing] maximum participation of small business firms in federally supported research and development efforts." March-in here could deter future small businesses from engaging in federally supported R&D, if they thought larger competitors would be able to easily leverage march-in requests to step in and take over development and commercialization.

Scenario 3

Background: The Federal Highway Safety Administration has identified a growing safety concern in which traffic accidents have risen 27% due in large part to drivers' inability to see traffic signs early enough to act accordingly. Having evaluated the growing number of incidents, it has been determined that the issue is the visibility of the traffic signs in lighting extremes (glare from bright sunshine during the day or lack of visibility of the signage during low light hours). Subject to a grant provided by the government, a contractor has developed a new retroreflective coating for traffic signs that improves the visibility of the signs by as much as 75% both during bright daylight without glare and at night by enhancing the indirect reflection of automobile headlights off the signage. The contractor is a medium-sized company that is seeking to grow, based on this new patented technology, but they are unable to keep up with demand for their new material from signage manufacturers who are receiving significant increases in demand from state Departments of Transportation (DOTs) seeking to improve or replace their signage. To date the contractor has only agreed to license its patent to one sign manufacturer. Others have sought licenses and been rejected. Several manufacturers have approached the government funding agency seeking assistance in licensing the patented material to manufacture and incorporate the material into the signs they sell to the state DOTs.

Discussion:

Statutory Criteria – First, the agency would investigate the scope of the unmet health and safety need and how this subject invention addresses that need (Statutorily Defined March-In Criteria; Criterion 2; Sections I-III). Based on this fact pattern, it seems more of the retroreflective coating product is needed to satisfy an unmet safety need (Section IV) and it could significantly impact, though not completely alleviate, the safety concerns (Section V). The agency may, for example, seek additional data to understand how much the new coating has actually improved safety and how many accidents have been prevented due to use of this coating. If there is strong evidence of a steep drop in accidents, that could weigh more in favor of march-in. However, if there's not yet sufficient evidence that the improved visibility is positively impacting driver safety, march-in may at the very least be premature. The agency would also consult with the contractor and gather additional information as to why it has been denying licenses (Section VI). Perhaps the contractor has a valid reason, e.g., limited worldwide access to necessary raw materials, or it may have a concrete plan to increase production in the near future; these factors could weigh against march-in. Likewise, the contractor and the agency may be able to work out a plan or timeline for addressing the safety need without march-in. However, if the contractor cannot present a rationale to refuse more licenses and it has no discernable plan to meet increasing demand, then that could weigh in favor of march-in.

Policy & Objectives of Bayh-Dole - The agency would also need to determine whether march-in would alleviate the health or safety need (Would March-In Support the Policy & Objective of Bayh-Dole; Section I). In this case, the answer likely depends on the further factual development referenced above. For example, if the raw materials necessary to make this new coating are in very short supply—and the contractor is already using all the available raw materials—then march-in would be unlikely to alleviate the health or safety need by increasing coating production. The agency would also consider the relevant timelines (Section I, C). For example, if the contractor would be able to satisfy all outstanding state DOT orders within the year and march-in proceedings are likely to take longer, that would weigh against march-in. The agency would also explore other alternatives to address traffic safety in parallel (Section II, A). For example, are there other products that could support the market need while the contractor increases its production capacity? Alternatives need not be superior to the subject invention to be a consideration weighing against march-in. Finally, the agency would consider the wider implications of march-in. For example, would march-in here deter smaller or medium sized businesses from commercializing subject inventions, out of fear that they would lose exclusivity or patent protection to larger companies with more capacity (Section III, B-C)?

Scenario 4

Background: A small pharmaceutical startup that has received extensive government funding developed a monoclonal antibody that currently is the only treatment for a rare disease. That company holds all of the patents covering the antibody, its use, and the methods of manufacturing—and each of those patents contains a clause acknowledging

government funding as required by the regulations. The startup does all its manufacturing at a plant in California, and severe rainfall caused substantial flooding that compromised the manufacturing plant. The plant will need substantial repairs, and it is unclear if and when the company will be able to resume production. Even if the company can resume production, it will take four months after the repairs to complete manufacturing a batch of the antibody. A rare disease patient group has asked the government to march-in and issue licenses to all of the patents necessary to make and use the antibody.

Discussion: Given the urgent need, march-in would be among a range of options the agency would likely consider for resolving this problem and promptly getting treatment into the hands of patients.

Statutory Criteria - In this scenario, it appears there may be health needs that are not being reasonably satisfied by the contractor (Statutory Criterion 2). The agency would first ask the contractor for information to confirm the basic facts—that the company has ceased manufacturing the treatment in question due to flooding and return to operations is uncertain. If that is the case, the agency would continue its inquiry to assess whether march-in would alleviate the unmet health need, exploring questions detailed in Statutorily Defined March-In Criteria; Criterion 2. In this scenario, more treatment for this rare disease is needed (Section III; IV,A).

From there, the agency would likely need more information to assess whether march-in could feasibly address the problem. For example, does the contractor have a back-up plan for manufacturing, and if so, how long would it be before the contractor can start delivering treatment to patients (Section VI)? If there's no back-up plan, that could weigh in favor of march-in. Likewise, the lack of clarity about if and when the contractor will resume manufacturing suggests a potentially prolonged unmet health need, which could also weigh in favor of march-in (Section VII). The agency would also consider whether there are other manufacturers—"responsible applicants"—that could quickly manufacture this (or another) product with FDA approval to treat the rare disease. If yes, then march-in might help address the health need; but, if no other manufacturers are willing to make the product in question or utilize the subject invention, then march-in may not provide a solution (Section V).

Policy & Objectives of Bayh-Dole – As part of this analysis, the agency would also look at whether exercising march-in would achieve the desired outcome and support the policy and objectives of Bayh-Dole (Would March-In Support The Policy & Objective Of Bayh-Dole; Section I). The agency would likely focus on whether there are other responsible applicants interested in manufacturing the product in question or practicing the subject invention to treat the rare disease (Section I, E). The agency would also look at timing considerations like the remaining term of the relevant patents, the time required for any regulatory approvals of new products or manufacturing facilities, and the potential length of a march-in proceeding and any appeals. Very lengthy timelines could weigh against march-in and towards more expeditious solutions. If all of the patents involved in making this treatment are subject inventions, that could weigh in favor of march-in as it is less likely other intellectual property would stand in the way of other manufacturers (Section I, B; II). Finally, the manufacturing problems in this scenario seem largely outside of the contractor's control. That suggests march-in would be unlikely to resolve non-use or unreasonable use of subject inventions in the future, although it could deter other future collaborators from developing subject inventions, weighing against march-in (Section III).

Scenario 5

Background: A water filtration company has an exclusive license from a government-funded university to patents covering a subject invention for point-of-use water purification technology. The company manufactures a small device, which can be used to remove organic contaminants like pesticides in households that get their drinking water from wells. Ten years ago, a certain pesticide became very popular because it was safe for native U.S. pollinators but effective at combatting an invasive beetle destroying crops nationwide. But recent studies have shown a ten-fold increase in pediatric cancers that is connected to drinking groundwater contaminated with that pesticide. The water filtration company's point-of-use purification device is uniquely able to remove even trace amounts of that pesticide. As a result, demand has spiked. However, the company has not increased its manufacturing pace, so the price of the

devices has jumped 1000% in the past three months. The combination of the limited supply and increased prices has resulted in a health emergency that cannot be adequately addressed without expanding capacity. Three other manufacturers and a dozen rural community groups have asked the government funding agency to march-in and issue licenses to increase supply and reduce cost of the specialized filters.

Discussion: Given the pressing need, march-in would be among a range of options the agency would likely consider for resolving this problem promptly and protecting children.

Statutory Criteria – In this scenario, it appears that march-in may alleviate a health or safety need that, at this time, is not reasonably being satisfied by the contractor or its licensee (Statutory Criterion 2). First, the agency would seek to confirm underlying information, including about the health or safety need. For example, the agency would consult with experts and appropriate agencies, seek available information about how the pesticide contributes to pediatric cancer, and investigate how (and how effectively) this purification device removes the pesticide (Statutorily Defined March-In Criteria; Criterion 2; Sections I-III). The agency would also confirm basic facts with the contractor, including whether it is refusing to ramp up manufacturing and how much the price has increased. All of this would be with an eye toward mitigating the risk of pediatric cancer, which in this scenario would appear to require an increased supply and accessible filtration devices (Section IV). The agency would likely assess whether the contractor is in fact exploiting the health or safety need to set a product price that is egregious within the U.S. market and unjustified given the totality of circumstances (Section IV, E). If the evidence suggests this 1000% increase was an intentional act by the company to “cash-in” on this newly discovered health and safety need, that would weigh in favor of march-in. However, if the entire market has seen similar price increases and there is a compelling justification for such a high price, e.g., a shortage of essential raw materials is making increased production impossible, that would weigh against march-in.

Policy & Objectives of Bayh-Dole – The agency would similarly need to assess the practical impact of march-in on the unmet need and carefully evaluate all alternatives (Would March-In Support the Policy & Objective of Bayh-Dole). For example, if the pesticide stays in the water supply long term and there’s no indication other solutions will become available very soon, that would weigh in favor of march-in. If farmers are no longer using the pesticide in question and it dissipates quickly, then the demand for filters could subside soon, weighing against march-in. Additionally, the fact that there are already other interested manufacturers suggests march-in could increase production by these entities soon, weighing in favor of march-in. However, the agency would need to examine the capability of the prospective licensees and manufacturers and be comfortable these are “reasonable applicants” that could get a product to market (Section I, E). Here again, the agency would also consider possible alternatives, like other technologies to protect children (Section II). For example, perhaps another agency has already banned the pesticide and that, combined with an alternative filtration technology, could bring the pesticide levels to a safe percentage within the year, weighing against march-in. Finally, the agency would analyze the wider implications of march-in to ensure consistency with Bayh-Dole policy and objectives (Section III). The agency may determine that exercising march-in rights would have a meaningful positive impact on child health, increase confidence that federally funded inventions are available to improve the lives of Americans, result in increased competition, and set an example of actions by contractors or licensees that are “off limits.” The agency may determine those factors outweigh any negative impacts on investments in future federal R&D, given the apparent bad-faith actions of the contractor (Sections III, A, 2; III, 3).

Scenario 6

Background: In the early stages of a respiratory virus pandemic, a consumer goods company working under a government contract developed improved face masks that filter out 99% of that virus’ particles. The contractor filed for a patent on its mask technology, and it reported the subject invention and associated patent application to the government. During a three-week window, several experts published studies confirming that the virus spreads easily and rapidly through airborne transmission. The following week, the consumer goods company increased the price of its masks 100%, and it continued to raise the price over the course of a month, resulting in a 400% price increase. The company has also sent letters to other mask manufacturers, flagging the pending patent application and promising to file lawsuits against any infringers as soon as the patent issues. Trade associations representing frontline healthcare workers asked the government funding agency to march-in and issue licenses to those other manufacturers to bring down the price of the masks.

Discussion: Given the urgent need, march-in would be among a range of options the agency would likely consider for resolving this problem promptly and protecting frontline workers.

Statutory Criteria - In this scenario, it appears there could be actions that promote nonuse or unreasonable use of the subject invention (Criterion 1) as well as health and safety needs that are not being reasonably satisfied by the contractor (Statutory Criterion 2). The agency would first ask the contractor for information to confirm the basic facts—for example, that the contractor has increased price 400%, how that increase compares to prices for other masks, how that price point compares to the cost of developing and manufacturing the masks, that the contractor has filed for patents, and that it is threatening to file suit against competing manufacturers when a patent issues. Based on that, the agency could continue its inquiry to assess whether march-in would alleviate an unmet health need and/or ensure the benefits of the mask are available to the public on reasonable terms, exploring questions detailed in Statutorily Defined March-In Criteria; Criterion 1 and 2. In this scenario, more affordable masks are needed and it may be that more mask production would bring down the price (Section III; IV, E). The agency would likely need more information to assess whether the contractor is exploiting the health or safety need in setting a product price that is egregious within the U.S. market and unjustified given the totality of circumstances and/or whether the masks are available on reasonable terms (Section IV, E). By rapidly increasing the price of masks and threatening other manufacturers with litigation during an urgent public health need, the contractor seems focused on keeping prices unusually high while not satisfying demand. This could weigh in favor of march-in. But the agency would need additional information, for example, to understand the unmet need, how march-in would impact it, and why the contractor is responding this way. Are other mask manufacturers charging similarly high prices under the circumstances, all to fund facility expansion? If so, that would weigh against march-in (Section IV, E). Is there a strong connection between mask usage (or mask availability) and public health benefit? Does this mask provide unique benefits over others? Stronger evidence the masks resolve a health need could weigh more in favor of march-in, whereas tangential evidence of unique benefits could weigh against march-in (Section III). Is there a legitimate reason not to license other manufacturers for this mask, e.g., they lack capacity or capability? Answers to those questions could justify the contractor's actions and weigh against march-in (Section IV, E).

Policy & Objectives of Bayh-Dole – The first part of this analysis looks at whether march-in would promote utilization and protect against non-use of the subject invention (Would March-In Support The Policy & Objective Of Bayh-Dole Section I). The agency would need to understand whether other manufacturers are “responsible applicants” that would be interested and willing to make the masks in question (Section I, E). The agency would also likely want to understand the impact of the pending patent application and threat of (possible) litigation on the other manufacturers (I, B; II, E). If the other manufacturers are actually deterred from making the product, then that could weigh in favor of march-in. However, if other manufacturers do not believe valid patents are going to issue on this subject invention, and those manufacturers are willing to immediately start manufacturing masks, that could weigh against march-in. The agency would also consider whether other action might be warranted—for example, the agency purchasing or manufacturing the masks itself at a lower price (Section II, A). Whether march-in would protect the public against non-use or unreasonable use of subject inventions more broadly likely depends on similar facts (Section III). However, in a situation of a pressing health or safety need, where a contractor is artificially keeping supply low while demand for a product is high or artificially increasing the price, march-in could deter others from similar actions in the future without impacting contractors and licensees who act in good faith to bring products to market and meet market demand (Section III, A, 2).

Scenario 7

Background: The Department of Transportation has been working with industry to develop the requirements and technologies for vehicle-to-everything (V2X) communications. This technology will allow vehicles to automatically communicate with each other basic safety messages including location, direction of travel, speed, and other relevant information that can serve to reduce traffic accidents. Additionally, the technology will allow vehicles to receive messages from networked roadside units that can warn a driver about work zones or traffic accidents miles ahead of them along their current path of travel or road conditions such as icy or wet roads. The National Highway Traffic Safety Administration (NHTSA) within the U.S. Department of Transportation is responsible for the Federal Motor Vehicle Safety Standards and the regulatory requirements that all automobiles must satisfy to be sold in the U.S. NHTSA has issued a regulation that requires the inclusion of a transceiver capable of transmitting and receiving such messages in all new automobiles. A contractor under government funding developed a technology essential to the operation of such transceiver but to date has refused to license the technology to any auto manufacturers, instead insisting that it can supply the entire automotive industry with the required equipment. Auto manufacturers have approached the government seeking assistance in getting a license to manufacture the equipment because the contractor has failed to satisfy industry demand.

Discussion:

Statutory Criteria - In this scenario, it appears that march-in may help meet requirements for public use specified by a federal regulation (Statutory Criterion 3). The federal regulation in question for this march-in analysis requires inclusion of a transceiver capable of transmitting and receiving basic safety messages in all new automobiles. The agency would need to investigate whether the contractor is meeting the industry's need in order to comply with this regulation and determine

whether the contractor is restricting access or imposing barriers (Statutorily Defined March-In Criteria; Criterion 3, II, A). The agency would discuss the issue with the contractor, and if the contractor is in fact unwilling to license the technology, the agency would likely discuss whether and how the contractor plans to individually meet the current or future needs (Section VI). If the contractor has discernable plans, the agency may choose to set certain timeframes or thresholds that the contractor must meet to avoid march-in. The agency may also assess whether the contractor is willing to license the subject invention on commercially reasonable terms—if it is refusing prospective licensees because it will only accept unreasonably high royalties, that could weigh in favor of march-in (Section II, A). If it is open to reasonable licensing offers, that cuts the other way. The agency would also need to explore whether there are other technologies that do or could also address this same need (Section IV). If the contractor's invention is the only one that could address this need, and the company cannot offer a plan to provide adequate supply and meet the regulatory requirements, these factors would weigh in favor of march-in. Whereas, if there are alternatives that could meet or implement the regulatory requirements, that would weigh against march-in.

Policy & Objectives of Bayh-Dole – The agency would assess the practical impact of march-in on regulatory compliance, carefully evaluate alternatives, and look at the broader context (Would March-In Support the Policy & Objective of Bayh-Dole). For example, the direct interest from auto manufacturers suggests that march-in might increase production of the subject invention, since there are already interested licensees (Section I). Although the agency may also want to look at timelines; for example, if these technologies have short life cycles and there is likely to be more advanced technology to meet the regulatory requirements within the year, that could weigh against march-in. Likewise, the agency would continue to look at viable alternatives that are already available to meet the regulatory needs and could be relevant to avoid march-in (Section II). Finally, the agency would review the broader impacts and policy and objectives of Bayh-Dole (Section III). The agency may determine, because the contractor cannot meet the industry need, that the negative impacts on future R&D and utilization are minimal and decide to exercise march-in.

Scenario 8

Background: A government-funded university, after years of both broad and targeted marketing efforts, executed an exclusive license for a new compound demonstrated effective in Phase III clinical trials for treating Alzheimer's disease with a large Swiss pharmaceutical company active in drug development and the manufacture of proprietary medicines. The new compound was government-funded in its initial stages of development. The terms of the exclusive license did not reference the Bayh-Dole regulations and requirement for U.S. manufacturing unless waived by the government. The exclusive licensee has begun manufacturing limited quantities of the active pharmaceutical ingredient (API) of the compound at its existing facilities in Switzerland prior to FDA approval. The Swiss company has no manufacturing facilities in the U.S. The government-funded university self-reported to the funding agency the deficiency in the terms of the exclusive license and reported the status of manufacturing the API. The government-funded university has not requested a waiver. The head of the agency has asked about possible use of march-in rights.

Discussion:

Statutory Criteria – In this scenario, it appears that the contractor did not include the agreement terms required by 35 U.S.C. § 204 in its exclusive license agreement (Statutorily Defined March-in Criterion 4). The agency would review the facts of the case to ensure that the U. S. industry preference under § 204 was triggered. Based on the facts presented, the contractor exclusively licensed the right to use or sell a product embodying the subject invention (Statutorily Defined March-In Criteria; Criterion 2, Section IV, A & C). The agency would need to confirm that the exclusive license included the right to use or sell in the U.S. (Section IV, B), and would need to confirm whether the preference for U.S. industry applies. Assuming § 204 is triggered, under this scenario the exclusive license does not include a provision requiring products to be manufactured substantially in the U.S. (Section I, C). The scenario provides that the licensee intends to manufacture only in Switzerland, but the agency would want to have the contractor confirm that the licensee has no U.S. manufacturing facilities (Section I, F). Finally, the scenario provides that the contractor has not requested a waiver of the preference for U.S. industry (Sections I, C, 1; I, F, 1). These facts, without more and if not remedied, would collectively weigh in favor of march-in.

Policy & Objectives of Bayh-Dole – Next the agency will consider Bayh-Dole's policy and objectives in its march-in assessment. As part of this analysis, the agency should consult with the contractor and determine whether the license agreement could be amended to include the preference for U.S. industry and whether the current licensee would be willing and able to manufacture substantially in the U.S. Perhaps the agency could even assist in identifying potential U.S. manufacturers (Would March-In Support the Policy & Objective of Bayh-Dole Section II, A-C). If the contractor and current licensee agree to a U.S. manufacturer or manufacturing facilities, this would weigh against exercising march-in. If they refused, that could weigh in favor of march-in. The agency should also consider whether, if the contractor had submitted a waiver, a waiver would have been granted; and it should inquire as to whether the contractor, following a notice of non-compliance by the agency, submits a domestic manufacturing waiver request (Section I, D). In this scenario, it appears the contractor conducted extensive marketing to find a licensee; suggesting it was difficult to line up a manufacturer anywhere in the world. If the agency, for example, finds that the contractor offered this technology for license under similar terms to companies who were likely to manufacture in the U.S., but none of those manufacturers were interested, then the agency may consider granting a domestic manufacturing waiver and decide not to march-in. If the contractor refused to apply for a waiver, that could weigh in favor of march-in. As part of this assessment, the agency could likewise consider whether there is another prospective licensee able to manufacture substantially in the U.S. (Section I, E). Finally, the agency would consider the wider implications of march-in, including whether exercising march-in—if the contractor refused to amend its license, seek a waiver, or relocate manufacturing—would send a message that the U.S. industry preference provisions of the Bayh-Dole Act will be enforced (Section III, A, 2).