

Comment on transparency of march-in proceedings (NIST–2023–0008)

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

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Introduction

The Draft Guidance describes the procedures for “when the agency decides to move forward with formal march-in proceedings.” Included in that description is a footnote 6 regarding the confidentiality of the proceeding. This footnote has drawn considerable attention and criticism.

In general, exceptions to transparency should be limited and with purpose.

In many government proceedings parties are permitted to mark certain information as confidential, and have the agency or a court determine if the assertion is warranted. In the Draft Guidance, NIST proposes something much broader, that “all portions of the proceeding are closed to the public and are held confidential.” This Draft Guidance is at odds with the statute, the regulation implementing the statute, a World Health Organization (WHO) resolution on transparency, and widely accepted notions of good governance.

The Draft Guidance is also at odds with the January 21, 2009 Presidential Memorandum for the Heads of Executive Departments and Agencies titled “Memorandum on Transparency and Open Government,”¹ which states:

Government should be transparent. Transparency promotes accountability and provides information for citizens about what their Government is doing. Information maintained by the Federal Government is a national asset. My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use. Executive departments and agencies should harness new technologies to put information about their operations and decisions online and readily available to the public. Executive departments and agencies should also solicit public feedback to identify information of greatest use to the public.

Footnote 6 regarding confidentiality of the march-in proceeding misstates the restrictions on transparency in the statute

Footnote 6 of the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights making a sweeping assertion of secrecy for march-in proceedings.

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

This footnote in the Draft Guidance, which refers to “all portions of the march-in proceeding” does not reflect the more limited restrictions on disclosures found in the Bayh-Dole statute or the relevant implementing regulation.

35 U.S.C. 202(c)(5)

¹ Memorandum of January 21, 2009, Transparency and Open Government, Memorandum for the Heads of Executive Departments and Agencies, Published in the Federal Register on January 26, 2009. 74 FR 4685. <https://www.federalregister.gov/documents/2009/01/26/E9-1777/transparency-and-open-government>,

The statute referred in Footnote 6, 35 U.S.C. 202(c)(5),² was amended in 1984³, and currently reads as follows:

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

Note that the statute's mandate is to treat as confidential information on the utilization of inventions, that is either, (1) collected from periodic reporting to a federal agency, or (2), obtained as part of a Section 203 march-in proceeding.

37 CFR § 401.6 (4)

The regulation on march-in proceedings that concerns confidentiality similarly addresses the issue of the utilization of inventions, and in this regard, refers only to information obtained during a march-in proceeding. The relevant part of the regulation is 37 CFR § 401.6 (4), which reads in full:

(4) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee) or otherwise required by law.

For the regulation to be read as implementing the statute, the restriction on disclosure concerns the documentary evidence of the utilization of inventions that is presented by or on behalf of the patent holder in the proceeding, and it is only this "portion of the march-in proceeding" that is considered closed to the public.

² <https://www.govinfo.gov/app/details/USCODE-2000-title35/USCODE-2000-title35-partII-chap18-sec202>

³ See the Annex on the history of 202(c)(5).

The original version of the regulation was published in 1987⁴, implementing 1984 changes in the statute.⁵ The only change since 1987 was a change the paragraph number from (e) to (4), and to add the last 5 words, “or otherwise required by law. When publishing the new version of 37 CFR § 401.6 (4), the National Institute of Standards and Technology (NIST) included this comment:

Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, A Rule by the National Institute of Standards and Technology on 03/24/2023, Document Citation: [88 FR 17730](#).

7. Comment:

Several comments were received relating to newly designated § 401.6(a)(4) (previously § 401.6(e)), which concerns the confidentiality of information obtained during march-in proceedings. Concern was expressed over the addition of language that allows an agency to disclose information obtained during a march-in proceeding to persons outside the Federal Government when “otherwise required by law.”

Response:

The intent of this additional language is to put contractors on notice that other laws may require disclosure of the information, and compliance with such laws is mandatory, whether or not the phrase in question is added to the regulations. NIST has maintained the phrase in this final rule.

Utilization is different from the obligation to make available to the public on reasonable terms.

Utilization is not defined by the Bayh-Dole Act statute, but there is a reference to “the invention is being utilized” in the definition of “practical application” in 35 U.S.C. 201(f).

§201. Definitions

(f) The term “practical application” means 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.

The term “being utilized” is one requirement to bring an invention to “practical application.” A different condition is that “Its benefits are . . . available to the public on reasonable terms.”

⁴ 52 FR 8554, Mar. 18, 1987.

⁵ Public Law 98-620.

In the previous march-in cases there has been no dispute about the inventions being utilized. Both the companies and the petitioners have agreed that products are manufactured, registered with the FDA and sold.

What is often in dispute in a march-in case is whether an invention's "benefits are . . . available to the public on reasonable terms." For two decades, the NIH has refused to address the "reasonable terms" issue, while focusing only on the "being utilized" requirement.

The fact that the NIH has repeatedly seen the "being utilized" part of the statute as independent of the "available to the public on reasonable terms" requirement just illustrates how these are different obligations, standards and subjects to address in fact finding.

Obtained as part of a proceeding under Section 203

The requirement that information on utilization be confidential only applies to information obtained from the contractor through periodic reports to the funding agency or as part of a Section 203 proceeding.

The companies themselves typically make public sales revenue in reports to shareholders. There are public (Medicare and Medicaid Dashboards, VA, State Medicaid, etc) and private (IQVIA) databases on revenues and units of products sold. In practice, none of this information is actually confidential for products with significant sales revenue.

The agency can and should make public information discussed in the march-in proceeding on the topic of the utilization of inventions, when that information is originally obtained outside of the march-in proceedings, such as from company SEC filings, merger reviews, third party databases or court records.

NIH practices in previous march-in cases

In all previous march-in cases, the NIH itself has made its own findings public about the utilization of the inventions. The NIH has cited the fact that inventions are available and used as its rationale to reject march-in petitions. What the NIH has been avoiding addressing in its findings are the reasonableness of the terms under which the inventions are available to the public.

Moreover, as noted above, the restriction on information on utilization obtained during a proceeding is not absolute. An agency may find that some disclosures are "otherwise required by law," and may also find that information on utilization has in fact already been disclosed outside of the march-in proceeding, is not in fact confidential, and/or, as is often the case, publicized by the patent holders themselves in public statements about the march-in case.

It is also the case that the NIH can hold a hearing or other fact finding proceeding, prior to a formal march-in case. This possibility is concretely illustrated by the hearing on the Novir march-in petition, or the published correspondence in the Cellpro or Fabrazyme cases.

The 2004 hearing on the Norvir march-in case was public and attended by news reporters.

In the CellPro case, where Birch Bayh represented the party asking for the march-in, the NIH has published extensive correspondence, including information on utilization efforts by the patent holder, as part of the public record published on the NIH web page.

In the Fabrazyme case, the NIH has released very detailed information on the supply of Fabrazyme, and even the NIH's demand that the patent holder abandon an injunction in Germany regarding the infringement of a German patent on the NIH-funded invention.

To bring this conversation back to more practical terms, the authors of the guidance should not only amend footnote 6 to reflect the far narrower scope of confidentiality, but also consider these public documents published by the NIH itself.

CellPro March-In Petition Documents

<https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/cellpro-march-petition-documents>

Fabrazyme March-in Case

Documents related to “the Fabrazyme matter” including periodic regular updates to the National Institutes of Health (NIH) required from the Mount Sinai School of Medicine and Correspondence, 2011: https://keionline.org/sites/default/files/Fabrazyme-NIH-Sinai_2011u.pdf

NIH Public Meeting on Norvir/Ritonavir March-in Request, May 25, 2004.

<https://www.techtransfer.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>

ANNEX 1: History of Section 202(c)(5)

For additional context it is useful to review the history of the statutory language of the statute quoted in footnote 6: 35 U.S.C. 202(c)(5).

The original 1980 version of 5 U.S.C. 202(c)(5) in PL 96-517 was 71 words, and read as follows:

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

In 1984, Public Law 98-620 made a number of changes in the Bayh-Dole Act, including this change to 202(c)(5) that changed a “may” to a “shall” and added 24 words to make the reference to Section 203, which is the march-in right.

by striking out "may" in section 202(c)(5) and inserting in lieu thereof "as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall";

It is worth noting that among the other changes to the Bayh-Dole Act in 1984 was the consequential and often overlooked elimination of the limit on the term of exclusivity of patents. The 1980 Act⁶ limited the term of exclusivity under Section 202 as follows:

(B) a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for a period in excess of the earlier of five years from first commercial sale or use of the invention or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance unless, on a case-by-case basis, the Federal agency approves a longer exclusive license.

Thus, in 1984, the Congress eliminated restrictions on terms of exclusivity for Section 202 licenses, and created new restrictions on the scope of disclosures in a march-in proceeding.

The 1984 amendments to Section 202(c)(5) did not extend to any information relating to a Section 203 march-in proceeding, but rather “periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees,” and “information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203.” (emphasis added)

⁶ 94 STAT. 3022 PUBLIC LAW 96-517-DEC. 12, 1980.

ANNEX 2: Change in 37 CFR 401.6 relating to confidentiality.

52 FR 8554, Mar. 18, 1987	88 FR 17735, Mar. 24, 2023
<p>(e) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee).</p>	<p>(4) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee) <u>or otherwise required by law.</u></p>

The one change in the regulation concerns the ending of the final sentence. The last sentence in the original version states, "agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee)." The amended regulation adds the exception: "or otherwise required by law." This clause introduces an additional condition under which agencies may disclose information, broadening the circumstances for disclosure beyond just the contractor's authorization. The additional clause is a significant difference, as it potentially expands the scope of information disclosure beyond the contractor's control. This includes situations where legal obligations necessitate the release of information that the contractor might not have otherwise authorized, such as for Medicare price negotiations, antitrust proceedings, private litigation, Congressional investigations, or other situations.

ANNEX 3: WHA72.8 - Improving the transparency of markets for medicines, vaccines, and other health products

In 2019, the United States government enthusiastically enforced the World Health Assembly resolution WHA72.8 - Improving the transparency of markets for medicines, vaccines, and other health products.⁷

This global norm, which the United States endorsed, included this obligation on transparency:

Agreeing that policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there are reliable, comparable, transparent and sufficiently detailed data¹ across the value chain,

1. URGES Member States in accordance with their national and regional legal frameworks and Contexts:

(3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;

⁷ https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/a72_r8-en.pdf