April 5, 2021

By Federal eRulemaking Portal

National Institute for Standards and Technology
101 Bureau Drive
Gaithersburg, MD 20899


I respectfully submit this comment in support of proposed rule § 401.6(e) in “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions,” which clarifies the “march-in right” created in the Bayh-Dole Act of 1980. This new rule should be adopted given a profound misunderstanding of the Bayh-Dole Act’s “march-in right” by some academics and activists. The National Institute for Standards and Technology (NIST) should promulgate this much-needed regulatory clarification on the legal predicates for a federal agency to exercise its march-in power. The proposed regulation achieves this important clarification of the march-in power by codifying in its enacting regulations the meaning of the statutory text and its longstanding interpretation by federal officials that it is not a price-control provision. I also propose additional edits to the final rule so that the purpose of this codification and clarification is fully achieved so that future regulatory clarifications will not be necessary.

NIST should adopt § 401.6(e), but, ideally, § 401.6(e) should be phrased more succinctly and more clearly in implementing the clear textual meaning and undisputed legislative intent of the Bayh-Dole Act’s march-in power. Section 401.6(e) would better achieve its clarifying function by eliminating all unnecessary adjectives and phrases. Thus, it should be read as follows: “March-in rights shall not be exercised based on the pricing of commercial goods and services arising from the practical application of the invention.”
This revised § 401.6(e) would eliminate all sources of potential confusion that will be created by academics and activists engaging in further policy-driven “interpretation” of the statute or its implementing regulations. This is not conjecture. This clarifying regulation is necessary precisely because some academics and activists have sowed unjustified confusion about the meaning of the march-in power. They will continue to do so with any implementing regulation that contains any language that gives them an opportunity to engage in further statutory petitfoggery, sowing more confusion or doubt where none exists or should exist. Brevity is the soul of clarity, to turn a phrase from Shakespeare, and ideally NIST should follow this principle in enacting § 401.6(e).

In support of § 401.6(e) in this comment, I will apply well-established canons of statutory construction to the conditions set forth in § 203 that authorize the march-in power, which make clear that § 203 is not a price-control statute. This is confirmed by the statutory text, by the understanding of its legislative drafters and sponsors, and by the consistent interpretation of this statutory provision by federal officials in the four decades since its enactment. Lastly, I will explain how a price-control theory was superimposed on § 203 by some academics and activists, which is contrary to the express meaning of this statutory provision within the Bayh-Dole Act.

The Statutory Meaning of the “March-In Right”

Section 203 in the Patent Act authorizes the “march in right” provided by the Bayh-Dole Act, enacted by Congress in 1980.¹ The statutory language is clear. Among the four conditions set forth in § 203 permitting a federal agency “to grant a nonexclusive, partially exclusive, or exclusive license,”² there is no authorization to do so for the purpose of limiting or otherwise controlling prices in the marketplace.³ If Congress wanted to authorize federal agencies to control prices of patented products or processes sold in the marketplace, it would have used express language in the text of § 203 stating that “price” or “reasonable price” is a triggering condition. It did not.

Instead, § 203 permits a federal agency to grant licenses “to a responsible applicant” only in four specific, delimited circumstances: (1) if the assignee or licensee “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) “to alleviate health or safety needs which are not reasonably satisfied,” (3) to meet requirements for public use set forth by regulatory mandates that are not “reasonably satisfied,” or (4) “a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement.”⁴ These are the four prerequisites, provided in the disjunctive, for a federal agency to exercise the march-in power. They state necessary conditions for the march-in power. None of these statutory conditions granting this power to a federal agency to license a patented product or process provides that “price” or the need for the government to set a “reasonable price” justifies this power.

As the United States Supreme Court has explained: “We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says

---

² § 203(a).
³ See § 203(a)(1)-(4).
⁴ § 203(a)(1)-(4).
there. When the words of a statute are unambiguous, then, this first canon is also the last: ‘judicial inquiry is complete.’”5 This is the “cardinal canon” that all courts apply “in interpreting a statute.”6

This cardinal canon makes clear that § 203 does not authorize federal patent licensing as a response to prices paid by consumers in the marketplace. Nowhere in § 203 can one find the terms “price,” “prices charged by an assignee or licensee,” or other price terminology as a triggering condition for a federal agency to grant licenses to set a “reasonable price” on a patented product or process under the Bayh-Dole Act.7 In sum, § 203 is not a price-control statute.

Additional canons of statutory construction reinforce the clear, legal meaning of the march-in conditions set forth in § 203. It is well established in statutory interpretation that a statutory list is an exclusive list, i.e., “the expression of one or more items of a class implies that those not identified are to be excluded.”8 (This is known as the expressio unius est exclusio alterius canon.) In 1978, for example, the Supreme Court applied expression unius to conclude that the specific list of “hardship exemptions” in the Endangered Species Act of 1973 were the only exemptions permitted by the statute.9 Applying this same canon of statutory construction to the Bayh-Dole Act of 1980, § 203 lists four “exemptions” from a patent owner’s exclusive right to license or assign its property rights in the marketplace—the triggering conditions for the march-in power to be invoked by a federal agency. “Price” is not included among these four statutory exemptions.

In sum, longstanding and well-established canons of statutory construction make clear that § 203 is limited to its four express “exemptions” from the fundamental rights of all patent owners to exclusively assign or license their property rights in the marketplace.10 Conditions of price, a reasonable price, or other price terminology are not found in any of the four conditions. According to expression unius, there is no basis in the statutory text in § 203 to argue that “price” is an exemption that justifies a federal agency to invoke the march-in power.

The Legislative Understanding and Intent of § 203

The statutory text is clear, and thus it is unnecessary to go further—the “inquiry is complete” that § 203 is not a price-control provision.11 Yet, if one does choose to look to extra-statutory sources of statutory meaning in interpreting § 203, it remains clear that this statute is not price-control provision. Long-established extra-statutory sources in construing the meaning of a statute, such as statements of sponsors of legislation or the consistent interpretation of an enacted statute by federal

7 See INS v. Phinpathya, 464 U.S. 183, 189 (1984) (stating that “in all cases involving statutory construction, our starting point must be the language employed by Congress, . . . and we assume that the legislative purpose is expressed by the ordinary meaning of the words used”) (quotations and citations omitted).
9 See Tennessee Valley Authority v. Hill, 437 U.S. 153, 188 (1976) (“In passing the Endangered Species Act of 1973, Congress was also aware of certain instances in which exceptions to the statute's broad sweep would be necessary. Thus, § 10, 16 U.S.C. § 1539 (1976 ed.), creates a number of limited ‘hardship exemptions,’ . . . meaning that under the maxim expressio unius est exclusio alterius, we must presume that these were the only ‘hardship cases’ Congress intended to exempt.”).
11 See supra note 5, and accompanying text.
officials authorized to apply that statute, compel the conclusion that § 203 does not authorize a march-in power to mandate lower prices in the marketplace.

First, Senators Birch Bayh and Robert Dole—the legislative sponsors of the Bayh-Dole Act—made it very clear that their statute did not create a price-control power in the march-in provision. They explained this in response to the novel argument by Professors Peter Arno and Michael Davis in a 2001 law journal article in which they superimposed a price-control theory onto the Bayh-Dole Act (and restated in an op-ed they published in the Washington Post the following year). Senator Bayh and Dole stated emphatically that Professors Arno and Davis’ academic theory was unjustified given the clear statutory text that Congress enacted into law in 1980:

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. . . . The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.13

Second, Senators Bayh and Dole’s statement of the legislative intent underlying the clear statutory text is confirmed by the consistent interpretation of the march-in power by federal agencies in the past four decades. A Congressional Research Service report on the march-in power published in 2016 details six petitions to the National Institutes of Health (NIH) requesting NIH to exercise its march-in power to lower the prices of patented drugs sold in the healthcare market.14 In every case, NIH denied the petition on the grounds that § 203 and its prior authoritative interpretation by NIH did not permit the march-in power to be used arbitrarily and capriciously to lower drug prices.15 Again, NIH emphasized that § 203 constrained federal agencies to only the four conditions set forth in the statute, and none of these conditions states that “price” or “reasonable price” authorizes the march-in power. In a more recent green paper published by NIST in 2019, NIST identifies ten petitions to NIH to invoke the march-in power for the purpose of lowering drug prices—all ten were rejected given that the statute did not authorize the agency to act on this basis.16

The statements by NIH in these petitions—released over the decades in both Democrat and Republican Administrations—are evidence of the clarity of § 203 and how the four specific conditions for authorizing the march-in power do not support the price-control theory asserted by petitioners, academics, or activists. In 2004, NIH explicitly stated in response to a petition to

---

15 Id.
16 See Return on Investment Initiative for Unleashing American Innovation 29 (NIST Special Publication 1234, April 2019) (“NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority.”).
exercise the march-in power to lower the price for a drug used to address the AIDS epidemic that “the extraordinary remedy of march-in is not an appropriate means of controlling prices.”\textsuperscript{17} This same point was reiterated in 2014 in NIH’s response to another petition submitted by Knowledge Ecology International and other organizations: “As stated in previous march-in considerations the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH’s march-in authorities.”\textsuperscript{18}

In sum, even if one finds the statutory text to be ambiguous, extra-statutory sources of meaning make clear that the march-in power is limited to the four conditions set forth in § 203, which are exclusive of any purported price-control theory. This is confirmed by Senators Bayh and Dole, and by the consistent and uncontradicted interpretation of § 203 by agency officials in bipartisan administrations for over four decades.\textsuperscript{19} As a matter of the statutory interpretation, this should have been the end of the matter and § 401.6(e) would not be necessary. Unfortunately, an imaginatively devised price-control theory was given the appearance of plausibility through reliance on a distinct definitional section in the Bayh-Dole Act. This price-control theory and why its argument is still unavailing as a matter of statutory interpretation is the focus of the next section.

A Price-Control Theory Superimposed on § 203 and Contrary to Its Meaning

Section 401.6(e) is necessary because an academic price-control theory was superimposed on the Bayh-Dole Act statutory regime in 2001—many years after its enactment in 1980.\textsuperscript{20} Policy activists picked up this theoretical argument—without any basis in the statutory language or other legitimate sources of statutory meaning and intent—and have pushed it in the public policy debates and in petitions to NIH, sowing confusion about the meaning of the march-in power in § 203. But the foundation of this price-control theory was—and is—unconnected to any rule or norm employed by agency officials or judges in interpreting statutes. Nonetheless, the confusion and policy-driven arguments about the nature and function of § 203 continue to be asserted to federal agencies, as evidenced in the public hearing on this proposed regulation.\textsuperscript{21} Thus, it is now required to codify the clear meaning of § 203 in the implementing regulations for the Bayh-Dole Act.

Before 2001, some march-in petitions to NIH invoked an expansive, policy-driven “interpretation” of the march-in power, and were similarly rejected;\textsuperscript{22} but it was not until the 2001 law journal article by Professors Arno and Davis (and their subsequent Washington Post op-ed) that their price-control theory of § 203 took hold of academics and activists’ imaginations. It bears emphasizing how much Arno and Davis’ price-control theory is completely divorced from the statutory language and the legislative record. To take one small example: Arno and Davis assert in their law journal article that, in enacting § 203, “Congress’s concern with march-in rights

\textsuperscript{17} NIH Office of the Director, In the Case of Norvir Manufactured by Abbott Laboratories, Inc. (July 29, 2004), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.


\textsuperscript{19} See Thomas, supra note 14, at 8-10; Return on Investment Initiative for Unleashing American Innovation, supra note 16, at 28-30.

\textsuperscript{20} See Arno & Davis, supra note 12.

\textsuperscript{21} See Joseph Allen, Setting the Record Straight on NIST’s Public Meeting: No, Senators Bayh and Dole Didn’t Sell Out Their Law, IPWatchdog (March 2, 2021), https://www.ipwatchdog.com/2021/03/02/setting-record-straight-nist-public-meeting-senators-bayh-dole-didnt-sell-out-law/id=130443/.

\textsuperscript{22} See, for example, NIH Office of the Director, Determination in the Case of Petition of CellPro, Inc. (Aug. 1, 1997), https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf (rejecting petition in part to invoke march-in power given argument that company was too slow in bringing a medical device to market).
focused exclusively on maintaining competitive conditions, controlling profits, and doing so through price control.”

After stating this, they produce a myriad of quotes from the legislative record allegedly supporting their factual claim that “Congress’ concern with march-in rights focused exclusive on . . . price control” in enacting § 203, but not a single quoted source refers to either “price” or “price control.”

Instead, the quoted participants in the legislative process repeatedly refer to a concern with the “public interest,” which clearly is a function of the four specific triggering conditions set forth in § 203. It is only in the minds of academics that “public interest” is literally a synonym for “price control”—just as they equally and mistakenly equate “reasonable terms” with “reasonable prices,” as will be explained.

Unfortunately, the Bayh-Dole Act contains language that has been exploited by the academics and activists pushing this price-control theory to give their arguments a patina of plausibility. One of the four authorizing conditions in § 203 is when the patent owner or licensee “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.”

The phrase “practical application” is further defined in § 201(f) to “mean 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 phrase “available to the public on reasonable terms” in a portion of the § 201(f) definition of “practical application” in § 203(a)(1) has been exploited by advocates for the price-control theory of § 203. They have argued that “reasonable terms” means “reasonable prices.” Their arguments have sown unnecessary confusion.

In the 2019 NIST green paper, for instance, it states that “reasonable terms” is ambiguous, and thus the green paper appeals to longstanding agency interpretations to construe this phrase as referring only to “reasonable licensing terms.”

This confusion, while understandable given the untold number of times this phrase has been invoked over the past two decades as a justification for the price-control theory of § 203, is still deeply mistaken simply as a matter of canons of statutory interpretation.

It is a basic canon of statutory interpretation that a phrase must be construed within the context of the statutory regime in which it exists. The Supreme Court has repeatedly explained: “It is a ‘fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.’”

“We do not . . . construe statutory phrases in isolation; we read statutes as a whole.”

In the Bayh-Dole Act, the price-control theory results from a myopic focus on “reasonable terms” as a definitional element in § 201(f) without regard to the complete statutory condition set forth in § 203(a)(1) in which the defined phrase “practical application” appears. Even NIST has been

[24] Id.
[25] Id.
confused by this sleight-of-hand statutory argument by academics and activists,\textsuperscript{31} which perhaps explains the additional and unnecessary adjectives and phrases in the proposed regulation in § 401.6(e). But once “reasonable terms” as a definitional element for “practical application” is viewed within the full context of the Bayh-Dole Act and the condition set forth in § 203(a)(1), any confusion about or misrepresentation that this sub-section is a price-control provision ends.

First and foremost, the Bayh-Dole Act addressed the problem that important innovations were not being commercialized in the marketplace given lack of certainty about title in the underlying invention due to federal funding of upstream research.\textsuperscript{32} The function of the Bayh-Dole Act was not to impose price controls on these patented inventions, but to resolve this fundamental legal confusion by making clear that innovations ultimately derived from original research that received even a portion of federal funding are patentable by the inventors or discoverers.\textsuperscript{33} This advanced the commercialization function of the patent system,\textsuperscript{34} as patent owners like universities would transfer their property rights via assignments or licenses into the marketplace.

In the context of the Bayh-Dole Act, § 203 provides for circumstances in which federal agencies can “march in” and license patented products or services when the patent owners are not achieving the commercialization function of this statutory regime. This core commercialization function of the Bayh-Dole Act animates all four conditions set forth in § 203, which all address circumstances in which a patented product or service is not available in the marketplace. For example, § 203(a)(3) authorizes the march-in power for a federal agency to license a patent when a patent owner fails to take the necessary steps to “reasonably satisfy” other legal requirements before a patented product can be made available for “public use,” such as satisfying the regulatory testing and approval requirements of the Food and Drug Administration (FDA) for new drugs. A failure to obtain FDA approval for a patented drug would prevent the “public use” of this drug by patients.

The condition set forth in § 203(a)(1) that the march-in power may be invoked when “effective steps” are not taken by the patent owner or licensee “to achieve practical application” must be read in the “context and with a view to [its] place in the overall statutory scheme” of the Bayh-Dole Act and the other three conditions set forth in § 203.\textsuperscript{35} To focus exclusively on the single definitional element of “reasonable terms” in § 201(f) as applied to the single phrase “practical

\textsuperscript{31} See supra note 27, and accompanying text.

\textsuperscript{32} See Joseph Allen (2019), New Study Shows Bayh-Dole is Working as Intended—and the Critics Howl, IPWatchdog (March 12, 2019), https://www.ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225/ (explaining regulatory history reaching back to 1940s evidencing that the phrase “practical application,” as used in § 203, means the “successful development and terms of the license, not with a product’s price”); Stephen Ezell, The Bayh-Dole Act’s Vital Importance to the U.S. Life-Sciences Innovation System 24 (ITIF, March 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system?mc_cid=1a53e317fe&mce_id=5c5d018a35 (“[T]he 1980 Bayh-Dole Act, which gave universities rights to the intellectual property generated from federal funding, spurred vastly more universities to work more closely with industry, and so created a powerful vehicle for leveraging U.S. investment in basic research into a far stronger engine for commercialization and job creation.”).

\textsuperscript{33} See Ezell, supra note 32, at 24-27 (detailing inability or lack of licensing of government of inventions developed from federally funded research).

\textsuperscript{34} See B. Zorina Khan, The Democratization of Invention: Patents and Copyrights in American Economic Development, 1790-1920, at 9-10 (2005) (In early U.S. history, “patents and copyrights played a role in the securitization of ideas through the creation of tradeable assets: intellectual property rights facilitated market exchange, a process that assigned value, helped to mobilize capital, and improved the allocation of resources. . . . Extensive markets in patent rights allowed inventors to extract returns from their activities through licensing and assigning or selling their rights.”).

\textsuperscript{35} Davis, 489 U.S. at 809.
application” in § 203(a)(1) without regard to this statutory context violates basic canons of statutory interpretation long employed by courts.36

In applying proper interpretative rules for construing phrases and provisions within a statutory context, it is clear that § 203(a)(1), as distinguished from the other three march-in conditions set forth in § 203(a)(1)-(4), governs a situation in which a patent owner or licensee fails to deploy through regular commercial means a product or process in the marketplace. In the healthcare market, for example, § 203(a)(1) would apply when a drug, device, or a method of treatment is not manufactured, distributed, or sold to patients at all, as distinguished from a failure to obtain FDA approval, as provided for under § 203(a)(3). Section 203(a)(2) governs classic public interest concerns about harms to “health or safety” arising from a failure to manufacture, distribute, or sell a patented drug. Section 203(a)(4) governs a failure by a patent owner or licensee under § 204 (mandating manufacturing the product in the U.S.) or a breach by a licensee that results in it not producing the drug at all. In sum, the definitional element of “reasonable terms” in § 201(f) is not an open-ended authorization to a federal agency to impose price controls under § 203—it is part of a statutory regime whose function is to ensure that patented products or services are in fact commercialized as such in the relevant marketplace.

When one sets aside the myopic and out-of-context focus solely on “reasonable terms” in § 201(f), the plain meaning of “effective steps to achieve practical application” in § 203(a)(1) comes into focus: it refers to efforts, or the lack thereof, to achieve the commercial deployment of a patented product or process. This is why federal officials—spanning bipartisan administrations over the course of several decades—interpreted and applied § 203 in this sense. In 1997, for instance, a petition submitted to NIH asked it to invoke the march-in power and license the Isolex 300, a patented device used to assist in organ transplant procedures.37 NIH rejected the petition as failing all four conditions in § 203 for justifying the march-in power, finding that efforts at licensing, seeking regulatory approval, and in meeting research demands were sufficient, even if greater availability and lower prices might be achieved in the short term by invoking the march-in power.38 NIH was emphatic that the march-in power was not created for the purpose of “forced attempts to influence the marketplace,” concluding that “such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally funded medical technologies.”39 This conclusion is not merely a policy choice by NIH; it is necessitated by the plain meaning of § 203, as confirmed by canons of statutory construction that mandate interpreting this provision within the Bayh-Dole Act and its clear commercialization purpose.

**The Key Function of Licensing in the U.S. Patent System**

In commenting on the proposed regulations, universities, startups, and other organizations working in the innovation industries have commented on the key role of licensing in their business models and in driving economic growth in the U.S. innovation economy generally. These patent owners are the real-world experts who can speak to this central economic function of the U.S. patent system, which has been the “gold standard” in securing reliable and effective property rights in the

---

36 The same rule of construction applies to the use of the phrase “upon terms that reasonable for the circumstances” in the preamble of § 203 that sets forth what a federal agency may do in licensing the patented product or process through its march-in power. In sum, this is not an open-ended reference to or authorization for price controls, but rather it ensures the context-specific commercial conditions for differing innovations are recognized and respected by the agency in its licensing agreements.

37 See supra note 22.

38 Id.

39 Id. at 7 (emphasis added).
fruits of innovative labors.⁴⁰ The function of the Bayh-Dole Act in incentivizing licensing of patented products and services—and authorizing a march-in power only when such licensing or related activities, such as obtaining FDA approval, do not occur—has long been a key feature of the U.S. patent system in driving economic growth and promoting a flourishing society.

Economists, historians, and law professors widely recognize that reliable and effective property rights in inventions—the ability to transfer freely these property rights in the marketplace and to receive a remedy of an injunction against ongoing infringement—have been key factors in the explosive growth in the U.S. innovation economy from the Industrial Revolution through today.⁴¹ Unlike other countries, the U.S. has consistently rejected proposals since 1790 to create in its organic patent statutes any general compulsory licensing requirements.⁴² Even more important, the U.S. has long secured under the Takings Clause patents against unauthorized use by public officials,⁴³ as contrasted with other countries that have long adopted and enforced an automatic right of use of patents by their governments, such as the “Crown’s right” in England.⁴⁴

This history is highly relevant to understanding the meaning of § 203, and not simply as a matter of statutory interpretation. If the U.S. would adopt a compulsory licensing mandate for the purpose of controlling prices in the marketplace, it would be contrary to over two-hundred years of established patent policy doctrine and policy. In such a context, courts require some form of clear statement when Congress acts to abrogate a longstanding legal understanding of a federal statutory regime—in this case, the right of patent owners to sell their property at prices the market will bear.⁴⁵ Any court would find it exceedingly odd to conclude that Congress sought to upend over 200 years of settled legal practices in the patent system by adopting a price-control measure via a generalized cross-referenced phrase, “reasonable terms,” defining another generalized phrase, “practical effect,” in a statute specifically designed to promote and foster commercialization of patents.

**Conclusion**

In adopting § 401.6(e), NIST is correct to recognize in the implementing regulations for the Bayh-Dole Act that the price-control theory of § 203 is not supported by the statutory text, by its extra-


⁴⁵ See Morton v. Mancari, 417 U.S. 535, 549 (1974) (stating canon of statutory construction that “repeals by implication are not favored”) (quoting Posadas v. Nat'l City Bank, 296 U.S. 497, 503 (1936)) (internal quotation mark omitted); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 318 (West 2012) (“A statute will be construed to alter the common law only when that disposition is clear.”).
statutory sources of meaning, or by the well-established commercialization policy that animates this statutory regime. This regulation is necessary to codify the clear meaning of the statutory text. Ideally, NIST should go further in § 401.6(e), removing all textual sources of confusion. If it does not, these unnecessary adjectives and phrases will be exploited by academics and activists seeking to create more ambiguities or unjustified powers to impose price controls were none exist.

Sincerely,

Adam Mossoff