Comments on the Proposal to Eliminate Unreasonable Prices as a Standalone Basis for March-in Rights (Modify 37 CFR § 401.6)

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(Note: The contents of this briefing note were submitted to the public comment docket of the Department of Commerce's National Institute of Standards and Technology (NIST) request for comments on proposed changes in regulations related to the Bayh-Dole Act governing "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions.")

These comments focus on one issue in the NIST proposal, a modification that would prevent the government from exercising "march-in rights" on the basis of price:

> Clarify § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.

As our comments will show, this proposal is not only inconsistent with the Bayh-Dole Act but it would harm the public interest in the affordability of publicly-funded inventions.

Relevant Previous Experience

Before addressing the substantive issue, I will note some of my experience on this particular topic. In 1991, I was asked by then-Representative Ron Wyden to review the reasonable pricing clause in a Cooperative Research and Development Agreement ("CRADA") involving Bristol-Myers Squibb (BMS) and the National Institutes of Health (NIH) for the development of Taxol. I was subsequently involved in a number of research projects and Congressional hearings on the pricing of federally-funded medicines and presented on the reasonable pricing issue at the 1994 NIH panels on CRADAs. (National Institutes of Health, 1994).

I have also been directly or indirectly involved in several march-in cases.

In 1997, I was asked by a pediatric oncologist to request that Johns Hopkins University moderate its licensing demands in the Cellpro case, and I unsuccessfully appealed to the lead inventor to agree to a non-exclusive royalty-bearing license to Cellpro, in order to ensure that pediatric patients would have access to two rather than one option for treating pediatric cancer. For a sobering account of the outcome of that case by the Wall Street Journal, *see*: (Richards, 1999).

In 2004, I was the lead proponent of the Norvir/ritonavir march-in petition, the only Bayh-Dole march-in case in which the NIH held a hearing to date. I was also the lead proponent of the 2004 Xalatan/lantanoprost march-in petition, a 2012 march-in petition concerning ritonavir, the 2016 Xtandi/enzalutamide march-in petition, and the 2017 Zinbryta march-in requests, all of which addressed concerns over unreasonable prices. Some of these cases also included requests to use the federal royalty-free right in the inventions. I also provided advice or assistance in the 2010 Fabrazyme march-in case, and in the 2019 Xtandi/enzalutamide case which is still pending before the Department of Defense.

KEI has previously provided comments on this topic in the NIST request for comments on a Green Paper on Return on Public Investment, and recently hosted a roundtable on the NIST proposals which was recorded and is submitted for the record. (For a link to the recording, see: https://www.keionline.org/35140).

KEI has reviewed a number of other cases where federal agencies have considered march-in rights or the use of a royalty free right, including disputes involving:

- 1999, the DoE/Ventana Medical Systems march-in regarding fluorescent in situ hybridization (FISH) tests;
- 2001, the NIH/WARF Stem Cell case;
- 2002, the DoE/Berkeley HeartLab case;
- 2006, CDC/NIH Reverse Genetics patents; and
- 1999 to 2007, requests to HHS and OMB to more broadly use the government's royalty free right in patents for several drugs.

These are some but hardly all of the occasions I have had to reflect on the issues raised by the NIST proposal to modify 37 CFR § 401.6.

What does "available to the public on reasonable terms" mean, and why does it matter?

The Bayh-Dole Act authorizes the government to "march-in" and issue a compulsory license to a federally-funded invention in four circumstances, including when a contractor fails to take "effective steps to achieve practical application of the subject invention [.]" 35 U.S.C. § 203(a)(1).

Practical application is now defined by statute in 35 U.S.C. § 201(f) as follows:

> (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**. (Emphasis added).

NIST is proposing a change in the regulations to change the meaning of "[p]ractical application" as it concerns march-in authority, by adding the following language to 37 C.F.R. u§ 401.6:

> (e) March-in rights 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.

Though the plain language and intent of the statute is clear, opponents of march-in authority have disputed the degree to which "available to the public on reasonable terms" goes to the prices charged for products that use the inventions. The proposed regulation seeks to narrow the grounds for a march-in in such a way that "the pricing of commercial goods and services

arising from the practical application of the invention" cannot be the "exclusive" basis for a march-in.

The history behind this dispute is worth reviewing.

The Davis/Arno Paper

In 2001, Professors Michael Davis and Peter Arno published an article in the Tulane Law Review, titled "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research." (Arno and Davis, 2001).

Davis and Arno followed with further commentary elsewhere, including on March 27, 2002, in an op-ed in the Washington Post, titled "Paying Twice for the Same Drugs." (Arno and David, 2002). Davis and Arno argued that "available to the public on reasonable terms" included the price to the public, including as patients.

Bayh Comments in the 1997 Celpro Case

Earlier, former Senator Birch Bayh made a similar case. Bayh, who lost his Senate seat in the 1980 election, was working in a series of lobbying and advocacy positions on behalf of corporate clients. In a March 3, 1997 letter to HHS Secretary Donna Shalala, co-signed by Loyd Cutler, Bayh and Cutler asked the HHS to exercise its march-in rights on behalf of Cellpro, a company selling a medical device.

Cellpro was in a dispute with Johns Hopkins University (JHU) over infringement of a patent on an invention that had been funded by HHS. At the time of the litigation, the patent had been licensed by JHU to Baxter, a company developing a device to compete with the Cellpro device. Bayh noted that the Bayh-Dole Act gave federal agencies the right to march-in to prevent "nonuse or unreasonable use of inventions." Bayh argued that the march-in was justified by the restrictive licensing terms offered by Baxter. Bayh also stated:

> CellPro submits that there may well be reason for the government to adopt regulations covering situations like the present where the same product may be claimed to be covered by patents arising out of work done by more than one federal grantee. Moreover, investigation may be needed to determine whether the royalty layering that plainly exists in the present case . . . is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation.

In his March 3, 1997 letter, Bayh refers to the prices of medical care to the public as relevant to the march-in request, and proposed that that royalty layering be addressed by regulation in order to protect the public from high prices. On August 1, 1997, Dr. Harold Varmus denied the Cellpro march-in request on the grounds that (1) the grantee or licensee had taken effective steps to achieve practical application of the patented invention, and (2) that health and safety needs of the public were reasonably satisfied by the licensee. (Varmus, 1999). Many felt the Cellpro decision was a very bad outcome for patients. (Richards, 1999).

The 2002 Bayh/Dole Letter to the Washington Post regarding Arno/Davis

On June 14, 2001, Birch Bayh joined Venable Baetjer Howard & Civiletti as a partner. In the press release, Bayh was described as “co-author of the Bayh-Dole” act, and that he would be “enhancing the firm's growing public policy advocacy practice.”

Senator Bob Dole had left the U.S. Senate in 1996, after his loss to President Clinton in the presidential election. Shortly thereafter, Dole became a beltway lawyer/lobbyist, as well as a star in Pfizer ads for Viagra. Around the time of the Davis and Arno article in the Washington Post, Bob Dole was working for the law firm Verner, Liipfert, Bernhard, McPherson and Hand, whose lobbying clients included included such companies as Amgen, American Biosystems, Biovail, Eli Lilly, and Genentech as well as trade association such as the Intellectual Property Owners Association and PhRMA.

On April 11, 2002, the Washington Post published a letter to the editor from Bayh and Dole, which claimed that Davis and Arno had “mischaracterized the rights retained by the government” and claiming that it was “intentional” that the Act made “no reference to a reasonable price.” (Bayh and Dole, 2002).

The 2004 Norvir/Ritonavir March-in Case

The following year, two events prompted the NIH to consider the extent to which march-in rights reach the reasonableness of a price. In June 2003, Bristol-Myers Squibb introduced the drug atazanavir (ATV) into the market. Research showed that ATV had its best efficacy when combined with ritonavir, an HIV drug sold by Abbott as Norvir. Abbott also sold a combination of ritonavir and the drug lopinavir, as a fixed dose combination for the treatment of HIV under the trade name Kaletra (LPV/r). In 2003, Kaletra dominated the market for protease inhibitor drugs, but many treatment experts thought that ATV with ritonavir (ATV/r) was a superior treatment. (Carreyrou, 2007).

In December 2003, Abbott Laboratories increased the price of Norvir by 400 percent when used as a standalone drug, for example, with the BMS drug atazanavir. (Fuhrmans, 2003, Carreyrou, 2007). The price hike led to an uproar among HIV patients and patient groups, including letters

from patients and health care providers to Abbott. (See: http://www.cptech.org/ip/health/aids/norvir.html).

On January 29, 2004, the non-profit Essential Inventions filed a march-in petition with the NIH on the grounds that the price of Norvir was not reasonable, and that the pricing policy had an anticompetitive purpose. (Essential Inventions, 2004). On the same day, Essential Inventions also filed a complaint regarding anti-competitive practices with the Federal Trade Commission (FTC). (Love and Flynn, 2004).

On February 6, 2004, Abbott issued a press release, announcing "initiatives to further enhance patient access, address community concerns regarding re-pricing" for Norvir. (Abbott Laboratories, 2004). These initiatives included promises to:

- "Permanently freeze the price of Norvir soft gelatin capsules for AIDS Drug Assistance Programs (ADAPs) at the price in place prior to the December 4, 2003, re-pricing;"
- "Offer free Norvir to patients without drug coverage" in the United States "without income requirements;"
- "Give free Norvir to patients who exceed their annual drug coverage maximum;" and
- "Freezing the 100 mg cost of Norvir soft gelatin capsules at $1.71 or less for use in clinical development with new chemical entities."

On May 24, 2004, the NIH then held its first and only hearing on a march-in petition. At the time of the hearing Abbott had already made several concessions on pricing and access to the NIH, as its defense against the petition. At stake in the hearing was the durability of those promises, the reasonableness of the price to persons who had private insurance, and in particular, the ability of companies like BMS to obtain a license to co-formulate ritonavir with ATV or other drugs.

At the May 24, 2004 Norvir march-in hearing, Senator Bayh gave a statement against the march-in request, focusing on the relationship between the march-in statute and the reasonable pricing obligation. (Bayh, 2004). Bayh began his testimony stating "[b]efore proceeding, I should emphasize that I am not being compensated to appear here today." Bayh failed to disclose that Venable, the firm where he was a partner, represented Abbott in other matters, as well as other organizations and firms in the life sciences field.

Bayh's testimony in the Norvir march-in case largely expanded on the themes of his 2002 Washington Post letter to the editor, arguing that that the march-in grounds and the requirement that the benefits of inventions be made "available to the public on reasonable terms" had nothing to do with prices. Bayh complained that the petition and the earlier Arno and Davis articles referred to Congressional testimonies on bills "other than Bayh-Dole" or that some quotes from testimonies were to the different parts of the bill, including a section that was eliminated before passage, requiring a pay-back of the government's support for commercially successful inventions.

A Deeper Look at the 1977 to 1979 Legislative Discussions

Bayh's complaint that Arno and Davis and Essential Inventions had referred to different bills in describing the legislative debate on the Bayh-Dole Act merits a comment. In 2009, Dianne Schauburg was commissioned to provide a "Legislative History Report and Analysis" for Public Law 96-517, as it relates to the 1980 additions to sections 200 through 211 to Title 35 of the United States Code, or the original version of the Bayh-Dole Act. (Schauburg, 2009). Schauburg notes that:

> Understanding the legislative intent of any legislative measure necessarily includes knowledge about various other measures competing with or preceding the bill ultimately enacted, particularly where the focus is on specific language. As you compare that enacted with the unsuccessful proposals in the failed bills, you may be able to discern useful insight as to the intended meaning.

The Bayh-Dole Act was the product of a longer debate in Congress over government patent policy, including legislative hearings and consideration of bills on the same topic. One discussion of the longer debate on march-in rights is a memorandum prepared by David Halperin in May 2001. (Halperin, 2001). Halperin cites a number of hearings, reports and actions by the government, beginning in 1963, including those cited in his footnote 16. Note that Halperin includes an exchange between Senator Bayh and Dr. Betsy Ancker-Johnson on the topic of march-in rights.

> The march-in rights provision of the law was contained, essentially verbatim, in the original version of the bill as it was introduced by Senators Bayh and Dole on February 9, 1979./9 However, the concept of government march-in rights, and the 'reasonable terms' standard for exercising them, were much older. In 1963, President Kennedy issued a Presidential Memorandum on patent policy that allowed for exclusive licensing of government patents in some circumstances but required that such licensing be on reasonable terms./10 A 1968 government commissioned report supported the use of march-in rights when a contractor failed to offer the invention on reasonable terms./11 President Nixon's Patent Policy Statement of 1971 tied the exercise of march-in rights to whether a licensed invention is being worked and ... its benefits are reasonably accessible to the public./12
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> Another provision in the original Bayh-Dole bill, section 204, provided for automatic recoupment of part or all the government investment in R&D after the subject invention had earned a particular level of profits./13 Although at least one of the billís sponsors, Senator Thurmond, considered this provision *[p]erhaps* the most significant feature of the bill,/14 and it was included in the Senate-passed version of the bill/15, it was eventually dropped.
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> The legislative history of the Bayh-Dole Act and similar bills introduced in the same period shows that the march-in rights provision was repeatedly cited by bill advocates as a meaningful and appropriate guarantee that the public interest would be protected./16
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> For example, there is this testimony from Dr. Betsy Ancker-Johnson, vice president

of General Motors and former Assistant Secretary of Commerce:

> DR. ANCKER-JOHNSON. Mr. Chairman ... you have written into this legislation march-in rights which, should something go wrong, gives the Government an absolute method to correct it. It seems to me that you have made the possibility for abuse virtually nonexistent by including this section in the bill.
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> Senator BAYH. How do you perceive those march-in rights would accomplish what you suggest?
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> DR. ANCKER-JOHNSON. Should there be any abuse, Mr. Chairman, whatsoever, these criteria would be applied by the Federal Government and so make it possible for the Government to ... obtain the rights to that patent and distribute them to whoever it deemed best for the exploitation of that technology for the welfare of the people. So you have this excellent guarantee written into the bill, and it seems to me you have fully provided for any remote possibility of abuse.

It is notable that the witness spoke not of patent non-use -- the danger that the government contractor would simply leave the technology on the shelf -- but patent abuse.

(footnotes 9-15 omitted)

16 See The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96 th Cong., 1 st Sess., 1979, at 44 (statement of Elmer B. Staats, Comptroller General of the United States), 70 (statement of Dr. Hector F. DeLuca, chairman, biochemistry department, University of Wisconsin Madison), 187 (statement of Howard Bremer, president, Society of University Patent Administrators); Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 96 th Cong., 1 st Sess. at 182 (statement of Gerald J. Mossinghoff, Deputy General Counsel, NASA); Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 96 th Cong., 1 st Sess., at 366 (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy); Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96 th Cong., 1 st Sess., 1979, at 54 (statement of John E. Maurer, director, Patent Department, Monsanto Corp.) ; Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96 th Cong., 1 st Sess., 1979, at 182 (statement of Dr. Ralph L. Davis, Purdue Research Foundation); 1977 Small Business Hearings at 189-95 (statement of John H. Shenefield, Asst. Attorney General, Antitrust Div., Dept. of Justice).

In his 2004 testimony, Bayh said that one quote by him about the safeguards in the bill was intended as a question, not a statement, as if that somehow made a difference. He was referring to this exchange.

> Mr. Bayh: "The other criticism comes from those that feel that this bill is a front to allow the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense. We thought we had drafted this bill in such a

way that this was not possible. Would you care to comment on this scenario as a valid criticism?"

Mr. Staats: "Of course, this is the key question. There is no doubt about that. In my opinion, the bill does have adequate safeguards . . . ".

Bayh suggests in his 2004 testimony, that this was a debate over a section of the bill on the recoupment of the government's investments for commercially successful inventions, which was one safeguard that was dropped in the final bill. But as recounted by Arno and Davis in their Tulane law review article and by Halperin in his May 2001 memo (which was submitted to the record in the Norvir march-in hearing), march-in rights were frequently referred to as an essential safeguard for the public.

Bayh acknowledges that the Senate Judiciary Committee report language on the bill stating "The agencies will have the power to exercise march-in rights to insure that no adverse effects result from the retention of patent rights by these contractors." (United States Senate, Committee on the Judiciary, 1979). "No adverse effects" seems fairly open ended.

In the 2004 testimony, Bayh did not quote the Senate Judiciary Committee Report's section by section analysis of march-in rights. This section of the report largely refers to the grounds as described in the statute, but also notes that the procedures were not required to adhere to the Administrative Procedures Act "because of concerns that this could frustrate the effectuation of the march in remedy," suggesting the Congress wanted the agencies to actually use the march-in right.

35 USC 203. MARCH-IN RIGHTS

Section 203 establishes situations in which the funding agencies may require small business firms or nonprofit organizations, or their assignees or licensees to license subject inventions to which the contractor has retained tItle. The Government may "march-in" if reasonable efforts are not being made to achieve practical application, for alleviation of health and safety needs, and in situations when use of the invention is required by Federal regulations. Finally, a march-in is included that ties into the U.S. manufacture requirement of section 205.

"March-in" is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action.

Adherence to Administrative Procedures Act procedures is not required because of concerns that this could frustrate the effectuation of the

march in remedy. On the other hand, arbitrary exercise of such rights must also be avoided. The agencies and Office of Federal Procurement Policy (OFPP) should give this question careful and thorough consideration and develop a procedure that carefully balances the considerations on both sides.

No specific provision has been included for judicial review of agency decisions under section 203, because it is assumed that such review will be available under Chapter 7 of Title 5 of the United States Code.

S.1215, 96th Congress, H.R. 8596, 95th Congress

During this period, there were, as noted, competing bills covering the same essential topics, including S.1215, 96th Congress, titled the "Science and Technology Research and Development Utilization Policy Act." Like HR 6933 which became law as PL-96-517, the 1980 version of the Bayh-Dole Act, S.1215 had a march-in section, and a definition of practical application. The march-in provisions in S.1215 were similar to those included by the Bayh-Dole Act, including the first march-in ground, which was to remedy a failure to achieve practical application of the invention.

The S.1215 definition of practical application distinguished between a general obligation to make benefits available the public on reasonable terms, and making benefits available “through reasonable licensing arrangements”:

> (12) "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 worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements;

The definition in S.1215, 96th Congress was the same as was used in H.R. 8596, 95th Congress (and perhaps in other bills we have not reviewed). In some hearings, several bills covering the same topic were discussed, and the march-in issue was not significantly different in terms of the issues raised or even the language considered. Further, as documented in the research by Arno, Davis and Halperin, march-in rights were at different times considered a broad safeguard of the public interest, and the march-in right was held out to argue that the proposed privatization of patent rights would be balanced by and subject to public interest safeguards.

Central to the arguments by Arno and Davis and Halperin, and in the Essential Inventions Norvir petition, is the notion that the statutory definition of practical application gives the federal agency the authority to consider the price to the public as one of the terms that must be reasonable.

The 2002 Washington Post letter to the editor by Bayh and Dole claimed that “The law makes no reference to a reasonable price” and “[t]his omission was intentional.” But “reasonable terms” was and is considered a more general term, to include not only prices, but other terms one might find objectionable in a march-in case. Indeed, in the Norvir march-in case, the issues at hand were both the price of the standalone product, but also the unwillingness of Abbott to license the rights to ritonavir to BMS to co-formulate with ATV.

To the degree that ambiguity can be claimed, it is for the benefit of a federal agency to determine on a case by case basis the if, why and when to intervene.

In discussing the definition of reasonable terms in the 2004 Norvir case, Professor Jerome H. Reichman, the Bunyan S. Womble Professor of Law at Duke University School of Law, made it clear that the words “reasonable terms” included both the price *and* the licensing practices that would impact the price. (Reichman, 2004).

> The legislative history of the Bayh-Dole Act confirms that qualified experts viewed the relevant provisions as authorizing a compulsory license either for abuse or on public interest grounds. For example, Harry. F. Manbeck, then General Patent Counsel for General Electric [and later a Commissioner of Patents] stated that “[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work.” /10
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> . . .
>
> Apart from the legislative history, which is consistent with international practice, it cannot logically be doubted that the language in the Bayh-Dole Act requiring patented products to be made available to the public on reasonable terms encompasses the patentee’s pricing strategy. All unreasonable terms and conditions that rise to the level of actionable abuses have as their object the power, directly or indirectly, to increase the licensor’s prices beyond the level that competition would otherwise ensure and thus to enhance profits. When patentees impose “field of use” or other licensing restrictions, when they engage in illegal tying, or as in the case at hand, they adopt a marketing strategy consistent with the practice known as “monopoly leveraging,” they are not conducting scientific or economic experiments for the sake of increasing academic knowledge. They pay their lawyers to devise contractual conditions that will enable them to raise prices and make more money.
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> In this connection, one should recall that individual members of the public do not typically negotiate with their pharmacies when they purchase medicine. They buy the product and pay the price that market conditions permit the pharmacist to charge. These conditions, in turn, result from the contracts stipulated between patent holders as licensors and their various licensees. When the Bayh-Dole Act affirms that the resulting products must be made available to the public on reasonable terms, it can only mean that the underlying licensing

agreements should not undersupply the market, unduly distort competition, or otherwise leverage the procurement of active ingredients in ways that boost the price to unreasonable "windfall" levels that many users cannot afford.

While the Bayh-Dole march-in provisions thus clearly contemplate practices that produce excessive prices—what Manbeck and others called "windfall profits"—and would make no sense if they did not, I hasten to add that the Act in no way implies a regime of price controls, like that adopted in Canada and many EU countries. Indeed, loose assertions about "price controls" merely create confusion and divert attention away from the real issues bearing on the patentee's specific marketing strategies.

Statutes that seek to prevent abuses or otherwise to protect the public interest, like the march-in provisions of the Bayh-Dole Act, normally leave patentees free to adopt the marketing strategies they deem suitable. They do not require regulatory approval of prices, as would be the case under, say, Canada's regulatory agency, the Patented Medicines Prices Review Board (PMPRB)./16/ By the same token, the marketing strategies that the patentee actually adopts, and their impact on the availability of the relevant products to the consumers on reasonable terms, is always open to public scrutiny and challenge on objective grounds of abuse. In the Bayh-Dole context, this would necessarily require attention to the taxpayers' interests as well as those of the patentee, including the ability of purchasers to afford critical, life-saving medicines and not be charged prices that "create … hardship for the overall public or for individual members of the public."/17/

/10/ [cite Halperin, n. 21] (emphasis supplied).
/16/ See Reichman with Hasenzahl, The Canadian Experience, supra note 1, at 43-44.
/17/ Halperin, at 13.

The NIST Green Paper

In 2018, NIST published the "Draft Green Paper: Return on Investment Initiative for Unleashing American Innovation" (U.S. Department of Commerce, National Institute of Standards and Technology, 2018). The draft included a proposal to eliminate an unreasonable price as a grounds for a march-in request. The Draft Green paper cited the 2002 Bayh and Dole letter to the editor published in *the Washington Post* as evidence regarding legislative intent, without noting that the comments came more than 22 years after the Act was enacted and during a period when both were working as corporate lobbyists. Nor did the Draft note that Bayh himself asked in the context of the Cellpro march-in to consider the impact of decisions on the prices for health care.

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C. March in Rights

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As seen in the petitions to NIH, much of the discussion of march-in rights focuses on the definition in the statute for “practical application,” which includes the idea of “reasonable terms.” The meaning of “reasonable terms” has proven to be ambiguous. In requests for the government to exercise the march-in right, “reasonable terms” has been interpreted as a reasonable price to the consumer or use to control price. /53/ . . . To date, the government has not taken march-in action deferring to a different interpretation based on reasonable licensing terms. The original sponsors of the Bayh-Dole Act have noted that their intent was to ensure that products were licensed for reasonable terms rather than being used as a price control. (Refer to “Statements by Senators Bayh and Dole on March-In.”)

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3. INTENDED ACTION

Intended Action 2. Define the circumstances under which the government may exercise march-in rights consistent with the uses of march-in specified in statute and not as a regulatory mechanism for the Federal Government to control the market price of goods and services.

. . .
Implement regulatory change under the Bayh-Dole Act by specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Provide a clear and consistent definition for “reasonable terms” contained within the existing statutory definition of “practical application.” Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace but not as terms (i.e., price control mechanism) for consumer use./59/,/60/ Clarifications for “reasonable terms” and “practical application” should allow flexibility in crafting commercial or other terms in license agreements to achieve effective technology transfer.

/53/ Peter S. Arno and Michael H. Davis. 2001. “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research,” Tulane Law Review, vol. 1, pgs. 631-692, http://www.cptech.org/ip/health/bd/arnodavis012001.pdf.

. . .

/59/ 37 CFR 401.14(j) details the march-in rights in standard Bayh-Dole Act patent rights. The four enumerated circumstances that the government would elect to assert march-in rights are: 1) contractor has not taken or is not expected to take effective steps to achieve practical application of the subject invention, 2) there is a health or safety need which is not reasonably satisfied by contractor or its licensees, 3) there is a public use requirement

specified by Federal regulations that are not reasonably satisfied by contractor or its licensee, and 4) march-in is necessary because of preference of U.S. manufacturing has not been met, a waiver was not granted or obtained, or licensee is in breach of such agreement. Suggested changes to the enumerated circumstances may include language that makes clear that march-in will not be used for anti-competitive reasons such as price control.

37 CFR 401.6 details the procedures that govern the exercise of march-in rights. Language may be added to this section to provide procedural guidance regarding march-in right proceedings, factfinding, and determination.

/60/ 37 CFR 401.2 is the definitions section for Bayh-Dole Act rights regulation. The current definition of practical application, per 401.2(e), is "The term practical application means to manufacture in the case of a composition of 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 used and that its benefits are, to the extent permitted by law or government regulations, available to the public **on reasonable terms**." The bolded text has been used to support the use of march-in rights as a price control mechanisms as reasonable terms has been interpreted to mean "low price."

At the time the Draft Green Paper was published, Dr. Walter Copan was the Under Secretary of Commerce for Standards and Technology and NIST. Prior to joining NIST, Copan was working for rights holders, as CEO of the IP Engineering Group and a founding board member of Rocky Mountain Innovation Partners as well as President and Managing director of his own consulting businesses, Copan Associates and LLC/EnergyInsight LLC. On his Linkedin page, Copan describes his work for the IP Engineering Group Corporation as a group that "provides leading edge service and support for intellectual property owners to maximize the value of their innovations, and to secure market position and competitive advantage."

Patient advocates, academics, and members of Congress criticized the Draft Green Paper. On April 5, 2019, eleven non-governmental organizations wrote to members of Congress, asking them to oppose "any effort to undermine the public interest safeguards in the Bayh-Dole Act." (Eleven non-governmental organizations, 2019).

An April 18, 2019 article by Christopher Rowland in the Washington Post (Rowland, 2019) titled, "A rare deterrent to limitless drug price increases may die under Trump" quoted Representative Lloyd Doggett (D-Tex.) as follows:

> The pharmaceutical manufacturer takes taxpayers' money that was invested, and takes the government monopoly that is granted, and charges monopoly prices without any countervailing force[.]

Constituents in his Texas district, Doggett added, "think they are getting ripped off by the same company that used their tax money.''

Rowland also quoted Georgetown Law School Professor John Thomas, the author of a 2016 report on march-in rights for the Congressional Research Service (Thomas, 2016), as follows:

> We have march-in rights for a reason, as a safety valve, and pricing is one of just many issues that could make something not reasonably available [.] The idea that the price is too high fits pretty comfortably in the wording of the statute.

On April 24, 2021, six days after the Washington Post article appeared, NIST published the Final Version of the Green Paper. (U.S. Department of Commerce, National Institute of Standards and Technology, 2019).

KEI published comments on the Final Version the same day, including this passage on the march-in/reasonable terms issue. (Love, 2021).

> In the section of the report on march-in rights, NIST quotes selectively critics of the march-in rights, and suggests that rulemaking could be used to define the phrase "available to the public on reasonable terms" so the obligation is only "to allow a product or service to reach the marketplace rather than reasonable pricing terms to the consumer." [Page 33]. This is justified on the grounds that it would address a "lack of clarity" in the statute, and is consistent with current practice by the NIH and the U.S. Army, but is controversial. A regulatory change would make it binding on agencies to ignore excessive and unreasonable prices for drugs and other health technologies invented on federal grants or research contracts, and eliminate an important if underutilized tool the government has to reduce prices.

The Final Green Paper claimed there was a "lack of clarity" on the whether or not to use march-in rights to address prices, and on the definition of "reasonable terms." On page 29, NIST claimed that "NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority."

Page 29.

Although the march-in right has not been used, the National Institutes of Health (NIH) has received 12 requests to initiate march-in proceedings./64/ In each case, NIH determined that the criteria to exercise march-in rights were not met. In two cases, the NIH monitored plans by the company to make the product available to satisfy public need and demand. In the remaining 10 cases, two for the same drug, petitioners argued that march-in rights should be used to curtail high drug prices and ensure U.S. citizens receive public health benefits from accessible and affordable drugs. Ultimately, for each of these requests, NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority.

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B. AMBIGUITIES IN MARCH-IN RIGHTS PROCESSES AND TERMINOLOGY

March-in rights processes and terminology fall within the scope of Bayh-Dole Act implementing regulations. According to stakeholders, there is a lack of clarity on: (i) whether

or not to use march-in rights as a mechanism to control or regulate the market price of goods and services, and (ii) definitions for “reasonable terms” contained within the existing statutory definition of “practical application.” Stakeholders indicated that the regulatory process is well suited to collect and analyze formal comments on proposed language regarding the use of reasonable licensing terms to allow a product or service to reach the marketplace rather than reasonable pricing terms to the consumer. /74/,/75/ Clarifications for “reasonable terms” and “practical application” would allow flexibility in crafting commercial or other terms in license agreements to achieve effective technology transfer and allow agencies the flexibility needed to accomplish their mission

/64/ Data provided to NIST by the NIH. Six of the march-in requests and NIH determinations are detailed in: Thomas, John. 2016. March-In Rights under the Bayh-Dole Act. CRS Report No. R44597. Washington, D.C. Congressional Research Service. https://fas.org/sgp/crs/misc/R44597.pdf

/74/. 37 CFR 401.14(j) details the march-in rights in standard Bayh-Dole Act patent rights. The four enumerated circumstances that the government would elect to assert march-in rights are: 1) contractor has not taken or is not expected to take effective steps to achieve practical application of the subject invention, 2) there is a health or safety need which is not reasonably satisfied by contractor or its licensees, 3) there is a public use requirement specified by Federal regulations that are not reasonably satisfied by contractor or its licensee, and 4) march-in is necessary because of preference of U.S. manufacturing has not been met, a waiver was not granted or obtained, or licensee is in breach of such agreement. Changes that could be considered to the enumerated circumstances may include language that makes clear that march-in will not be used for anti-competitive reasons such as price control.

37 CFR 401.6 details the procedures that govern the exercise of march-in rights. Language could be considered in this section to provide procedural guidance regarding march-in right proceedings, factfinding, and determination.

/75/. 37 CFR 401.2 is the definitions section for Bayh-Dole Act rights regulation. The current definition of practical application, per 401.2(e), is “The term practical application means to manufacture in the case of a composition of 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 used and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.” The bolded text has been used to support the use of march-in rights as a price control mechanisms as reasonable terms has been interpreted to mean “low price.”

What began as a promise during the negotiations on the Bayh-Dole Act that march-in rights would be a broad remedy to prevent abuses by holders of patents on federally subsidized inventions, was now presented in the NIST Green Paper as an area where the march-in right could address any term except the prices to the public, even though, the statutory language was “available to the public on reasonable terms.”

There is no doubt that rights holders, including universities, researchers and corporations, want the broadest possible rights and the complete freedom to set prices, even on life saving biomedical inventions, that are excessive and/or unaffordable. There is also no doubt that some funding agencies, including but not limited to the NIH, have sought to avoid any connection between their research grants, contracts, or patent licenses with pricing disputes.

The fact that “available to the public on reasonable terms” includes price, and that agencies understand this, is also evidenced by the recent experience in the context of COVID-19, where a series of U.S. government contracts were entered into under “Other Transactions Authority,” a provision that allows agencies to bypass the Bayh-Dole framework and negotiate non-standard patent provisions. (Ardizzone and Love, 2020). Several of the negotiated contracts modified the definition of practical application to eliminate references to “reasonable terms” and to change practical application into an obligation to make the resulting product simply available to the public or capable of being utilized. Moreover, an NIH Other Transactions Authority participant guide states that one of the benefits of an Other Transaction Agreement (OTA) is the ability to negotiate a new definition of practical application, and attaches a sample OTA that deletes the words “on reasonable terms” from the definition, further suggesting that NIH is aware that this language reaches pricing and wants to avoid that dimension.

KEI has collected several of these contracts and published a research note that compares the terms in the OTA COVID-19 contracts concerning the non-Bayh-Dole contractual definitions of practical applications. (Knowledge Ecology International, 2021). All of these COVID-19 contracts illustrate the opposite of the NIH view, as attributed by NIST. “Available to the public on reasonable terms” is a term that is broad and not limited to licensing terms. Indeed, in the legislative debates in 1977 and 1979, reasonable terms and reasonable licenses were considered two separate obligations. Marching in for a failure to achieve practical application was defined both as failure to make an invention available to the public on reasonable terms and as failure to offer a license to another company on reasonable terms. The phrase “on reasonable terms” was retained because it was the broader construction.

NIST can also consider the Policy and Objective of the Bayh-Dole Act, which states as follows:

> **35 U.S. Code § 200 - Policy and objective**
> 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 Policy and Objective of the Bayh-Dole was amended only once, in 2000, to add the words, “without unduly encumbering future research and discovery.” The key phrase for the discussion regarding the definition of practical application, is the Policy and Objective that “the Government obtains sufficient rights . . . to meet the needs of the Government and protect the public against

nonuse or unreasonable use of inventions." Note, this is "nonuse" or "unreasonable use." The mere fact that an invention is used does not satisfy the Policy and Objective unless the public is protected against unreasonable use.

Changing Rationales for Rejecting March-in Petitions.

In the 2004 Norvir/ritonavir case, Elias A. Zerhouni, advised by Mark Rohrbaugh, focused on a policy argument that "the extraordinary remedy of march-in is not an appropriate means of controlling prices," as opposed to making a legal argument that the NIH lacked authority to do so.

> Drug Pricing
>
> Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand./6/ In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.
>
> /6/ In addition, NIH addressed "The NIH 'Reasonable Pricing' Clause Experience" in its report to Congress, "A Plan to Ensure Taxpayers' Interests are Protected," July 2001, available at http://www.nih.gov/news/070101wyden.htm.

When this decision was revised in 2012, under a different President and different NIH Director, but many of the same technology transfer agency staff, the 2004 policy was cited by Francis Collins in denying the march-in petition. But again, the decision did not question the legal authority of the NIH to consider a price to the public.

> Drug pricing and patient access are broad and challenging issues in the United States. The NIH continues to agree with the public testimony in 2004 that the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients.
>
> In conclusion, as set forth in this determination, the information and justification provided in the Request, as well as publicly available information, do not support re-consideration of the NIH determination to decline to initiate a march-in proceeding for the Subject Patents used by Abb Vie in the production of Norvir® and other combination products. 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. The exercise of the Government's use license to the Subject Patents is not appropriate in this case. Finally, the NIH declines to set the rules proposed by the Requestors directing the initiation of such proceedings based on certain price disparities between the United States

and other developed countries.

The Xtandi/enzalutamide case

On January 14, 2016, Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) submitted a request to the National Institutes of Health (NIH) and Department of Defense (DoD) asking that they exercise their authority under the Bayh-Dole Act to authorize the generic production of an expensive prostate cancer drug, based upon the fact that the price in the United States was dramatically higher than in any other country, despite the public investment in its development.

On March 7, 2016, Congressman Lloyd Doggett issued a statement in support of the January 14, 2016, march-in request over prostate cancer drug Xtandi.

On March 28, 2016, six Senators and six members of the House of Representatives sent a letter to the NIH calling for an "open and transparent public hearing" to discuss the January 14, 2016 Xtandi march-in request.

HHS Secretary Sylvia Burwell assigned the case to the NIH. On June 20, 2016, NIH Director Francis S. Collins rejected the march-in request. Collins noted that the statute referred to an obligation to make a product "available to the public on reasonable terms," but that the NIH was determining that practical application was satisfied by "availability to and use by the public," and that "Xtandi is broadly available as a prescription drug" and was not "in short supply." Collins attached a companion letter to Representative Doggett by Secretary Burwell dated June 7, 2016 which referred the Congressman to an NIH web page for more information on how the NIH "would justify the exercise of its march-in authority." (archive of the NIH web page from July 2016 here: https://web.archive.org/web/20160709081926/http://www.ott.nih.gov:80/policies-reports).

On August 5, 2016, Alejandro Lopez-Duek, the Chief of Staff for the Department of the Army also rejected the Xtandi march-in, on the grounds that there was no evidence that "supplies of Xtandi were running low or that health or safety needs are not being met by the manufacturer."

On April 19, 2017, KEI and the Union for Affordable Cancer Treatment appealed the Xtandi march-in decision to HHS Secretary Tom Price and DOD Secretary Jim Mattis. The petition also attached a separate March 20, 2017 submission to the U.S. Army Medical Research and Materiel Command regarding a proposed license to Sanofi for a Zika vaccine. The Zika submission included a discussion of the U.S. and international jurisprudence over the phrase "reasonable terms," which is attached to this submission as an ANNEX.

Price assigned Collins to conduct the administrative appeal review, effectively reviewing his own decision. In a June 7, 2017 letter, Collins found in favor of Astellas, stating Xtandi was "widely available in the market" and that Astellas had claimed publicly it was making the drug available

free to uninsured patients who have an income of less than $100,000. The enormous price difference between the United States and every other country in the world was not addressed. Collins concluded by stating, once more, that the NIH "continues to believe the broader issue of drug pricing would be more appropriately addressed through legislative channels to develop remedies that have implications for the costs of healthcare overall."

On July 17, 2017, the Senate Armed Services Committee unanimously approved a Directive that would tie the licensing of patent rights to a price ceiling based upon an international reference price.

> ***Licensing of federally owned medical inventions***
> The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.
> [115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, page 173.]

On February 4, 2019, Clare Melvin Love and David Reed submitted a request to the Army asking them to use march-in or royalty-free rights in enzalutamide patents.

The NIH has consistently justified its rejection of the requests on empirical grounds, including in particular that the companies were indeed manufacturing and selling products, and maintaining some type of patient assistance programs. And while Director Collins has on more than one occasion testified before Congress that the NIH does not have the authority to consider excessive or unreasonable prices for a march-in request, the written decisions are more nuanced, avoiding a specific claim that the NIH lacks the statutory authority to do so, focusing instead on the agency discretion and the policy reasons for rejecting the requests.

No weight should be given to post legislative statements regarding legislative intent.

Reliance on the decades-later statements of Birch Bayh and Bob Dole about the meaning of the Bayh-Dole Act is not a legitimate method of interpreting the statute. This is true for obvious practical reasons, as well as a matter of law.

The practical reasons are obvious. Even if Bayh and Dole were both still serving in the Senate, and the Act passed yesterday, they would be only two members of the 100 members of the U.S. Senate and of the 535 members of the U.S. Congress involved in the passage of the bill, including members who clearly expressed different views and concerns about the privatization of rights in publicly-funded research, the role of march-in rights, the government use rights and

the meaning of practical application. The actual committee reports and records from the proceedings speak for themselves.

But more to the point, in this case, we are talking about two men who had left the Senate and immediately entered into lucrative careers as paid lobbyists or influencers for corporate clients and patent holder groups.

As a matter of law, the Supreme Court has recognized on several occasions that "post-enactment" legislative history is not a legitimate method of statutory interpretation and does not have persuasive value. The following is a summary of the jurisprudence on this issue by Kathryn Ardizzone. (Ardizzone, 2021).

> In *Graham County Soil and Water Conservation District v. United States ex rel. Wilson*, the U.S. Supreme Court held that a statement by the sponsors of a statute, made 13 years after the law was enacted, "d[id] not qualify as legislative 'history,'" and "[wa]s consequently of scant or no value" in construing the statute. G*raham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 298 (2010). Similarly, in *Bruesewitz v. Wyeth*, the Supreme Court observed that "[p]ost-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation[,]" because "by definition" it "could have had no effect on the congressional vote[.]" *Bruesewitz v. Wyeth LLC,* 562 U.S. 223, 242 (2011)(quotation omitted). There are at least sixty-two cases that quote *Bruesewitz v. Wyeth* for this proposition. Even the contemporaneous statements of a bill's sponsors are not legitimate, relevant, or controlling in interpreting the legislation. *See* 73 Am. Jur. 2d Statutes § 82 (stating that when interpreting statutes, "[t]he opinions of individual legislators, or the testimony of a member of the legislature as to the intention of the legislature in enacting a statute, may not be given consideration"); 73 Am. Jur. 2d Statutes § 88 (observing that the "views of a single legislator, even a bill's sponsor, are not controlling on the meaning of legislation" and that "[t]he motive or purpose of the drafters of a statute is not relevant to its construction").

To further illustrate the point that the views of a former Member of Congress are not given weight in evaluating the legislative history of an Act, one can look to the *amicus curiae* brief filed by Birch Bayh in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc*., 563 U.S. 776 (2011). The brief was filed on December 23, 2010, on behalf of Stanford. Bayh presented himself as the co-principal Senate sponsor of the Bayh-Dole Act. On the central issue in dispute, Bayh stated "[t]he statute gives universities, small businesses, and nonprofit organizations presumptive ownership rights to patents, and an inventor may obtain an ownership interest only if the contractor surrenders its rights and the funding agency approves." The Supreme Court decided the issue on June 6, 2011. The Court's opinion ruled against Stanford, and not only decided the case contrary to the position taken by Bayh, but did not even bother to cite his *amicus* brief.

What is at stake?

NIST, an agency of the U.S. Department of Commerce, is seeking to change the meaning of the obligations for patent holders that are a consequence of the definition of the term “practical application,” and this action is entirely a consequence of lobbying by universities, drug and vaccine companies, and, to some extent, investor groups, all of whom perceive that their economic interests are in line with unconstrained pricing of biomedical inventions. It should also be mentioned that federal employees share in royalties from licensed inventions and often leave the government to join drug or vaccine companies. For all of these actors, privatization of government-funded inventions and unconstrained pricing seems like a great policy, almost manna from heaven. But there is a cost, and that cost is borne by taxpayers, by persons or businesses who pay for health insurance, by patients who pay out-of-pocket or high co-payments for products or services, and by patients who never have access to treatments because of high prices.

In the case of Xtandi, a drug for prostate cancer -hardly a rare disease- the U.S. price is more than $150,000 per year, more than three to five times higher than in any other country. The cost of Xtandi to Medicare and private insurers is in the billions of dollars. Copayments for people with Medicare and/or private insurance are often harsh, directly as a consequence of the high price. Outside the United States, in developing countries, the high prices have been a significant barrier to access. KEI worked with a prostate patient in Chile who lobbied for a compulsory license on the Xtandi patents in Chile, and he died before getting access to the drug. This is the reality for many excessively priced drugs. The primary beneficiary of the high prices for Xtandi is Astellas, a Japanese drug company.

Spinal muscular atrophy is a terrible childhood disease that is associated with either severe disability or death. The two leading treatments, Spinraza, a drug, or Zolgensma, a gene therapy, were both invented on grants from the NIH. The initial price for one injection of Spinraza was $125,000. Six injections are required the first year, and then three injections per year for maintenance of treatment. This very high cost for Spinraza was then used to justify the $2.1 million initial cost of Zolgensma by Novartis, the swiss firm that acquired the patent and data rights. Zolgensma and Spinraza have very limited access globally. The leading scientist for the development of Zolgensma was Brian Kasper, working at Nationwide Children's hospital, supported by the NIH and charities. Kasper personally earned more than $400 million from the sale of the technology to Novartis, so one can see why the privatization of federally-funded inventions, with unconstrained pricing, is popular in some quarters.

Perhaps the most expensive drug in the FDA Orange Book is Zokinvy (lonafarnib), at an average annual cost of $1,032,480. (Carroll, 2021). Zokinvy was approved by the FDA in 2020, on the basis of evidence from 62 patients. (*Drug Trials Snapshots: ZOKINVY*). There are two patents in the FDA Orange Book for Zokinvy, both of which include an assignment to the U.S. government. Note that the United States of America is one of the assignees of the invention, and that the NIH Director Francis Collins is among the inventors earning royalties from the drug sales.

Table 1. Orange Book Patents for Zokinvy

Patent number	Inventors	Assignments
7,838,531	Gordon; Leslie B. (Foxboro, MA), Collins; Francis S. (Rockville, MD), Glover; Thomas (Ypsilanti, MI), Glynn; Michael W. (Darien, CT), Capell; Brian C. (Rumson, NJ), Cox; Adrienne D. (Chapel Hill, NC), Der; Channing J. (Chapel Hill, NC)	The United States of America as represented by the Department of Health and Human Services (Washington, DC) The Regents of the University of Michigan (Peabody, MA) Progeria Research Foundation, Inc. (Chapel Hill, NC) The University of North Carolina at Chapel Hill (N/A)
8,828,356	Gordon; Leslie B. (Foxboro, MA), Collins; Francis S. (Rockville, MD), Glover; Thomas (Ypsilanti, MI), Glynn; Michael W. (Darien, CT), Capell; Brian C. (Philadelphia, PA), Cox; Adrienne D. (Chapel Hill, NC), Der; Channing J. (Chapel Hill, NC)	The United States of America as represented by the Secretary of the Department of Health and Human Services Progeria Research Foundation, Inc. The Regents of the University of Michigan The University of North Carolina at Chapel Hill

Cancer treatment Folotyn (pralatrexate) has an annual cost of $793,870. (Carroll, 2021). There are three Orange Book patents, 6,028,071, 7,622,470 and 8,299,078. Only one of the patents disclosed federal funding originally, but the NIH support was disclosed in subsequent corrections to the patents for the other two. The 2009 price was $30,000 per month, and was then described as “at least triple that of other drugs that critics have said are too expensive for the benefits they offer to patients. . . . The price of Folotyn ‘seems way higher than I heard of before,’ Robert L. Erwin, president of the Marti Nelson Cancer Foundation, a patient advocacy group. ‘I can’t imagine there not being a backlash against the pricing.’” (Pollack, 20009). Since then the cost has more than doubled.

For the HIV treatment Truvada, a potential treatment for preventing HIV infections, the utilization of the drug has been severely limited due to the high costs.

> “If there is any example of the dysfunction in the American pharmaceutical system, it is this case," says James Krellenstein, a member of the AIDS advocacy group ACT UP New York. "We have the most effective tool for ending the HIV epidemic, and one reason we're unable to scale up is because it costs so [much] unnecessarily. (Luthra & Gorman, 2008).

In all of these cases and many others, the decision by the U.S. government to forgo the enforcement of the obligation to make the benefits of the inventions “available to the public on reasonable terms” is associated with access barriers and fiscal toxicity.

Is it too hard to evaluate when prices are unreasonable or excessive?

One argument put forward against the exercise of march-in or other government rights in federally-funded inventions is that it is too hard to evaluate when prices are unreasonable or excessive, and/or that the government lacks the competence to “set prices” for products. None of the actual disputes over march-in rights in patents have centered on the notion that the U.S. government would set prices. Rather, the disputes have been about whether the exclusive rights would be limited or eliminated if prices were determined to be unreasonable or excessive, and only in the special cases where a march-in remedy was proposed.

The standard for determining if prices were not reasonable in the Xtandi case was that U.S. residents should not pay considerably more than the median price the seller charged in other high income countries (countries with at least 50 percent of U.S. GNI per capita) with large GDPs. This was a minimalist request, one that did not require the U.S. government to tell companies what to charge, but simply to avoid negative price discrimination against U.S. residents. Some of the recent COVID-19 R&D contracts have used a similar approach, and it is not a term difficult to administer.

The 2004 ritonavir case also focused on the international reference price standard, but in addition raised the fact that the price increase only applied to use of ritonavir with a non-Abbott protease inhibitor, and was anticompetitive in intent. This type of standard on pricing is also not hard to administer.

The Truvada case, often discussed but never formally filed, would have been focused on the fact that the high price was clearly inhibiting access, for which the empirical evidence was strong.

In the case of drugs like Spinraza, Zokinvy, Folotyn, or Zolgensma, the international reference price standard could be used, but the government could also ask for evidence of the extent to which the extremely high prices are justified by the investments in development, even when risk-adjusted, or in instances in which a proxy for investment costs is used (such as estimates of costs associated with a class of products with similar characteristics) when compared to the global revenues for the product. The rationale is that a super high price for a product may be justified if the number of patients is very small, but when revenues for the product become large, the justification for a high price is no longer there. A march-in petition might ask the NIH to determine that when the price per QALY for a drug exceeds three times the GNI per capita in the United States that a test be applied to see if the high price is necessary, given global revenues and the benchmark for risk-adjusted R&D costs.

The NIH could make this approach even more workable if it required drug developers to report the actual outlays on human subject clinical trials, in order to develop evidence-based benchmarks for risk-adjusted costs.

In a number of NIH licensing cases, KEI has asked that exclusivity be limited by one year for every $0.5 billion in global revenue that exceeds a threshold in global sales. This test only requires transparency of global sales data, and would only be relevant to those products that actually had significant global sales. (*Licensing NIH-owned patents and data, including KEI comments on proposed exclusive licenses*, n.d.)

The U.S. government has an unlimited number of options to consider in seeking to remedy an unreasonable price. For example, the NIH could determine that exclusive rights would continue to exist in all high income countries except the United States, if revenues exceeded a benchmark that seemed more than adequate as the incentive to bring a government funded invention to the market, and prices were otherwise considered excessive.

In the past, the NIH was more creative about how it addressed the balance between R&D incentives and prices. In a 1983 case involving cisplatin, the continued ability to exercise exclusive rights was tied to a 30 percent reduction in the price of a product and to a mandate that the company fund third party cancer research at academic institutions. (*The current and potential role of biomedical research mandates*, 2020)

Critics of a reasonable pricing obligation describe only one possible scenario if such an obligation were enacted: where the NIH and other federal agencies are in charge of setting prices for every product with federal rights in an invention. But the actual alternative is far less ambitious. The U.S. government can use its rights to address specific cases where the need for an intervention is clearly warranted, such as the Xtandi/enzalutamide, Norvir/ritonavir or Truvada cases, and in doing so, slowly create a set of standards on what constitutes a reasonable price for a product with federal rights in the patents. The alternative of no standards, and the privatization of rights with unconstrained pricing, is costly, and runs counter to the "policy and objective of the Congress" to "protect the public" against both "nonuse OR unreasonable use of inventions." [35 U.S.C. 200]

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ANNEX - Legal Definitions of Reasonable Terms

Excerpt from March 10, 2017 submission to the U.S. Army Medical Research and Materiel Command from KEI regarding a license to Sanofi for patents on a Zika vaccine.

Excerpt from March 10, 2017 submission to the U.S. Army Medical Research and Materiel Command from KEI regarding a license to Sanofi for patents on a Zika vaccine.

Reasonable Terms in U.S. Case Law

"Reasonable terms" has been regularly interpreted in case law in both federal and state courts to include price.

In *American Liberty Oil Co. v. Fed. Power Comm'n*, the Fifth Circuit Court of Appeals interpreted the Natural Gas Act's provision allowing the Federal Power Commission to establish "reasonable terms and conditions" as including price.[1] *See also*, *United States v. Mississippi Vocational Rehab. for the Blind*, 812 F. Supp. 85, 87-89 (S.D. Miss. 1992) (interpreting 20 U.S.C. § 107d-3 provision allowing for federal entities to negotiate reasonable terms as including price).

In a case regarding the abuse of monopoly power, the Sixth Circuit Court of Appeals in *Byars v. Bluff City News Co.* stated that "The difficulty of setting reasonable terms, especially price, should be a substantial factor when confronted with the latter situation."[2]

In *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n*, 641 F. Supp. 1179 (S.D.N.Y. 1986), an antitrust case, the Court recounted facts on the record, including a willingness of the players association to negotiate a license on "commercially reasonable terms," which the Court "assume[d] means at a price higher than Topps currently pays under its player contracts." *Id.* at 1191.

In contractual and commercial matters governed by the Uniform Commercial Code, Art. 9, § 610, on the disposition of collateral after default, contains an official comment on the "Relevance of Price" that suggests that price may not allow for a per se violation, but is to be considered: "While not itself sufficient to establish a violation of this Part, a low price suggests that a court should scrutinize carefully all aspects of a disposition to ensure that each aspect was commercially reasonable." See also *68A Am. Jur. 2d Secured Transactions* § 646 (1993) (stating that price is a term of commercial reasonableness, but low price alone will not render a sale commercially unreasonable).

Under the proceeds test under Article 9, some courts have accordingly held that price is a term of commercial reasonableness. *See, e.g.*, *ITT Indus. Credit Co. v. Chasse*, 25 U.C.C. Rep. Serv. (CBC) 914, 917-18 (Conn. Super. Ct. 1978); *Farmers Bank v. Hubbard*, 276 S.E.2d 622, 626-27 (Ga. 1981) (price is term of commercial reasonableness that secured party must establish is fair and reasonable); *McMillian v. Bank S., N.A.*, 373 S.E.2d 61, 62 (Ga. Ct. App. 1988) (sale's method and manner were commercially reasonable, but that price was a "term"); *FDIC v. Herald Square Fabrics Corp.*, 439 N.Y.S.2d 944, 955 n.8 (N.Y. App. Div. 1981) (stating that a "wide or

[1] 301 F.2d 15 (5th Cir. 1962).
[2] 609 F.2d 843, n.58 (6th Cir. 1979).

marked discrepancy in disposal and sale prices is an independently adequate reason to question the commercial reasonableness of a disposition").

Reasonable Terms in U.K. Patent Law

In the United Kingdom, the Patents Act 1977 includes a "reasonable terms" requirement in § 48A, on compulsory licensing in the case of WTO proprietors, providing for the ability to obtain compulsory licenses in cases where "demand in the United Kingdom for that [patented] product is not being met on reasonable terms," or for a refusal to license on reasonable terms.[3] The U.K. Manual of Patent Practice, an official government document provided by the Intellectual Property Office, explains that the requirement of reasonable terms is meant to contemplate price:

> **48A.03**
> The applicant needs to show that such a demand is not being met on reasonable terms. What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.[4]

The Manual of Patent Practice cites the case of *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 as instructive. In that case, the Court addressed the question of reasonable terms in a case involving a refusal to license patents used for radio amplifiers. The case involved a prior version of the UK patent law (§ 27 of the Patents and Designs Act 1907 and 1919), which provided for compulsory licenses in cases of an abuse of the patent right, explicitly including excessive pricing.[5] The Court stated that "reasonable terms" was an "elastic phrase:"

> The grant of the licence which is refused must be a grant "on reasonable terms", an elastic phrase which can only be construed with certainty with reference to the actual facts of each particular case. No one can hope to lay down any exhaustive rules to enable the question whether the terms of a proposed licence are reasonable or not to be answered with certainty in every case. The answer to the question must in each case depend on the careful consideration of all the surrounding circumstances. The nature of the invention covered by the patent, the terms of the licences (if any) already granted, the expenditure and liabilities of the patentee in respect of the patent, the requirements of the purchasing public, and so on.[6]

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[3] The Patents Act, 1977 (as amended), Section 48A(1)(a)-(b).
[4] The Manual of Patent Practice is available at https://www.gov.uk/guidance/manual-of-patent-practice-mopp.
[5] *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457. Available at https://goo.gl/oK9KBY.
[6] *Id.* at 473.

In the case of *Cathro's Application* (1934) 51 RPC 75, the Court addressed an application for a compulsory license of patents pertaining to electric valves, on grounds that demand was not being met on reasonable terms under § 27 of the Patents and Designs Acts 1907 to 1932.[7] The Court cited *Brownie Wireless*, stating:

> Now I think in the first place that the expression "on reasonable terms" in paragraph (c) refers mainly to the price charged for the patented article, and I am fortified in this view by a consideration of the summary of the kinds of abuses dealt with by Section 27 given by Mr. Justice Luxmoore in Brownie Wireless Company's Applications (46 RP.C. at page 471) where the reference to "excessive price" (see line 31) clearly refers to the abuse covered by paragraph (c). No doubt, however, this statement of the 30 learned Judge should not be considered to be exhaustive as to the scope of the paragraph, and it may be that in some cases other terms than those referring merely to price should be taken into account.[8]

Reasonable Terms in South African Patent Law

South Africa has a similar provision in its patent law for compulsory licenses where there has been an abuse of the patent right, including where “demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms.”[9]

In a case on this issue, *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, the Court of the Commissioner of Patents referred to the UK decisions in *Cathro’s Application* and *Brownie Wireless* among others as being persuasive, and held that “on the charge of not granting a licence, the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are.”[10] While the compulsory license in that case was denied, it failed because the petitioner had not met its evidentiary burden of demonstrating the price to be unreasonable.

Reasonable Terms as Interpreted by the World Trade Organization

In the dispute settlement case of Mexico-Telecoms brought before the World Trade Organization (case DS204), the WTO addressed the question of what constituted “reasonable terms.” The complaint brought by the United States alleged, *inter alia*, that Mexico had violated its commitments under GATS by failing to ensure access to and use of public telecommunications transport networks and services on reasonable and non-discriminatory terms and conditions for the supply of basic and value-added telecommunications services.[11]

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[7] *Cathro's Application* (1934) 51 RPC 75. Available at https://goo.gl/FUbKe2.
[8] *Id.* at
[9] Patents Act No. 57 of 1978, section 56(2)(c). Available at http://www.cipc.co.za/files/9513/9452/7965/Patent_Act.pdf.
[10] *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, available at http://www.wipo.int/scp/en/exceptions/replies/safrica.html.
[11] Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds204_e.htm.

The United States put forward an argument regarding restricted supply directly linked to pricing:

> IV.230 In terms of the context, the United States argues that the interconnection obligations of Section 2 are especially important for the cross-border supply of basic telecom services – particularly in markets like Mexico, which legally bar foreign service suppliers from owning facilities and therefore force foreign suppliers to rely on the major supplier to deliver their services to the end-user. In such cases, foreign suppliers have no choice but to pay a domestic service supplier (such as Telmex) an interconnection rate to terminate their calls. As a result, the major supplier has the power and incentive to price this input at levels which extract as much revenue as possible from cross-border suppliers. Thus, by raising the wholesale price of cross-border interconnection, the major supplier has the power to raise the retail price, reduce demand for the retail service, and thereby restrict the cross-border supply of services into Mexico.

The Panel found that “terms” would implicitly include pricing elements:

> VII.325 As discussed in part B of these findings, the words "terms and conditions" may have many meanings. In relation to contracts and agreements, the word "terms" is defined to mean "conditions, obligations, rights, price, etc., as specified in contract or instrument", while "condition" is defined, inter alia, as "a provision in a will, contract, etc., on which the force or effect of the document depends". **Although the words "terms" and "conditions" are closely related, and are frequently used concurrently, the ordinary meaning of the word "terms" suggests that it would include pricing elements, including rates charged for access to and use of public telecommunications transport networks and services.** (Emphasis added.)