KEI Comments Regarding the NIST Special Publication 1234 Draft Green Paper on Return on Public Investment

January 9, 2018

Introduction

In December 2018, the Department of Commerce National Institute of Standards (NIST) published NIST Special Publication 1234, “Return on Investment Initiative for Unleashing American Innovation,” as a draft Green Paper. According to the initial release (prior to the government shutdown), comments were due by January 9, 2019.

The publication was available from: https://doi.org/10.6028/NIST.SP.1234, but is currently offline due to the federal government shutdown.

The draft Green Paper is 135 pages long, with 313 footnotes, and 8 pages of references. On page 7, there is a "Summary of Intended Actions" which is divided into 5 strategies.

The initiative was launched after the April 19, 2018 "Unleashing American Innovation Symposium" in Washington, DC, and followed four public hearings and a request for comments noticed on May 1, 2018 (83 FR 19052). The initial comment period closed July 30, 2018.

What started out as a review of licensing practices by federal labs has become a broader attack on reasonable pricing obligations for drugs and other inventions, and on several measures designed to enhance the private returns on public investments in research and development (R&D).

While some of the proposals may be promising, others are designed to neuter safeguards written into the Bayh-Dole Act, and in particular, to protect companies that sell expensive drugs, vaccines, diagnostic tests and gene- and cell-treatments like chimeric antigen receptor T-cell (CAR T) therapies from obligations to ensure products are affordable and accessible.

Among the recommendations are proposals to modify statutes to extend copyright of software authored by federal employees,[1] raise the cap on the amount in royalties federal employees can earn to $0.5 million per year,[2] and implement other measures such as the adoption of "business-friendly intellectual property rights"[3] in licensing agreements. The paper also includes a number of proposals by "stakeholders" to modify U.S. patent law on everything from standards for patentability to the USPTO post-grant review of patent claims and the enforcement of injunctions for patent infringement, which would serve to overturn eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388.[4]

Among the appalling recommendations in the draft Green Paper are those that relate to three public interest safeguards in the Bayh-Dole Act, including:

1. The federal government's royalty-free right to inventions it funded, as mandated under 35 USC § 202 and 35 USC § 209;
2. March-in rights on federally-funded inventions, under 35 USC § 203; and
3. The obligation to bring federally-funded inventions to practical application, including in particular the requirement that the benefits of the inventions be made "available to the public on reasonable terms."

[1] Pages 38-43.
[2] Pages 49-50.
[3] Page 61, on extending the provisions of the Agreement for Commercializing Technology (ACT).
[4] Page 26, See "What we heard: America Invents Act."

The draft Green Paper includes analysis that is in some cases factually incorrect, incomplete or out of context, and/or lacks balance, in order to justify the argument that the U.S. government should not use its rights in federally-funded inventions to ensure that biomedical products and services are reasonably priced, or to otherwise justify the expansion of private rights in publicly-funded inventions.

Our comments begin by reviewing the proposed changes in the regulations and policies relating to the use of the royalty-free and march-in rights in federally-funded patents, and the efforts to use regulations to narrow the statutory definition of "available to the public on reasonable terms."

Government Use License (Royalty-Free Right in Inventions)

The federal government currently has a royalty-free right to use any invention it funded, worldwide. The statutory obligations for retaining such rights include 35 USC § 202 and 35 USC § 209.

For example, in 35 USC § 202, "Disposition of rights," the Bayh-Dole Act states:

> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

There is a similar provision in 35 USC § 209, concerning federally-owned inventions.

Note that the statue ensures the government retains the right "to practice or have practiced for or on behalf of the United States" the federally-funded invention. This right is limited, but only in that the royalty-free right has be used "for or on behalf" of the United States.

The Green Paper *Intended Action 1* proposes policies and regulations to limit such rights.

Intended Action 1.

Define the scope of the “government use license” for use directly by the government—or a government contractor in the performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government. The scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services.

A. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR EXTRAMURAL R&D PROGRAMS

Implement regulatory change under the Bayh-Dole Act to (i) update the definition of government use license and its use directly by the government—or a government contractor in the performance of an agreement with the government—for government purpose only and not for the use of a third party,43 and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.44

B. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR INTRAMURAL AND PARTNERSHIP R&D PROGRAMS

Implement regulations under the Stevenson-Wydler Act/45/ (consistent with the Bayh-Dole regulatory change) to (i) update the definition of government use license and its use directly by the government for government purpose only and not for use by a third party, and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.

/footnote 42/ U.S. Government Accountability Office (GAO). 2003. “Agencies’ Rights to Federally Sponsored Biomedical Inventions.” https://www.gao.gov/new.items/d03536.pdf

/footnote 43/ Two regulatory changes suggested:

> * Insert new definition in 37 CFR 401.2: “The term government use is defined as use directly by the government for a government purpose and

the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included."

* Insert new language into existing standard patent rights clause in 37 CFR 401.14(b) "Allocation of Principal Rights" clause: "The government use license is restricted by the following conditions:

(A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract."

/footnote 44/ 37 CFR 401.14

/footnote 45/ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

Consequence of Intended Action 1

The consequence of *Intended Action 1* would be that the government license would protect uses only when the government uses an invention "for its own consumption or practice for its own direct benefit"(emphasis added) and "to continue to perform research" but would prohibit the use of the license in cases where "the government is not procuring the goods or services for its own direct use or consumption through a contract."

The primary motivation for the proposal in *Intended Action 1* is to **limit** the use of the government's royalty-free right to provide the **public access to affordable versions** of patented drugs, vaccines, gene- and cell-treatments and other therapies and diagnostics that are based upon federally-funded patented inventions.

March-in Rights

There are 63 references to march-in rights in the draft Green Paper.

The proposals to narrow the use of march-in rights are set out in *Intended Action 2*.

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.

A. DEFINE CIRCUMSTANCES UNDER WHICH MARCH-IN RIGHTS MAY BE EXERCISED

Implement regulatory change under the Bayh-Dole Act to make explicit that the use of march-in rights specified in statute is reserved for a compelling national issue or declared national emergency when other remedies have failed. When a Federal agency receives information that it believes might warrant march-in, regulation will require that the agency first conduct an informal consultation with the contractor, grantee, or licensee to understand the nature of the issue and consider other potential alternatives to remedy the concern. The agency will summarize the efforts made to correct the non-compliance when notifying the contractor or licensee if it intends to proceed with a potential march-in action.

B. CLARIFY AMBIGUITIES IN MARCH-IN RIGHTS PROCESSES AND TERMINOLOGY 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.

/footnote 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, fact finding, and determination.

/footnote 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."

Consequence of Intended Action 2

One of the proposed actions in *Intended Action 2* is to limit the circumstances in which a march-in can be used to situations where there is "a compelling national issue or declared national emergency when other remedies have failed." This is a higher standard than set out in the statue, and presents issues that a rights holder can litigate, making it all the more difficult to use march-in rights.

Another proposed action is to issue regulations that greatly narrow the definition of "available to the public on reasonable terms" (emphasis added). Specially, the draft Green paper would require statements:

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**. (emphasis added)

Commentary

What is a "Compelling National Issue"?

The draft proposal would limit march-in cases to a "compelling national issue or declared national emergency."

Unless a "declared national emergency" can fail to qualify as a "compelling national issue," the reference to a declared national emergency seems either unnecessary, or designed to color the standard in a way that will narrow the use of march-in rights.

Ultimately, what the Green Paper proposes is to eliminate the use of march-in rights when there are abuses of patent rights, unless such abuses meet some vague standard of being a "compelling national issue." The new standard is vague and invites litigation, for example:

- Are unreasonable prices for biomedical inventions "a compelling national issue"?
- Is a specific overpriced drug or cell therapy for breast cancer a "compelling national issue"?
- Was a shortage of Fabrazyme, which was a personal tragedy for patients, a "compelling national issue"?
- If the NIH threatens to use march-in rights if patent holders don't have more liberal licensing terms for upstream uses of patents on stem cells or CRISPR inventions, does that meet the "compelling national issue" standard?

The Policy and Objective of the Bayh-Dole Act as Described in the Statute

The Bayh-Dole statutes give a much broader mandate for the use of the royalty-free or march-in rights. The "Policy and objective" of the Act is set out in 35 U.S. Code § 200, and includes this mandate:

> It is the policy and objective of the Congress . . 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; (emphasis added)

The Bayh-Dole Act Statutory Standards for March-in Rights

The specific grounds for using the march-in rights do not require extreme tests, or meeting the proposed and vague status of "compelling national issue." On the contrary, they are fairly straight forward:

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

The problem today is not that agencies use the march-in rights too frequently, but rather on the contrary, that the rights are rarely invoked, despite cases where there is a clear abuse of patent rights.

In January 2016, 51 members of Congress wrote to HHS Secretary Sylvia Mathews Burwell and NIH Director Francis S. Collins (copy at https://www.keionline.org/22983) urging both "to utilize your existing statutory authority to respond to the soaring cost of pharmaceuticals," noting:

> When declining to exercise these march-in rights in response to previous petitions, NIH has suggested that controlling drug costs is a legislative duty. While that is accurate, Congress legislated long ago on a bipartisan basis in delegating authority to federal agencies such as NIH the responsibility to address one aspect of this problem. We call upon you to do that job. The failure to act in the past has undoubtedly sent an unfortunate signal that prices for federally-funded inventions can be set as high as a sick

> or dying consumer will pay. In 2013, for example, NIH rejected a request to issue rules related to pricing disparities between the United States and other high-income countries. While this may not be the sole standard considered, it exemplifies the type of standard which could be set.

In the Senate report to accompany the National Defense Authorization Act for Fiscal Year 2018, the Senate Committee on Armed Services sought to remedy this for a different funding agency by providing a directive to the Department of Defense:[5]

> **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.

Both the 2016 Congressional letter and the 2017 National Defense Authorization directive focused on a particular rule that could be invoked to protect U.S. residents from unreasonable prices, namely that U.S. residents should not pay more than residents of other high income countries for drugs where public funds were used for the patented inventions. The 2016 Congressional letter and the 2017 directive to the DoD were motivated by public debate on the problem of high drug prices, which is certainly a "compelling national issue."

Available to the Public on Reasonable Terms

The draft Green Paper seeks to narrow the meaning of the statutory requirement to make the benefits of inventions "available to the public on reasonable terms." This obligation is found in the statutory definition of "practical application", in 35 USC § 201(f) of the Bayh-Dole Act, which reads 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)

Dr. Francis Collins and before him Elias A. Zerhouni, M.D both have taken the position that obligation to make the benefits of inventions "available to the public on reasonable terms" will be satisfied if a company makes a product "available to the public at any price." This is a tortured

[5] 115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, on page 173

interpretation of “available to the public on reasonable terms”. Price is the term that counts the most for “the public.” What other terms do NIST experts think the public is concerned about?

The Culture of Private Benefit from Public Funded Research

The culture at the NIH is to ignore concerns the public has over the pricing of products. NIH scientists themselves are often named as inventors on patents, and under current law, are able to receive as much as $150,000 per year in royalties on such inventions, while employed by the NIH, in addition to whatever salary they earn. The Green Paper is proposing increasing the royalty cap to $0.5 million per year for all federal employees.

In 2016, KEI requested from the NIH records on royalty payments to its employees. The NIH has yet to provide such information.

Federal employees also often leave the government and join biomedical companies, large and small. There is an extensive revolving door, from the government and government-funded research institutions to private industry, and sometimes back to government or non-profit research jobs.

For example, until April 2018, Dr. Zerhouni was the President for Global Research and Development at the French pharmaceutical company Sanofi. Charles Sawyers, MD, from Sloan Kettering, is the principal investigator for more than $26 million in NIH grants from 1990 to 2018, including $5 million for 2017-2018 fiscal years. He has also advised the U.S. Army on prostate cancer research, co-founded biotechnology companies, and holds a seat on the Novartis Board of Directors, while working with Vice President Biden and NIH Director Francis Collins on the Cancer Moonshot. It is not surprising that many NIH-funded researchers support policies on government-funded research that provide huge benefits to private interests.

Increasing Interest in the Use of Royalty-free or March-in Rights in Federally-funded Biomedical Inventions

In general, federal agencies have been reluctant to use the government’s royalty-free rights or the funding agency’s march-in rights in federally-funded inventions. That said, such rights have been used in the past, and there is increasing interest in such use going forward.

Table 1 provides a list of notable cases where various federal agencies have considered or been asked to consider the use of royalty-free or march-in rights to address issues of drug

pricing and affordability, shortages of products, or use of technologies to create new biomedical products, involving the NIH, the CDC, DOE and the U.S. Army.

Table 1: Examples of march-in and royalty-free cases

Type	Year	Invention/product	Petitioner or intended petitioner, and outcome
March-in	1997	Ceprate SC, bone marrow transplantation	CellPro v Johns Hopkins, Link Outcome: CellPro was able to stay an injunction until a competing product was FDA approved, benefiting CellPro and patients using the CellPro device, but CellPro ultimately failed to obtain a license. Of note: Former Senator Birch Bayh represented Cellpro, and argued that John Hopkins University's demand for high royalties would lead to high prices and that high prices would have a negative impact on patients.
March-in	1999	Fluorescent in situ hybridization tests	Ventana Medical Systems (now owned by Roche) *v* the University of California. Outcome: DOE had funded the technology. After a 30-month fact-finding process determination by DOE, Ventana was able to obtain a license and marketed a FISH test in competition with Vysis, a subsidiary of Abbott laboratories.
Royalty-free	1999	Several drugs	Ralph Nader, CPTech and Essential Action, Link Outcome: NIH Director Dr. Harold Varmus rejected the request to allow the World Health Organization (WHO) to use the U.S. government's royalty-free rights in drug patents in low income countries.
March-in/royalty-fr	2001	Stem cells	WARF

ee (threat)			Outcome: NIH negotiated two agreements with WARF on licensing stem cell patents.
March-in	2004	Norvir/ritonavir	Essential Inventions v Abbott, Link Outcome: NIH rejected the march-in request, but only after Abbott agreed to roll back a 400 percent price hike for patients on federal programs.
March-in	2004	Latanoprost	Essential Inventions v Pfizer, Link Outcome: NIH rejected the march-in request.
March-in (threat)	2006	Reverse genetics for avian flu	Centers for Disease Control Outcome: More liberal licensing of reverse genetics patents.
Royalty-free	2007	Stavudine/d4T and ritonavir	Essential Inventions, Link Outcome: OMB head Robert Porter rejected the request to use the federal royalty-free rights.
March-in	2010	Fabrazyme shortage	Joseph M. Carik, Anita Hochendoner, and Anita Bova v Mount Sinai School of Medicine of New York University/Sanofi/Genzyme, Link Outcome: The NIH prevented Genzyme/Sanofi from enforcing an injunction against Shire in Germany until Sanofi restored manufacturing capacity.
March-in, royalty-free	2012	Ritonavir and other drugs	American Medical Students Association (AMSA), Knowledge Ecology International (KEI), U.S. Public Interest Research Group (PIRG) and the Universities Allied for Essential Medicines (UAEM), Link Outcome: NIH rejected march-in request.

March-in, royalty-free	2016	Xtandi (enzalutamide)	Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) v University of California/Astellas, Link Outcome: NIH rejected march-in request andU.S. Army rejected march-in request.
March-in, royalty-free	2017	Zinbryta (daclizumab)	Knowledge Ecology International (KEI), Link Outcome: Product withdrawn from market.
March-in/royalty free right (ongoing campaign)	2018	Truvada (emtricitabine/tenofovir disoproxil fumarate)	PrEP4All v Gilead Outcome: Ongoing. HHS has not yet acted.

Two potential march-in or royalty-free rights cases

The following are two cases where the use of royalty-free or march-in rights are under active consideration, and which would be prejudiced by the proposed changes in *Intended Actions 1* and *2*.

1. Spinraza/nu. The high price of Spinraza ($750,000 for first year of treatment, and $375,000 for maintenance) has created restrictions on access to this treatment for spinal muscular atrophy (SMA) a neuromuscular disorder that harms children. The price for this treatment, invented at the University of Massachusetts and Cold Spring Harbor on NIH grants is reportedly less than $100,000 per year in some European countries.
2. Xtandi/enzalutamide. A veteran is expected to petition the Department of Defense to use its Bayh-Dole rights to enable competition for enzalutamide, a drug for prostate cancer invented on a grant from the U.S. Army that has an average wholesale price of $159,000 per year in the United States, and a much lower price in other high income countries. This petition will ask DoD to apply the 2017 DoD authorization directive described above.

CRISPR and CAR T

Extensive patent thickets are emerging in CRISPR and CAR T technologies, two promising areas of biomedical innovation.

On June 6, 2017, Knowledge Ecology International wrote to the U.S. Department of Health and Human Services (DHHS) asking the Department to adopt a policy on the licensing of federally-funded CRISPR patented inventions (link here). The NIH has declined to do so, but at a future date, under different leadership, may revisit this issue.

CAR T-Cell therapies are also plagued with extensive patent filings and overlapping claims, leading to considerable litigation, high costs for acquiring intellectual property rights and legal-related business risks.

For both CRISPR and CAR T, the NIH has played a key role in funding the most important and foundational innovations, and can use the royalty-free and march-in rights to pressure rights holders to more liberally license platform patents.

Relationship Between Royalty-free and March-in rights and 35 USC § 1498.

35 USC §1498(a) "Patent and copyright cases," provides for a limitation on the remedies for nonvoluntary government use of patented inventions. Injunctions are not available, but patent holders are entitled to compensation, which is set by courts. Proposals have been made since 2001 to use §1498(a) to obtain low cost generic versions of a variety of drugs, including in 2001 CIPRO/ciprofloxacin, in 2005-6 Tamiflu/oseltamivir, in 2006 Avastin/Bevacizumab, in 2014-2018 sofosbuvir-based HCV drugs, and in 2016-2018, various anti-overdose remedies. (See: https://www.keionline.org/cl/28usc1498). A constant objection from federal agencies is the risk of a costly compensation obligation, by a federal court.

In the ritonavir march-in cases, the NIH expressed concern that a march-in license on the federally-funded inventions would not be sufficient, if other non-federally-funded patents were infringed.

The Section 202 and 209 government use license can mitigate the risks of large judgements for non-voluntary use of patents, and Section 1498 can mitigate the problem of not having access to all relevant patents under march-in. Taken together, Section 1498 can clear out any evergreening patents that may present issues, and the Section 202 or 209 licenses can eliminate the risk of large compensation judgements. The draft Green paper would limit the ability of the federal government to take advantage of these opportunities where there is a clear need to remedy an excessive price.

The 202 and 209 licenses can also be used to register drugs, as noted by Alfred Engelberg and Aaron Kesselheim in a 2016 article in Nature Medicine.[6]

[6] "Use the Bayh-Dole Act to lower drug prices for government healthcare programs," Nature Medicine 22, 576 (2016) doi:10.1038/nm0616-576, Published online 07 June 2016.

Hatch-Waxman requires a manufacturer that is seeking approval to sell a generic copy of a patented new drug like enzalutamide to certify that any patents on the new drug are invalid or will not be infringed. This requirement may seem to prevent a generic manufacturer that has no basis for substantively challenging enzalutamide's patents from obtaining FDA approval before the patents expire. But because of the government's Section 202 license, we believe that a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose producing enzalutamide for sale to the government. Any suit claiming infringement of the enzalutamide patents despite such a certification should be dismissed by a federal court, because law /fn3/ prohibits the court from interfering with the right of a government supplier to bid on or participate in the sale of products to the government, irrespective of the existence of patents. /fn4/ The only available course of action for acts of patent infringement by or for the government is to initiate a suit in the US Court of Federal Claims—but the Section 202 license would provide the government with a complete defense.
fn3/ 28 USC 1498(a)
fn4/ Gore v. Garlock, 842 F.2d 1275, 1282 (Fed. Cir. 1988).

The Views of Senators Birch Bayh and Robert Dole

The draft Green Paper quotes former U.S. Senators Bayh and Dole to support the notion that march-in was not intended to address pricing issues.

This deserves some commentary. First, this is how the Green Paper presented the views of Senators Bayh and Dole:

> 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.")
>
> > **Statements by Senators Bayh and Dole on March-In**
> > The "Bayh-Dole [Act] did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that

http://www.nature.com/nm/journal/v22/n6/abs/nm0616-576.html

> should be dictated by the government...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 [federally] 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," among other circumstances.
>
> Source: Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002.

The Green Paper quotes a letter to the editor by Bayh and Dole[7], responding to an op-ed and earlier academic article by Professors Peter Arno and Michael Davis.[8]

Bayh's Views Shifted with Client's Interests

Bayh would later repeat this argument in the 2004 hearing on ritonavir march-in petition, in support of Abbott. At the 2004 hearing, Bayh claimed that no one had paid him to testify at the hearing. What he neglected to disclose, was that he was a partner in a firm representing Abbott. Moreover, Bayh neglected to note that in 1997, he represented Cellpro in a march-in request, and made the contrary argument.

> In enacting Bayh-Dole, Congress made the judgment that policy objectives of commercializing the results of federally-funded research were better served by allowing federal nonprofit grantee institutions like Johns Hopkins to obtain and hold patent rights, with exploitation of inventions generally left to the nonprofits' licensing programs and competitive forces. At the same time, however, Congress recognized that in particular cases the public interest might require government action and therefore included in the Act 'march-in' provisions "to ensure that the

[7] Letter to the editor, Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, April 11, 2002, page A28.
[8] Peter Arno & Michael Davis, Paying Twice For the Same Drugs, *Washington Post*, March 27, 2002, page A21; summarizing their earlier academic article, Peter Arno & Michael 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, 75 TULANE L. REV. 631.

Government obtains sufficient rights in federally supported inventions to . . . protect the public against nonuse or unreasonable use of inventions." . . .

To carry out these federal policies, the Bayh-Dole Act provides that a Federal agency may exercise its march-in rights and require the exclusive licensee of an invention made with Federal funds to issue a license to a responsible applicant's "upon terms that are reasonable under the circumstances" if the Federal agency determines that

> (a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; [or]
>
> (b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees. 35 U.S.C. 203.

In the present instance, both of these statutory bases have plainly been met.

. . .

In fact, the circumstances — and the interests of the public which paid for the research that led to the patents and is now being asked to pay again — cry out for a far lower royalty payment by CellPro.

. . .

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.

Source: The March 3, 1997 march-in petition to Secretary Donna E. Shalala from Lloyd Cutler and Birch Bayh, on behalf of Cellpro. (Copy here).

Bayh's views, set out in an amicus brief, on what the Bayh-Dole Act required regarding the ownership of federally funded inventions, was rejected by the U.S. Supreme Court in *Stanford University v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011), illustrating the risks of relying

upon the recollections and opinions of former members of Congress, as regards the intent of a U.S. statute.

Dole was a Spokesperson for Viagra, Employed by Pfizer and Representing other Corporate Clients

Upon leaving the U.S. Senate, Dole joined Verner, Liipfert, Bernhard, McPherson and Hand, as a lobbyist. In 2003, after Verner, Liipfert was acquired by Piper Rudnick, Dole joined the Washington, D.C. law and lobbying firm Alston & Bird LLP.

By the time Dole co-signed the letter with Bayh, he was working for Pfizer. Dole began doing television commercials for Pfizer in 1998.[9]

[9] Pfizer Hires Bob Dole for TV Ad Campaign, December 12, 1998, Associated Press. http://articles.latimes.com/1998/dec/12/business/fi-53139