March 28, 2021

Submitted through the Federal eRulemaking Portal

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

AUTM's Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327)

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

AUTM appreciates the opportunity to comment on the above captioned Notice of Proposed Rulemaking regarding Rights to Federally Funded Inventions and Licensing of Government Owned Inventions. As a non-profit association focused on advancing federally funded inventions to the marketplace, AUTM has witnessed the robust success of the Bayh-Dole Act over the past forty years. We applaud the National Institute of Standards and Technology (NIST) for their careful and deliberate efforts to further strengthen this crucial statute that is being emulated across the globe.

The Bayh-Dole Act has had a profound impact on American health, security and prosperity. We have all benefited from the broad and numerous innovations arising from federal funding. They include:

- firefighting drones that saved homes as fires ravaged Arizona and Colorado;
- FluMist doses a pediatrician administers to your children in lieu of a shot; and
- high-definition TVs you watch while at home during the pandemic.

But these are just three of the thousands of new products and services that came about through technology transfer since the passage of the Bayh-Dole Act. AUTM has been collecting data on the impact of technology transfer since 1991. Our 2019 Infographic, a copy of which is attached to these comments, illustrates that U.S. universities, hospitals, research institutes and government labs developed over 25,000 inventions, closed almost 10,000 deals with commercialization partners to bring them to market, and resulted in over 700 products in 2019 alone – many funded by the federal government. In the absence of the Bayh-Dole Act, many of these inventions would have withered on the proverbial vine with the benefits of that federal funding never reaching the public.

New products and services are not the only outcome of the Bayh-Dole Act. It is also an economic catalyst. In fact, we reported 1,040 new startup companies arising from technology transfer just in 2019. Another 2019 economic report found that over a 22-year period, inventions arising from universities or hospitals or other public sector research institutions have accounted for up to 5.9 million jobs and added up to 865 billion dollars to the U.S. GDP – much of it catalyzed by the Bayh-Dole Act.[1]

AUTM supports many of the proposed changes to the Bayh-Dole regulations which NIST has described in its Notice of Proposed Rulemaking. Herein, we would like to comment on several of those changes that are of particular import to AUTM and its members.

I. BAYH-DOLE MARCH-IN

Our comments on march-in are multi-faceted:

Clarify that (A) "reasonable terms" as used in the definition of "practical application" in 35 U.S.C. § 203(a)(1) refers to the terms of the *license agreement* between the contractor/assignee and its licensee and that (B) the end-user price of a successfully commercialized product may not be used as a basis for exercising march-in rights.

These clarifications are needed to ensure the intent of the Bayh-Dole Act, i.e., to turn the federal funding of early-stage research into new products and services, and the resulting improvement in the American standard of living and increased U.S. economic growth, is preserved. As reflected in the public comments that NIST received as part of its ROI Initiative, the Bayh-Dole Act has become an important driver of the U.S. economy while promoting the public welfare.

Nevertheless, concerns remain among universities and their licensees that the march-in provision of the statute will be misused to allow the government to set end-user prices on successfully commercialized products. While such an action is not supported by the statute, it is important to provide reassurance to stakeholders (e.g., universities, licensees and prospective licensees, investors) and federal agencies implementing the law, as even the slightest perceived potential for misuse will have severe detrimental effects on our ability to continue to successfully translate federally funded inventions to the marketplace to improve the standard of living and contribute to the growth of the U.S. economy. Therefore, AUTM supports clarifying the march-in provision of the statute (35 U.S.C. § 203) with the proposed new regulation, 37 C.F.R. § 401.6(e).

However, AUTM recommends two (2) modifications to the proposed language as follows:
The current proposed language states that "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 practical application of the invention" (emphasis added). Because so much confusion has been generated from misconstruing the words of the statute, AUTM recommends removing (i) the word "exclusively" and (ii) the phrase "of the contractor" so there is absolute clarity that end-user pricing may not be used as a factor in determining whether to exercise march-in rights.

---

[1] "Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2017" https://autm.net/AUTM/media/About-Tech-Transfer/Documents/Economic_Contribution_Report_BIO_AUTM_JUN2019_web.pdf

As outlined below, any assertion that pricing can or should be used as a basis for exercising march-in rights on a product developed, commercialized and sold by our licensees and sublicensees is inconsistent with both the letter and the spirit of the Bayh-Dole Act. Moreover, it could have devastating consequences to this country's leadership position in basic and applied research and its long history of success in commercializing university discoveries. NIST can best protect the public investment in federally funded research by providing clear guidance now to address the very real concerns of stakeholders have that the law will be misapplied to their detriment. Misapplication of the law will create a disincentive to invest in the long and expensive process of commercializing early-stage research discoveries. If the partnerships that have been built between academia and the private sector as a result of the Bayh-Dole Act over many decades are eroded, this foundational component of the U.S. economy that has served as a springboard for entire industries, thousands of jobs, and many life-enhancing products will be seriously weakened.

A. AUTM's proposed edits are consistent with the statutory language and historical intent of § 203(a) of the Bayh-Dole Act.

The controversy surrounding the application of march-in rights is focused on § 203(a) of the Bayh-Dole Act. Some helpful background on the intent of the law and the rationale for § 203(a) are provided in a new article[2] by Joseph P. Allen, who served on Senator Birch Bayh's staff and put together the hearings in the Senate Judiciary Committee as well as writing the Committee's report on the Bayh-Dole Act. Mr. Allen later oversaw the implementation of the Bayh-Dole Act as the Director of the Office of Technology Commercialization at the U.S. Department of Commerce. This oversight authority is currently delegated to NIST.

Of note is what Mr. Allen wrote regarding march-in rights:

> *Twenty years after Bayh-Dole's enactment, its opponents claimed to have discovered a previously hidden meaning in the law giving the government price control authority. When that argument appeared in The Washington Post, it was immediately rejected by Senators Bayh and Dole who replied in "Our Law Helps Patients Get New Drugs Sooner:" (https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/)*
> *Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional…*
>
> *The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.*

[2] https://www.ipwatchdog.com/2021/02/04/biden-administration-innovation-crossroad/id=129725/

Nevertheless, attempts were made to have the government "march in" against drugs developed from federally funded inventions so copiers can make them. Those efforts were uniformly rejected by every past Democratic and Republican Administration as unauthorized under the law…

Because effective commercialization was its objective, the law includes a fail-safe mechanism termed the "march in" provision. It has four triggers, three of which cover the patent owner, the assignee and the licensee. Those three say that the government can require the patent owner (normally an academic institution) to issue additional licenses if required to address health, safety or regulatory needs which are not being met, or if an exclusive licensee fails to honor its pledge to produce the product substantially in the U.S.

The controversy arises from the first trigger which ***applies only to the patent owner****. The government can march in if the patent owner or their 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 the field of use." The definition of "practical application" states that the invention's benefits are "available to the public on reasonable terms." Critics of the law seized on that language to insist that the government can march in if a product isn't "reasonably priced."*

That argument quickly breaks down on closer examination. To understand the meaning, we need to go back to 1978 when Bayh-Dole was written. At that time, few academic institutions had technology transfer offices, so many assigned their inventions to patent management entities like University Patents, Inc. or Research Corp.

Congress was concerned that a safeguard was needed as the law immediately transferred the ownership of federally funded patents to many institutions that were new at technology licensing. Some feared that dominant companies would take advantage of this inexperience to license inventions in order to suppress them if they threatened existing products. Others feared that universities might insert unreasonable terms and conditions in their licenses which discouraged commercialization. The first march in trigger addresses those concerns.

However, as Senators Bayh and Dole stated, their law does not give the government the authority to set prices for successfully commercialized inventions. If that had been the intent, this trigger would have included the licensee, not just the patent owner. After all, pricing decision are not determined by academic institutions but by their licensees. And, as Senator Bayh told NIH (https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf) in response to a petition to march in to regulate prices, if Congress ever wants to grant that authority, it must define a "reasonable price" in the statute. That has never been done.

Clearly, the law was never intended to permit price-based march-in and, thus, in the pending regulatory clarification NIST must reassure stakeholders that the march-in provision of the statute will continue to be applied as the law intends.

B. AUTM's proposed edits are necessary to ensure federally funded inventions continue to make a positive impact on the standard of living for Americans and the growth of the U.S. economy.

Even if the statutory framework and historical intent of § 203(a) of the Bayh-Dole Act is set aside, there are numerous reasons from a public policy perspective why it is important to clarify that pricing may not be used as a basis for exercising march-in rights. The threat that the Bayh-Dole Act's march-in provision could enable the government to indirectly impose price restrictions is causing considerable concern and, if carried out, will disrupt the delicate balance between protecting the public's investment in federally funded research and maintaining the private sector's incentive to accept the risk involved in commercializing the technology. Preserving the enormous benefits that the Bayh-Dole Act has had on public welfare and the U.S. economy requires that this balance be carefully preserved.

Below is a diagram that depicts the widely acknowledged risks and uncertainty involved in licensing university-generated inventions. Since universities by law and per their missions are restrained in their ability to commercialize new technologies, university inventions are nearly always licensed at a very early stage in their development, and sometimes only shortly after establishing proof of concept. As a result of this early handoff to the private sector – **often start-up companies formed by entrepreneurs and supported by venture capital which have an enormous positive impact on local economies** – a large development gap exists between the time the license is executed and when the licensed technology reaches the market in the form of a new product or service (in the pharmaceutical and medical device sectors it can be well over a decade and the failure rate is nearly 90%). This gap is routinely characterized as the "Valley of Death" due to the very few inventions that are able to secure the investment necessary to successfully traverse this gap[3] (see Figure 1 below.)

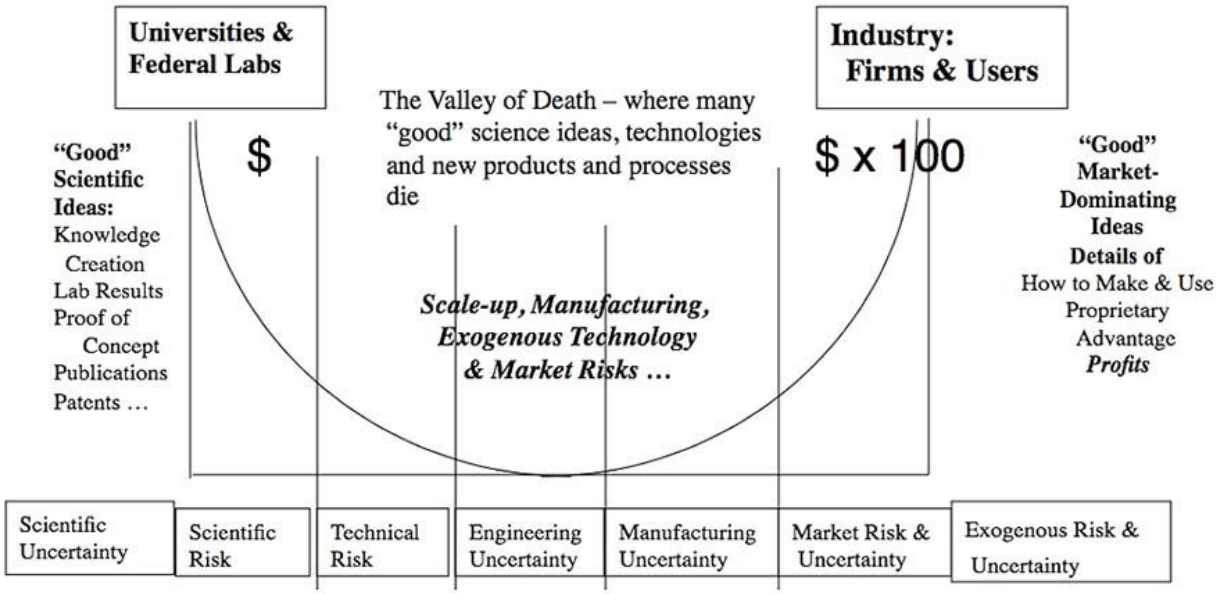


Figure 1

[3] University of Central Florida I-Corps Program "Take Your Innovation to Market" https://icorps.cie.ucf.edu/category/featured-on-home/

In determining whether to make that sizeable investment with an acceptable return, the licensee has to assess a host of unpredictable factors including: the cost of the product, the average development cost, the opportunity costs, failure costs, average industry margins, relative contributions of the partners, the marketing and distribution costs, presence and prices of similar competing therapies, likelihood and timing of market entry for potentially competing products, projected time to recover development costs, and special discount and access programs. Adding a cloud of uncertainty to this already complicated assessment by introducing the specter of government-exercised march-in rights based on the product's end-user price introduces additional complexity and adds significant additional risk to a long, expensive R&D program that is already fraught with tremendous risk.

Thus, any perceived risk of a price-based march-in will discourage potential licensees and will disincentivize the commercialization of federally funded inventions. Even a vague threat of potential for march-in based on price will likely have a chilling effect on the development of federally funded inventions. **If potential licensees and their investors determine that the risks involved in further developing and commercializing federally funded inventions is too great, then price of the end-user product becomes a moot point because <u>there will be no product to price</u>.** As a result, the public and the U.S. economy will suffer and the federal government's investment in the underlying research will have been for naught.

C. If price is a basis for exercising march-in rights, private sector entities will shun licensing of federally funded IP from universities and will avoid collaborating with universities. The private sector will no longer view its robust partnerships with universities as mutually beneficial, but rather as a poison pill that could endanger their broader IP portfolios.

As depicted in the diagram in Section I.B above, licensing early-stage technologies developed in a lab and translating it to a product in the marketplace requires the licensee to invest in extensive and lengthy research, development, scale-up and manufacturing activities. These activities often generate new and distinct intellectual property (IP) rights and/or require the in-licensing of IP from other patent holders. Often by the time the product reaches the market, the product is covered by a number of patents and other IP rights that were not derived from federal support. Such non-federally funded IP rights may be equally as instrumental to the university's technology crossing the Valley of Death. Clearly, the Bayh-Dole Act's march-in provision was not intended to implicate IP owned or controlled by private industry that was not created with federal support.

The Bayh-Dole Act has also served to build collaborations among universities, federal labs, industry, and state and local governments. It is unquestionable that these collaborations have accelerated the progress of science and technology to the benefit of the public. Universities support basic research, which often involves the investigation of fundamental biological structures and mechanisms to determine the activity and effectiveness of molecules or compounds for the treatment of diseases. This research provides a foundation for education and future endeavors with great commercial potential. On the other hand, the private sector possesses the infrastructure and expertise to take such knowledge and translate it to an actual products and services so that the benefits of research can be realized by the public.

The energy devoted by universities to building and maintaining strong academic/private-sector collaborations has been increasing since the mid-1960s. As reflected by the chart below[4], the percentage of total U.S. R&D expenditures by businesses has also been increasing over that same time period while the percentage of total U.S. R&D expenditures by the federal government has been steadily declining. In 1980, the percentage of total U.S. R&D expenditures by businesses actually eclipsed the federal government's percentage of total U.S. R&D expenditures. More importantly, in about 1988, presumably after enough universities created the technology transfer infrastructure spawned by the Bayh-Dole Act, there are noticeable trendline breaks resulting in an even larger separation between businesses and the federal government in terms of their percentages of total U.S. R&D expenditures. Universities are keenly aware of these trends and appreciate that their private sector partnerships are instrumental to their continued success in transferring early-stage inventions from their academic labs to the commercial marketplace. Policymakers must join universities in their awareness and appreciation of these trends.

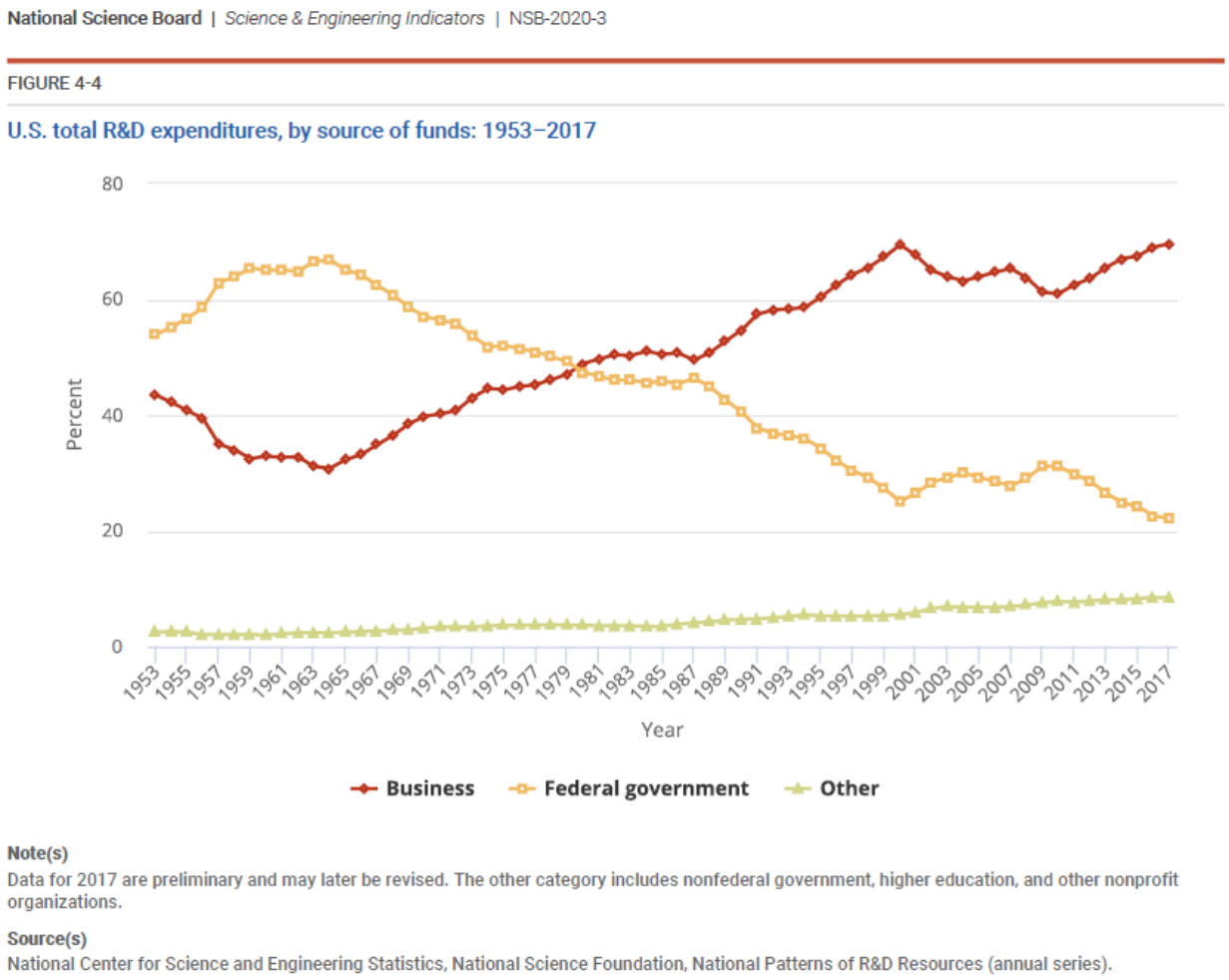


Figure 2

[4] National Science Board Science & Engineering Indicators 2020. "Research and Development: US Trends and International Development" NSB-2020-3 https://ncses.nsf.gov/pubs/nsb20203/assets/nsb20203.pdf

If our private sector partners and licensees become fearful that their proprietary technologies and IP portfolios could be tainted by a price-based march-in right through the in-licensing of federally funded inventions, they may decide to distance themselves from the many fruitful and synergistic relationships that have been built between academia and industry over the last four decades. Providing greater clarity as to the limited scope of the march-in provision would ease the confusion and frustration, and diminish the misunderstanding, that currently exists among the stakeholders operating in the context of the Bayh-Dole Act.

D. The Bayh-Dole Act's march-in provision was never intended to be used, and is not the proper mechanism, to control end-user prices (e.g., drugs, medical devices, computers, etc.).

The march-in provision controversy is a complex matter that has arisen from a mischaracterization that the government's interest in using the Bayh-Dole Act to spur innovation and facilitate the transfer of technology is somehow coupled to the government's interest in containing health care costs through drug pricing. The two interests are not coupled, and the Bayh-Dole Act was never intended to provide such a coupling. Attempting to create such a coupling would be contrary to the very goals that the Bayh-Dole Act has proven to successfully achieve. Some consumer advocates have argued that the march-in clause was intended to protect the public's investment in products which arise from federal funding. They further argue that the public is left in a position in which it might be forced to pay inappropriately high prices for drugs whose research and development they have financed as taxpayers. Private sector entities, on the other hand, view this misreading of the march-in clause as threatening their intellectual property and the substantial investments they have made to bring their products to a highly competitive marketplace.

University technology transfer offices are then placed in the difficult position of asking their licensees to accept the march-in provision without being able to fully reassure licensees that the government will not be permitted to march-in based on price when it is time to market a product. The position increases the likelihood that an agreement will not be reached and runs counter to the mission as university technology transfer offices are keenly aware that **fewer licenses will result in fewer new products, a less competitive marketplace and, as a result, higher, not lower, prices.**

Even more troubling, if the Bayh-Dole Act can be used to control drug prices, then presumably it also could be used to control the price of any other type of consumer product that arises from federal government support. The federal government invests in research in a wide array of scientific disciplines, including engineering, environmental sciences, life sciences, and computer sciences and mathematics. This research results in diverse inventions such as computer chips, self-driving cars, MRI and other imaging technologies, energy, etc. Clearly the Bayh-Dole Act was never intended to be used to control prices in all of these markets and it would be equally inappropriate to use the march-in provision to control prices within the pharmaceutical market.

NIST plays an important role in helping the broader policy community understand that the Bayh-Dole Act's continued success is dependent on reducing uncertainty over whether pricing may be used as a basis for exercising the march-in provision. This misunderstanding, if permitted to continue or even build, has the potential to disrupt the balance between the competing objectives of protecting the public's investment in academic research and industry's incentive to accept the risk involved in translating the results of that research back to the public to improve lives.

This controversy threatens to undermine the Bayh-Dole Act's long track record of having a positive impact on the U.S. economy and the greater public good. Thousands of federally funded therapeutics are currently under development, some of which will be lucky enough to make it to market. If mischaracterizations of § 203(a) of the Bayh-Dole Act remain unchallenged, it could jeopardize U.S. universities' ability to out-license their federally funded, inventions resulting in slower economic growth, fewer high-paying jobs and a reduced number of life-improving new products becoming available to the public.

II. INFORMATION SHARING

37 C.F.R. § 401.6(a)(4) adds, at the very end, "… or otherwise required by law." There is concern that proprietary and confidential information shared with the federal agency during a march-in proceeding should continue to be protected if a request for information is submitted to the federal agency. The Freedom of Information Act (FOIA) allows protection of unpublished, proprietary or confidential information. We encourage NIST to ensure strong automatic protection of such confidential or proprietary information under any provision of the Bayh-Dole Act or its implementing regulations, including consultation and redaction by the owner of such information should a request arise.

III. LICENSING PROCEDURES

Myriad factors come into play when selecting a licensee, and individual circumstances dictate whether a small business is successful. Universities across the nation are setting up incubators to nurture startup companies and stimulate local economic development. 37 C.F.R. §401.14(k)(5) is a new section that *requires* the contractor to "negotiate changes to its licensing policies, procedures, or practices" when a federal agency determines that the contractor could take reasonable steps to more effectively implement the small business preference. Without understanding the nuances and complexities of individual circumstances, the federal agency can dictate changes to the university's policies and practices. We recommend changing "negotiate" to "consider" to foster a meaningful dialogue.

IV. TEN-MONTH RULE

The revisions in sections 37 C.F.R. § 401.14(c)(3)(i-iii) require a contractor to file a non-provisional application within 10 months of filing the provisional application, unless extended under 37 C.F.R. § 401.14(c)(5). AUTM members are at the forefront of research and often times file provisional patent applications with preliminary data so that our researchers are able to publish and seek grant funding. It is uncertain from where the 10-month time period came. One can only assume that the 10-month deadline was calculated based upon the 60-day notification period to protect the federal agency rights under § 401.14(f)(3). However, in practicality, this artificially shortens the time period for our researchers to perform the research and gather results needed to support a non-provisional application. It also forces AUTM members to have conversations with inventors and make decisions with reduced information at around the 8-month mark in order to give our attorneys sufficient time to prepare the non-provisional application. In reality, many of AUTM's members request an extension under § 401.14(c)(5), often at the time of notifying the federal agency of the provisional filing, so that they can have the additional time period for the research to be performed, data gathered, and more thoughtful decisions made.

AUTM urges NIST to eliminate the requirement in § 401.14 (c)(3)(i) that a non-provisional application be filed within 10 months of the filing of the provisional application when the provisional application is the initial patent application. In other words, AUTM urges the return to allowing contractors the full 12-months to "convert" the provisional application as set forth in the patent statute. This change will ease the substantial burden on the federal agency in dealing with numerous extension requests and, more importantly, on technology transfer offices which are constantly having to submit those extension requests. Most importantly, it will restore those valuable two (2) months which will allow contractors to file more robust non-provisional patent applications and, thus, increase the likelihood of future commercialization and the benefits to the U.S. economy and Americans that come with it.

In the absence of the aforementioned elimination of the 10-month requirement in § 401.14 (c)(3)(i), at a minimum, AUTM requests clarification and/or additional context regarding the one-year extension of time to file a nonprovisional application after filing a provisional application as provided in § 401.14 (c)(5); specifically, as it relates to the filing of follow-on provisional applications as described in § 401.14 (c)(3)(ii). In other words, if § 401.14 (c)(3)(ii) requires new subject matter in all follow-on provisional applications, what is the thinking behind a 1-year extension? In a first-inventor-to-file system, contractors will rarely, if ever, want to risk losing the priority date by extending the filing of a non-provisional application more than two (2) months such that the provisional application will have expired and its priority date will have been lost.

V. REFILING OF AND FOLLOW-ON PROVISIONAL PATENT APPLICATIONS

The above notwithstanding, AUTM does not support 37 C.F.R. § 401.14(c)(3)(ii) as proposed. Contractors occasionally use the tactic of refiling the initial provisional application in order to avoid waving its rights in the technology to the government. This tactic is particularly useful in a first-inventor-to-file system for very early-stage technologies when significant further development is required but did not take place during the first year for myriad reasons. Thus, AUTM urges NIST to amend § 401.14(c)(3)(ii) to allow the refiling of a provisional application, at least on a limited basis.

Moreover, it has come to AUTM's attention that NIST may be intending to require agency approval before the filing of follow-on provisional applications as permitted by the proposed § 401.14(c)(3)(ii) (i.e., those containing new matter). AUTM strongly opposes such a requirement. Given the surge in the number of provisional applications filed since the U.S. became a first-inventor-to-file system, follow-on provisional applications have increased significantly as well. As such, the administrative burden of seeking agency approval for each such follow-on provisional application would crush even the most well-resourced TTOs.

VI. U.S. MANUFACTURING WAIVER

AUTM enthusiastically supports 37 C.F.R. § 401.14(i), Preference for United States Industry. AUTM recognizes the critical role that manufacturing plays for the U.S. economy and its national security; particularly the advanced manufacturing of the 21st century. AUTM further recognizes advanced manufacturing is a significant source of high-paying jobs for American citizens and that this advanced manufacturing is often required for inventions arising under the Bayh-Dole Act.

However, as the economy has become more global, licensees are more frequently and proactively planning for the possibility they might need to seek a waiver of this provision. Thus, AUTM requests that § 404.14(i) be amended to provide additional clarity, uniformity and objectivity to the contemplated waiver process. Specifically, as part of the implementation of the new waiver process, AUTM requests the following three (3) changes as being particularly helpful: (i) in situations where two or more federal agencies provided funding for the creation of the subject invention, identify one of the agencies as the "lead" to make the waiver process more efficient and, (ii) establish that the waiver will be automatically granted unless the agency notifies the contractor to the contrary within ninety (90) days, and, (iii) consistent with Section VII below, utilize iEdison as the portal through which all such waiver requests are to be submitted and managed.

VII. FEDERAL REPORTING

AUTM urges NIST to take the necessary steps to require all federal agencies to use iEdison. AUTM further urges NIST to limit the information it requires from the agencies in 37 C.F.R. § 404.16 to that which is provided to and/or available from iEdison. This limitation will create a uniform set of contractor-provided metrics leading to more accurate and more efficient reporting.

VIII. DEFINING THE SCOPE OF THE GOVERNMENT USE LICENSE

AUTM continues to support 37 C.F.R. § 404.14(b) (Allocation of Principal Rights) but suggests additional clarity on the scope of that governmental use license. Having additional guidance to assure our licensees that this authority is limited and will not be abused would be very helpful as AUTM members and their organizations frequently hear incorrect interpretations from their private sector partners about the breadth and scope of the statutory language defining the government's right to use resulting inventions and practice them throughout the world.

One such abuse of this right is when a licensee refuses to pay agreed upon royalties to academic institutions when they sell resulting products to federal agencies without the agency's authorization to utilize the government's right to a royalty free license. As made clear in the Government Accounting Office's report "Agencies' Rights to Federally Sponsored Biomedical Inventions[5]" cited in the Green Paper:

> "*The government's right to practice an invention is limited to federal agencies* ***and their funding recipients specifically authorized to use the invention for federal purposes"*** (emphasis added). (GAO report p. 6)
>
> "*The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license.*" (GAO p.2)
>
> "*The statute does not give the federal government the far broader right to purchase, 'off the shelf' and royalty free (i.e., at a discounted price), products that happen to incorporate a federally-funded invention when they are not produced under the government's license.*" (GAO p. 7)

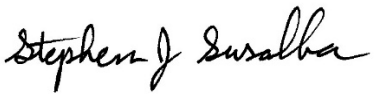
[5] "Agencies' Rights to Federally Sponsored Biomedical Inventions" General Accounting Office (GAO) https://www.gao.gov/assets/gao-03-536.pdf

Thus, it is clear the government's use license can only be invoked by the agencies or those they authorize to act on their behalf. It does not provide a pretext for those licensing federally funded inventions to avoid paying agreed upon royalties.

Therefore, AUTM seeks a clarification that the government's license can only be invoked by an agency or those it officially authorizes to act on its behalf and does not automatically extend to private parties licensing federally funded inventions who sell resulting products to a federal agency.

In conclusion, AUTM again wishes to thank NIST for taking a leadership role in ensuring that America's technology transfer engine will continue to power America's innovation ecosystem to the great benefit of the United States, its citizens and the entire world. These revised regulations will help the Bayh-Dole Act continue its 40-plus year mission of fostering increased economic growth, a higher standard of living and numerous high-paying jobs here in the United States.

Sincerely,



Stephen J. Susalka, PhD, CLP, RTTP

Chief Executive Officer

AUTM

Enclosure: 2019 AUTM Infographic (https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-2019-Infographic-FNL.pdf)

Driving the Innovation Economy

Academic Technology Transfer In Numbers

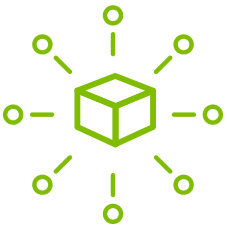
From 1996 to 2017, up to...

$1.7 trillion

contributed to **U.S. gross industrial output**

$865 billion

contributed to **U.S. gross domestic product**



5.9 million

jobs supported

490,000+

inventions disclosed...

108,000+

U.S. patents issued...

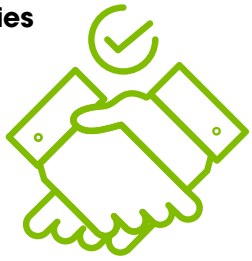
to research institutions since 1996

14,000+

start ups formed

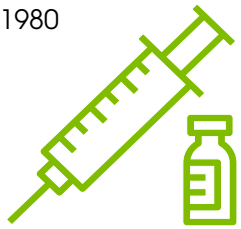
67%

of university licenses are to **start-ups and small companies**



200+

drugs and vaccines developed through public-private partnerships since **Bayh-Dole Act** enacted in 1980



autm

Transforming Ideas into Opportunities

For more information visit
www.autm.net

This information was compiled from AUTM and the Biotechnology Innovation Organization: The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2017; June 2019 as well as the AUTM 2019 Licensing Activity Survey and Statistics Access for Technology Transfer Database, www.autm.net/STATT, and the Academic Patent Licensing Helps Drive the U.S. Economy, IPWatchdog.com, June 20, 2017.

Benefiting Society and the Economy

Academic Technology Transfer For 2019

autm
Transforming Ideas into Opportunities

For more information visit
www.autm.net

Every year university research yields discoveries with commercial potential.

Technology transfer professionals associated with universities and other academic institutions manage the complex process of shepherding ideas from the lab to the marketplace — from evaluating and protecting discoveries to commercializing the inventions through new and existing companies.