



ASSOCIATION
OF AMERICAN
UNIVERSITIES



ASSOCIATION OF
PUBLIC &
LAND-GRANT
UNIVERSITIES



DATE: December 9, 2016

TO: Courtney Silverthorn, Host Agency Representative, Executive Board
Courtney.silverthorn@nist.gov

FROM: Anthony DeCrappeo, President, COGR Ross McKinney, M.D., Chief Scientific Officer, AAMC
Mary Sue Coleman, President, AAU David Winwood, President, AUTM
Peter McPherson, President, APLU

SUBJECT: Docket ID No. 160311229-6229-01

Rights to Federally Funded Inventions and Licensing of Government Owned Inventions
81 FR 78090: RIN 0693-AB63

On behalf of the Association of American Universities (AAU), the Association of Public Land-grant Universities (APLU), the Association of University Technology Managers (AUTM), the Association of American Medical Colleges (AAMC) and the Council on Governmental Relations (COGR), we write to comment on the Rights to Federally Funded Inventions and Licensing of Government Owned Inventions 81 FR 78090: RIN 0693-AB63.

AAU is an association of sixty U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. APLU is a research, policy, and advocacy organization with a membership of 238 public research universities, land-grant institutions, state university systems, and affiliated organizations. APLU's agenda is built on the three pillars of increasing degree completion and academic success, advancing scientific research, and expanding engagement. AUTM is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnering and advocacy. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions and teaching hospitals around the world, as well as numerous businesses and government organizations. The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 147 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems and more than 80 academic societies. Through the AAMC's member institutions and organizations, the AAMC represents nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and post-doctoral trainees. COGR is an association of over 190 research-intensive universities in the United States. COGR works with federal agencies and research sponsors to develop a common understanding of the impact that policies, regulations and practices may have on the research conducted by the membership.

We were pleased to participate in the November 21 NIST public meeting and webinar on the proposed changes to the regulations in 37 CFR 401 and 404, which implement the University and Small Business Patent Procedures Act of 1980 (P.L. 96-517; 35 USC 200 *et. seq.*), commonly known as the Bayh-Dole Act. Our comments below reflect the statement submitted on behalf of our associations at the webinar and provide further details on a number of concerns that we have identified with the proposed changes.

The Bayh-Dole Act of 1980 has been a tremendous success and is widely credited for the growth of university technology transfer, thus enabling results of federally funded research to reach the marketplace with products to help all Americans. The latest Association of University Technology Managers (AUTM) survey data show that in 2015, U.S. universities and non-profit research institutions executed 7,942 license and option agreements with industry, created 1,012 startup companies based on academic intellectual property, filed 15,953 new patent applications and were awarded 6,680 patents.

In addition, 879 new products were introduced and net product sales by licensees exceeded \$28 billion. Significant investment of resources is required to achieve such successes with over \$380 million dollars in legal fees expended in 2015 alone. This activity and investment helped ensure that the benefits of academic discoveries are available to the public and demonstrate that academic innovation has real-world value.

Long term and multi-year results are no less impressive: AUTM data show that universities have created 11,000 startups since 1991, with more than 5,000 still active today. This past March, the Biotechnology Innovation Organization (BIO) reported that from 1996 to 2013 the economic impact of university and non-profit patent licensing was enormous: \$518 billion in U.S. gross domestic product, \$1.1 trillion in U.S. gross industrial output and up to 3.8 million jobs supported through such licensing. In terms of direct effects on public health, a recent publication cited at least 153 new drugs and vaccines that have been introduced to the market as a result of university-industry partnerships facilitated by the Bayh-Dole Act. We understand that number has grown significantly as the authors continue to update their study.

These and other data show conclusively that Bayh-Dole has had a deep and far reaching positive effect, both in the U.S. and globally. Numerous examples of innovations from university laboratories have had a tremendous, recognizable impact on our daily lives, including cochlear implants, synthetic Taxol, radio tomography imaging, and cystic fibrosis diagnostic gene.

Any changes to the law and implementing regulations should be carefully considered to avoid undermining or adding unnecessary administrative burdens to this thriving and successful academic tech transfer system. We are therefore gratified that NIST has sought to enhance the effectiveness and efficiency of the technology transfer infrastructure while protecting Bayh-Dole's basic framework. Many of the proposed changes are primarily directed to the federal agencies themselves and businesses. Several of these changes will be helpful, such as the clarification that written assignments of invention rights are required from contractor employees. This change addresses some uncertainties for Bayh-Dole implementation resulting from recent court decisions.

Comments on NPRM

We have a number of concerns with the proposed changes. They are listed below. In particular, **the proposal in section 401.14(f)(3) to require 120 days' notice if a contractor decides not to continue to prosecute applications or to abandon patents has caused significant concern in our community**, as reflected in the comments at the November 21 webinar. More details on this and other concerns follow:

1. Requiring 120 days' notice prior to filing deadlines, versus the current 30 days, if a contractor decides not to continue to prosecute applications or to abandon patents is potentially detrimental in numerous ways. While it is understandable that agencies may need more than 30 days to determine their response, our members are concerned that 120 days seems excessive. Section 401.14(f) also is silent as to whether the proposed 120 days' notice is the period of time before a statutory deadline or 120 days' notice from the period of reply set by the patent office that is extendable to the statutory deadline. Most time periods set by the USPTO are between 60-90 days and a time period longer than these periods would require contractors to incur the cost to respond and then notify the agency after the response is filed. Additionally, section 401.14(f)(3) requires action to be taken prior to deciding not to defend a patent in reexamination or opposition proceeding but most due dates within the *inter partes* review proceeding require responses in 90 days or less.

Besides these technical issues, often decisions to proceed with patents cannot be made until close to the deadlines in order to fully assess market demand. Further, the decision to establish a start-up company around a new university technology requires extensive research, capitalization and IP valuation. Increasing the notice period for abandoning patents will significantly limit the prosecution options available to forming companies, possibly precluding downstream successes. The existing 30-day period is most supportive of start-up companies. The proposed change severely limits the amount of time to make prosecution decisions and ultimately reduces licensing (or potential licensee) evaluations. In many cases it will require contractors to expend additional

resources on responding to deadlines for patents and patent applications that may no longer have commercial value in light of the decisions from the USPTO.

There is no evidence that providing more time to agencies would increase the number of patent applications they file, but it is likely to decrease the number of patents filed or maintained by contractors. If this period must be expanded, then a 45-day period would be more reasonable, but in any event the period should not exceed 60 days. Additionally, language clarifying whether it is the statutory deadline or the extendable deadline from which the days would track is needed in this section.

2. The proposed rule also now would allow agencies to shorten the current two-year period in 401.14(c)(2) for contractors to elect to retain title when the agency “determines that a shorter period is necessary to protect the government’s interest.” No criteria are provided for such determinations, or any minimum time specified, or is there any requirement for when the contractor would be notified. As worded, it appears agencies could arbitrarily lower the period beyond a reasonable time for contractors to properly evaluate the technology. The Bayh-Dole Act appears to allow shortening of this period only when the statutory one-year period would end before the end of the two-year period (35 USC 202(c)(2)). In any event we believe there should be a lower bound and that it should occur only when agencies have reason to believe that the contractor will not obtain necessary protection in a timely manner, with proper advance notice to the contractor. Further, as other non-profits and commercial partners look to the Bayh-Dole regulations as a guide to the processes followed by universities, the changes proposed in (f)(3) and (c)(2) could indirectly result in a reduction of time for universities to engage in commercial assessment of an innovation as these other funding partners seek to similarly restrict the periods of action by the university.
3. A related provision (401.14(d)(1)) would remove the current 60-day period for agencies to request contractors to convey title when they fail to either disclose or elect title to inventions. With no time period required for agency action, the result might be to cast an indefinite cloud over the invention title. For example, if the contractor fails to disclose in the two month window under § 401.14(a)(c)(1) due to lack of information from the inventor on funding leading to the invention, but the contractor later learns about funding and then takes appropriate steps to inform the government to fulfill reporting requirements, the fact that the government can take title at any time over the course of the patent life is troubling. This change presumably means the government could step in at any time, even long after a license has been executed, and take title. This will not advance university—industry relationships or commercialization. We appreciate the intent to improve due diligence, but we believe the current time period should be retained, especially given the stated intent of enhancing the ability of agencies to work with contractors.
4. The proposed rule would define “initial patent application” to include the first provisional application or an international application designating the U.S. This change would require contractors to consider whether to proceed with a provisional filing in instances where there is insufficient time for the contractor to determine if there could be a potential disclosure of the invention, especially with the proposed changes in 401.14. Currently, contractors can file a precautionary provisional application and then later make a determination if the priority date of the precautionary provisional application is required and, if not, thereby allow a subsequent provisional filing at a later date for the contractor to utilize for purposes of priority. Specifically, if there are no public disclosures of the invention, a contractor is able to fully assess the invention during the provisional patent period without electing title and thereby subjecting the contractor to the waiver periods under Section 401.14(f)(3). While the existing regulations recognize provisional applications, their importance has increased since passage of the American Invents Act (AIA). We believe the contractor should have the ability to designate the provisional application as the initial patent application. See additional discussion in the response to question #2 below of some of the issues associated with provisional applications.
5. Section 401.10(a) in the proposed rule would allow employing agencies to file initial patent applications on subject inventions with federal and contractor co-inventors, provided that the contractor retains the ability to elect rights. The related change in the patent rights clause (401.14(c)(4)) provides that agencies may do so when in the

interests of the government. Our members view this as a positive change, since currently some agencies refuse to file an initial patent application on a joint invention unless the institution waives title. However, it leads to a number of concerns:

- a. There may be agreements between agencies and contractors on invention management in co-inventor situations. A provision should be added to clarify that this is not intended to preempt such agreements.
 - b. 401.10(a) is directed to the employing agency, but 401.14(c) is addressed to funding agencies. This seems to allow either to file, which could result in confusion and uncertainty. Clarification is needed.
 - c. 401.14(c)(4) provides for consultation with the contractor, but provides no guidance on the scope of the consultation. For example, the scope of the application might be directed to narrower claims than the contractor would want. Additional guidance would be helpful, such as requiring that a filing by the government agency ensure that a plan for commercialization of the technology is agreed to by the contractor. A reference to the required consultation also should be included in 401.10(a)(2)).
 - d. When the contractor elects to retain rights, 401.14(c)(3) requires it to file a patent application. It is not clear how this can be reconciled with the proposed (c)(4). It also could result in double patenting or internal interference issues.
6. The proposed changes to 401.10(a) also raise other concerns with co-inventor situations. 401(a)(3)(ii) addresses situations where contractors waive rights. Subsections (ii), (iii), and (v) refer to the situation where the contractor has waived rights, but subsections (iv) and (vi) do not. Are these subsections meant to be sequential? If so as we assume, this should be clarified by adding in (iv) "in which the contractor has waived rights" following "... government interest in patenting the subject invention..." Similarly, "...when a contractor has waived rights." should be added at the end of the first sentence in (vi).
 7. The scope of the change in 401.3(a)(5) is unclear. The effect appears to be to remove the existing appeals language in the second sentence of 401.3(a)(5). The appeal procedures should still be made available to contractors when alternative provisions are used; we recommend restoring this sentence. Additionally, it would make sense to add "(5)" in the list in 401.3(b) line 1 requiring limited modifications to address the exception or concern. This is important because in the experience of our members federal agencies do not always tailor the provisions to address the exceptional circumstances.
 8. Section 401.3(a)(6) allows alternative provisions in a service contract when the contractor is not a nonprofit organization. There could lead to a situation where the contractor needs to collaborate with a university or other nonprofit and the contractor flows down the alternate provisions. This creates a potential conflict with 401.14(g). The university or nonprofit should get standard Bayh-Dole rights in that circumstance provided there are license rights for the contractor to meet the government obligations. Language such as the following could be added at the end "...provided that if a subawardee is otherwise eligible for standard patent rights for the scope of work of the subaward, then it should receive the appropriate standard clause under Section 401.14(b)."
 9. The proposed changes to 401.7(b) and 401.14(k) would involve funding agencies in concerns about contractor compliance with the small business preference provisions in the regulations (401.7). We are not sure what expertise funding agencies bring to these situations. It would add an additional layer of review and could lead to inconsistent outcomes. In our view the interests of uniform interpretation and administration of these provisions would be better served by leaving the responsibilities with NIST, as in the current regulation.
 10. We note that the new provisions in 401.5 that allow agencies to request enhanced invention reporting will add burden and transactional costs, particularly the requirement for annual listings. Given existing issues with current government invention reporting requirements that are discussed below, we urge that the government carefully

consider whether the benefits of adding reporting requirements justify the added burden on contractors that will result.

As discussed in the meeting/webinar, it is important when finalizing these changes that they not be made retroactive. This is especially important when time limits are involved or changes in rights to existing inventions. We urge NIST to clarify in the final rule that the changes are prospective only, and apply to new awards made after the effective date. It is unfair to have the rules change in the middle of projects. Contractors may have entered into agreements with other entities in association with a Federal award that might include specific language re e.g. timing of reporting, notices, etc. that might not be compatible with the proposed rule changes.

Responses to Questions

In the NPRM NIST asks for comments on five questions. A summary of the questions and our comments follow:

1. Changes in regulations to accelerate the transfer of federally funded research.
 - a. U.S. research institutions increasingly are participating in consortia and other collaborations with foreign institutions. Allocation of rights to inventions in such cases often can be complicated, particularly when Federal funding is involved. NIST could facilitate such arrangements by adding to 401.3(a)(1) a provision that foreign contractors engaged in research collaborations with Federally-funded U.S. research performers may receive standard Bayh-Dole rights.
 - b. With increased globalization, it has become more difficult for institutions to find licensees able to comply with the U.S. manufacturing requirement in 414(i). The difficulty is compounded by slow or in some cases lack of responses by agencies to waiver requests. While we understand the requirement is statutory, we suggest that a provision be added requiring a 60-day response period, with the presumption that the request is approved if there is no response from the agency within 60 days.
2. Inconsistencies between the Section 401 regulations and the AIA.

The restrictive interpretation of the 35 USC 102(b) AIA exception by USPTO has led to a significant increase in provisional patent application filings by many research institutions. NIST should consider clarifying the government's rights in abandoned provisionals in the case of successive provisional filings. For example, at 401.14(d)(3), the Government may obtain title to any subject invention "In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention." In the case of a provisional application intentionally abandoned in favor of a subsequent provisional application filed by a contractor, it could be argued that the contractor is strategically and diligently pursuing rights in a Subject Invention and should not lose rights thereto. The suggestion above to have the contractor designate whether a provisional is the initial patent application would help address this problem.

3. Better information sharing on Federally funded inventions to increase licensing.

Various portals currently exist that list technologies available for licensing from research institutions and identify possible collaborative opportunities. A widely used example is the AUTM Global Technology Portal (<http://autmvisitors.net/find-technologies>). There also are agency invention portals (e.g. <http://techportal.eere.energy.gov/>). It is not clear that an additional Federal-wide portal would add significant value. While our members have found portals useful, they tend to rely more on establishing relationships for licensing purposes. Partnering and venture forums also have been useful.

4. Incentivizing reporting compliance, particularly with regard to the government support clause.
 - a. NIST might consider establishing a training program for Federal funding recipients, which could be tailored not only for tech transfer offices but also include grant principal investigators. AUTM recently

hosted a highly successful compliance course on invention reporting, which included participation from a number of Federal agencies. One possibility would be for NIST to partner with AUTM to organize a series of such courses, in various locations.

- b. NIST might also consider establishing a training program for federal agencies so that all agencies are aware of not only the contractor responsibilities proscribed in Bayh-Dole, but of the role and obligations of the agencies. This type of training program would provide an ideal setting for agencies to collaborate on establishing standard reviewing criteria as well as comprehensive request forms and processes for grantees to use when requesting the various types of waivers allowed under Bayh-Dole which are currently prohibitively delayed by agencies without procedures and processes in place for their management.
- c. Our members have experienced rejections of invention reports from agencies due to trivial variations in the prescribed government support clause language. This adds burden and delay to the reporting process. Rather than prescribing precise language, amend 401.14(f)(4) to provide only that the statement must identify the contract and that the government has rights.

5. Issues in the reporting process and ways to reduce barriers.

It is difficult for grantees and contractors to fully appreciate the value and time sensitive nature of complying with reporting requirements when not all agencies commit the required staffing and time to facilitate proper grantor compliance. Agencies like the NIH and NSF actually review invention disclosures and respond to questions and requests from the contractor while other agencies cannot even provide current contact information.

Contractors are expected to provide federal agencies with sufficient time prior to a statutory bar date to pursue an abandoned subject invention, but the same courtesy is often not provided to the inventors of said subject invention who are attempting to take title to a waived subject invention and who have a better understanding of the technology and market for the technology. The waiver request period drags on and forces inventors interested in commercializing their technology to either give up on the technology or file on the invention without a guarantee that they will actually have rights in their invention.

We are very appreciative of the recent improvements that NIH has made in the iEdison reporting system, but many issues remain with that system. Our members find the system cumbersome and outdated and long overdue for a systemic upgrade.

One of the biggest challenges is that various iEdison reporting seems to be gated. If one reporting requirement is incomplete or marked with an error it prevents further reporting or action. In particular it can make it impossible to waive title to a disclosed invention. The system should allow all reporting even if the requirement remains open. In addition, the system often seems to require greater specificity than is strictly called for in the law, further adding to the administrative burden of accurate and timely reporting. The level of detail and format required by the electronic system can add to the challenge. For example the system requires reporting on an invention by invention basis. However it is not uncommon to license multiple inventions together in a single license which creates difficulties with utilization reporting. One frequent complaint from our members is the continuing requirements for reporting or corrections on abandoned or expired patents, which have become very burdensome.

There also is the fact that iEdison is not universally used by federal agencies, requiring our members to deal with widely different reporting requirements of various agencies. A good example is the NASA New Technology Reporting System (<https://invention.nasa.gov/>). Some of our members have experienced significant compliance issues with that system due to misunderstandings as to what technology must be reported. DOE has three different reporting portals which are not necessarily consistent with one another. Even where an agency participates in iEdison it still may require a specific agency invention report. An example is ARO (DD Form 882) and other defense agencies.

Many of the issues discussed above with iEdison result from the fact that it is a legacy system which until recently has lacked the necessary resources and staffing. The recent National Academy of Sciences Report on Reducing Research Regulations identified similar problems. A single, coherent streamlined government-wide reporting process would greatly improve compliance. The process should be overseen by an entity that has adequate resources and sufficient authority. Agencies that seek to impose additional or different requirements should be required to specifically justify the added requirements to that entity, subject to public comments.

Again we appreciate the collaborative spirit in which NIST has approached these changes, and the opportunity to comment. Please contact Robert Hardy, Director of Contracts and Intellectual Property (COGR) at rhardy@cogr.edu or (202) 289-6655 x 114 if you have any questions. We would be happy to further discuss our comments.