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Submitted via NSF website.

AUTM's Comments on the U.S. National Science Foundation (NSF) request for comments to inform the proposed implementation of new intellectual property (IP) provision options for use in NSF public-private partnerships, particularly those advancing research and development, that include co-funding of awards by private partners.

(1) Overall Impact

How do you believe these proposed IP options will impact innovation, technology transfer, and economic growth?

First, AUTM thanks NSF for its efforts to support the development and commercialization of NSF-funded inventions. AUTM supports IP options that incentivize industry partners to either (i) develop and commercialize federally funded university technologies or (ii) relinquish rights to allow the university to work with other partners to develop the technology.

AUTM recognizes the importance of research partnerships with industry and industry's need for assured access to rights in commercially valuable results generated by such research. While the proposed IP options provide that assurance to industry partners (in the form of guaranteed exclusive options and research licenses), the IP options, as written, would reduce the Project IP owner's flexibility in making licensing decisions, one of the primary mechanisms that the Bayh-Dole Act successfully enacted to drive innovation, launch technology transfer, and maximize economic growth.

Commercial licensing terms for federally funded inventions should consider (i) the nature and stage of the development of the technology; (ii) the breadth and complexity of the potential fields of use; (iii) the product development path and timeline; (iv) the extent of intellectual property protections; (v) the relevant markets; (vi) unique needs of prospective licensees; (vii) ethical considerations for the use of future products; and (viii) emerging issues. There is no "one size fits all" licensing option that would enable universities to meet the Bayh-Dole Act requirements "to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor...."

To better align the IP options with the goals of, and accomplishments under, the Bayh-Dole Act, AUTM respectfully submits the following recommendations.

1. AUTM appreciates that the IP options do not mandate an automatic commercial non-exclusive, royalty-free license (NERF) to all partners, because such an automatic NERF often hinders—rather than incentivizes—development and commercialization of federally funded innovations. See BALANCE.
2. The IP options should restrict research use rights to a defined length of time to protect the licensee’s exclusive commercial interests. See BALANCE.
3. Direct partnership agreements between NSF and industry partners should stipulate that federally funded inventions must be managed in the best interest of the public. In some instances, the public is best served through a licensing strategy that includes non-exclusive licensing, field-of-use restrictions, and/or commercial diligence milestones. See FLEXIBILITY, and TRANSLATION AND INCENTIVES.
4. The option exercise and negotiation periods should be shortened to align with deadlines applicable to Project IP established by the USPTO and federal rules (as implemented in iEdison). See BARRIERS.
5. NSF should consider including pathways for more than one partner to exercise the right to negotiate for commercial rights. See ADDITIONAL OPTIONS.
6. NSF should exclude works of authorship from mandatory exclusive commercial licensing. See ADDITIONAL COMMENTS.

(2) Balance

**Do these options ensure a balanced distribution of IP rights between academia and industry partners?
How can the proposed IP options be further refined to ensure maximum balance in IP arrangements?**

1. First, the goal of balanced distribution of IP rights between academic and industry partners should be a secondary consideration. The highest priority should be ensuring that federally funded inventions are managed in the public’s best interest.
2. If no partner elects to secure a commercial license under Option A or B, the university could seek potential licensees beyond the research partners. The perpetual research use rights granted to all partners upon expiration of the Option/Negotiation Period in Options A and B—and in the Research-Only License of Option C—may disincentivize other companies from licensing the Project IP.
3. If a partner executes an exclusive, commercial license to Project IP, the perpetual research use rights that are automatically granted to other partners may interfere with the exclusive licensee’s commercial interests.
4. To address items 2 and 3 above, options that require or incentivize holders of a Research-Only License to release rights would be helpful. For example, any nonexclusive, research-only license could be limited to twelve (12) months.
5. To ensure integrity and clear identification/tracking of license rights, any grant of commercial rights (even if time-limited) should be documented in a bilateral agreement including legal protections for the university (e.g., indemnification, insurance, limitation of liability, restricted use of university name, etc.).

(3) Flexibility

What additional flexibility should be incorporated into the IP options to accommodate and incentivize a range of research initiatives?

Direct partnership agreements between NSF and industry partners should stipulate that federally funded inventions must be managed in the best interest of the public. This goal is best accomplished through exclusive commercial licensing when Project IP requires significant investment to reach the market (such as regulatory mandates or infrastructure requirements) or is so nascent that exclusivity is necessary to induce the investment needed to develop, test, and commercialize the invention. Conversely, non-exclusive licensing (or exclusive licensing within defined fields of use) is appropriate when an invention is broad in scope and can be used in multiple industries as well as for a platform technology that could form the basis of new industries.

An exclusive “field-of-use” license is a way to create market incentives for one company while enabling the Project IP owner to identify additional licensees to commercialize the invention in additional markets. AUTM appreciates that the IP options as written do not prevent the Project IP owner from defining field-of-use restrictions and establishing appropriate commercial diligence milestones based on the capabilities and industry breadth of the sponsoring partner. However, for technologies that would best benefit the public through non-exclusive licensing, universities may consider forgoing the patent process (by not electing title) and instead put the invention in the public domain by way of appropriate publications. Because the complexity of IP licensing makes “cookie-cutter” solutions unlikely to be successful, NSF should build in flexibility for universities to make thoughtful, invention-by-invention licensing strategies, including non-exclusive licensing when appropriate.

In this regard, AUTM appreciates the RFC’s statement that “[t]hese IP options can be tailored according to the particular research area and the specific terms and conditions agreed upon between NSF and the partner(s) in a particular public-private partnership.” Consistent with that statement, the articulated IP options should be viewed as facilitating (and perhaps simplifying) negotiations, but they cannot replace negotiations. Flexibility is critical, such that universities can employ fact-specific strategies to maximize the likelihood that the particular technology at issue can and will be developed.

The AUTM publication, “[In the Public Interest: Nine Points to Consider in Licensing University Technology](https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university-technology)” (the “Nine Points Document” available at <https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university-technology>) has been adopted by over one hundred academic institutions and associations around the world and articulates the time-tested reasons why flexibility is so crucial in university licensing. For example:

- “Universities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology.”
- “Universities are encouraged to use approaches that balance a licensee’s legitimate commercial needs against the university’s goal (based on its educational and charitable mission and the public interest) of ensuring broad practical application of the fruits of its research programs.”
- “In situations where an exclusive license is warranted, it is important that licensees commit to diligently develop the technology to protect against a licensee that is unable or unwilling to move an innovation forward.”

Should a partner determine that it will not exercise its first right to negotiate (Option A or B), such partner can provide written notice of non-election to the Project IP owner. Upon receipt of such notice from all partners, the Project IP owner should be immediately free to broadly market the technology to non-partner companies, even if the partner option and negotiation periods have not yet expired.

(4) Adoption

What strategies could NSF employ to encourage widespread adoption of these IP grant-of-rights options among potential partners?

NSF could work with other federal agencies to promote uniform IP guidance to improve the likelihood that all federally supported inventions can be developed for the public benefit. Inconsistent expectations across federal agencies make university technology transfer more cumbersome and less successful. Moreover, we appreciate NSF’s efforts to engage stakeholders to discuss impediments to technology transfer, and we will be happy to continue such discussions. NSF’s willingness to continue such discussions and revise its guidance when needed will make the guidance more credible and more likely to be implemented by stakeholders.

(5) Barriers

What potential barriers exist to implementing these IP grant-of-rights options, and how might they be overcome?

AUTM supports IP options that incentivize industry partners to either (i) develop and commercialize federally funded university technologies or (ii) relinquish rights to give the university an opportunity to work with other partners to develop the technology. Finding a commercial partner quickly is essential to maintaining patent rights, as it is cost-prohibitive for universities to maintain large portfolios of patent rights absent reimbursement from a commercialization partner.

Bayh-Dole regulations require that, if a contractor elects title to a federally funded invention, the contractor must file an initial patent application within one year after election or earlier if a statutory period has been triggered by public disclosure. (See 37 CFR 401.14(C)(3)(i).) Universities often file less-expensive provisional applications to preserve patent rights while they broadly market the technology. Bayh-Dole regulations further require contractors to file a non-provisional application within ten months of the filing of the provisional application. (See 37 CFR 401.14(C)(3)(i).) Absent a licensee capable of reimbursing past and future patent costs, a university may decide against filing a non-provisional application at its own fiscal risk and instead release title back to the government sponsor.

The option exercise and negotiation periods within IP Options A and B (twelve month “right of first negotiation” or “ROFN” period followed by a six-month negotiation period) fail to consider the time-constraints of Bayh-Dole regulations. The RFC suggests that universities would carry the burden of patent costs through the filing of a non-provisional patent application and beyond with no assurance of reimbursement. AUTM recommends that the ROFN period be limited to six months and the negotiation period be limited to three months. This would enable an end date of the Project IP owner’s obligation to the sponsor (whether an exclusive license is completed or not) that will allow for the Project IP owner to make timely filing decisions in line with iEdison reporting requirements.

(6) Translation and Incentives

Do the proposed IP options effectively promote the translation of research into practice while incentivizing industry participation and ensuring benefits for universities and researchers? What improvements could be made to enhance these aspects?

1. AUTM questions the value of the 18-month commercial license to all partners established by Option B. The period is too short to be meaningful for partners wishing to commercialize a product. Further, if no partner executes an exclusive license to the Project IP within the 18-month period, the limited commercial license will likely have already hindered the Project IP owner’s chances of securing another licensee to commercialize a product thereafter.
2. For some inventions, non-exclusive licenses can better promote the translation of research into practice, maximizing public access to the invention. As one example, if a technology will create the

greatest public benefit if it becomes an industry standard, the Project IP owner should consider making it readily accessible to all interested parties through non-exclusive licenses. A second example is where an invention is useful primarily as a research tool. AUTM thus recommends that Project IP owners be entrusted to employ a licensing strategy that best enables translation of the research into a product for the public marketplace.

(7) Additional Options

Are there other IP grant-of-rights options or frameworks that NSF should consider to better support collaborative research initiatives and facilitate research impact?

AUTM recommends a modification that contemplates multiple partners exercising their rights to negotiate a license. In such a case, the Project IP owner could use reasonable efforts to grant nonexclusive (or co-exclusive) commercial licenses to all interested partners under similar terms and conditions.

Universities often work in collaborative environments. IP that a university brings into a research arrangement with an industry partner may include contributions from other universities and other third-party partners. In those situations, the university is limited in terms of what rights it can grant to an industry partner.

(8) Additional Comments

Is there anything else you would like to add?

The Bayh-Dole Act focuses on the Project IP owner's use of the patent system for "Subject Inventions" (see 37 CFR 401.2) conceived or reduced to practice in the performance of a federally funded award. NSF's IP options govern a broader definition of "Project IP" that includes "works of authorship." AUTM recommends that the IP options cover and use "Subject Inventions" consistently with the Bayh-Dole Act. In addition to research, universities focus on teaching, public service, freedom of expression, and an open exchange of ideas. The term "works of authorship" is broad enough to encompass works that are not typically owned or licensed by universities. Therefore, AUTM recommends that "works of authorship" be excluded from any mandatory exclusive grant-of-rights options.