**University of California, San Diego response to the Request for Information Regarding Federal Technology Transfer Authorities and Processes, as notified by NIST (83 FR 19052)**

**Submitted to the**

**National Institute for Standards and Technology**

**By: Paul Roben**

**Associate Vice Chancellor, Innovation & Commercialization**

**pwroben@ucsd.edu**

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**Summary**

The nation needs more efficient processes to commercialize the $150 billion of Federally-funded research annually. The technology transfer framework, catalyzed by Federal laws such as Bayh-Dole has served the nation well for 40 years. But the world has changed, and now we need a new model. UC San Diego would like to thank NIST for its leadership in developing this RFI and would like to submit our response with our thoughts on how to develop this new model. There are certainly systemic issues which, if addressed, could bring new efficiencies to the technology transfer system, as we have discussed below. In addition, we feel that, to truly unleash the economic power of the national research enterprise, we, as a nation, must also address culture development and talent and technology acceleration. We submit that working in partnership, we can meet these challenges, and maximize the global competitiveness of the U.S. economy, well into the future.

**Background**

As noted in the RFI, the Federal government invests approximately $150 billion annually in R&D, the results of which need to be efficiently and appropriately commercialized in order to maintain a strong national security innovation base and global competitiveness. University leaders are increasingly responding to this need by including innovation, entrepreneurship, and “economic engagement” programming in their strategic planning processes. As part of this response, university technology transfer offices are evolving, moving beyond a revenue-driven, transactional approach and integrating the efforts of technology management offices into the broader engagement activities of institutions. In evolving toward broader participation in economic engagement, universities are developing deeper relationships with industry and other community partners; broadening their economic engagement efforts to areas such as education, technology development, and entrepreneurship; and aligning more closely a variety of administrative functions such as technology transfer, industry contracting, alumni engagement, and career development.

Again, as noted in the RFI, Federal technology transfer laws have served the nation well for nearly four decades. However, the world has become a very different place in that time. Technologies such as the internet, social media, and now blockchain continue to alter the fabric of our society, and our economy operates on different business models to what it did 30 years ago. The Federal Government, in partnership with the national research enterprise must acknowledge these changes and develop culture, systems and programs to ensure the U.S. stays competitive, if not a leader, in this changing landscape.

Technology Transfer is a key element in meeting these challenges. Our response to this RFI is focused on 3 areas: Systemic concerns; culture modification; talent and technology acceleration.

Maintaining our competitiveness will require us not just to fix those “systemic issues”, but to bring about a culture change that will firmly establish commercialization activity as a core mission of the R&D enterprise, whether that be in Federal labs, universities or other entities. In parallel, we need to take a fresh look at those programs that facilitate talent and technology development, thereby accelerating commercialization activity.

*What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?*

The fundamental core of Bayh-Dole, empowering institutions to take ownership of federally-funded intellectual property (IP) and mandating disclosure of such IP to those institutions, is a good principle, and should be retained. This permits the effective management of the IP, and the development of processes to provide industry and others with access to that IP.

However, there are a number of other principles in this legislation and other Federal practices that should be considered for modification, as discussed in the next section. Since the process of commercializing inventions developed at universities is often influenced by the local economic realities and local understanding of the relationships between inventors and potential partners interested in commercial aspects, it is best to empower those local institutions with the tools to carry out the commercialization efforts.

*What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider those identified in the RFI as well as others that may have inhibited collaborations with Federal laboratories, access to other federally funded R&D, or commercialization of technologies resulting from Federal R&D.*

There are a number of systemic challenges that have a negative impact on commercializing Federally-funded IP. Those that have been experienced at UC San Diego include:

* iEdison reporting of inventions: The current system is confusing and difficult to use, even for an experienced individual. One of the most common challenges are error messages indicating that the invention description is not “detailed enough”, when in fact most initial invention disclosures to an academic center will not be detailed. Another example is the limitation of 2 years to elect title on an invention, since in many occasions, it takes more than two years to determine the commercial potential of an invention.
* March-in Rights: In a number of instances, this has discouraged companies from licensing technologies. Companies are unclear on the process and the basis on which the Federal government makes decisions on march-in rights. They also are unwilling to commit significant resources to the development of technologies, if, at a future date, the government will exercise its march-in rights.
* Inability to assign IP to companies: In a variety of cases companies have informed us that they simply will not deal with US universities due to their reluctance to assign IP to them, even when it is, in part, funded by that company. Their preference is often to work with European universities that do permit assignment of IP.
* Conflict of Interest Rules: COI can vary from institution to institution. However, in general, the COI rules for Federal labs are vastly more restrictive than those in other research entities. This can impede the formation of startup companies that involve investigators from Federal labs, and can have a negative impact on partnerships with other institutions. In certain instances (but not all), startups are the appropriate vehicle to commercialize a technology. More and more we are seeing business models (particularly in life sciences) where the first commercialization step involves formation of a company, which is then acquired, or funded by a bigger player in the market. Preventing an investigator from participating in that startup, and benefiting from any upside, removes any incentive for him or her to pursue that course. As a result, we are losing technologies that otherwise could lead to the development of products and services.
* Tax issues: For-profit activity on a university campus in bond-funded buildings, often referred to as “private activity”, is limited to a certain percentage of overall campus activity. Private activity can include everything from the gift store, food sales, services and industry research collaborations. By including all of these activities in one bucket, and then limiting the overall permissible levels, this can often impede the ability of campuses to bring industry research collaborations on campus, thus impeding the commercialization of technologies.

*What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider the approaches identified in the RFI.*

iEdison reporting of inventions: We suggest that the Federal government invests significant resources to modernize and improve the process used to report the status of technology and inventions via its iEdison interface to be improved for clarity and congruency with commercialization, patent prosecution and invention disclosure practices.

March-in Rights: The lack of clarity around both the march-in process, and the implications of that process, can hamper commercialization efforts.

1. Not all technologies should be subject to march-in rights. Identify those technologies that are subject to potential march-in processes and be clear that technologies not on an identified list are not subject to march-in rights. we recommend using the already-existing export control lists of technologies. Those inventions that are not on those lists, would not be subject to future march-in obligations.
2. Time limit: Put time and investment limits on march-in rights. Just as universities have a time period to elect title of patents, we suggest that the Federal government have 2 years from the execution of a license to exercise their march-in rights. Should they not elect to exercise their march-in rights in that time period, then those rights expire for the technologies that are the subject of that license.
3. Investment limits: We also suggest putting a technology-appropriate investment limit on the ability of the government to exercise these rights. If a company invests significant resources, above these limits, in a particular technology, we don’t believe that it is fair and equitable that the government could march in on that technology, following that investment. At a minimum, we recommend that if a company has invested above the limits, that the march-in rights not be automatic, but be subject to negotiation of the terms of those rights with the company.

Inability to assign IP to companies: We recommend that universities be permitted, in cases where they believe that it is in the best interests of commercializing a technology, to assign Federally-funded IP to U.S. companies only. This would give U.S. companies a competitive advantage, over foreign companies, to engage with the American research enterprise.

Conflict of Interest Rules: Relax the rules for Federal employees, thus allowing them to participate in startup companies, and work with existing companies. This should include the ability to act as an advisor or consultant to the company, own equity in a startup, and take sabbaticals to work on their commercial interests without fear of losing seniority at the Federal Lab.

Tax Issues: Exempt research-based collaboration activity with for-profit entities, from the private activity rules. This would include industry-sponsored research collaborations, location of company research resources on university campuses, and startup companies spinning off campus. The criteria around this would need to be clear, and this activity would have to contribute directly to the economic impact generated by the university, but we believe this is very achievable. Relaxing these rules would increase our ability to engage meaningfully with the private sector and accelerate the translation of technologies to commercial products and services.

*What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy? What changes would these proposed improvements require to Federal technology transfer practices, policies, regulations, and legislation?*

The systemic issues have been addressed above. We now wish to address culture development and talent/technology acceleration.

Culture development

Addressing the systemic issues will certainly increase the level of economic impact from any given institution. At UC San Diego, we addressed some of these systemic issues to the extent that we could, and effectively doubled the level of economic impact as measured by licenses, startup formation, and company funding of research. However, addressing systemic issues only gets you so far. To truly reach the full potential of the system, together we must address the issue of culture. The national research enterprise, at all levels, from senior leadership to students, must be incentivized to support commercialization as a core mission of their institution. The first step is to define the metrics of impact and, then, to develop incentives that encourage activities aimed at growing those metrics.

1. **Metrics of Impact**: Success in technology transfer should not be measured by revenue, but by contributions to social and economic prosperity. We need to shift away from licensing revenue as a driving metric, to a broader set of measures that takes into account the full breadth of contributions to economic development and other societal benefits. The emphasis needs to move from transactional to relationship building; from revenue-generation to realizing the translational potential of the technology. The new metrics should include measures such as licenses, startups, jobs created, investment secured, industry collaborations, community engagement, workforce development, etc. Each university must be in a position to tailor their impact metrics to their particular ecosystem, within a framework. There are a number of existing platforms that could form the basis for this broader set of measures. These include the APLU Innovation and Economic Prosperity (IEP) university designation (<http://www.aplu.org/projects-and-initiatives/economic-development-and-community-engagement/innovation-and-economic-prosperity-universities-designation-and-awards-program/index.html)> and IRIS (<http://iris.isr.umich.edu)>. Both of these approaches provide frameworks that allow universities to emphasize those metrics most appropriate to their institution, while most effectively measuring economic impact in their regions and beyond. They both recognize that there is a wide diversity of institutions and very varied environments in which they exist.
2. **Institutional Incentives**: We recommend that the Federal government reward institutions that allocate and structure their resources in such a way as to maximize their economic impact, as measured by the metrics above. A recent APLU report (http://www.aplu.org/library/technology-transfer-evolution-driving-economic-prosperity/file) identified 5 areas in which they recommend that universities focus, in order to maximize economic impact. These areas include:

* Engaging the Local and Regional Ecosystem: Industry and Community engagement
* Redefining Expectations of Tech Transfer: Appropriate metrics and expectations.
* Adapting Innovation Management Structures: Aligning all resources across a campus to ensure impactful economic engagement. Includes other functions across the organization, such as alumni, careers, industry engagement, development, etc.
* Fostering and Entrepreneurial Culture: Experiential and supported (mentors, space, etc) education.
* Supporting University Startups: Infrastructure to support startups at all levels.

Other activities to be encouraged could include an expansion of the criteria on which faculty promotion and tenure is based, to include metrics of economic impact, such as patents that have been successfully licensed to a commercial partner, startups, etc.

**3-year** **Pilot Program Proposal.**

Develop an RFP to solicit strategic plans from universities, based on the criteria above, that will address the 5 areas of focus, identify the metrics most appropriate to them, and then set goals to increase those metrics with demonstrated economic impact, over time. Provide an incentive which initially would be a 25% a financial match of resources directly applied to the technology transfer enterprise. This would increase to a 50% match, as the institution met or exceeded the agreed goals.

1. **Commercialization Incentives in Research Grants**: It is crucial that Faculty regard commercialization activities as part of the core mission. To that end, we are recommending that every Federal granting agency consider an incentive system built into each and every one of their grants. This would provide funding, as a percentage of the total award, for activities related to commercial development. This could include activities such as market research/reports, travel to meet companies, preparation of marketing materials to present to companies, training in pitch presentations, or business development activities. Any researcher applying for such funds would be required to report on the activities described, and on the outcomes of such activities. Such outcomes could include patent applications, industry engagement and company formations. A further incentive could be provided as a percentage of the original grant, based on successful outcomes, to be used in the further development of related research.

Talent and Technology Acceleration

Research universities supply the nation with **talent and technologies**, that underpin the economy and contribute to social prosperity. However, maximizing that impact requires much more than ingenious discovery; it requires a diversity of innovators and entrepreneurs who can inspire confidence in a larger vision and, ultimately, recognize opportunities for bringing new solutions to societal challenges. In addition, it requires an ability to take ideas from research to a stage in technology development where investors/companies will invest in those technologies and bring them to the market.

We must, therefore, incubate both people and technologies to fully realize the power of the national research enterprise to drive global economic competitiveness.

**Talent Acceleration.** There are a number of successful programs nationally that incubate the leaders and entrepreneurs of the future. Notable among those is I-Corps, sponsored by the NSF (one of the first I-Corps programs was located at UC San Diego). All of these programs provide students with an experience-based opportunity to develop their own ideas, in a supported environment that provides programming and mentorship. Years of experience has taught us what the impact measures should be for these programs, and have also shown us that these measures need to be appropriate to the desired outcome and environment. For example, a program developed to support prototype commercialization is very different from a program for policy development, or one to encourage more diverse engagement from minority groups. This needs to be taken into account when designing the programs.

We also recommend that these programs become better aligned with the education and research missions of the universities. To this end, universities should be encouraged to align this activity with the educational mission through the awarding of academic credit for students who participate in these programs. Further, there could be greater alignment with the research activities through engagement of Faculty in a number of capacities- as mentors, as a source of new ideas, as a gateway to a vast network of people and resources that the students would benefit from, in developing their own ideas. We believe that this alignment of talent acceleration programs with the core missions of a university would facilitate scaling of these programs, and vastly accelerate their impact.

We recommend initiating a competitive program to fund the expansion and scale-up of I-Corps and other similar accelerator programs that operate within defined criteria and meet agreed impact measures. This could be operated on a competitive basis, contingent on achieving defined metrics (reflecting the institutional economic impact metrics discussed above), and giving the institution the flexibility to develop the program that best fits their particular circumstances. We also recommend that particular attention be paid to inclusion criteria, with additional credit being awarded to programs that achieve higher engagement from certain populations such as women, ethnic minorities, first time college attendees, and veterans.

**Technology Acceleration.** Much of the national research enterprise is engaged in “fundamental research”. This is critical for developing the future technology pipeline. However, it also means that, using current Federal funding sources, many (if not most) of this research results in technologies that are not at a point where a company or investor feels they are sufficiently de-risked to engage. We need a more efficient process to bridge the gap between research and development.

**3-year Pilot Program for Technology Acceleration**

We recommend that the Federal government implement a program that does for research what the SBIR/STTR did for small business. We envision a program where research institutes could apply for funding, in a competitive process, to fund initiatives that develop technologies, in a milestone-driven process, to a point where they can enter the next phase of commercialization. This could include licensing, industry collaboration, company formation or product development. Again, since the process of commercializing inventions is heavily influenced by local economic realities, it is best to empower those local institutions to develop initiatives that best suit the local environment, but meet agreed commercial objectives.

We recommend that such a program be funded in a similar way to the SBIR/STTR program as a small percentage allocation (for example: 0.5% in the pilot phase) of the R&D budgets from those agencies with annual budgets in excess of $100M. Reflecting that the I-Corps success is based on market engagement and expert mentorship, these technology acceleration programs should also demonstrate true industry engagement. Industry and investment experts should be given a central role in selecting, shaping and monitoring the technology development programs, in order to maximize commercial success. There are many examples of this approach across the country, but one such example at UC San Diego is AIM: Accelerating Innovations to Market (<http://innovation.ucsd.edu/aim/)>. Specific projects with commercial potential are solicited from Faculty, then prioritized by industry, and funded on a milestone-driven basis. The first year of operation funded 8 projects with only $250k, and resulted in 6 startup companies, 4 industry collaborations and 1 product manufacture. This is real, measureable impact.

References

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