AAU Association of American Universities
APLU Association of Public and Land-grant Universities
ACE American Council on Education
AAMC Association of American Medical Colleges
COGR Council on Governmental Relations

#### **MEMORANDUM**

May 10, 2010

FROM: Association of American Universities

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**TO:** James Kohlenberger

Chief of Staff

Office of Science and Technology Policy

Diana Farrell

Deputy Assistant to the President for Economic Policy

National Economic Council

**RE:** Commercialization of University Research

Dear Mr. Kohlenberger and Ms. Farrell:

On behalf of research universities, affiliated research institutions, medical colleges, and the higher education community represented by our five associations, we appreciate the opportunity to comment on the White House Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) March 26, 2010 Federal Register request for information (RFI) issued concerning the commercialization of university technology and proof of concept centers (POCCs).

# I. Introduction

Our associations believe strongly that university research and education benefit society at large. Therefore, supporting and enhancing technology commercialization is essential to universities' public mission and their societal responsibility. At the same time, increased commercialization must not come at the expense of our universities' primary education, research, and public service missions. It is, in fact, these missions that have

historically led to universities' most important contributions to economic development, job creation, and technology commercialization. In a similar fashion, it is important to recognize that the transfer of new knowledge from universities to the public domain and marketplace occur through a wide range of mechanisms, including publication and the movement of people both into and out of our institutions.

Through education, colleges and universities have prepared generations of students to become productive members of the workforce by equipping them with the skills and training relevant to the economy of the times. Through research, universities create valuable knowledge which, in turn, has served as the foundation for many major technological advances that have had significant economic impacts and led to vast improvements in our quality of life. Through community outreach and engagement, universities have served as socioeconomic anchors for entire regions and contributed in immeasurable ways to the development of socially and economically vibrant communities.

We appreciate the Obama Administration's deep commitment to and support for university research. As the Administration looks to improve commercialization by universities, we feel strongly these efforts should be closely coupled with broader attempts to improve and strengthen the health of the entire U.S. research university enterprise. There are a number of such efforts currently underway, including one to be undertaken by the National Academies to examine the overall health of U.S. research universities. Given the degree to which effective commercialization and knowledge transfer are based on our traditional missions of education, research, and service, ensuring our universities' abilities to effectively carry out these missions will perhaps be the most critical factor in ensuring effective commercialization by universities.

# The Importance of Maintaining the Bayh-Dole Act

By allowing universities to retain intellectual property from the federally funded research they perform, the Patent and Trademark Law Amendments Act of 1980, commonly referred to as the Bayh-Dole Act, provided an incentive that did not previously exist for universities to seek private sector partners to invest in the development and commercialization of research. As a result, since Bayh-Dole's enactment, universities have taken a much more active role in seeking out private sector partners to invest in the commercialization of promising technologies emerging from their research efforts.

Since the passage of the Bayh-Dole Act, the nation has witnessed a remarkable increase in patents and licenses resulting from university research. Prior to 1981, fewer than 250 patents were issued to U.S. universities annually and discoveries were seldom commercialized for the public's benefit. By contrast, according to the Association of University Technology Managers' (AUTM) most recent licensing survey, 3,280 U.S. patents were issued to U.S. universities during 2008 alone, while 595 new companies were formed and 648 new products were introduced based upon university inventions. According to a 2009 study by the Biotechnology Industry Association, university technology licensing had a \$187 billion positive impact on the U.S. gross domestic product between 1996 and 2007, resulting in the creation of approximately 279,000 new jobs.

<sup>&</sup>lt;sup>1</sup> Q. Todd Dickinson, "Reconciling Research and the Patent System," *Issues in Science and Technology*, Summer 2000, <a href="http://www.issues.org/16.4/dickinson.htm">http://www.issues.org/16.4/dickinson.htm</a>.

<sup>&</sup>lt;sup>2</sup> AUTM U.S. Licensing Activity Survey Summary: FY2008, http://www.autm.net/AM/Template.cfm?Section=Licensing\_Surveys\_AUTM&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=4208.

<sup>&</sup>lt;sup>3</sup> David Roessner, Jennifer Bond, Sumiye Okubo, and Mark Planting, *The Economic Impact of Licensed Commercialized Inventions Originating in University Research*, 1996-2007, September 3. 2009, http://www.bio.org/ip/techtransfer/BIO final report 9 3 09 rev 2.pdf.

This leads us to an important overarching statement with which our associations agree: <u>The current legal</u> framework for university technology commercialization, as set forth by the Bayh-Dole Act of 1980 and implementing regulations, is effective and needs to be maintained.

Despite the effectiveness of the overall legal framework for technology commercialization, improvements can be made to our institutions' technology commercialization and knowledge transfer functions. Some of these improvements need to be made by universities themselves, while others can be facilitated by changes in government policy and new government programs at both the federal and state level.

While there are some voices suggesting the need to change the Bayh-Dole Act, we caution against generalizing about the overall state of technology commercialization based upon a few examples of how commercialization allegedly may not be working as well as we would all prefer in some industrial sector or subsector. As in business generally, some deals and relationships are successful, while others are not. Since effective methods for commercialization in one sector do not always work in another sector, various models should and are being explored by our universities to ensure effective technology commercialization across all sectors, from the biotechnology industry, to the IT industry, to the non-profit and social services sector. Models must also take into account geographic location. For example, models that may be effective in urban high technology areas may not work in more industrial or rural areas of the country.

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The remainder of this letter will focus on barriers that exist to effective technology commercialization and what actions both universities and the government might take to reduce these barriers and enhance technology commercialization efforts. We have also encouraged our member institutions to submit their own suggestions and views in response to the RFI.

# II. Challenges and Barriers to Commercialization

# a) Finding Resources to Support Commercialization by Universities

One of the greatest challenges facing universities in the area of technology commercialization is finding funds to support the infrastructure for commercialization and technology transfer and, in particular, support for early stage (gap and proof of concept) funding for new inventions. Technology transfer imposes significant costs on universities at a time when they are already under significant financial stress due to the economy and resulting declines in state support, endowments, and donor giving.

The intent of commercialization by universities should be to transfer technology for further development and effective application to ensure broad public access and increased social welfare. The lack of adequate institutional and/or government resources for commercialization activities, however, may have driven some university technology transfer offices (TTOs) to focus disproportionately on revenue generation as opposed to moving new knowledge into the public domain for the public good. This situation creates the wrong incentives for optimizing technology transfer. While many TTOs operate at a loss, at times, commercialization generates net revenues. However, universities should not pursue commercialization of research primarily for this purpose. Universities, government, and industry have a responsibility to find new ways of providing university technology transfer operations with necessary support so that these operations have the correct incentives to be successful in achieving their broader mission.

To ensure that revenue generation does not drive negative behaviors that can impede technology commercialization, universities must evaluate the indicators that they use to judge the effectiveness and quality of their technology transfer and licensing operations. Indicators that have traditionally been used to measure successful commercialization efforts at universities (e.g. patents, licenses, and revenue generation) have been overused, misapplied, or are sometimes inappropriate surrogates to measure the effectiveness of efforts by universities to commercialize research. Many of our institutions are aware of these issues and are seeking to develop better measures. As discussed below, our associations, as well as others such as AUTM, are also taking steps to develop better commercialization effectiveness measures.

### b) State Policies

Some states forbid equity participation in companies (i.e. startups) by state institutions, while others have policies limiting involvement of faculty in such activities due to their status as state employees. There also may be tax and funding issues associated with states that can be problematic. Additionally, states may have specific policies about use of state "facilities" for commercial activities which affect public universities. We encourage the Obama Administration to work with the nation's governors to examine the impediments these laws and regulations may create for economic innovation and growth, as well as possible solutions.

# c) Conflict of Interest

Increased economic engagement inevitably raises the likelihood of more financial relationships between institutions and their researchers and the companies with which they engage. In fact, one gauge of the effectiveness of commercialization is the growth of such relationships. Current perceptions that such relationships are inherently suspicious or invariably lead to unmanageable conflicts of interest must be changed. Both policymakers and the public must understand that these relationships are positive and necessary for universities to achieve greater success in commercializing their research. At the same time, it is critical that as federal agencies move to regulate potential conflicts of interest, they do not put in place regulations which inadvertently discourage appropriate interactions among research faculty, universities, and industry. We understand that conflicts of interest must be closely monitored and kept in check. However, an overly strong focus on elimination, rather than management, of conflict of interest by federal agencies would produce a chilling effect on universities' willingness and ability to engage in economic development and be directly counter to the Administration's interest in increasing commercialization by universities. As purveyors of objective knowledge, universities have their own built-in interest in managing conflicts of interest, or perceptions of such conflicts, to ensure that the integrity of research findings are not compromised.

#### III. Models

As the federal government and universities look for new models to support commercialization by universities, we must carefully balance the need for basic research and knowledge creation against the need to increase commercialization. Many investments in basic research have resulted in new ideas and knowledge that ultimately led to commercial goods. In fact, the National Science Foundation (NSF) reported in the late 1990s that over 70 percent of references to scientific publications listed as "prior art" on the front pages of U.S. patents were linked to public science authored at academic, governmental, and other public institutions, as

opposed to private businesses or companies.<sup>4</sup> Turning the fruits of basic research into products, however, is not an overnight process, nor can anyone predict up front what the specific results will be.

University contributions to economic development take many forms including not only technology transfer and licensing, but also student education and training, faculty consulting, and the publication of research results, to name just a few examples. Technology transfer and technology licensing are tools to help achieve a key university mission, but their role in this complex equation is sometimes overemphasized.

The human capital aspect of technology transfer is often undervalued, but it is a fact that the students our universities educate and the faculty who conduct our research are usually the most effective means through which translation and technology transfer occurs. For example, many of the most successful university-industry interactions are based on the education and training of students who have the specific skills to meet industry needs, or on relationships that top-notch faculty members have with particular companies. These interactions do not center on intellectual property (IP) at all. Therefore, as new models for commercialization are developed, an emphasis should be placed upon fostering new interactions, relationships, and linkages, both formal and informal, that help to facilitate these efforts. Education and training must also be considered to be major components of such models.

Many universities have created innovative new models. These include new programs and courses that focus on entrepreneurial education, training and incentives for faculty, and competitions that encourage students to engage in entrepreneurial activities.

### IV. Changes in Public Policy and Funding

# a) Support for Current Administration Initiatives

Our associations support the development of new policies that seek to enhance commercialization efforts at universities. We were pleased to see proposals in the Administration's FY 2011 budget that are designed to address this issue.

The President's FY2011 Budget Request contains \$12 million for a new "NSF Innovation Ecosystem" component within the Partnerships for Innovation (PFI) program. As we understand it, this initiative would provide grants to universities in partnership with other institutions to: 1) increase engagement of faculty and students across all disciplines in the innovation and entrepreneurship process; 2) increase the impact of the most promising university innovations through commercialization, industry alliances, and start-up formation; and 3) develop a regional community that supports the innovation ecosystem around the university. The university community welcomes this new program and will urge Congress to fund it.

We also support the \$75 million in funding proposed for the Commerce Department's Economic Development Administration (EDA) to support the creation of regional innovation clusters. We believe that universities can and should play an important role in the development of such clusters, given universities' unique capacity to bring together a region's disparate political, industrial, and societal interests. The Administration's EDA Regional Cluster Initiative could enable universities to play this convening role, which would be a catalyst to identifying regional core competencies; defining the appropriate roles for regional institutions, the private

<sup>4</sup> National Science Board, "Private Use of Public Science," *Science & Engineering Indicators* – 1998, Arlington, VA: National Science Foundation, 1998 (NSB 98-1), <a href="http://www.nsf.gov/statistics/seind98/pdf/c6.pdf">http://www.nsf.gov/statistics/seind98/pdf/c6.pdf</a>.

sector, and governmental organizations; and developing a comprehensive regional strategy for economic growth and job creation.

# b) Additional Policy and Funding Recommendations

In addition to the programs referenced above, we suggest consideration of the following changes to existing government policies to enhance efforts by universities to commercialize research.

- Reconsider the current cap and other restrictions on the reimbursement of university administrative costs. To address the issue of resources, we urge the government to consider eliminating or lifting the existing 26 percent cap on reimbursement of university administrative costs. Costs of supporting commercialization are not allowed as direct costs of research in traditional federal research grant mechanisms. Currently, some of these costs, namely patent costs and related expenses, may be charged to universities' administrative cost pools for purposes of facilities and administrative (F&A) cost reimbursement. However, since the administrative components of F&A are capped and subject to pressures to support increased costs of regulatory compliance, there is little flexibility to support other activities such as patent and other costs related to commercialization. Removing or lifting the cap would help to ease current financial pressures universities face as a result of growing compliance demands and free up resources for other areas. Additional resources could also be freed up if certain costs, such as those associated with human subject protection, were allowed to be directly charged to grants.
- ➤ Provide for supplemental grants to support the translation of research with a high potential for commercialization. A great deal of focus recently has been placed on developing new translational research programs by federal research agencies. While we believe such programs can play an important role in helping to transfer research into the marketplace, effectiveness at translating research for commercialization is not necessarily the same as translational research. Indeed, there are many good ideas with significant commercialization potential already being generated from existing and more traditional federal research programs. The problem is that researchers and universities do not have resources available to support the proof of concept work, market analysis, and mentoring needed to translate these ideas from the university laboratory to the marketplace.

To address this situation, we recommend that the Administration consider the establishment of new "Translational Supplemental Awards." These awards would be made by the major federal research agencies to support proposals jointly submitted by an existing principal investigator and the university TTO or another appropriate institutional research or technology commercialization official. These awards would be made at the tail end of federally funded awards to support next stage research for projects that show strong clinical or market potential. We believe that providing such awards would both incentivize researchers to think about the potential commercial applications of their research and help to change the culture of the federal research agencies in ways that would help facilitate the commercialization goals of the Administration.

➤ Modify the R&D tax credit. The Administration is already on record in support of making the existing R&D tax credit permanent, a goal we support. In addition, we encourage the Administration to seek modifications to the R&D tax credit so that it provides a greater incentive for such investments instead of penalizing companies that invest in university research by not granting them full credit for research performed outside of the company, as is currently the case.

- ➤ Create additional tax incentives to promote commercialization. We encourage the exploration of additional ways in which the tax code could be used to encourage early stage investment in university technologies and to reward companies that license university technologies. For example, tax credits or deferral of taxes for angel investors in emerging companies can help spur additional investment at a critical period in a company's development.
- > Seek new ways to reduce or supplement the growing expenses involved in patents. While we realize that increasing the degree to which universities obtain patents does not necessarily result in increased commercialization, patenting costs are increasingly becoming a barrier to commercialization by universities. We recommend consideration of new methods to support such expenses, perhaps along the lines of the competitive allocation process that is currently being used in the United Kingdom. One example might be to develop a separate commercialization rate supplement based on a set of indicators of commercialization success compared to total federal research dollars received.

#### c) Metrics for Success

As previously mentioned, in the past, too much weight has been assigned to the role of intellectual property and revenue generation in defining university success in commercialization and economic development. Indeed, the statistics on university licensing revenues contained in the annual AUTM Licensing Activity Survey have too often been used as metrics by the media and others, including state governors, to determine the "success" of university technology transfer and commercialization efforts.

Government at all levels, universities, industry, and the non-profit sector should develop a consensus on new metrics that accurately and appropriately reflect the range of university contributions to local, regional, and national economies.

There are significant efforts underway within and outside the university community to identify new measures of economic contributions to regional economies. AUTM, for example, has undertaken a significant effort to reexamine the information it collects annually from its members and has also undertaken an effort to collect examples of success stories in technology commercialization through the *Better World Report*. The Association of Public and Land-grant Universities recently held a national workshop to identify additional measures of university contributions to regional economic growth and innovation. The workshop included a focus on how new measures of economic growth and commercialization might determine or influence institutional behaviors. Meanwhile, the Association of American Universities is examining new indicators that can be used specifically by universities in evaluating their own technology commercialization efforts and TTOs.

### d) Forums for Ongoing Dialogue

Universities and industry need to engage in a robust dialogue to identify and disseminate key factors underlying successful university-industry arrangements. The University-Industry Demonstration Partnership (UIDP) has invested considerable energy in developing tools to identify areas of common ground and divergence between university-industry partners. This work builds upon previous efforts undertaken by the National Academies Government-University-Industry Research Roundtable (GUIRR). In addition, the National Academy of Sciences' forthcoming report, *University Management of Intellectual Property*, will lay the groundwork for further discussion of this issue. These existing and other forums for dialogue should be encouraged and supported by all interested parties – government, universities, industry, and non-profits.

# V. Proof of Concept Centers

Part II of the RFI specifically asks for input concerning the underlying conditions and infrastructure required to support and enhance the success of POCCs.

Our associations believe that POCCs can be an important, but not the only, ingredient in helping universities commercialize technologies. In fact, we have been active in helping to shape and advocate proposals (e.g., the <a href="IMPACT proposal">IMPACT proposal</a> developed by Krisztina Holly at the University of Southern California) that would help to develop and support such centers.<sup>5</sup>

We are concerned, however, about the significant degree of attention given to POCCs in the RFI. While we view POCCs as one important mechanism through which commercialization can be improved, there are many other effective tools, including those discussed earlier in this letter. We are also concerned that the exact definition of POCCs in the RFI is unclear. We believe there are very few truly effective university POCCs currently operating. These include the Deshpande Center at MIT and the von Liebig Centers at the University of California, San Diego. Yet the RFI talks about NSF Engineering Research Centers (ERCs) as if they were initially designed as POCCs. The third generation (Gen-3) ERCs that NSF is now establishing appear more like POCCs in concept. However, we think that existing first and second generation ERCs were established for different reasons and serve a significantly different role than POCCs. It would be misguided to try to characterize or define their purposes and roles to be the same as POCCs. For this reason, we urge OSTP and NEC to be more precise and narrow in their definition of POCCs as they move forward with these initiatives.

Perhaps the real question to be addressed is how some of the practices of existing POCCs can be replicated in other settings, both within and outside of universities, to help facilitate technology commercialization in other models. One major issue concerns how to support and incentivize efforts to enhance "Proof of Concept" work as a part of existing universities' TTOs. Expanding the operations of TTOs to include some of the functions that have made POCCs effective might be an important step that could be taken to enhance commercialization. We point to our recommendation for the provision of Translational Supplemental Awards as one way to help enhance the ability of universities and their TTOs to support such translational efforts. We must also look closely at the role that entities such as university research parks play in commercialization and the unique role that universities can play in facilitating the development of regional clusters.

Finally, we note that, as with other models, the POCC model is likely to work well for commercialization of some technologies but not for others. Many university technologies are in life science areas where the role of POCCs may be less clear given the typically long developmental cycles in this field. For example, there are concerns that POCCs are not as effective in facilitating development of early-stage therapeutics compared to engineering technologies such as those that might be developed by ERCs.

<sup>5</sup> Krisztina "Z" Holly, *IMPACT: Innovation Model Program for Accelerating the Commercialization of Technologies - A Proposal for Realizing the Economic Potential of University Research*, 2010, <a href="http://stevens.usc.edu/reports\_impact.php">http://stevens.usc.edu/reports\_impact.php</a>

### VI. Conclusion

Our associations look forward to continuing to work closely with the Administration as it seeks to facilitate university knowledge transfer from our campuses into the marketplace. At the same time, we reemphasize the need to focus on helping to facilitate the transfer of knowledge from our universities for broader societal benefit through multiple avenues and not to focus efforts too narrowly. We pledge to do what we can to seek improvements and new ways of thinking at our universities that will enable them to continue to provide this important service to the nation and to do so even more effectively.