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Commmittee on Science, Space and Technology
Subcommittee on Technology and Innovation
June 19, 2012

Mr. Chairman, members of the Committee, thank you for the opportunity to appear before you to discuss *Best Practices in Transforming Research into Innovation: Creative Approaches to Bayh-Dole Act.*

Background

As an innovation economy with massive future potential, Maryland ranks highly. Nationally, Maryland ranks **1st** in federal research and development dollars invested per capita and **1st** in Ph.D. scientists and engineers per capita. According to the Milken Institute, Maryland is in the **top two** for science and technology and we occupy the **top slot** for human capital investments. The U.S. Chamber of Commerce also puts Maryland in the **top five** for growth and Education Weekly has ranked Maryland's public schools **1st** for four years running. And finally, most recently in another report released by the U.S. Chamber of Commerce, Maryland was ranked **1st** in entrepreneurship and innovation. However, there is a clear gap between the significant potential suggested by these rankings and the current level of entrepreneurial activity across the State.

The 2010 Annual Survey of the Association of University Technology Managers (AUTM) reported the following data for Maryland institutions:

Total Maryland Invention Disclosures in FY 2010	768
National Ranking for Invention Disclosures per Research Expenditures	**45th**

The national rankings for start-up company formation suggest similarly low rankings, given Maryland's expenditures and assets:

National Ranking for Start-up Companies Formed per Research Expenditure	**40th**
National Ranking for Start-up Companies Formed per Invention Disclosure	**37th**

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National Ranking for University Start-ups Formed in Maryland	**38th**
National Ranking for License Agreements Completed per Disclosure	**30th**

The Maryland Innovation Initiative

The purpose of the *Maryland Innovation Initiative* (MI2) is to: promote the commercialization of research conducted in participating universities; encourage qualifying universities to partner on commercialization proposals, strategies, and funding sources, including with federal laboratories located in Maryland; and facilitate technology transfer from university labs to start-up companies.

MI2 is the first of its kind partnership between the State and Maryland's five academic research institutions designed to accelerate commercialization of technology, including, but not limited to, medical devices, imaging, informatics and cyber-security. Proof of concept and prototyping grants will be awarded to innovators and innovations best positioned to quickly create products that will meet needs present in the commercial marketplace. By supplying the right expertise and incentives, a relatively modest investment by the program can facilitate the transfer new technologies from the lab to the market within two years.

The State has appropriated $5M to establish MI2. Additionally, all five of the state's academic research institutions, University of Maryland College Park (UMCP), University of Maryland Baltimore (UMB), University of Maryland Baltimore County (UMBC), Morgan State University and Johns Hopkins University (JHU) are participating in the program. The three largest universities, UMCP, UMB and JHU are investing $200k each and the two smaller universities, UMBC and Morgan State are investing $100k each. These investments by the universities are new dollars expended beyond current resources to seed research. Combined, this provides an annual budget of $5.8M for the program.

MI2 will be managed by a full-time Director. The Director will report to the participating members of the initiative, which will include one representative from each participating university, one State official, and two private sector representatives with relevant professional expertise appointed by the Senate President and House Speaker.

MI2 will use "site miners" who will:

- Be either technology transfer professionals who work in consultation with university faculty, or members of university faculty;

- Create inter-disciplinary teams of clinicians, scientists, engineers, business strategists, lawyers, and pharmacists to solve existing problems identified in the commercial marketplace; and
- Will work within the academic research facilities, and will come together as a single group periodically to enable multi-university collaborative solutions to identified market needs.

The teams created by the site miners will compete for up to 40 grants of up to $100K. The grants will be awarded on a rolling basis over the course of 12 months by the MI2 board. The board will meet as often as necessary to ensure the grants are awarded in a timely manner.

By linking innovators with experienced entrepreneurs and the technology transfer offices at these five institutions, we anticipate 10% - 20% of the funded projects will become new start-up companies, be licensed to established companies, and/or become standards of clinical care within two years of receiving funding.

In addition to creating jobs, spinning off new businesses, and spurring growth in Maryland's innovation economy, MI2 will generate broader collaboration among the State's leading private and public research institutions. The partnership will further develop the existing entrepreneurial environment within the institutions, and allow all the institutions to seek outside funding for more technology transfer and commercialization projects.

Tech Transfer Best Practices and Policies

In an effort to think about what policy changes could be made in support of university technology transfer efforts, one approach is to start with the greatest obstacles to commercializing technology and consider the policies that could minimize these obstacles. To this point, university technology commercialization faces two significant challenges, which have the potential to be affected by federal policy:

1. Invention disclosures resulting from federal (and other) funding are not sufficiently mature for commercialization and cannot be evaluated effectively for their commercial applications and potential – there is insufficient funding for translational research in universities (the "Translational Research Problem"); and

2. There is not sufficient interaction between universities and industry to foster commercialization of university technology (the "Industry Involvement Problem").

Best Practice Approach to Translational Research Problem

The Translational Research Problem (#1 above) has two main causes. First, the majority of federal funding programs supporting university research are targeted to basic research. Long standing federal policies focused on basic research have positioned the United States as the world leader in scientific discovery and helped to position the nation as a leader in higher education. While a strong policy focus supportive of basic research has served this nation well by creating a wealth of new discoveries, it has ignored the step of commercialization that is required for these discoveries to be translated into products that can benefit the public good. Second, the academic culture that values independent, basic research and a focus on publication in academic journals, which also have a bias toward basic research, stifle translational research and commercialization.

Cognizant of the power of public funding to influence behavior, over the last 8 years TEDCO developed and refined two programs to promote desired behaviors.

TechStart

The techstart program is designed to validate the commercial need for an innovation developed by researchers in the insulated environs of a research lab. The program's key feature is that before excessive dollars are spent on pilot programs or proof of concept projects a team evaluates the commercial demand for the technology. Specifically, an entrepreneur, the inventor and a representative from the tech transfer office come together to answer a strategic question. Depending upon the technology this question or analysis may be what is the commercial market size, what is the competitive landscape, a freedom to operate evaluation, are there viable distribution channels, or the answer to any other strategic issue that would indicate commercial viability.

Only with an affirmative answer to the TechStart is further money invested in the translation, or commercialization of the technology at hand. The benefits of this approach are a significant savings of capital, human resources and infrastructure assets. First, this research can be done for $10k to $15k, a small fraction of the cost of a pilot project that can cost $100k or more and second, human resources and lab facilities and equipment can be directed at other innovations that have more commercial viability instead of driving to a dead end.

University Technology Development Fund & Maryland Innovation Initiative

Only once an affirmative answer has been established via a Techstart project, or a commercial need has been identified by the site miners deployed by MI2 is it time to expend resources on proof of concept to pilot projects. While MI2 is a new program, TEDCO's University Technology Development Fund (UTDF) has been in operation for many years and has demonstrated the

efficacy of similar programs. Like MI2, UTDF is designed to provide limited dollars to a university or federal lab researcher in order to complete a proof of concept project.

UTDF resources have been limited to providing $50k per project and have only been able to complete 112 projects. Despite its small scale, UTDF's results are impressive. Of the 112 projects funded, 43 resulted in new license agreements for the developed technology and 29 new companies were formed. MI2 will scale up the successes in Maryland. Federal funds, in keeping with the intent of the presidential memorandum dated October 11, 2011 regarding *Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses* would do the same for federal research laboratories.

Best Practice Approach to Industry Involvement Problem

The Industry Involvement Problem (#2 above) is created primarily by the difference in corporate and university cultures. This is compounded by issues related to intellectual property, publication, conflict of interest, and other issues that are rooted in public policy, e.g., Bayh-Dole. The cultures at universities and those in industry are well-entrenched and would require policy changes that create strong incentives to have an impact. TEDCO, in collaboration with the University System of Maryland has developed an effective program to address this problem.

The Maryland Industrial Partnerships Program

The Maryland Industrial Partnerships Program (MIPs) primary objective is to promote collaboration between commercial enterprises and a university research lab. The basic premise of the program is that there are resources and know-how in university labs that can solve commercial problems. The economic element is a sliding scale of state matching funds to the dollars invested by the company. Depending upon the size and maturity of the company, the state will provide between 50% and 90% of the cost of the project. This effort has been highly successful resulting in 1000's of jobs, billions of dollars in revenue and at least one public company.

Other Policy Changes to Support Technology Transfer

The recent increased focus on innovation and the creation of new jobs at the federal and state levels creates an opportunity for new policies that loosen the bottleneck between university discovery and the development of new products. Fundamentally there needs to be more emphasis placed on translational research. This may come at the expense of basic research or it may come as a further compliment to basic research, either way the additional emphasis is needed.

Following are a number of thoughts for consideration in discussions about policies that address the specific problems listed above:

Translational Research Problem

- It might be useful to allocate a percentage of the federal extramural research budget for programs directed to translational research in universities. Translational research will need to be defined carefully for these programs, but applicants could be required to include a commercialization plan with a description of potential products as part of the proposal process. In addition to academic reviewers, individuals from industry should be included on review committees for these proposals, as these individuals are more likely to have an understanding of the market demand for university innovations that might arise from the proposed project.

- Traditional basic research programs should add a review criterion requiring the applicant to describe the potential commercial application of any newly discovered knowledge that could result from the proposed project. In addition, some programs should be targeted for specific public needs – even if they are for basic research. For example, an NIH funding program supporting basic research that could lead to the reduction of some aspect of healthcare costs would be more likely to generate an invention that could be commercialized. Such a program could help to focus basic research toward specific outcomes rather than just the pursuit of new knowledge. Again, these statements are not intended to suggest that all research programs should change; rather, a portion of programs should consider this approach.

Industry Involvement Problem

- The SBIR/STTR programs are great resources for entrepreneurs and small businesses, but they could be modified to foster more university commercialization. First, more people from industry, rather than just academics, should be used on review committees so proposals are evaluated with a bias toward commercial research rather than academic research. Second, setting aside a percentage of SBIR/STTR funding for companies that are commercializing technologies licensed from universities (or federal labs, to be inclusive) would foster more commercialization of university technology. Third, limiting the number of companies that can apply for SBIR funding might create more opportunity for small business, which is where most job creation occurs. To this point, policy could create a preference for micro enterprises (less than 50 employees) or give preference for companies that have only been in business for less than 5 years. The current definition of "Small Business" includes 99.7% of all companies in the U.S. This

makes it difficult for start-up companies (like the ones commercializing university technologies) to compete with larger, established companies.

- One way to force companies to interact with industry is to change the dynamic with respect to who is funding university research. For example, providing industry tax credits for sponsoring research in universities would incentivize interaction. The potential success of such a fund matching program is demonstrated by the state matching dollars in the MIPS program previously described. The tax credits could be paid for by reallocating research funds in the federal research budget. Moreover, the tax credits, which would only be a percentage of the industry-funded research, would be leveraged by industry funding and ultimately could lead to greater university research funding. A similar model could be used as an incentive for companies licensing technology – i.e., tax credits for licensing fees, much of which is returned to the university to support research in accordance with Bayh-Dole. With universities and industry working closely, more opportunities for collaboration, licensing, and commercialization would result.

- Industry often claims that it is difficult to negotiate license agreements with universities. A guidance or effort in conjunction with the Association for University Technology Managers (AUTM) and the Licensing Executives Society (LES) for standardizing licensing terms for federally funded inventions might help to address this issue and facilitate the licensing and commercialization process. There are already some efforts to accomplish licensing standardization at the University of North Carolina and at NIH. Expanding these efforts would be beneficial.

Other General Suggestions

- Programs like the NSF's *Partnerships for Innovation* should be created at other agencies to explore new models of technology transfer and commercialization. NSF's PFI was used to fund two highly successful programs in Maryland, Activate and Innovate. These programs were an experiment in entrepreneurship and tech transfer targeted at women and post-doctoral fellows respectively. Deemed very successful tech transfer programs, they also helped to foster relationships between universities and industry.

- University policy changes regarding tenure and sabbaticals could also have an impact on commercialization efforts. Currently, and simplistically, success, defined as tenure, for a university researcher is accomplished in part by the publication of a paper, the filing of a patent, or a speaking engagement at a conference. Nowhere in that success formula is commercialization. The Regents of the University System of Maryland, however,

recently modified tenure criteria to include commercialization. Likewise, universities offer sabbaticals for research but not for entrepreneurship. A sabbatical program offering a year to go start a business with the security of returning to the university if needed would go a long way to incenting the desired actions.

The initial thoughts that are described above are specifically for improving university technology transfer. While these ideas could benefit technology transfer from the federal labs, the federal labs have a unique set of challenges that could also be addressed with changes to policy. Such challenges are not specifically addressed in this document.

The ideas contained in this document are preliminary in nature and intended to foster discussion. Clearly, additional thought and discussion would improve these ideas and generate others.