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STATEMENT TO THE SENATE COMMITTEE ON THE JUDICIARY
ON
The Role of Federally-Funded University Research in the Patent System
BY
THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS (AUTM)

Thank you for presenting us with the opportunity to submit a statement for inclusion into the record as part of your October 24, 2007 hearing on “The Role of Federally-Funded University Research in the Patent System.”

It is a real privilege to be able to comment on the impact of the University and Small Business Patent Procedures Act, or as it is universally known, the Bayh-Dole Act. This subject is particularly important to our organization because some of our founders were privileged to work closely with the Committee in passing this historic legislation.

The Senate Judiciary Committee should feel rightly proud of its role in developing a sea change in U.S. policy of which the **Economist Technology Quarterly** wrote:

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... This unlocked all of the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

Similarly, Chairman Leahy, an original sponsor of the bill, rightly noted:

In 1980, Congress passed the Bayh-Dole Act, which encouraged private entities and not-for-profits such as universities to form collaborative partnerships that aid innovation. It worked, and as a result the Bayh-Dole Act has contributed billions of dollars to the United States economy and has produced hundreds of thousands of jobs.

AUTM concurs. Because of the Senate Judiciary Committee's vision many years ago the United States is once again a leader in science and technology. That this was accomplished while academia remains focused on its primary mission of education and the advancement of science, only makes the achievement more profound.

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Before quickly reviewing the law's impact, it is worthwhile to reflect on how far we have come since the Senate Judiciary Committee held the first Bayh-Dole hearing on May 16, 1979.

That day many believed that America's best days were receding and the U.S. simply could not compete in a high technology economy. These stark realities were aptly reflected in Senator Bayh's opening statement:

The United States has built its prosperity on innovation. That tradition of unsurpassed innovation remains our heritage, but without continued effort it is not necessarily our destiny. There is no engraving in stone from on high that we shall remain Number 1 in international economic competition. In a number of industries we are no longer even Number 2. New incentives and policies are needed to reverse this trend.

The immediate focus was reversing a policy whereby federal agencies routinely took inventions away from the university and small business innovators they funded, effectively destroying the incentives of the patent system to attract the significant dollars and years of effort needed to turn early stage research results into products that benefit the American public.

Senator Bayh added:

This problem is especially serious in the field of biomedical research programs where delays by the agencies in granting patent waivers for new drugs and processes have condemned many people to needless suffering. Unless universities and small businesses receive the right to retain the patent on these inventions, valuable discoveries wind up wasting away on the funding agency's shelves, benefitting no one.

Illustrating the remarkable bi-partisan agreement that has always characterized the issue, Senator Dole showed how the public was ill served by prior policies placing federally funded inventions into the public domain without necessary incentives for their development:

The effect of this policy is twofold, bearing on the consumer as well as on the economy in general. In both cases, the public is the victim. When large amounts of taxpayers' money are directed to the research field, the public expects and deserves to reap the benefit of its investment in the form of products available for its consumption. When this fails to materialize, it is obvious that the Government has reneged on its promise.

Before we end this reflection on the past, passage of the Bayh-Dole Act was also a seminal event in the development of AUTM. Two of the witnesses before the Committee in 1979 were founders of our organization. The incredible immediate impact of the new law stimulated a

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tremendous increase in universities and non-profit organizations forming technology transfer offices. Our members translate the results of federally funded R&D into new products advancing the health, wealth and knowledge base of the nation. The impact of the Bayh-Dole Act on campus is reflected in the rapid growth of AUTM membership from 133 practitioners in 1980 to 3,662 today.

It is not an exaggeration to say that because of the Senate Judiciary Committee's leadership, universities have become important components of the economic development plans of their surrounding regions. They are rich sources of cutting edge discoveries, for the formation of venture capital, and the creation of technology clusters driving state and regional economies.

What evidence is there that Bayh-Dole has succeeded? Here's a snapshot:

- The U.S. is once again a leader in basic and applied research and in applying research and innovation to improve economic performance according to the National Academy of Science's report **The Gathering Storm**.
- University research helped create whole new industries like biotechnology and is now a leader in the rapidly growing field of nanotechnology.
- More than 5,000 new companies have formed around university research, the majority locating in close proximity to the university. Such companies are vital to continued economic growth.
- University patenting exploded from just 495 issued patents in 1980 to 3,278 in 2005.
- In the latest AUTM survey, universities helped create 527 new products in 2005 alone and 3,641 new products since 1980. *This represents 1.25 new products based on academic inventions introduced every single day over the last eight years!*

As Senator Leahy stated, estimates are that university technology transfer contributes *billions of dollars* to the U.S. economy each year

Just as remarkable is that after more than twenty five years, the impact of Bayh-Dole continues to grow. Here are some highlights from the most recent 2005 AUTM survey of our members and what they are doing under the authorities of the law you passed:

- 4,932 new licenses were signed in one year alone.
- 28,349 current licenses were in place, each representing a one on one partnership between a company and a university. The great majority of these licenses are going to small companies.
- 628 spin-off companies were created or *1.7 new companies every day of the year!*

The Bayh-Dole Act is an internationally recognized best practice. Other countries have benchmarked the law to encourage partnerships between their own universities and industry.

While we have clearly come a long way from the initial hearing in 1979, we cannot afford to rest on our laurels. The U.S. is facing new challenges to our technological leadership. A new model arising in China and India seeks to link their own cutting edge university research with low cost manufacturing. Efforts are underway to lure U.S. companies to fund research there. It is in

everyone's interest to encourage the rapid development of science and consequent economic growth. Fostering economic growth around the globe is an important tool in creating a stable, peaceful world.

Still, we cannot be naive that the world is standing still and that our current hard won prosperity can be taken for granted. Ironically, just as the results of Bayh-Dole have never been more evident, some voices seek to return to the old policies that failed in the past. This would be a tragic mistake. When viewed objectively, the predictions of the critics have simply not been borne out in the light of day.

Some critics expressed fears that allowing universities to partner with industry would undercut traditional academic excellence in research. Bayh-Dole wisely allowed non-profit organizations to manage their inventions, confident that a decentralized system of technology management would be vastly more efficient than the bureaucratic system it replaced. Congress also believed that universities would be able to balance their emphasis on maintaining excellence in education and the advancement of science with an ability to partner with industry. The evidence shows that this trust was well placed.

1. University research has not shifted from its traditional emphasis on fundamental, basic research.

The National Science Foundation reported in its 2006 **Science and Engineering Indicators** reported that evidence "*does not show any decline in the basic research share since the late 1980's.*" The report concluded:

The available data, although limited, provide little evidence to date of a shift toward more applied work.

2. Bayh-Dole has not harmed the publication of scientific papers, but appears to have increased university/industry joint publications.

The National Science Foundation noted in its July, 2007 **The Changing Research and Publication Environment in American Research Universities:**

The study's findings provide little support for the idea that competing institutional demands are diverting faculty from research and publication. For the most part, informants said that neither teaching nor commercial activities were absorbing time that in the past would have been devoted to research and writing.

The report added:

Very few informants, however, thought that commercially oriented activity had significantly reduced the amount of publication-oriented research. Most reported that faculty colleagues who had gotten involved with start-up companies had continued to publish. They noted that these researchers tended to be very active and innovative, so that their commercial activity was more an addition to

their academic research than a replacement for it. In addition, commercial involvements sometimes enriched the published work of faculty researchers, involving them in new areas of research. Many people observed that awareness of the commercial potential of research sometimes prompted brief delays in publication, but they generally doubted that these delays caused an overall reduction in publication.

Interestingly, one reason given for the slower growth of scientific publication in the U.S. was our leadership in integrated collaborations across institutions. This change has been encouraged by the funding agencies as good for science.

If U.S. researchers, compared to researchers in other countries, had been more rapidly increasing their investment of time and resources in this type of collaboration, this might help explain the change in article counts.

Indeed, twenty eight percent of academic articles in 2003 were co-authored with non-academic partners, up from 22% in 1988. Before passage of the Bayh-Dole Act, industry was very reluctant to allow their leading researchers to work with their academic counterparts. Removal of this barrier is making U.S. science more robust.

According to the National Academy of Science's **Rising Above the Gathering Storm**, the United States continues to *"lead the world in the volume of articles published and in the frequency with which those papers are cited by others. US-based authors were listed on one-third of all scientific articles worldwide in 2001. Those publication data are significant because they reflect original scientific research productivity and because the professional reputations, job prospects, and career development of researchers depend on the ability to publish significant findings in open peer-reviewed literature."*

In biotechnology, the Milken Institute found that the top ten U.S. universities in the field account for 11.8% of world-wide publications, with U.S. publications responsible for 46% of all scientific papers. European universities were second with 35%.

Another criticism raised during the hearing was that agencies like the National Institutes of Health were not using the authorities of the law to "march-in" to insure that resulting drugs are affordably priced. While concerns over the costs of health care are certainly legitimate, regulating prices is not an intended agency authority under the Bayh-Dole Act. Arguments that this was the intent of Congress in passing the law were soundly rebutted, most emphatically by former Senator Birch Bayh himself. Rather than trying to capture the essence of this debate here, attached is a clarifying statement of Senator Bayh to the National Institutes of Health. NIH upheld these views when they dismissed a petition to regulate a drug developed by Abbott Laboratories under the march-in provision. Interestingly, the drug in question was not invented by a university, but by Abbott itself with NIH funding.

The conclusion is obvious. The Bayh-Dole Act is a success in terms of bringing new science to the public's benefit in the form of new products, jobs and companies. It has helped to restore U.S. competitiveness. This has been accomplished while our universities have maintained their

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leadership in pushing forward the frontiers of science as evidenced that the best and brightest in the world still want to come to the United States to study.

The Senate Judiciary Committee should be commended for its role in this achievement. Involvement in developing and implementing the Bayh-Dole Act is something in which AUTM takes great pride.