

Statement of

Arundeeep S. Pradhan
Director, Technology and Research Collaborations
Oregon Health & Science University

Vice President for Annual Meetings and Board of Trustees
Association of University Technology Managers

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Mr. Chairman, Ranking Member Gingrey and honorable Members of the Subcommittee, thank you for the opportunity to testify before you today on the important topic of the Bayh-Dole Act which has been instrumental in accelerating the evolution of innovation in the United States, and hopefully will continue to be a key factor in driving the U.S. innovation policy for the next 25 years..

My name is Arundeeep S. Pradhan, and I am currently the Director of Technology and Research Collaborations at the Oregon Health & Science University (OHSU) in Portland, Oregon and serve on the Board of Trustees for the Association of University Technology Managers (AUTM). AUTM is a nonprofit organization dedicated to promoting, supporting and enhancing the global academic technology transfer profession through education, training and communications. AUTM's more than 3,500 members, primarily managers of intellectual property, represent more than 300 universities, research institutions and teaching hospitals as well as numerous businesses and government organizations.

My office at OHSU is responsible for managing and commercializing the intellectual assets of the university; forging ties with industrial partners; and participating in various programs and initiatives with institutional, local, state and regional groups to align the interests of universities, city and state constituencies as to effectively achieve success in technology transfer objectives.

I have been asked to give my opinion, as well as express the views of the AUTM Board, on various aspects of the Bayh-Dole Act (35 U.S.C. 200-212) and how it relates to academic technology transfer. These views are a result of my 19 years of experiences in this industry, which began as a student working in the technology transfer office at the University of Utah where we established the culture for collaborating not only with numerous start-up companies, but also with existing companies in the fields of biotechnology, pharmaceuticals, electronics and software. I subsequently spent five years at the Colorado State University Research Foundation in Fort Collins, where we continued the proactive approach to collaborating with state, local and regional organizations to further technology transfer and economic impact missions of the university.

Historical Perspective

In 1980 prior to the Bayh-Dole Act, the federal government held title to approximately 28,000 patents of which fewer than 5% were licensed to companies for commercialization into products per the 1998 GAO Report on the Act. This lack of commercialization can be attributed to several factors, among which are a lack of incentives for universities and faculty to engage in technology transfer, patent policy that varied by federal agency, and a lack of clarity of ownership of patents developed under federal funding.

The Bayh Dole Act represented a fundamental change in government patent policy. It provided ownership and title to any invention made in whole or in part with federal funds under Bayh Dole to universities and small business. The government reserved for itself a royalty-free license to practice any such invention for governmental purpose. Further, the Bayh Dole Act was instrumental in establishing a Federal patent policy that was uniformly applied to all of its agencies, as well as providing the first statutory authority for the government itself to obtain, own and license patents.

The Committee on Science and Technology has been instrumental in recognizing that federal patent policy is an integral part of U.S. competitiveness and helped to shape the current environment in which we function. This Committee not only was instrumental in fashioning the Bayh-Dole Act, but also the Federal Technology Transfer Act in 1986. We thank you for your foresight in establishing policies that have helped the U.S. be a leader in innovation.

Summary Conclusions

1. Impact of the Bayh-Dole Act on Research, Technology Transfer and Commercialization

On December 14, 2002, The Economist stated that “Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that have been made in laboratories throughout the United States with the help of taxpayer’s money. More than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance.” The Bayh-Dole Act truly has been instrumental in achieving that goal.

The Bayh Dole Act is as fully viable today as it was when passed in 1980. Since 1980, American universities have spun off more than 5,000 companies, which have been responsible for the introduction of 1.25 products per day into the marketplace and have contributed to the creation of over 260,000 jobs. The result has been a contribution of over \$40 billion dollars annually to the American economy.

The Biotechnology Industry Organization (BIO) has identified 60 drugs derived from university research, and there are over 300 biotechnology therapeutic products based on federally funded research that are now in clinical trials. Examples of these include the Hepatitis B Vaccine (Fox Chase Cancer Center); New Therapeutics for Prostate Cancer (OHSU); New Treatments for Heart Disease (Emory University).

These breakthroughs of commercial applications occur not only in the field of biotechnology and life sciences, but in all fields ranging from electronics to agriculture^{7, 8}. A few examples from AUTM’s Better World Report series (<http://www.betterworldproject.net/>) are:

Arizona

- Lighting strike detection technology that is now deployed in over 40 countries (University of Arizona)
- Chemical-free technology to help control crop diseases is licensed to companies in the Midwest (University of Arizona)
- A new class of carbon compounds based on fullerenes which can be the basis for among other things new flat panel display technologies, batteries, and capacitors(University of Arizona)

California

- Topical gel treatment for AIDS-related Kaposi's sarcoma (Salk Institute for Biological Studies)
- Electrodes that enable three-dimensional imaging with atomic force microscopy (Stanford University)
- Novel IV catheters that eliminate risks of potentially dangerous needlesticks (City of Hope)

Oregon

- Rib-fixation device for fractured ribs (Oregon Health & Science University)
- Improved three-dimensional depiction of proteins and large molecules (University of Oregon)
- Novel non-toxic wood adhesives (Oregon State University)

Nebraska

- Drought tolerant grass (University of Nebraska-Lincoln)
- New Organo-metallic reagents for the synthesis of drugs (University of Nebraska-Lincoln)

And there are numerous more examples ranging over many areas of research.

2. How has the Bayh-Dole Act Shaped University-Industry Relations?

Prior to passage of the Bayh-Dole Act and with no uniform government patent policy in place, each of the government agencies had developed its own patent policy. The majority of those were "title" policies, where ownership resided in the government as represented by the agency. Most agencies had also adopted a non-exclusive licensing policy to such inventions. As a consequence industry was highly reluctant to obtain non-exclusive licenses from the government knowing it could not really exercise control over the invention licensed and that a competitor could obtain a similar license. Simply put, there was no reward, in the form of marketplace exclusivity to justify the risk and expense necessary to develop an invention for the market.

Moreover, industry was reluctant to fund research at the universities for fear of government funds "contaminating" the research that was sponsored and because of the "title" policy adopted by the agencies, depriving the particular sponsor of the right to assert ownership to any invention arising from the sponsored research. The "contamination" principle was particularly onerous since there was no de minimis amount of federal funding specified for triggering the government's right to take title to an invention and even a single dollar of government money co-mingled with the industry-sponsor research funds could permit the government to assert rights to the invention or, at least, put a cloud on the title.

The passage of the Bayh-Dole Act established certainty of title in and to inventions conveyed to the universities under the Act and alleviated the industry-sponsor's fears, thereby encouraging additional sponsorship, collaborative efforts, and expanded licensing opportunities. Since the government retains a non-exclusive right to inventions made in whole or in part with government funds but only for governmental purposes, the relationship with the private sector is truly a university-industry-government relationship and one which industry has been willing to accept.

The Bayh-Dole Act has made institutions more aware of their role in being good stewards of public resources, including capturing a fair economic value of federally funded research contributions, and as Bayh-Dole requires, reinvesting any return in research and education. While Bayh-Dole does not directly govern industry sponsored research, it establishes good practices within our offices that ensure that federally-funded technologies are commercialized for the public benefit, both as a result of licensing inventions directly from federally funded research as well as obtaining exclusive licenses to inventions resulting from industry sponsored research. It is incumbent on both sectors to foster, encourage and grow these collaborations.

3. Effects of Globalization of Research

The global environment has changed considerably in the last two decades. Countries, such as Germany, United Kingdom, Singapore, China and India, are increasingly pumping resources into research and development and establishing ties between industry and academic institutions. The technological and basic research leads that the U.S. has enjoyed over the last two decades should not be taken for granted. Recognizing the success of the Bayh-Dole Act in the U.S., other countries are emulating our lead by passing similar laws. Bayh-Dole has reduced certain barriers for collaborations with companies and also encouraged entrepreneurship across all aspects of university research. This entrepreneurial environment provides a key element in attracting, training and retaining students, young faculty and thought leaders when other countries are becoming more welcoming to entrepreneurship.

Mr. Chairman, I understand that the Committee has heard reports that industry is looking for research partners overseas because they find it so hard to negotiate with universities in the United States. I cannot vouch for whether those reports are accurate, or what role different factors, including cost, play in those decisions. I can speak to my experiences and to the issues that take up the most time in university negotiations with industry.

The biggest, most time-consuming issue involves faculty researchers' right to publish their research findings and share the research data with their colleagues. This is a core issue for universities. The ability of faculty to publish, and thus to advance the state of the art, is central to our mission and is probably the most important method of knowledge transfer we have. Intellectual property rights are also a point of negotiations. They are complicated because a fair allocation of rights and access to rights really depends on the particular facts of the research. It is hard to articulate a general rule for what is fair because the facts and circumstances are so important. These issues do not arise from Bayh-Dole, but from the fundamentally different roles that universities and industry have in society.

In my capacity at OHSU, as well as historically, I have seen significant increases in university-industry partnerships. Over the last five years at OHSU, the number of industry-sponsored research agreements has doubled and the amount of research funding has almost tripled. I feel that these

collaborations will continue to grow in the future. It is critical that the U.S. preserve Bayh-Dole and its fundamental elements and continue to support the funding of basic research so that our country can maintain our leading edge in innovation in this increasingly competitive global environment.

4. The Bayh-Dole Act's Influence on Basic Research

A study by the American Association for the Advancement of Science (AAAS) indicates that there is no significant “negative” impact of technology patents and commercialization on scientific research in terms of access and sharing. There has however, been net positive outcome in terms of collaborations with industry, as is highlighted by the fact that the U.S. has seen a significant increase in joint industry-university scientific papers that the National Science Foundation cited as a significant achievement for science in their annual *Science and Engineering Indicators*.

In 2006, key individuals from the university technology transfer community and Association of American Medical Colleges (AAMC), developed “Nine Points to Consider when Licensing University Technology” (attached). This document has been adopted by AUTM and recommended to its members; the list of signatories is now kept by the AUTM, much like AUTM serves as a repository for signatories of the Uniform Biological Materials Transfer Agreement. This document is a set of guiding principles that illustrate general good practices. The first point in this document is to reserve the right to practice licensed inventions and to allow other non-profit and government organizations to do so. The National Institutes of Health which provides substantial funding for basic research also supports this approach. While Bayh-Dole allows licensing of inventions for commercialization, it does not preclude use of such inventions for continued research. This and the other points in this document are meant to provide good practice guidelines for licensing. As each negotiation and relationship is unique, it is incumbent to strike a balance between the business needs of our industry partners as well as the fulfillment of the core mission of the universities.

5. Bayh-Dole: The Next Twenty-five Years

The architects of the Bayh-Dole Act, in which this Committee played a role, exhibited profound insight as Bayh-Dole serves as the foundation for technology-based economic development by allowing universities to work regionally with established or start up companies to launch new products to benefit the public and at the same time, remains flexible to encourage partnerships across a broad spectrum of industries for a wide variety of technologies that are commercialized under different business models. Bayh-Dole has been instrumental in linking the federal and state governments, research universities, small business and the corporate worlds¹¹. Because the impact of the Bayh-Dole is now far reaching and affects the economy at multiple levels, any changes, if warranted at all, need to be evaluated prudently and carefully to avoid disruption of the innovation ecosystem. I, the AUTM Board of Trustees, as well as other organizations, believe that Bayh-Dole works well as intended and we anticipate that Bayh-Dole will continue to accelerate technology transfer and foster university-industry partnerships far into the future.

What has been the impact of Bayh-Dole on federally funded research and technology transfer and commercialization of that research?

It has now been twenty eight years since Bayh-Dole passed. In those twenty eight years the Bayh-Dole Act has had tremendous impact on the innovation economy of the United States and has become the model for technology-based economic development not only in the U.S., but on a

global scale. Countries such as Japan, United Kingdom, Germany and others hope to achieve the same success as we have in the U.S., and even developing countries are instituting means to utilize their universities' talents and research results to boost their economies.

The fundamental stated goal of Congress in passing the Bayh Dole Act was to promote the utilization of inventions arising from federally supported research and development. I, as well as the AUTM Board, believe that those goals have been achieved and we are becoming more effective in how this intention is implemented. One clear indicator of innovation is the increase in "invention disclosures" from university faculty. There is imaginative research, at which faculty excels, from which, in turn, arises invention and innovation. The increase in invention disclosures is an indication that there has been a cultural change in how faculty and academic institutions view transferring the results of research in a manner to further benefit the public. In addition to the traditional method of publishing research results which continues to be pursued vigorously, universities and their faculty are increasingly aware that commercialization of research results can significantly impact society through improving the health, welfare and safety of the public. And, as with any cultural changes, it takes time; it is not something that will be adopted at the turn of a switch. In 1980, approximately 25 U.S. universities had technology transfer offices and no uniform federal patent policy existed. Today, more than 230 U.S. universities support such offices. In 1980, only a few patents were issued to universities. Today, universities are granted approximately four percent of U.S. patents. This success has its roots in the Bayh-Dole Act.

The academic community and federal agencies continue to find new ways to innovate. This is evidenced by new programs, such as NIH's Clinical and Translational Science Awards that encourage inter-disciplinary collaborations, collaborations with companies and movement of research from the bench to its applications. While this may indicate a willingness to use federal research funding to implement applications of basic research, the emphasis of federally funded research clearly continues to be on basic research. A recent study conducted by the AAAS concludes that scientific research has not been hindered significantly by technology patents and licensing activities⁴. Therefore, federally-funded inventions can continue to stimulate more research while being developed into useful, commercial products.

There are annual increases in the activities and outcomes that AUTM has been tracking for the last fifteen years. Since 1980, there are now over 28,000 active licenses of technologies to companies, and, 5,171 spin-off companies based on university research². A great majority of these, in fact, arose during the last decade, indicating an acceleration of the rate at which research is transferred into the market place. These numbers only tell part of the story. Over the last two years, AUTM has documented specific societal impact through the Better World Reports that contain descriptions of university-based discoveries and inventions that have had a significant impact on the health of our citizens and the economic well-being of our society. This is not the only measure of the innovation economy on which the success of Bayh-Dole should be based. According to the former President of the NASDAQ stockmarket, an estimated 30% of its value is rooted in university-based, federally funded research results which might never have been realized but for the Bayh Dole Act. Technology transfer as it exists today is a complex process that has multiple roles and objectives defined by local, regional, and national needs and regulations.

Since 1997, when AUTM started tracking this metric, 3,641 new products were introduced in the economy, 527 in 2005 alone. This represents 1.25 products per day². This illustrates significant

innovation occurring in our universities and nation that is directly based on federally funded research at universities and small businesses.

State investment in innovation has also been a key, although unanticipated, outcome of the Bayh-Dole Act. A significant number of these investments involve academic institutions which are viewed as key partners and drivers of regional economic development. Since 2005, 19 states have begun initiatives targeted to innovation in the form of investment into university R&D; these include providing private sector R&D incentives to partner with academic institutions, new business innovation support, and tax credits for new business R&D investment. This incremental investment represents approximately \$4 billion in the next ten years and is only a sample of programs being initiated by various states.

In Oregon, as in many other states, several programs were initiated to encourage the transfer of research from research institutions to the marketplace. In the last six years, Oregon has committed to the formation of Signature Research Centers in the fields of nanotechnology, bio-economy & sustainable technologies, and drug development and translational research, the purpose of which, among other things is to foster university-industry partnerships. The Oregon universities have been active in this field in the last decade.

- Since the Oregon Nanoscience and Microtechnologies Institute (ONAMI) has been in existence, ONAMI has been able to leverage state and federal resources for cutting edge research and launch start-up companies such as HomeDialysis+ (a light-weight medical device that will allow patients with failing kidneys to receive dialysis over night in their own homes).
- Research at Oregon Health & Science University has been the basis of over 60 start-up companies, half of which have been started since 2002.
- Oregon is unique in the creation of University Venture Development Funds, by offering donors state tax credits, which are paid back to the state through generation of income resulting from commercialization of university research.

All of these programs and activities, not only in Oregon, but across the country in different states reflect the impact of Bayh-Dole.

How has Bayh-Dole shaped University-Industry research collaborations?

Federally funded research leverages a tremendous amount of investment into the research and development infrastructure. This occurs not only in the form of direct investment into research by non-federal entities but ranges from investment into companies that are spun off and investment into products that are developed from licensed technologies.

Bayh-Dole has encouraged the formation of productive university-industry partnerships, especially in light of diminishing resources at all levels. The demise of corporate research laboratories has led to the increasing tendency of U.S. industry to look to universities to perform research that a decade or two ago industry was more likely to perform itself. Both companies and universities seek to leverage their respective expertise in science and product development to further advance respective goals. While AUTM does not directly track the number of industry-university research collaborations, the number of such research collaborations seems to be on the increase. While the

absolute number of dollars spent on research at academic institutions has increased, the latest data indicate that the relative percentages from federal, industrial and non-federal sources have been relatively stable for the last decade². At a time where the resources for research and development have not kept pace with need, it is important to recognize these cultural differences and arrive at pragmatic solutions that benefit both industry and universities. This represents a highly effective mechanism through which technology is transferred and not always in the form of patents and licenses.

It is important to highlight at this point the differences in culture between academia and industry, and even within industry, variations in culture by industry cluster as well as by the size of a company and institutions. These cultural differences have led either to successful collaboration or complete breakdown of communication between respective participants³. A fundamental tenet of a university is the broad dissemination of knowledge through peer-review publications and education and training of students. Companies maintain a more secretive environment for their proprietary technologies and to ensure a return to their shareholders. University-industry partnerships in the field of biological or life sciences are most often highlighted as these products require significant investment by industry and remain visibly available for many years. In other fields where an exclusive position is less critical and product life cycles are measured in months, federally-funded research still plays a role as academic institutions transfer both knowledge and technology developed under federal funding.

Any partnership which is based on economic incentives needs to be fair to the parties in that arrangement. It is therefore incumbent on both parties to recognize the synergies, differences, as well as activities that may be prohibited not only by federal statute, but also state laws and regulations and policies to arrive at mutually beneficial partnerships⁵. The Bayh-Dole Act, while significant, represents one of several pieces of legislation that plays a role in defining the interactions and relationships between academic and non-profit research institutions and industry.

What is the possible effect of the increasing globalization of research?

U.S. universities and companies increasingly function in a global environment. Both universities and companies have to therefore recognize additional cultural differences and address issues that arise from crossing international borders. These differences are also evident in dealing with local divisions of larger multinational companies which now have access to expertise and facilities on a global basis.

Universities have traditionally fostered research collaborations both nationally as well as internationally. The issues of intellectual property development have not typically been a stumbling block in such collaborations. As other countries see the success of Bayh-Dole, they have increased their respective funding of basic research and implemented laws, regulations and policies that mimic Bayh-Dole in an effort to become successful in the innovation economy. Whereas in the U.S., federal funding for research has grown in the last decade, but has been flat over the last few years – increasing number of applicants for the same size pie – this is also true for industry based research funding at universities. This only serves to highlight the increasing amount of competition for limited research resources in the U.S.

However, a large proportion of university-industry collaborations involve not large multinational companies, but more medium and small businesses that do not have the resources for international

collaborations. For U.S. institutions, this means that actual barriers in collaborating with industry need to be reduced and perceived barriers need to be addressed in order to achieve success in this area.

How has Bayh-Dole influenced Basic Research?

As indicated earlier, an AAAS study indicates that there is no significant impact of technology patents and commercialization on scientific research. This study surveyed respondents in the U.S., United Kingdom, Germany and Japan. This is true of collaborations, access to research tools and publications especially between academic institutions. Such interactions between institutions and industry are also commonplace, but usually proceed at a slower pace due to the differing cultures.

Bayh-Dole in giving great impetus to technology transfer and to cultural changes on how best to utilize research results for the public benefit, providing some focus on the potential commercial applications derived from basic research. Most research results still get published without the need for review for patent protection. There is a small subset of research results that technology transfer staff as well as faculty are learning to recognize to have commercial potential that does get published after review, and if necessary after filing for appropriate protection. It is the intent of academic institutions to pursue commercialization of those research results for the public benefit, but not to obstruct others from doing research in the same field.

What changes in Bayh-Dole if any, may be appropriate as look to the next 25 years to promote commercialization of federally funded research and US economic development?

The Bayh-Dole Act fundamentally provides a simple structure that works as intended and should not be substantially altered. Further, Bayh-Dole offers greater opportunity to ensure that technology can be appropriately packaged and commercialized. If anything, this opportunity needs to be strengthened. There are numerous initiatives that are being implemented at the state and regional levels that are facilitating the transfer of federally funded research into commercial applications. A comprehensive look at such initiatives can be conducted to determine appropriate models for adoption. In addition, there are several outstanding technology transfer programs that have been successful that can provide information on creating infrastructure that leads to effective transfer. It must also be taken into account that local, regional, and state stakeholders also play a significant role in the commercialization of federally funded research.

Any development of programs that would augment Bayh-Dole should take into account such regional drivers, industry-academic institution cultural differences, resources allocated for technology transfer at institutions, education and training of technology transfer professionals as well as university faculty and staff, and appropriate metrics.

One glaring weakness in the current law is the absence of effective Executive branch oversight. Congress made it clear that it expects for this function to be performed by an entity with both the policy background and clout to insure that federal agencies do not start interpreting the law on their own. We have noticed that the implementation of Bayh-Dole is increasingly uneven across federal agencies. The oversight authority has been moved over the years from the Office of Federal Procurement Policy to the Department of Commerce. It is now time to re-examine the current assignment of this oversight role since the Department of Commerce has now shown little interest in fulfilling this responsibility for many years and in fact recently abolished the office that previously

had been assigned the oversight responsibilities. Without continued effective central oversight, agencies may tend increasingly to subordinate Bayh-Dole to individual policy and program priorities and objectives, thus weakening the ability to accomplish the broader Bayh Dole goals, and we will de-evolve back into the situation Congress passed Bayh-Dole to remedy: agencies developing their own patent policies to the detriment of the American public's health and future prosperity.

One thought is that this oversight authority might be better implemented in the Office of Science and Technology Policy. While this makes sense in looking at the Executive branch organization chart, to really be effective what is really needed is having someone who understands the importance of Bayh-Dole at the helm.

General Conclusions

Studies have found that universities are now drivers of regional economic development that encourages the development of technology based clusters which are important factors and may be attributable to Bayh-Dole. . . . Many countries are now adopting Bayh-Dole type laws, as they see its successful implementation in the U.S. The benefits derived directly as well as indirectly from Bayh-Dole are extensive and should not be treated lightly due to a few anecdotal incidents

The primary missions of universities to maintain academic freedom to conduct research, educate and train students, and pursue and disseminate knowledge for the public benefit are protected by Bayh-Dole. In the course of the last 25 years, universities have learned a tremendous amount on how to interact with industry. Universities are learning to recognize that relationships with industry are dynamic; vary with industry sectors; and, above all that we must adapt to changing environments as per the respective sectors. As I have indicated, the concerns of industry do not lie with the Bayh-Dole Act itself, but in the manner in which some universities have chosen to implement it, taking a narrow perspective on what defines technology transfer. In order to address this, several universities created, and the AUTM Board of Trustees and additional universities have endorsed, the “Nine Points to Consider when Licensing University Technology”. These points not only address licensing but can also be applied broadly to university-industry research relationships.

While the Bayh-Dole Act allows universities to collect royalties from the licensing of subject inventions, the core mission of universities remains education and generation and dissemination of new knowledge. Some universities may focus purely on the licensing revenues to measure success of academic technology transfer, but the real impact is reflected in the impact on the lives of the American public. In addition, many inventions generate little revenue, and the amount of revenues that a particular university receives is usually miniscule compared to the size of that university's research budget. A part of the dissemination mission is to provide the information, whether it is in the form of education or in the form of technology transfer, to those who can best utilize it for the public benefit. Prior to Bayh-Dole, this was primarily in the form of publications, and as we now know, it takes more. It has taken us over twenty-five years to get to this point, and we should not disrupt this trend. I, AUTM, as well as other organizations, believe that the Bayh-Dole Act will continue to be a catalyst for innovation in the U.S. economy for the next twenty-five years as well.

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Attachment

In the Public Interest: Nine Points to Consider in Licensing University Technology