Testimony of

Dr. Charles F. Louis

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Full Committee Hearing

On

"The Role of Federally Funded University Research in the Patent System"

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Introduction

Good afternoon, Chairman Leahy, Ranking Member Specter, Senator Feinstein from my home state, and Committee members. Thank you for the opportunity to appear before you today to address the very important issue of the "Role of Federally Funded University Research in the Patent System." First, I should introduce myself and my institution. My name is Charles Louis and I serve as the Vice Chancellor for Research at the University of California at Riverside (UC Riverside). I also hold a concurrent faculty appointment of Professor of Cell Biology and Neuroscience.

After a long career as an academic scientist, most of this being spent in the United States, may I first profoundly thank the U.S. Congress for the sustained support you have provided by ensuring the allocation of federal funding for the support of basic research in our nation's universities - which has contributed to the release of new products into the economy, creation of new jobs, and regional economy of cities across the nation. The benefits of this federal funding are well recognized by our economic competitors around the world who hold the U.S. system of federal research support as a model, and I strongly encourage you to continue supporting this worthy and vital cornerstone of our U.S. economy that is the subject of today's hearings.

As Vice Chancellor for Research, I am responsible for advancing the research mission of the university that includes significant responsibilities as the Institutional Official managing Sponsored Programs, Research Integrity and Compliance, and the Office of Technology Commercialization, which oversees patenting and technology commercialization efforts for the Riverside campus. I also have oversight of campus research centers and institutes as well as the support and administration of new interdisciplinary and federal initiatives by UC Riverside. Currently, I am helping to oversee the planning for a new medical school to be housed at UC Riverside.

I maintain an active role as a researcher with over 25 years of continuous NIH funding that has allowed me to train a large group of graduate students and postdoctoral fellows. My research on muscle and the lens of the eye has brought new understanding as to how altered regulation of intracellular calcium concentration results in significant diseases of the heart and skeletal muscle, as well as lens cataract formation. As a user of the patent system, I am an inventor of a patent with colleagues at the University of Iowa and University of Minnesota entitled "Diagnosing

Malignant Hyperthermia Susceptibility by Detection of Abnormal Proteolytic Enzyme Digestion Fragments of the Ryanodine Receptor."

Staying abreast of national issues, I serve as a member of the Board of Council of Research Policy and Graduate Education of the National Association of State Universities and Land Grant Colleges (NASULGC) and remain active in the Association of University Technology Managers (AUTM). Prior to joining UC Riverside in 2004, I served as Vice President for Research at Georgia State University and previously held faculty and/or administrative appointments at the University of Minnesota, University of Connecticut Health Center and Leeds University in England.

I would also like to thank the U.S. Senate and this Committee in particular for its hard work in passing the Bayh-Dole Act almost 30 years ago, which first allowed universities to take title in federally-funded inventions and translate them into good and useful products for the public. It is a privilege to be able to thank so many of the original sponsors of this law in person, including yourself, Mr. Chairman.

UC particularly appreciates passage by the House of Representatives last year of a Sense of the Congress to honor the 25th Anniversary of the Bayh-Dole Act (H.Con. Res 319, 109th Congress). This resolution was an important recognition by Congress of the "successful and substantial contributions" of the Bayh-Dole Act. The House Resolution importantly notes that "the Bayh-Dole Act fundamentally changed the Federal Government's patent policies by enabling inventors or their employers to retain patent rights in inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application."

According to the Economist (Dec. 12, 2002), the Bayh-Dole Act is "perhaps the most inspired piece of legislation to be enacted in America over the past half-century." The piece goes on to state that "[m]ore than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance." Senator Leahy, you accurately reflected the importance of the Bayh-Dole Act during the consideration of the CREATE Act in 2004, when you stated:

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.

A university's ability to ensure that its federally-funded technologies are successfully translated into useable products is predicated on having a strong, reliable and predictable patent system and laws like Bayh-Dole that encourage industrial partners and private equity funding sources to invest resources and commit to moving a laboratory-based discovery through the arduous and often risky development and commercialization process, and the Senate's commitment to that system is greatly appreciated.

Universities Use Federally-Funded Research to Develop Ideas that Have the Potential to Become Useful Products

The University of California ("UC") is comprised of ten campuses, including five medical schools, and participates in the management of three national laboratories, with over 170,000 faculty and staff and serving 200,000 undergraduate and graduate students. Over 17,000 students are enrolled at UC Riverside. In fiscal year 2006, investment by the federal government in basic research at UC was over $2.6 billion dollars, and at UC Riverside alone totaled over $52 million dollars. Through this federal investment, UC Riverside is conducting leading edge research in areas that include nanotechnology, genomics and gene silencing, invasive species and vector borne disease, ecology and sustainability, environment and energy, bioengineering, and biomedicine that will significantly increase with the new medical school plan for the campus.

The University's many scientists and engineers conduct basic and applied research, collaborate with other research partners, publish important research results that build on the nation's scientific knowledge base, and educate and train students at all levels. In the process, we also make discoveries that may be patentable and have the potential to be developed into products that will ultimately benefit the general public. Our innovations in those areas have resulted in UC being awarded the highest number of patents by any American university for the last twelve years.

UC Riverside, as part of the country's larger academic community, contributes to what is ultimately one of the primary forces of economic development for our nation: our institutions of higher education and research. Federal investment in basic research conducted by our nation's universities has a payoff not only in the creation of new knowledge, but in the form of a highly skilled workforce, the creation of jobs, economic growth, enhancement of the tax base, the introduction of new products that can be used by the public, and technological advancement. The United States and its universities are the envy of the world in terms of the grand scale of potential and advancement that are made possible by the commitment of the federal government to funding basic research at U.S. universities.

The innovations that stem from university research reach beyond the borders of individual states and the U.S. to affect the lives of humanity around the globe. By way of example, UC Berkeley is collaborating with a for-profit company and a non-profit pharmaceutical organization on an affordable malaria drug with the goal of reducing the price tenfold.

At the Riverside campus, with federal support through the USAID-sponsored Collaborative Research Support Program, and now support from the Consultative Group for International Agriculture Research Generation Challenge Program, Dr. Jeff Ehlers is investigating the breeding of cowpea varieties with improved drought tolerance and resistance to pests as part of a consortium of U.S. and African scientists developing new varieties of tropical legumes. Cowpea is the most important grain legume and hay crop in Africa, widely cultivated across semi-arid, drought-prone regions of this continent. However, drought and pest attack take their toll on production, so that cowpea yields in Africa are less than one third of their potential. UC Riverside researchers are developing and applying genomic technology to develop new and improve cowpea cultivars that have tolerance to drought and improved resistance to pests and diseases coupled with superior yield potential and yield stability.

The Need For University Technology Transfer

Universities across the nation perform the vast majority of the basic research funded by the U.S. Government. Public support of basic research funding has been critical to our nation's prosperity and has driven economic growth. The basic research and development conducted at universities is often at the leading edge of the country's technological advancement. In fact, it is generally much further upstream than the commercial sector is willing or able to conduct its activities. Yet the basic research conducted by universities with financial assistance from the federal government has led to some of the most important discoveries and patents of our lifetime: whether life-saving medical devices or revolutionary scientific insights or innovative agricultural products, the partnership between universities and the federal government has played a vital role in significantly improving the quality of lives in the U.S. and throughout the world.

The primary objective of basic research is the creation of new knowledge, but in the conduct of such research, discoveries occasionally are made that have more practical potential, such as a molecule that shows unusual promise for the diagnosis or treatment of a disease, or a gene that makes a plant immune to particular pathogens without use of chemical pesticides. The process of university technology transfer, as set forth in the groundbreaking Bayh-Dole Act of 1980, has set forth an efficient and effective system of university patent ownership to ensure that federally-funded discoveries can be developed in partnership between universities and private industry for the public's benefit.

The Bayh-Dole Act: Translating Federally Funded Research Into A Tangible Public Benefit

A Historical Perspective on University Technology Transfer

Prior to passage of the Bayh-Dole Act in 1980, later updated in 1984, the process of university technology transfer was difficult, if not impossible, for federally-funded inventions.

The idea of university technology transfer can be said to have originated in 1945, with prominent American scientist Vannevar Bush's report to President Truman, entitled "Science: The Endless Frontier," which became the genesis of the creation of institutions like the National Science Foundation and the National Institutes of Health.

In his report, Bush drew on his involvement in the Manhattan Project in recognizing the crucial nature of university research in national defense and urged the government to increase its support of basic academic scientific research as a result. Bush believed this type of federal support would be invaluable in creating a pipeline for these cutting-edge ideas to be transmitted to the private sector for development in order to facilitate the national interest.

Accordingly, throughout the 1950s and 60s, increasing amounts of research money began to be directed towards universities and academic research centers. However, the government had not yet adopted any type of uniform patent policy concerning the ownership of such inventions or the considerations to be weighed in determining how best to develop these ideas into commercial products - instead, each individual agency promulgated its own policies and guidelines. Thus, universities seeking industry partners to assist them in the development and commercialization of their government-funded research were faced with reconciling up to 26 different agency policies before being able to proceed. As a result, only a handful of universities had any structured technology transfer programs in place. And very few of the federally-funded patents, less than 5% in 1980, were ever licensed for development, in part due to the government's practice of issuing only non-exclusive licenses which did not provide an incentive for a company to risk investing in commercializing a technology if its competitors could reap the benefits of its development efforts.

The government recognized that this situation was not ideal. In 1963, President Kennedy issued a Policy Statement that a more uniform governmental patent policy was urgently needed. Almost 10 years later, in 1971, President Nixon issued a revised Statement of Government Patent Policy. This Statement of Governmental Patent Policy acknowledged the value of patenting and the need to facilitate the transfer of patent rights to the private sector to further the commercial development of these products, while also balancing the interests of the public in ensuring that marketplace competition was not stifled. This led to the establishment of Institutional Patent Agreements (IPA) that a couple of the federal agencies were willing to establish and allow individual universities to own the inventions funded by that agency. The certainty of title in the university provided the impetus for universities to engage in technology transfer.

The Bayh-Dole Act Allowed Universities To Take Title To Federally-Funded Inventions in Exchange for Diligent Development

In 1980, this new policy was codified into law, under the leadership of former Senators Birch Bayh (D-IN) and Robert Dole (R-KS), as the Bayh-Dole Act. The Bayh-Dole Act established a consistent and uniform policy across agencies, allowing universities to elect to retain title in inventions created by their researchers in the course of federally-funded research, on the condition that the universities diligently work with private industry to ensure that the technology is developed in a timely and beneficial manner.

Codification of this approach appropriately shifted development of the technology from distant federal agencies with little knowledge about the applicability of the invention, to the local university which possessed the most knowledge about the mechanisms of the technology and could more effectively determine what inventions to patent or not. Universities were able to maintain control over the development of their technology, harness their understanding of the science in question to ensure the most beneficial development of their inventions, and work with local industry to stimulate the regional economy.

The policy and objective of the Bayh-Dole Act remains applicable today as when the Act first passed - using patent law to:

promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

The Bayh-Dole Act requires universities to give preferences to small businesses and to ensure that federally-funded inventions are manufactured in the United States. This provision have encouraged formation of start up companies and investment by local industries in university research and allowed the U.S. economy to harness the benefits of academic research.

The Bayh-Dole Act also includes several safeguards against abuse, which reflects the government's concern for a flexible policy that nonetheless balances the interests of the public with the economic interests of private industry,. For instance, universities are mandated to require their licensees make diligent progress towards commercial development, the revenue generated by university licensing must be dedicated to supporting additional science and educational research after deduction of an inventor share and recovery of costs, and the government retains the right to practice the invention by or on behalf of the government. The government also retains, under specific circumstances, the right to "march in" if the university or its licensee has not been effective in commercializing the invention in a timely manner. These safeguards, coupled with university self-generated initiatives and policies to promote technology transfer in the public interest, ensure that the balance between the public good and private initiative is carefully maintained.

Academia-Industry Partnerships Can Translate Federally-Funded Research Into Useful Products to Benefit the Public

While U.S. universities have a mission of conducting cutting-edge research and furthering human knowledge, and perform that job exceedingly well with the generous assistance of the federal government, they are neither positioned nor equipped to develop their discoveries into viable commercial products that can be used by the general public. Nor is doing so consistent with their overarching mission of research and education. Universities were thus faced with a problem - how would they translate their federally-funded discoveries into a tangible public benefit?

The Bayh-Dole Act anticipated this issue, and encouraged an innovative solution: it created the possibility of university partnerships with private industry to develop federally-funded inventions for the general marketplace.

Bayh-Dole thus allowed the academic community to rely on industry to do what industry does best: commercial development of a technology into a viable product, scale-up and production of that product, and ultimately commercial sales making the product available to the public. Without this industry participation, the public may never see the product of laboratory research.

However, it is not enough simply to offer the technology to private industry without some corresponding exchange of rights by the university. Because university technologies are inherently embryonic and early stage, the process of commercialization is not at all a sure thing and carries a high level of risk. Industry may not recognize the commercial value of an early stage invention, unresolvable technical difficulties may arise during the development process that would affect the technology's viability, or venture capital financing may not be available. Further, when a company does step up to the challenge, it must invest a tremendous amount of its own resources and take on the risk that the commercial development may not pan out.

Thus, universities offer limited licenses to private companies in exchange for their acceptance of the risk inherent in developing early-stage technology. In exchange for a company's investment, the university provides the company with the benefit of rights under a patent with the hope that the technology can be successfully commercialized. Through a license to the underlying patent, a company is given the economic incentive of a competitive advantage to offset the risk it must take in such early-stage investment, and is encouraged to develop and commercialize a product in a timely manner and distribute it as widely as possible, in order to recoup their investments and reap the benefits of the limited patent monopoly. Universities have found that this has been an ideal way to encourage the commercialization of its inventions and induce investment in their licenses, in large part because of the benefits offered by a strong and predictable U.S. patent system in the U.S. If companies are not assured of the strength of the patent and the predictability of the patent system, it is unlikely that they would license university technology and invest in a risky development and commercialization effort. If that occurs, then the public may never see the commercialized product.

Inventions Made Possible By University Technology Transfer

After the passage of Bayh-Dole, university technology transfer skyrocketed. Now, over 230 universities have technology transfer offices, and the UC is proud to have one of the top technology transfer offices in the world, as recognized in the recent Milken Institute Report, "Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization."

UC manages over 7,500 active inventions in its current portfolio. Eighty percent of those inventions have generated interest in either the private and public sector. Of those interest-generating inventions, over 50% have resulted in a financial investment in the development of a product. As of FY 2003, over 700 products have been developed from UC discoveries, which have benefited the U.S. economy and has had a positive profound effect on the quality of human lives. Examples of some of UC's important inventions include:

- A vaccination for the potentially-fatal Hepatitis B disease (UCSF);

- The Cohen-Boyer recombinant DNA patent held jointly by UC and Stanford University that helped to spawn the development of the biotechnology industry (UCSF);

- Phosphite fertilizer that has superior qualities for plant growth (UC Riverside);

- Lung treatments for respiratory problems associated with premature births (UCSF);

- A laser/water Atomic Force Microscope that helps scientists to better view and analyze different properties of matter at the nanoscale (UC Santa Barbara);

- A diagnostic method for detecting feline AIDS (UC Davis);

- The minimally invasive Guglielmi Detachable Coil used to treat brain aneurysms (UCLA);

- A plasma electric generator to create power without the use of fossil fuels (UCI);

- The Cochlear Ear Implant to assist those with hearing loss (UCSF);

- Glucose monitoring techniques useful for diabetics (UCSF);

- Strawberry varieties that create an annual $1 billion-plus industry in California, provide quality fruit to consumers across the nation, and are grown throughout the world (UC Davis); and

- The Nicotine Patch that assists smoking cessation (UCLA), among many others.

- Other universities throughout the nation have developed significant products that benefit society as well, such as:

- An anticoagulant that treats heart patients and prevents blood clotting (University of Wisconsin-Madison)

- The diagnosis and treatment of diseases of the blood (University of Vermont)

- An antimicrobial treatment for food (University of Arkansas)

- The Mouseopause? mouse model to study postmenopausal conditions (University of Arizona)

- A treatment for rheumatoid arthritis (Massachusetts General Hospital)

- An ultrasonic method to determine beef quality (Kansas State University, Manhattan)

- A treatment to promote growth in premature babies (Columbia University)

- An under vehicle inspection robot for security uses (Utah State University)

According to data provided by the Association of University Technology Managers ("AUTM"), 4,338 new products were introduced between FY98 through FY06 as a result of university technology transfer efforts. Additional discoveries from academic institutions that benefit society are highlighted in a recent report from AUTM's "Better World Project," which is available at: http://www.betterworldproject.net/.

Bayh-Dole Has Also Nurtured Start-Up Businesses and the U.S. Economy Nationwide

Bayh-Dole also encourages universities to actively license federally-funded inventions to small businesses whenever possible. This has stimulated general university interest in their local community and promoting new companies and industries. According to AUTM data, 628 new spin-off companies based on university technology were created in 2005 and 554 in 2006 with 5,725 originated since 1980. UC takes this responsibility seriously -- UC ranked second only to MIT in the number of licenses entered into with new startup companies during 2003-2005, as reported by the AUTM U.S. Licensing Survey (http://www.autm.net/surveys/dsp.Detail.cfm?pid=194).

UC is proud to have contributed to the vibrant California entrepreneurial economy and believes that research results, thoughtfully and carefully distributed to private companies through technology transfer, has been a crucial element of California's economic success. As of March 2007, UC's licensed technologies can be linked to approximately 300 existing startup companies that are developing technology ranging from medical compounds and devices to electronics to biotechnology to semiconductors/nanotechnology. (See Figure 1.)

Over the past 20 years, on average over 80 percent of companies founded based on a license to UC technologies are still in operation, either as stand-alone entities or through a merger and acquisition. (See Figure 2.) This observation is not unique to UC, but common among university based startups. These resilient university-based startup companies create long-term jobs and lead to sustainable regional economies.

An example at UC Riverside, Dr. David Bocian has been performing research in creating electrically-addressable molecular-scale features that can function as the circuit elements in microelectronic devices like logic chips, processor chips, and memory chips. The invention of molecular-scale circuit elements will create electronic devices of greater density and smaller size that today are beyond the physical limits of semiconductor technology. The technology will lead to significant advances in memory capability, playing a key role in new generations of electronic devices, both large and small. UC Riverside has licensed this technology to a start-up company that Dr. Bocian has co-founded.

In addition, many universities through their educational mission nurture an entrepreneurial environment that stimulates the formation of local start up companies. A number of universities have programs to educate technology managers on entrepreneurship, as well as cross disciplinary programs that pair up these programs with the business school and technology transfer office through business plan competitions. Federally-funded research thus affects not only science research but other aspects of academia as well.

This type of innovation ecosystem, in which the universities, inventors, entrepreneurs and investors interact, has the potential to reinvent local economies. By way of example, such an innovation ecosystem helped the San Diego economy transition to one of the nation's leading high tech and biotechnology centers after the downsizing of the U.S. military presence there. Originally started at UC San Diego, CONNECT, a non-profit organization that is globally recognized as a public benefit organization in the San Diego region, played a key role in nurturing an entrepreneurial environment that helped the region to flourish.

In my neighborhood, Riverside County in Inland Southern California has the second fastest growing population of any U.S. county, and the goal for the City of Riverside is to grow its technology industries. Working in concert with a group of local high technology CEOs, "The CEO Forum", UC Riverside is promoting the growth of these new industries, some of which stem from the start-up companies resulting from the inventions that have derived from the federally sponsored research on our campus. For the University this is the true value of its investment in technology transfer,

namely to facilitate and promote the success of these start ups - in partnership with the City and County of Riverside, and this devoted group of local high technology CEOs.

The types of relationships and the stimulation of the regional economy exemplified by San Diego and Riverside are replicated throughout the State of California and the nation with many other universities. University research and licensing programs touch various aspects of the economy and it is extremely important that universities continue to play an instrumental role in supporting and growing the economy, creating jobs, encouraging American ingenuity and entrepreneurship, and continuing basic research and making discoveries that are transferable to companies that are able to translate them into useful products.

Policies Surrounding University Licensing Have Evolved for the Public Benefit

As the field of university technology transfer has developed, so have solutions to the policy-based concerns that many of the critics of Bayh-Dole has raised. For example, a number of universities with well-developed technology transfer practices, including Stanford University, the University of Wisconsin and Cornell University, recently collaborated on a white paper setting forth their policy aspirations for university licensing. This document, "In the Public Interest: Nine Points To Consider In Licensing University Technology" (available at: http://www.autm.net/aboutTT/Points_to_Consider.pdf) sets forth certain basic principles that university technology transfer offices may wish to consider in their licensing arrangements to further the university missions of research, education, and public service. These include not only the promotion of academic research and the diligent development of inventions by licensees, but also goals such as increasing access to medical technology for developing countries.

The university community takes very seriously its responsibilities in ensuring that federally-funded inventions are developed for the public benefit, and has continued to demonstrate its commitment to these principles as the field has grown. We discuss some of these concerns below, and explain how the university community has acted to address the situation.

Technology Transfer Does Not Impede Scientific Research

Concern that licensing necessary scientific tools would pose a possible impediment to scientific research has been addressed by policies and guidelines set forth by the NIH with input from the university community, that encourage universities to share any ensuing inventions freely among academic institutions for research purposes. This approach has now evolved into common practice such that university-developed research tools are made widely available. Studies have shown that technology transfer has had little to no effect on the ability of scientists to conduct research and publish their research results in peer-reviewed publications.

Exclusive Licensing of Technology Can Promote Innovation, If Carefully Administered

Others voice concern that the exclusive licensing of university inventions stifles competition. In many industries, the best way to induce private industry to invest the substantial time and resources in developing an early-stage invention is to provide the company with an exclusive license to the patent covering the technology. Particularly in heavily-regulated fields such as biotechnology and pharma, companies are unable to justify the large amounts of money and resources required to obtain FDA approval for a new drug unless they can be guaranteed some period of exclusivity if the drug is allowed, in order to recoup their costs and to protect their investment from opportunistic rival companies who might otherwise jump into the market only after someone else made the sizable monetary investment to develop the drug.

Thus, it can be that in certain circumstances, an exclusive license represents the best chance that the university has to transform the results of its federally-funded research into a product with a very real benefit to the public. The university community is sensitive to the issues that exclusive licensing can raise and makes decisions on whether to offer an exclusive license on a case-by-case basis and in light of all the circumstances around the development of the technology as some industries operate under the nonexclusive licensing business model. In addition, universities build in many safeguards into these exclusive licenses to ensure that the licensee is working diligently to develop products as Bayh-Dole requires, and monitor these licenses closely.

University Technology Transfer Is Not Primarily Profit-Driven

Finally, many outside observers make the erroneous assumption that technology licensing is primarily an income producer for universities. While UC has been fortunate to reinvest into research and education some licensing revenues from its technology transfer activities, the majority of institutions do not. However, universities recognize that technology transfer serves an important public benefit, irrespective of its effects (either positive or negative) on the university's bottom line, and recognize it as a necessary service to enhance the value of federal funding for its research.

Licensing revenues that universities receive from royalties derived from licensing federally-funded technologies, after appropriate payment is made to the inventors and recovery of expenses, is reinvested into basic research and educational services, to ensure that further research and technological advancement can continue to occur. This reinvestment of these proceeds reflects an additional benefit to the original federal funding and is consistent with the statutory mandates of Bayh-Dole.

Bayh-Dole: Looking Forward

The benefits of the Bayh-Dole Act have been enormous not only for universities and the U.S. economy, but for the general public as a whole. And yet, activities conducted under this important piece of legislation are currently facing challenges that have the potential to severely limit its continued positive impact on the public benefit and the nation's economy. In the view of the University of California, any efforts that would undermine the effectiveness and proven success of the Bayh-Dole Act would not be in the public's best interest.

The current challenges come in two primary forms. The first involves increasing the burden or the cost for universities to engage in the technology transfer process. The second include actions that would reduce the incentives for industry to invest in developing a university's early stage technologies.

Increasing the Cost or Burdens of Protecting Inventions Will Harm University Technology Transfer

Because of financial constraints, universities do not have the resources to file patents on everything that is discovered by their researchers and must pick and choose the ones with the potential to be commercialized. Financial constraints are an important consideration for universities in fostering technology transfer and meeting the objectives of the Bayh-Dole Act. Any shifts in the current system could make it harder for universities to afford to engage financially in technology transfer efforts and would serve to undermine the Bayh-Dole Act's effectiveness.

UC is concerned for example, that some of the proposals being considered in the current debate over patent reform legislation could, if enacted in their current form, make it more difficult and more costly for universities and others engaged in technological advancements to continue to effectively make use of the patent system, as provided by the Bayh-Dole Act, and to ensure that advancements made in research laboratories reach the public. In addition, any rules promulgated by the U.S. Patent and Trademark Office that make it more burdensome and expensive for universities to obtain patents on their inventions, such as the new claims and continuation rules, would be detrimental to university technology transfer.

The uncertainty that these changes to the patent system will create for a university's patents has the potential to negatively impact private industry's interest in investing in the technology developed at universities. If it becomes more costly for universities to file and maintain patents, fewer patents will certainly be filed, resulting in fewer technologies that make it into the hands of the public. And if it becomes too risky for private industry to invest in patents because patent rights have become less certain under the law, the public's ability to reap the benefits of the initial federal investment in these inventions will be further curtailed.

If anything, it would be best to consider ways to further the success of the Bayh-Dole Act, and to reinforce the positive public benefit that has resulted, rather than limiting its application or success.

Any Reduction In Incentives For Industry To Partner with Universities Will Harm University Technology Transfer

As discussed above, the process of technology transfer, to be successful, must include sufficient incentive for a company to invest the time and resources necessary to engage in the risky process of developing a product for market. Any legislative or regulatory actions that increase a company's risk or uncertainty, will reduce their incentive to invest in an university's inherently early stage technology. Such action would certainly undermine the current success of the Bayh-Dole Act.

As an example, companies have expressed concern over the government's march-in rights. It was not clear how the government would exercise those rights, and there were companies that would not touch a federally funded invention, either through licensing or sponsored research. They were concerned that, after investing resources in commercial development of a technology, the government could step in and take it away. It was only years later, after it became clear that the government was not using its march-in right capriciously, that these companies were assured of an even-handed approach by the government for march-in rights and willing to take a chance on federally funded inventions.

Another impediment to industry participation in the technology transfer process is the imposition of pricing controls. When the NIH attempted to impose a reasonable pricing clause in its CRADAs in the mid-1990's, they noticed a chilling effect on their relations with industry as discussed in a July 2001 NIH report. Many companies viewed these terms as unacceptable and declined to collaborate with the NIH as a result as it is difficult to determine what is a reasonable price when early stage biomedical technologies are years and hundreds of millions of dollars from market launch and may be one innovation contributing to a new treatment. Ultimately, the NIH removed the reasonable pricing provision and since then has enjoyed a robust relationship with industry.

More currently, some of the changes that are being proposed to the patent system may serve to weaken patent protection, render it more difficult to enforce a patent if it is infringed, and reduce the certainty that the public currently has in a patent's validity. If patent protections are weakened, the incentives for industry to engage in technology transfer and for universities to participate in the patent system will likely be diminished, reducing the potential for public benefit that exists today.

Conclusion

The Bayh-Dole Act has shown itself to be a resounding success, benefiting the public through the availability of products and contributing to the U.S. economy. One of the beauties of the Bayh-Dole Act is that it lays a solid foundation for the success of technology transfer, including elements that ensure that the public interest is preserved, while at the same time providing recipients of federal funding with tremendous flexibility. Through this flexibility, we are able to address the unique needs of different industry sectors, we are able to adjust to the realities of small businesses and large companies, and we are able to adapt our practices to deal with emerging issues.

What is truly remarkable too is that these benefits have been realized and the Bayh-Dole Act has been administered without the necessity for Congress to appropriate any of the taxpayers' money for its operation. In other words, no separate appropriation of government funds was needed to establish or manage the effort. In fact, it has been estimated that the economic benefits flowing from the universities' licensing activities adds about $41 billion to the United States economy.

It has been the University of California's experience that the current patent system and the involvement of universities in the patent system has worked extremely well to foster innovation and has led to numerous discoveries that have been brought forward for the public benefit. The Bayh-Dole Act was indeed an inspired piece of legislation, and we hope that Congress will continue to nurture its success.

Thank you again for giving me the opportunity to testify. I look forward to answering any questions you may have.