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THE BAYH–DOLE ACT (P.L. 96–517, AMENDMENTS TO THE PATENT AND TRADEMARK ACT OF 1980)—THE NEXT 25 YEARS

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

JULY 17, 2007

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THE BAYH–DOLE ACT (P.L. 96–517, AMENDMENTS TO THE PATENT AND TRADEMARK ACT OF 1980)—THE NEXT 25 YEARS

TUESDAY, JULY 17, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 1:17 p.m., in Room 2318 of the Rayburn House Office Building, Hon. David Wu [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

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Subcommittee on Technology and Innovation

Hearing on:

The Bayh-Dole Act (P.L. 96-517, Amendments to the Patent and Trademark Act of 1980) – The Next 25 Years

2318 Rayburn House Office Building
Washington D.C.

July 17, 2007
1:00 p.m.

WITNESS LIST

Mr. Arundeep S. Pradhan
Director
Technology and Research Collaborations
Oregon Health & Science University

Dr. Susan B. Butts
Senior Director
External Science and Technology Programs
The Dow Chemical Company

Mr. Wayne C. Johnson
Vice President
Worldwide University Relations
Hewlett-Packard Company

Dr. Mark A. Lemley
Professor of Law, Stanford Law School
Director
Stanford Program in Law, Science, and Technology

Dr. Mark G. Allen
Professor, School of Electrical and Computing Engineering
Georgia Institute of Technology
Co-Founder & Chief Technology Officer
CarioMEMS, Inc.

HEARING CHARTER

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

The Bayh-Dole Act (P.L. 96–517, Amendments to the Patent and Trademark Act of 1980)— The Next 25 Years

TUESDAY, JULY 17, 2007
1:00 P.M.—3:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

1. Purpose

On Tuesday, July 17, the Subcommittee on Technology and Innovation of the Committee on Science and Technology will hold a general oversight hearing on P.L. 96–517, *Amendments to the Patent and Trademark Act of 1980,* commonly referred to as the Bayh-Dole Act. More than 25 years have passed since Bayh-Dole was enacted. The purpose of the hearing is to assess the current implementation of Bayh-Dole from the perspectives of universities and industry, and to hear recommendations that may be appropriate to improve the current implementation as we look toward the next 25 years.

2. Witnesses

Mr. Arundeep S. Pradhan is Director of Technology and Research Collaborations at Oregon Health & Science University.

Dr. Susan B. Butts is Senior Director of External Science and Technology Programs at The Dow Chemical Company.

Mr. Wayne C. Johnson is Vice President, Worldwide University Relations at Hewlett-Packard Company.

Dr. Mark A. Lemley is Professor of Law at Stanford Law School, and Director of the Stanford Program in Law, Science and Technology.

Dr. Mark G. Allen is Professor in the School of Electrical and Computing Engineering at Georgia Institute of Technology, and co-founder and Chief Technology Officer of CardioMEMS, Inc.

3. Hearing Issues

- **Impact of Bayh-Dole.** What has been the impact of the current implementation of Bayh-Dole on federally funded university research, and the technology transfer and commercialization of that research?
- **University-Industry Relations.** How has Bayh-Dole shaped university-industry research collaboration? Are there differences in interpretation of the statute and regulations by universities and industry? Are there differences in the impact across industry sectors, or for large and small businesses?
- **Impact of Globalization.** What is the possible effect of the increasing globalization of research? Are U.S. companies turning to foreign universities for research collaboration? How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries?
- **Impact on Universities and Innovation.** Has Bayh-Dole influenced basic university research, academic collaboration and the broad dissemination of knowledge? In what ways does the law promote innovation; has it created any barriers?

- **Legislation.** What changes in Bayh-Dole legislation, if any, may be appropriate as we look to the next 25 years, to promote innovation, commercialization of federally funded research, and U.S. economic development?

4. Background—Bayh-Dole Legislation

P.L. 96–517, *Amendments to the Patent and Trademark Act of 1980,* commonly referred to as Bayh-Dole, promoted the utilization of inventions arising from federally supported research and development. Bayh-Dole had other important policy objectives including (emphasis added):

- 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 U.S. by U.S. 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.

The legislation was motivated by a number of concerns in the 1970s. The U.S. lacked a uniform patent policy for federally funded research, and inventions from this research were not leading to commercial products and services. The Federal Government retained title to the inventions and licensed technology on a non-exclusive basis, providing insufficient incentive to make the sizable investment required to commercialize early stage, high-risk technologies.

Under Bayh-Dole, a uniform technology transfer policy was created along with new incentives for commercialization. Non-profit organizations, including universities, and small businesses, could take title to inventions based upon federally funded R&D, and license technology to companies with exclusive licenses.

The broader economic conditions were also important factor shaping Bayh-Dole. The U.S. economy was in a recession, productivity was declining, and the U.S. faced growing competition internationally from Germany and Japan. Promoting university based innovation and technology transfer to industry was seen as an important policy lever to counter these developments.

5. Hearing Issues

Impact of Bayh-Dole. The impact of Bayh-Dole can be measured in terms of technology innovation (patent disclosures and application), licenses granted, and new company spin-offs. It can also be measured in financial returns to the university to support further research and new jobs created in the region.

According to the most recent published survey for FY 2005[1] from the Association of University Technology Managers (AUTM) of their membership, 4,932 new licenses were signed in 2005 with 28,349 active licenses. 527 new products were introduced in 2005 from 151 organizations, and cumulatively 3,641 new products were introduced between FY98 through FY05. 628 new spinoff companies were created in 2005; 5,171 since 1980.

In 2005, technology transfer offices received 17,382 invention disclosures and filed 9,536 patent applications of which 69.9 percent were provisional applications which gave a one year opportunity to test company interest before filing a full utility application. Technology transfer offices licensed primarily to startups (12.7 percent), small companies (50.2 percent), and large companies (30.9 percent). 37 percent of total licenses and options reported in the survey were exclusive licenses.

However, the financial returns to universities from licensing or equity positions in spin-off companies are highly concentrated. Of 141 universities with licensing income in 1999 and 2000, 22 universities received almost 80 percent of the income and five universities received over 45 percent of the licensing income.[2] This pattern has resulted in some universities taking a broader view of the appropriate metrics of technology transfer activity to include regional economic development.

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[1] *AUTM U.S. Licensing Survey FY 2005.* This is a survey of technology licensing (and related) performance for U.S. Academic and Non-profit Institutions and Technology Investment firms.

[2] AUTM Technology Transfer Data for Two-Year Recurrent Respondents.

University-Industry Relations. Bayh-Dole has also shaped university-industry research collaboration in areas beyond direct licensing. Industry collaborates with universities across a wide spectrum of activities from the exchange of ideas and researchers to transactions involving intellectual property. There is a perception that Bayh-Dole has broadly influenced these activities.

Much of university licensing activity is focused on biotechnology where there is potentially larger financial return to the university, or at least the potential for some "big wins." In fact, the Biotechnology industry traces its explosive growth to three events in 1980: the Supreme Court decision in *Diamond v. Chakrabarty* (finding that Congress had intended patentable subject matter to "include anything under the sun that is made by man"), Bayh-Dole, and P.L. 96–480, the *Stevenson-Wydler Technology Innovation Act of 1980,* which covers technology transfer from federal laboratories.

Impact of Globalization. In the late 1970s, the U.S. faced increasing competition from Germany and Japan. Today, globalization is a much broader force with the increasing globalization of not only manufacturing and services, but research activities as well. U.S. companies are beginning to turn to foreign universities for research collaboration. This is in part driven by difference in business practices between U.S. and foreign universities and the opportunity for greater control of intellectual property. Agreements can be reached in days to weeks compared to what can be months and years in the U.S.

Impact on Universities and Innovation. There have been concerns raised about the impact of Bayh-Dole on the broad university research enterprise as well as the role of universities in the dissemination of knowledge. In particular, with Bayh-Dole's focus on "downstream" commercialization of research, there is concern that there is a negative impact on collaboration and innovation "upstream" in basic research.[3]

Recently, several universities and the Association of American Medical Colleges (AAMC) released a white paper, "In the Public Interest: Nine Points to Consider in Licensing University Technology."[4] The paper captures shared perspectives of the participating university research officers and licensing directors on policy issues related to university technology transfer, in particular, when universities license technologies "in the public interest and for society's benefit." The paper identified nine points and provided example licensing clauses to address each point. The nine points included:

- Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so.
- Exclusive licenses should be structured in a manner that encourages technology development and use.
- Strive to minimize the licensing of "future improvements."
- Ensure broad access to research tools.
- Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.

Legislation. What changes in Bayh-Dole legislation or regulations, if any, may be appropriate to address these issues as we look to the next 25 years, to promote innovation, commercialization of federally funded research, and U.S. economic development? The issues may be directly tied to the Bayh-Dole statute or a matter of implementation of the law.

The issues raised include addressing incentives that discourage scientific sharing of information, protecting access to research tools, and the role government should play in pricing to increase humanitarian access to products and services such as therapeutic drugs.[5]

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[3] Arti K. Rai and Rebecca Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *Law and Contemporary Problems 69, p. 289, 2003.*

[4] "In the Public Interest: Nine Points to Consider in University Licensing," March 6, 2007. *newsservice.stanford.edu/news/2007/march7/gifs/whitepaper.pdf*

[5] Sara Boettiger and Alan B. Bennett, "Bayh-Dole: if we knew then what we know now," *Nature Biotechnology,* March 2006 and Wendy H. Schacht, CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology,* December 8, 2006;

Chairman WU. Welcome everyone, to this afternoon's general hearing on Bayh-Dole legislation and its effect on our economic competitiveness and our university enterprise.

It has been a quarter century since Bayh-Dole was enacted. It is time to assess the impact of that legislation, and whether we can improve technology transfer from the federal investment in research. I want to mention that this will be only the first of several hearings on technology transfer. At this point in time, it is my intention to hold further subcommittee hearings on Stevenson-Wydler legislation.

It took a good while, perhaps close to 20 years, to achieve passage of the Bayh-Dole legislation. The House Committee on Science and Technology held hearings in 1979 and 1980 on the original legislation, and this committee has been a very strong supporter of improving technology transfer.

The broad economic conditions during the time of passage of Bayh-Dole were a factor in shaping it. The U.S. economy was in a deep recession. Productivity was declining, and our country faced growing competition internationally from both Germany and Japan and certain other countries. At that point in time, I was beginning to practice law in Silicon Valley, and quite frankly, there were folks who said that Silicon Valley was going to die, and that we just weren't going to compete in high tech any more. And there are others, policy-makers in Washington, D.C., who said potato chips, silicon chips, it hardly matters which one it is, because it is just all about money. And that is not true.

Now, promoting university-based research and its subsequent technology transfer to industry, was seen at that time, and continues to be seen as a very, very important policy tool to counter international competition, and to stimulate, irregardless of international competition, domestic, economic, and job growth.

The purpose of this hearing is to assess the current implementation of Bayh-Dole from the perspectives of universities and industry, and to hear recommendations to improve the implementation of Bayh-Dole, as we look forward to the next quarter century.

A few key questions that we will consider. What has been the impact of the current implementation of Bayh-Dole on federally funded university research, technology transfer, and the commercialization of that research? How has Bayh-Dole shaped university-industry research collaboration? Are there differences in interpretation of the statute and regulations by universities, industry, and others? What is the possible effect of the increasing globalization of the research enterprise? Are U.S. companies turning to foreign universities for research collaboration? Are foreign companies turning to U.S. universities to the same extent? How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries? Has Bayh-Dole influenced basic university research, academic collaboration, and the broad dissemination of knowledge? In what way does the law promote innovation? Has it created any barriers? Finally, how can we improve technology transfer as we look forward to the next 25 years, to promote innovation and commercialization of federally funded research, and promote U.S. economic development?

All of these questions are on the table today, and in our subsequent hearings, we look forward to hearing the thoughts of our witnesses, and also of the comments and questions from our fellow members of this subcommittee.

And now, I would like to recognize my colleague and good friend, the ranking member from Georgia, Dr. Gingrey, for his opening remarks.

[Statement of Mr. Wu follows:]

PREPARED STATEMENT OF CHAIRMAN DAVID WU

I want to welcome everyone to this afternoon's general hearing on Bayh-Dole. More than 25 years have passed since Bayh-Dole was enacted. It is time to assess the impact of Bayh-Dole and how we can improve technology transfer from Federal investment in R&D. I want to mention that this will be our first hearing on technology transfer issues. The Subcommittee will hold a subsequent hearing on Stevenson-Wydler.

It took almost 20 years to achieve passage of the Bayh-Dole Act. Indeed the House Committee on Science and Technology, held hearings in 1979 and 1980 on the original legislation. This committee has been a strong supporter of improving technology transfer.

Broad economic conditions were a factor shaping Bayh-Dole. The U.S. economy was in a recession, productivity was declining, and the U.S. faced growing competition internationally from Germany and Japan. Promoting university based innovation and technology transfer to industry was seen as an important policy lever to counter these developments. And it still is today as we face greater global competition—which now includes R&D.

The purpose of this hearing is to assess the current implementation of Bayh-Dole from the perspectives of universities and industry, and to hear recommendations to improve the current implementation as we look toward the next 25 years.

A few key questions we will consider today:

- What has been the impact of the current implementation of Bayh-Dole on federally funded university research, technology transfer and commercialization of that research?
- How has Bayh-Dole shaped university-industry research collaboration? Are there differences in interpretation of the statute and regulations by universities and industry?
- What is the possible effect of the increasing globalization of research? Are U.S. companies turning to foreign universities for research collaboration? How do the intellectual property and business practices at U.S. universities compare to universities in other developed and developing countries?
- Has Bayh-Dole influenced basic university research, academic collaboration and the broad dissemination of knowledge? In what ways does the law promote innovation; has it created any barriers?

And finally,

- How can we improve technology transfer as we look to the next 25 years, to promote innovation, commercialization of federally funded research, and U.S. economic development?

All these questions are on the table today for comment and discussion by our witnesses and we look forward to hearing your thoughts.

Now, I would like to recognize my colleague and the ranking member from Georgia, Dr. Gingrey, for his opening remarks.

Mr. GINGREY. Good afternoon, Mr. Chairman, and certainly, I appreciate your holding this hearing on the Bayh-Dole Act.

And certainly, as you point out, it is a timely issue. We have just celebrated the Act's 25 years of existence. I agree with you, Mr. Chairman, the time is indeed right to look at the program, and see where we can improve it, and ensure that the next 25 years are just as successful as have been the past 25 years.

In *The Economist,* and this is a quote: The Bayh-Dole Act is "probably the most inspired piece of legislation to be enacted in

America over the past half-century." I don't think that is an embellishment, when we think about the remarks that you just heard from the Chairman, in regard to the global economy, and what our concerns might be as we go forward.

The Bayh-Dole Act was passed in an era of deep concern that the United States was indeed losing that competitive edge to some of these foreign countries, certainly, India and China, to name two big ones. Its impact in reversing that trend has been phenomenal. In fact, Bayh-Dole has been the most successful technology transfer program ever implemented. Prior to Bayh-Dole, only five percent of government-owned patents were ever used in the private sector. Let me repeat that. Only five percent of government-owned patents were ever used in the private sector.

Since the passage of this landmark legislation, there has been a tenfold increase in academic patents. It is often said that the clearest form of flattery is imitation. Well, countries all over the world are indeed copying Bayh-Dole, from the Europeans to the governments of Japan and India, and I am sure China as well. As we are now combating the often negative effects of globalization, perhaps there is no better time, Mr. Chairman, to see if there are any improvements that we can make in this law.

Some of the principal players in this program, businesses do say that it has become increasingly difficult to come to an agreement with universities. I hope we will be able to find out in this hearing what is the problem. And so, instead, some businesses say they are increasingly making the sort of cooperative agreements that Bayh-Dole is supposed to facilitate in this country, but they are making them with foreign universities, not American universities. It is sort of a globalization of research, if you will.

So, we need to ensure that Bayh-Dole meets the 21st Century needs of both business and universities, in order to ensure that the United States' competitiveness is first and foremost; because we are, ladies and gentlemen, in an economic war. Make no mistake about that. The Economist went further, and said, and I quote: "A dollar's worth of academic invention or discovery requires upwards of $10,000 of private capital to bring it to market." So, clearly, there is a need to marry private enterprise with university research, as Bayh-Dole intended, when it was originally passed 25 years ago.

Mr. Chairman, I indeed, as a graduate of the Georgia Institute of Technology, would like to plug my alma mater at every shameless opportunity, I appreciate your holding this hearing on such an important topic, and I do look forward to hearing from all of our witnesses, not just the one from Georgia Tech.

[The prepared statement of Mr. Gingrey follows:]

PREPARED STATEMENT OF REPRESENTATIVE PHIL GINGREY

Good Afternoon Mr. Chairman. I appreciate you holding this hearing on the Bayh-Dole Act. It's a timely issue, as we have just celebrated the Act's first 25 years in existence. I agree with you, Mr. Chairman, that the time is indeed right to look at the program and see where it can be improved to ensure that its next 25 years are as successful as its first 25 years.

According to *The Economist,* "the Bayh-Dole Act is [p]robably the most inspired piece of legislation to be enacted in America over the past half-century." The Bayh-Dole Act was passed in an era of deep concern that the U.S. was losing its competi-

tive edge to foreign countries. Its impact in reversing that trend has been phenomenal.

In fact, Bayh-Dole has been the most successful technology transfer program ever implemented. Prior to Bayh-Dole, only five percent of government owned patents were ever used in the private sector. Since passage of this landmark legislation, however, there has been a tenfold increase in academic patents.

It is often said that the clearest form of flattery is imitation. Well, countries all over the world are copying the Bayh-Dole Act—from the Europeans to the governments of Japan and India.

As we are now combating the often negative effects of globalization, perhaps there is no better time to see if there are any improvements to be made to the Bayh-Dole law.

Some of the principal players in this program—businesses—do say that it has become increasingly difficult to come to agreement with universities. Instead, some businesses say that they are increasingly making the sort of cooperative agreements that Bayh-Dole is supposed to facilitate, but they are making them with *foreign* universities—a sort of globalization of research. We need to ensure that Bayh-Dole meets the 21S' Century needs of both businesses and universities, in order ensure that U.S. competitiveness is first and foremost.

Further, according to *The Economist,* "A dollar's worth of academic invention or discovery requires upwards of ten thousand dollars of private capital to bring [it] to market." Clearly there is a need to marry private enterprise with university research, as Bayh-Dole intended.

Mr. Chairman, I appreciate your holding this hearing on such an in important topic. and I look forward to hearing from all of the witnesses. Thank you.

Chairman WU. Well, Dr. Gingrey, I think that Georgia Tech always has a better football team than Oregon Health and Science University.

If there are Members who wish to submit opening statements, your statements will be added to the record.

[The prepared statement of Mr. Mitchell follows:]

PREPARED STATEMENT OF REPRESENTATIVE HARRY E. MITCHELL

Thank you, Mr. Chairman.

Throughout the twentieth century, the United States led the world in university-driven research and development.

This research inspired much of the innovation upon which we have come to rely. From the Internet boom to countless medical breakthroughs, university research has benefited us all.

There is no doubt that our world class university system with federal support, such as the Bayh-Dole Act, is one of the reasons our nation has enjoyed the technological success that it has.

This law enabled the spread of government funded research from the world of ideas into the world of application. The patent transfer policy enabled businesses to focus on production, while the government took on the risk associated with uncertain research projects.

Since enactment, Bayh-Dole related development has created over a quarter of a million jobs and added $40 billion annually to our economy. In my district, Bayh-Dole has benefited Arizona State University.

The advancement of communications technology and global trade agreements has led to the inevitable re-examination of university, government, and business research partnerships.

As we consider the next twenty-five years of this legislation, the growing global market cannot be too far from our consideration.

We must strive to maintain the high intellectual standards of our top universities, and ensure that their research makes it into real-world applications through strategic business and government partnerships.

I am looking forward to hearing from our witnesses to see how we can accomplish these complementary goals.

I yield back the balance of my time.

Chairman WU. As our witnesses are well aware, your time is limited to five minutes. Please feel free to summarize your written testimony, and now, let me introduce the witnesses.

Mr. Arun Pradhan, who is the Director of Technology and Research Collaborations at Oregon Health and Science University. We continue to have aspirations for your football team in the future.

Dr. Susan Butts is Senior Director of External Science and Technology Programs at the Dow Chemical Company.

Mr. Wayne Johnson is Vice President, Worldwide University Relations, at Hewlett-Packard Company.

Mr. Mark Lemley is Professor of Law at Stanford Law School, and let me warn you, Dr. Lemley, that you have the job that I want. And Professor Lemley is Director of the Stanford Program in Law, Science, and Technology.

And Dr. Mark Allen, Professor at a great institution in Georgia, in the School of Electrical and Computing Engineering at Georgia Institute of Technology, and Co-Founder and Chief Technology Officer of CardioMEMS.

We will begin testimony with you, Arun.

STATEMENT OF MR. ARUNDEEP 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

Mr. PRADHAN. Mr. Chairman, Ranking Member Gingrey, and honorable Members of the Subcommittee, thank you for this opportunity to testify before you today on the important topic of the Bayh-Dole Act. In addition to my role as Director for Technology and Research Collaborations at Oregon Health & Science University, I am also on the Board of Trustees for the Association for University Technology Managers, or AUTM.

I have been asked to provide my opinion, as well as express the views of the AUTM Board, on various topics related to the Bayh-Dole Act, and how it relates to academic technology transfer. These views are a result of my 19 years of experience in this industry, covering three institutions in Utah, Colorado, and now, Oregon. We believe that the Bayh-Dole has been instrumental in accelerating innovation in the United States, and hopefully, will continue to be a key factor in driving U.S. innovation policy for the next 25 years.

As Ranking Member Gingrey stated, The Economist called the Bayh-Dole Act one of the most possibly inspired pieces of legislation to be enacted in America, that unlocked inventions and discoveries throughout the United States. The Bayh-Dole Act is as viable today as it was when conceived and passed, and I believe that we are only seeing the proverbial tip of the iceberg. The impacts of Bayh-Dole are diverse, such as the 5,000 companies that are based on university research, the 1.25 products per day that have been introduced as a result of that over the last 10 years, the 260,000 jobs that have been created, and the addition of over $40 billion annually to the U.S. economy. The Biotechnology Industry Organization, or BIO, has identified over 350 drugs based on federally funded research that are either available now, or are currently in clinical trials.

Another impact of Bayh-Dole, according to the former President of the NASDAQ, is that approximately 30 percent of its value is rooted in university-based federally funded research, which might

never have been realized but for Bayh-Dole. State investment in innovation has also been a key, although unanticipated outcome of the Bayh-Dole Act. Just since 2005, 19 states have begun initiatives targeted to innovation, representing approximately $4 billion in the next 10 years.

A key similarity to a number of these initiatives is the role of universities as drivers of regional economic development. In Oregon, for example, several such programs are coordinated through the Oregon Innovation Council. Signature research centers in the field of nanotechnology, bio-economy, and sustainable technologies, and drug development and translational research, funding of programs to foster university-industry partnerships in seafood, manufacturing, and food technologies, and the creation of university venture development funds through Oregon tax credits, all come together in Oregon's investment into resources that foster innovation and development.

With respect to university-industry interactions, it is an issue of competing cultures and drivers, trying to create partnerships for societal and mutual benefit. These differences are most often highlighted in negotiations regarding the right to publish and intellectual property. These issues do not arise directly from Bayh-Dole, but from the fundamentally different roles that universities and industry play in society.

Any partnership based on economic incentives needs to be fair to both parties in order to succeed. It is therefore incumbent on both parties to recognize the synergies and differences, as well as federal and State regulations and policies that play a role to arrive at mutually beneficial partnerships. The Bayh-Dole Act is one such example.

The Bayh-Dole Act fundamentally provides a simple structure that works as intended, and should not be substantially altered. Further, the Bayh-Dole Act offers great opportunity to ensure that technology can be appropriately packaged and commercialized. As you yourself suggested, one dollar of academic research requires $10,000 of development to make it into a product. The *Nine Points to Consider* document that is being promoted by a number of organizations in AUTM, for example, begins to provide consistency to the implementation of Bayh-Dole to arrive at these objectives.

If anything, Bayh-Dole needs to be strengthened, starting with a comprehensive look at programs and initiatives being implemented, successful technology transfer programs, local and regional factors that contribute to the success of commercializing federally funded research. One such example would be to provide effective oversight, which would be able to address the implementation of Bayh-Dole across federal agencies.

In summation, I would like to emphasize that technology transfer at universities, as it exists today, is a complex process that has multiple roles, ranging from being good stewards of public resources to participants in economic development. These roles are, in turn, defined by local, regional, and national needs and regulations.

It is critical that the U.S. preserve Bayh-Dole and its fundamental elements, and continue to support funding of basic re-

search, so that our country can maintain its leading edge in innovation in this increasingly competitive global environment.

Thank you.

[The prepared statement of Mr. Pradhan follows:]

PREPARED STATEMENT OF ARUNDEEP S. PRADHAN

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 Arundeep 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, pharmaceutics, 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 that five percent 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 worlds [11]. 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 interdisciplinary 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 activities [4]. 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 research [2]. 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 stock market, an estimated 30 percent 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 day [2]. 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 decade [2]. 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 participants [3]. 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 partnerships [5]. 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 U.S. 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 accord 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 minuscule compared to the size of that uni-

versity'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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Jon Soderstrom, Managing Director, Office of Cooperative Research, Yale University; President-Elect 2007, AUTM

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Attachment:

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

Licensing approaches, even for comparable technologies, can vary considerably from case to case and from institution to institution based on circumstances particular to each specific invention, business opportunity, licensee and university. In spite of this uniqueness, universities share certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements.

In the summer of 2006, Stanford University's then Dean of Research Arthur Bienenstock convened a small meeting of research officers, licensing directors and a representative from the Association of American Medical Colleges to brainstorm about important societal, policy, legislative and other issues in university technology transfer. Representatives of the participating institutions, listed below, have tried to capture in this document certain shared perspectives that emerged from that meeting. Recognizing that each license is subject to unique influences that render 'cookie-cutter' solutions insufficient, it is our aim in releasing this paper to encourage our colleagues in the academic technology transfer profession to analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated herein when crafting agreements with industry. We recognize that many of these points are already being practiced. In the end, we hope to foster thoughtful approaches and encourage creative solutions to complex problems that may arise when universities license technologies in the public interest and for society's benefit.

California Institute of Technology
Cornell University
Harvard University
Massachusetts Institute of Technology
Stanford University
University of California
University of Illinois, Chicago
University of Illinois, Urbana-Champaign
University of Washington
Wisconsin Alumni Research Foundation
Yale University
and
Association of American Medical Colleges (AAMC)

Point 1
Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so

In the spirit of preserving the ability of all universities to perform research, ensuring that researchers are able to publish the results of their research in dissertations and peer-reviewed journals and that other scholars are able to verify published results without concern for patents, universities should consider reserving rights in all fields of use, even if the invention is licensed exclusively to a commercial entity, for themselves and other non-profit and governmental organizations:

- to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities; and

- to transfer tangible research materials (e.g., biological materials and chemical compounds) and intangible materials (e.g., computer software, databases and know-how) to others in the non-profit and governmental sectors.

Clear articulation of the scope of reserved rights is critical. Recent examples of such "retained rights" clauses are included in the Appendix for reference.

Point 2
Exclusive licenses should be structured in a manner that encourages technology development and use

When significant investment of time and resources in a technology are needed in order to achieve its broad implementation, an exclusive license often is necessary and appropriate. However, it is important that technology transfer offices be aware of the potential impact that the exclusive license might have on further research, unanticipated uses, future commercialization efforts and markets. Universities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology.

Special consideration should be given to the impact of an exclusive license on uses of a technology that may not be appreciated at the time of initial licensing. A license grant that encompasses all fields of use for the life of the licensed patent(s) may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is particularly troublesome if the licensee is not able or willing to develop the technology in fields outside of its core business. Universities are encouraged to use approaches that balance a licensee's legitimate commercial needs against the university's goal (based on its educational and charitable mission and the public interest) of ensuring broad practical application of the fruits of its research programs. There are many alternatives to strict exclusive licensing, several of which are described in the Appendix.

In situations where an exclusive license is warranted, it is important that licensees commit to diligently develop the technology to protect against a licensee that is unable or unwilling to move an innovation forward. In long-term exclusive licenses, diligent development should be well-defined and regularly monitored during the exclusive term of the agreement and should promote the development and broad dissemination of the licensed technology. Ideally, objective, time-limited performance milestones are set, with termination or non-exclusivity (subject to limited, but reasonable, cure provisions) as the penalty for breach of the diligence obligation. Examples of diligence requirements (also known as performance milestones) are described in the Appendix.

Another means of ensuring diligent development, often used in conjunction with milestones, is to require exclusive licensees to grant sublicenses to third parties to address unmet market or public health needs ("mandatory sublicensing") and/or to diligently commercialize new applications of the licensed rights. Such a requirement could also be implemented through a reserved right of the licensor to grant direct licenses within the scope of the exclusive grant to third parties based on unmet need. In such situations, it is important to ensure that the parties have a common understanding of what constitutes a new application or unmet need for the purpose of implementing such a provision. An example of mandatory sublicensing language is provided in the Appendix.

Absent the need for a significant investment - such as to optimize a technology for wide use - broad, non-exclusive licensing of tools such as genomic and proteomic inventions can help maximize the benefits derived from those technologies, in part by removing obstacles to further innovation. Unlike most research tools or manufacturing methods, diagnostic tests often must go through the regulatory approval process, and so may warrant exclusive licensing when the costs of test development, approval or diffusion require substantial investment of capital. Nevertheless, licensing of diagnostic tests based on broadly applicable genomics or proteomics methods should strive to preserve sufficient flexibility to permit testing for multiple indications (i.e., not an exclusive licensee's single disease of interest) perhaps through multiple field-restricted or non-exclusive licenses. Exclusive licensing of a single gene for a diagnostic may be counterproductive in a multi-gene pathology where only a panel of genes can yield an adequate diagnosis, unless the licensee has access to the other genes of the panel. Such licenses can also be limited in other ways. For example, a university might license a genomics method exclusively for a company to optimize and sell licensed products for diagnostic use. The drafting of the exclusive grant could make it clear that the license is exclusive for the sale, <u>but not use</u>, of such products; in doing so, the university ensures that it is free to license non-exclusively to others the right (or may simply not assert its rights) to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in-house for their own use.

In general, when no alternative testing strategy is available for a given indication, consideration should be given to means of ensuring reasonable access for patients and shielding individual healthcare providers from the risk of suit for patent infringement. As with any medical technology, licenses should not hinder clinical research, professional

education and training, use by public health authorities, independent validation of test results or quality verification and/or control.

Point 3
Strive to minimize the licensing of "future improvements"

Although licensees often seek guaranteed access to future improvements on licensed inventions, the obligation of such future inventions may effectively enslave a faculty member's research program to the company, thereby exerting a chilling effect on their ability to receive corporate and other research funding and to engage in productive collaborations with scientists employed by companies other than the licensee – perhaps even to collaborate with other academic scientists. In particular, if such future rights reach to inventions made elsewhere in the university, researchers who did not benefit from the licensing of the original invention may have their opportunities restricted as well, and may be disadvantaged economically relative to the original inventors if the licensing office has pre-committed their inventions to a licensee.

For these reasons, exclusive licensees should not automatically receive rights to "improvement" or "follow-on" inventions. Instead, as a matter of course, licensed rights should be limited to existing patent applications and patents, and only to those claims in any continuing patent applications that are (i) fully supported by information in an identified, existing patent application or patent and (ii) entitled to the priority date of that application or patent.

In the rare case where a licensee is granted rights to improvement patents, it is critical to limit the scope of the grant so that it does not impact uninvolved researchers and does not extend indefinitely into the future. It is important to further restrict the grant of improvements to inventions that are owned and controlled by the licensor institution - i.e., (i) not made by the inventor at another institution, should they move on or (ii) co-owned with, or controlled by, another party. One refinement to this strategy would be to limit the license to inventions that are dominated by the original licensed patents, as these could not be meaningfully licensed to a third party, at least within the first licensee's exclusive field. As was discussed earlier, appropriate field restrictions enable the licensing not only of the background technology, but also of improvements, to third parties for use outside the initial licensee's core business. In all cases, a license to improvements should be subject to appropriate diligent development requirements.

It should be recognized, however, that not all "improvements" have commercial potential (for example, they may not confer sufficient additional benefit over the existing technology to merit the expense of the development of new or modified products), in which case a licensee might not wish to develop them. In general, it may be best simply not to patent such improvements.

Point 4
Universities should anticipate and help to manage technology transfer related conflicts of interest

Technology transfer offices should be particularly conscious and sensitive about their roles in the identification, review and management of conflicts of interest, both at the investigator and institutional levels. Licensing to a start-up founded by faculty, student or other university inventors raises the potential for conflicts of interest; these conflicts should be properly reviewed and managed by academic and administrative officers and committees outside of the technology transfer office. A technology licensing professional ideally works in an open and collegial manner with those directly responsible for oversight of conflicts of interest so as to ensure that potential conflicts arising from licensing arrangements are reviewed and managed in a way that reflects well on their university and its community. Ideally, the university has an administrative channel and reporting point whereby potential conflicts can be non-punitively reported and discussed, and through which consistent decisions are made in a timely manner.

Point 5
Ensure broad access to research tools

Consistent with the NIH Guidelines on Research Tools, principles set forth by various charitable foundations that sponsor academic research programs and by the mission of the typical university to advance scientific research, universities are expected to make research tools as broadly available as possible. Such an approach is in keeping with the policies of numerous peer-reviewed scientific journals, on which the scientific enterprise depends as much as it does on the receipt of funding: in order to publish research results, scientists must agree to make unique resources (e.g., novel antibodies, cell lines, animal models, chemical compounds) available to others for verification of their published data and conclusions.

Through a blend of field-exclusive and non-exclusive licenses, research tools may be licensed appropriately, depending on the resources needed to develop each particular invention, the licensee's needs and the public good. As suggested with respect to genomics and proteomics method patents in Point 2 above, a university might license a research reagent, kit or device exclusively to a company to optimize and sell licensed products and services for research, diagnostic or other end uses. The drafting of such an exclusive grant should make clear that the license is exclusive for the sale, <u>but not use</u>, of such products and services; in doing so, the university ensures that it is free to license non-exclusively to others the right to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in-house for their own use.

Point 6
Enforcement action should be carefully considered

In considering enforcement of their intellectual property, it is important that universities be mindful of their primary mission to use patents to promote technology development for the benefit of society. All efforts should be made to reach a resolution that benefits both sides and promotes the continuing expansion and adoption of new technologies. Litigation is seldom the preferred option for resolving disputes.

However, after serious consideration, if a university still decides to initiate an infringement lawsuit, it should be with a clear, mission-oriented rationale for doing so-one that can be clearly articulated both to its internal constituencies and to the public. Ideally, the university's decision to litigate is based on factors that closely track the reasons for which universities obtain and license patents in the first place, as set out elsewhere in this paper. Examples might include:

- Contractual or ethical obligation to protect the rights of existing licensees to enjoy the benefits conferred by their licenses; and

- Blatant disregard on the part of the infringer for the university's legitimate rights in availing itself of patent protection, as evidenced by refusal on the part of the infringer to negotiate with or otherwise entertain a reasonable offer of license terms.

Under all circumstances, it reflects poorly on universities to be involved in "nuisance suits." Exclusive licensees should be encouraged to approach patent enforcement in a manner that is consistent with the philosophy described in this Point 6.

Point 7
Be mindful of export regulations

University technology transfer offices should have a heightened sensitivity about export laws and regulations and how these bodies of law could affect university licensing practices. Licensing "proprietary information" or "confidential information" can affect the "fundamental research exclusion" (enunciated by the various export regulations) enjoyed by most university research, so the use of appropriate language is particularly important. Diligence in ensuring that technology license transactions comply with federal export control laws helps to safeguard the continued ability of technology transfer offices to serve the public interest.

Point 8
Be mindful of the implications of working with patent aggregators

As is true of patents generally, the majority of university-owned patents are unlicensed. With increasing frequency, university technology transfer offices are approached by parties who wish to acquire rights in such 'overstock' in order to commercialize it through further licenses. These patent aggregators typically work under one of two models: the 'added value' model and the so-called 'patent troll' model.

Under the added value model, the primary licensee assembles a portfolio of patents related to a particular technology. In doing so, they are able to offer secondary licensees a complete package that affords them freedom to operate under patents perhaps obtained from multiple sources. As universities do not normally have the resources to identify and in-license relevant patents of importance, they cannot offer others all of the rights that may control practice (and, consequently, commercialization) of university inventions. By consolidating rights in patents that cover foundational technologies and later improvements, patent aggregators serve an important translational function in the successful development of new technologies and so exert a positive force toward commercialization. For example, aggregation of patents by venture capital groups regularly results in the establishment of corporate entities that focus on the development of new technologies, including those that arise from university research programs. To ensure that the potential benefits of patent aggregation actually are realized, however, license agreements, both primary and secondary, should contain terms (for example, time-limited diligence requirements) that are consistent with the university's overarching goal of delivering useful products to the public.

In contrast to patent aggregators who add value through technology-appropriate bundling of intellectual property rights, there are also aggregators (the 'patent trolls') who acquire rights that cut broadly across one or more technological fields with no real intention of commercializing the technologies. In the extreme case, this kind of aggregator approaches companies with a large bundle of patent rights with the expectation that they license the entire package on the theory that any company that operates in the relevant field(s) must be infringing at least one of the hundreds, or even thousands, of included patents. Daunted by the prospect of committing the human and financial resources needed to perform due diligence sufficient to establish their freedom to operate under each of the bundled patents, many companies in this situation will conclude that they must pay for a license that they may not need. Unlike the original patent owner, who has created the technology and so is reasonably entitled to some economic benefit in recognition for its innovative contribution, the commercial licensee who advances the technology prior to sublicensing, or the added value aggregator who helps overcome legal barriers to product development, the kind of aggregator described in this paragraph typically extracts payments in the absence of any enhancement to the licensed

technology.[1] Without delving more deeply into the very real issues of patent misuse and bad-faith dealing by such aggregators, suffice it to say that universities would better serve the public interest by ensuring appropriate use of their technology by requiring their licensees to operate under a business model that encourages commercialization and does not rely primarily on threats of infringement litigation to generate revenue.

Point 9
Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world

Universities have a social compact with society. As educational and research institutions, it is our responsibility to generate and transmit knowledge, both to our students and the wider society. We have a specific and central role in helping to advance knowledge in many fields and to manage the deployment of resulting innovations for the public benefit. In no field is the importance of doing so clearer than it is in medicine.

Around the world millions of people are suffering and dying from preventable or curable diseases. The failure to prevent or treat disease has many causes. We have a responsibility to try to alleviate it, including finding a way to share the fruits of what we learn globally, at sustainable and affordable prices, for the benefit of the world's poor. There is an increased awareness that responsible licensing includes consideration of the needs of people in developing countries and members of other underserved populations.

The details involved in any agreement provisions attempting to address this issue are complex and will require expert planning and careful negotiation. The application will vary in different contexts. The principle, however, is simple. Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations.

We recognize that licensing initiatives cannot solve the problem by themselves. Licensing techniques alone, without significant added funding, can, at most, enhance access to medicines for which there is demand in wealthier countries. Diseases that afflict only the global poor have long suffered from lack of investment in research and development: the prospects of profit do not exist to draw commercial development, and public funding for diseases suffered by those who live far away from nations that can afford it is difficult to obtain and sustain. Through thoughtful management and licensing of intellectual property, however, drugs, therapies, and agricultural technologies developed at universities can at least help to alleviate suffering from disease or hunger in historically marginalized population groups.

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[1] A somewhat related issue is that of technology 'flipping', wherein a non-aggregator licensee of a university patent engages in sublicensing without having first advanced the technology, thereby increasing product development costs, potentially jeopardizing eventual product release and availability. This problem can be addressed most effectively by building positive incentives into the license agreement for the licensee to advance the licensed technology itself – e.g., design instrumentation, perform hit-to-lead optimization, file an IND. Such an incentive might be to decrease the percentage of sublicense revenues due to the university as the licensee meets specific milestones.

Summary

As often is the case, guidance as to implementation of practices that will advance the mission of university technology transfer lags behind our collective awareness of both the needs that exist and our obligations to foster an environment in which they can effectively be met. While we may generally agree on the commonality of the above challenges, a multiplicity of approaches are possible to address the dual goals of nurturing future research and using the innovations of university research to provide the broadest possible benefit to the public. The participating universities put forth these considerations in an aspirational sense and we encourage all of our colleagues to stretch the boundaries of conventional technology transfer practice and share with the greater technology transfer community the insights that they gain in doing so.

APPENDIX

1. Commentary and examples of reserved or retained rights clauses and annotations as discussed in Point 1

Example 1

"Institution retains the right, on behalf of itself and all other non-profit academic research institutions, to practice the Licensed Patent and use Technology for any non-profit purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Institution and any such other institution have the right to publish any information included in the Technology or a Licensed Patent."

Example 2

"Nothing in this Agreement will be deemed to limit the right of the Institution to publish any and all technical data resulting from any research performed by the Institution relating to the Invention and to make and use the Invention, Licensed Product, and Licensed Services and to practice the Licensed Method and associated technology and allow other educational and non-profit institutions to do so for educational and research purposes."

Example 3

"INSTITUTION reserves the rights, for itself and others, to

(i) make and use, solely for NON-COMMERCIAL RESEARCH PURPOSES, the subject matter described and claimed in PATENT RIGHTS and covered by PROPERTY RIGHTS; and

(ii) provide to others the BIOLOGICAL MATERIALS;

each solely for NON-COMMERCIAL RESEARCH PURPOSES.

As used herein, the term "NON-COMMERCIAL RESEARCH PURPOSES" means: Use of PATENT RIGHTS for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use PATENT RIGHTS in

the production or manufacture of products for sale or the performance of services for a fee."

Definitions of non-commercial uses should be considered in light of John M.J. Madey v. Duke University. 307 F.3d 1351; 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002), *cert. denied,* 123 S. Ct. 2639; 156 L. Ed. 2d 656; 71 U.S.L.W. 3799. In Madey, the Court of Appeals of the Federal Circuit narrowly interpreted the so-called "experimental use" exception to patent infringement, such that use of patented technologies in the course of "business" activities of universities and other not-for-profit organizations (which activities include education of students, making application for grant funding and patenting of inventions) falls outside its scope. The decision effectively limits permitted uses of unlicensed technology to aimless tinkering with patented technologies, and sets the stage for infringement suits against non-commercial researchers.

To address the Madey issue in recent agreements, we have attempted to make clear that we are reserving rights broader than those of a mere unlicensed party, and that activities held under Madey to be the "business" activities of universities are within the scope of our reserved rights. One current example reads:

"NON-COMMERCIAL RESEARCH PURPOSES" means: Use or practice of LICENSED PATENT RIGHTS for academic research and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee. Without limiting the foregoing: (i) "academic research and other not-for-profit or scholarly purposes" includes, in non-limiting fashion, research that leads, or may lead, to patentable or unpatentable inventions that may be licensed or otherwise transferred, either directly or indirectly, to third parties; and (ii) neither (A) receipt of license revenues on account of such inventions or receipt of reimbursements for the costs of preparation and shipping of samples of materials provided to third parties as a professional courtesy, in response to post-publication requests or otherwise in accordance with academic custom nor (B) receipt of funding to cover the direct and/or indirect costs of research, shall constitute sale of products or performance of service for a fee.

Another case (*Merck KGaA v. Integra Lifesciences I, Ltd.*) clarifies the scope of a 1984 safe-harbor that exempts some patent users from suit for patent infringement. That case, as reviewed by the Supreme Court, protects infringing activities that are directed at the generation of data in support of FDA filings; however, it affords academic researchers and institutions far less cover than it does corporate infringers who actually are preparing FDA filings. Typically, academic research is too remote from the regulatory filing process to fall within the safe harbor, for which reason it remains crucial to reserve under license agreements all of the rights, for one's own institution and others, that will enable academic research to proceed unimpeded.

In drafting reservation of rights clauses and associated definitions, it is always important to keep both the *Madey* and *Merck* decisions in mind.

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2. Commentary and examples of exclusive license terms that encourage technology development as discussed in Point 2

While reservations of rights, above, enable continued innovation in non-profit and governmental laboratories, the suggestions contained in this section are intended to ensure that licensed inventions achieve broad commercialization.

2.1 Restrictions on fields of use, territory and term

- "Field-restricted" licenses grant rights that cover only specific products that a licensee is able, and will undertake a firm commitment, to develop. This approach safeguards the licensee's investment in a technology, while still leaving it open for development by other parties who do not compete with them (i.e., those who do not operate in the field of the exclusive license grant).

- "Co-exclusive" licenses may be granted to a small, limited number of licensees. Such a licensing structure has the advantage of permitting competitive optimization of a product by spurring each member of the limited pool of licensees to attempt to achieve product launch and market penetration first, or to develop a product that is simply better than that which is marketed by the other licensees. This strategy, in which multiple licensees carry out their research and development efforts in parallel, is particularly justified where there is a significant unmet need for a given product (e.g., a critically-needed diagnostic test or vaccine), as it minimizes the delay inherent in an exclusive license, where failure by the licensee to appropriately develop a product necessitates license termination, identification of a new licensee, negotiation of a new license and re-initiation of product development efforts, perhaps from scratch.

- "Convertible exclusive" licenses permit the licensor to render an exclusive license either co- or non-exclusive if a third party wishes to develop products not yet made available by the exclusive licensee, usually after the initial licensee has had a time-limited opportunity to bring to market the product in question.

- "Convertible nonexclusive" licenses where if additional expressions of interest are not received within a defined period of time, then a non-exclusive license converts to exclusivity, at least within a particular territory or field of use.

- "Term-limited" licenses, wherein the period of exclusivity is limited to the time necessary to afford the licensee the competitive advantage conferred by early market penetration and to permit them to make a reasonable profit on their investment in research and development, after which the grant converts to that of a nonexclusive license and the market opens up to other companies. Times may vary from a few years for a technology that requires little optimization to much longer times for products requiring many years of development and/or testing to obtain regulatory approval.

- Territorial limitations, where patent rights exist in multiple jurisdictions (e.g., the U.S. or North America; Europe; Asia; major-market countries; or developing countries)

Hybrid license grants that combine features of those described above (e.g., a non-exclusive license with a standstill for a given area of art, for a given period of time) expand the range of creative possibilities for delineating an exclusive licensee's rights.

2.2 Mandatory sublicensing

The concept is that when the University grants a broad exclusive license then we must have a mechanism to ensure that the market demand is met. As future, perhaps unanticipated, new uses arise we have an obligation to fill new market niches for the public good. This is especially important when our inventions are developed using federal funds. If we become aware of a new use that our licensee is not addressing, or if a third party approaches us for the (licensed) rights in order to develop a new use or other unmet need then we ask our licensee to tell us within 90 days if it will: (a) develop the new application on its own, or (b) grant a sublicense to the third party. If the licensee chooses to develop the new application then it must diligently undertake the new development (and report such progress to us).

Suggested language:

> *"If Institution or if a third party discovers and notifies the Institution that the INVENTION is useful for an application covered by the LICENSED FIELD OF USE but for which LICENSED PRODUCTS have not been developed or are not currently under development by LICENSEE, then the Institution shall give written notice to the LICENSEE, except for: 1) information that is subject to restrictions of confidentiality with third parties, and 2) information which originates with Institution personnel who do not assent to its disclosure to LICENSEE.*
>
> *Within ninety (90) days following LICENSEE's receipt of Institution's notification LICENSEE shall give Institution written*

notice stating whether LICENSEE elects to develop LICENSED PRODUCTS for the application.

If LICENSEE elects to develop and commercialize the proposed LICENSED PRODUCTS for the new application, LICENSEE shall submit a progress report describing LICENSEE's commercialization efforts in developing the new application every six months to Institution pursuant to Article xx herein."

2.3 Examples of diligence requirements/milestone clauses

Example 1

"Milestones. Because the invention is not yet commercially viable as of the Effective Date, Licensee will diligently develop, manufacture, and sell Licensed Product and will diligently develop markets for Licensed Product. In addition, Licensee will meet the milestones shown in Appendix X, and notify Institution in writing as each milestone is met."

Example 2

A second approach, drawn from a distribution license covering a nucleic acid sequencing reagent, reads:

> *X.1 Appendix A sets forth the development and commercialization plan under which LICENSEE intends to develop and sell LICENSED PRODUCTs (the "PLAN"). LICENSEE shall be entitled, from time to time, to make such adjustments to the then-applicable PLAN as LICENSEE believes, in its good faith judgment, are needed in order to improve LICENSEE's ability to meet the PERFORMANCE MILESTONES, as defined below.*
>
> *X.2 LICENSEE shall use reasonable efforts (including, without limitation, commitment of funding and personnel consistent therewith) and/or shall cause its AFFILIATEs and/or SUBLICENSEEs to use reasonable efforts (including, without limitation, commitment of funding and personnel consistent therewith): (i) to develop LICENSED PRODUCTs in accordance with the PLAN during the periods and within the timetable specified therein, (ii) to introduce LICENSED PRODUCTs into the commercial market and (iii) to market LICENSED PRODUCTs, and to keep each LICENSED PRODUCT reasonably available to the public, following introduction thereof into the market.*

In addition, LICENSEE shall achieve the following within the designated time periods:

> *(a) On or before January 1, 2009, offer for sale a first LICENSED PRODUCT or SERVICE for nucleic acid sequencing.*
>
> *(b) On or before January 1, 2009, initiate pre-clinical tests of a LICENSED PRODUCT that is a diagnostic kit for the detection of disease in humans.*
>
> *(c) On or before January 1, 2012, offer for sale a first clinical diagnostic LICENSED PRODUCT or SERVICE for the detection of disease in humans.*

Each of the activities recited in this Paragraph X.2 shall be referred to herein as a "PERFORMANCE MILESTONE".

X.3 LICENSEE shall inform INSTITUTION, on or before the deadline for meeting any PERFORMANCE MILESTONE, whether such PERFORMANCE MILESTONE has been met.

X.4 No later than sixty (60) days after December 31st of each calendar year, LICENSEE shall provide to INSTITUTION a written annual progress report describing progress by LICENSEE and any SUBLICENSEE(s) on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending December 31st and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. LICENSEE also shall provide any additional data INSTITUTION reasonably requires to evaluate LICENSEE's performance and compliance with the terms of this Agreement.

X.5 If LICENSEE fails to meet any of its obligations pursuant to Paragraphs X.1 through X.4 of this Agreement, INSTITUTION may notify LICENSEE in writing of LICENSEE's failure and, in such event, shall allow LICENSEE ninety (90) days to cure. LICENSEE's failure to cure such breach within such ninety (90) days shall constitute a material breach of this Agreement and

INSTITUTION shall have the right to terminate this Agreement forthwith.

A version of Paragraph X.2 drawn from a clinical diagnostics license sets forth the following Performance Milestones:

(a) within one (1) year after EFFECTIVE DATE, establish a Scientific Advisory Board that will oversee the development of LICENSED PRODUCTs;

(b) commence a human clinical trial of a first LICENSED PRODUCT as follows: (i) if the patient data collected in the RESEARCH can be used to support the filing of an investigational device exemption (IDE), within two (2) years of the EFFECTIVE DATE or, (ii) if the patient data collected in the RESEARCH cannot be used to support the filing of an investigational device exemption (IDE), then within three (3) years of the EFFECTIVE DATE; and

(c) within two years of commencement of the human clinical trial described in clause (b), conclude analysis of data from such clinical trial and submit to the FDA any and all documentation required for marketing approval of a first LICENSED PRODUCT.

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3. Commentary and examples of limitations on grants of rights in improvements as discussed in Point 3

Example 1

"Patent Rights" means the Valid Claims of, to the extent assigned to or otherwise obtained by the Institution, the United States patents and patent applications, corresponding foreign patents and patent applications (requested under Paragraph xx.x herein), and any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (only to the extent, however, that Valid Claims in the continuation-in-part applications are entirely supported in the specification and entitled to the priority date of the parent application) based on the following patents and patent applications: _____. This definition of Patent Rights excludes any rights in and to New Developments.

"New Developments" means inventions, or claims to inventions, which constitute advancements, developments, or improvements, whether or not patentable and whether or not the subject of any patent application, but if patentable, are not sufficiently supported by the specification of a previously-filed patent or patent application within the Patent Rights to be entitled to the priority date of the previously-filed patent or patent application.

Example 2

"Continuations-in-Part" means all continuation-in-part patent applications that are filed within two years of the original application and only to the extent that they cover technology disclosed, claimed in and dominated by the original application. The continuations-in-part also do not include continuations-in-part that have different named inventors than the original application or that are burdened by, for example, sponsored research or any other collaboration between Institution and a third party.

Example 3

"IMPROVEMENT" means: Any invention the practice of which would infringe at least one claim within the PATENT RIGHTS, which invention is made by at least one or both of the INVENTORS and is owned and controlled by INSTITUTION.

In a license that contains a field-exclusive grant of rights under PATENT RIGHTS and IMPROVEMENTS, PATENT RIGHTS are defined, in relevant part, as including any claim of a continuation-in-part application that is (i) directed at subject matter described in at least one listed patent application or patent and (ii) is entitled to the priority date thereof. The effect is to grant rights in technology dominated by what exists at the time of license. Tracking of the promised improvements is facilitated by their limitation to the work product of a defined pool of inventors. The institution is further buffered against liability (i.e., for breach of contract on account of inadvertent grants to different parties of overlapping rights or failure to meet obligations as to licensee participation in patent prosecution) by restricting IMPROVEMENTS only to those which the institution owns and controls.

Example 4

"IMPROVEMENT" means: Any invention the practice of which would infringe at least one claim within the PATENT RIGHTS, which invention is made by at least one or both of the INVENTORS and is owned and controlled by INSTITUTION and is disclosed to the TLO within 3 years of the date of the license and subject to any rights of sponsors in the research leading to the invention.

BIOGRAPHY FOR ARUNDEEP S. PRADHAN

Arundeep currently serves as Oregon Health & Science University's Director of Technology & Research Collaborations and has over 20 years of experience in technology transfer. He started his technology transfer career at the University of Utah.

Arundeep has developed and implemented several programs for seed research funding, gap funding and business development such as the Innovation & Seed Fund (Oregon Health & Science University), Springboard for University Entrepreneurs and the Commercialization Opportunity Fund (Colorado State University Research Foundation) and Technology Innovation Grant (University of Utah). He currently participates in various programs and initiatives such as the Oregon Innovation Council and the Oregon University Research Council to align the interests of universities, city and State constituencies as to effectively achieve success in technology transfer objectives. In the past Arundeep has worked with groups in Colorado and Utah to achieve these objectives. He continues to work with local and State economic development agencies and industry groups to forge ties between these entities and the institution.

As a member of AUTM (Association of University Technology Managers) and LES (Licensing Executive Society), Arundeep has participated in and moderated workshops on a variety of topics relating to technology transfer. Arundeep served on the AUTM Program and Survey Committees from 1993–1997. He was the Program Chair and Co-Program Chair for the AUTM Western Region Meeting in 2000 and 2001 respectively. More Recently, Arundeep was the Program Chair for the AUTM Annual Meeting in 2004 and 2005, which had record numbers in attendance. He is also the current Vice President for Annual Meeting and the Board of Trustees for AUTM (2007 & 2008).

Arundeep currently serves on the Board of the Oregon Bioscience Association and as an observer on the Board of several university research-based start-up companies. In the past he has served on the Oregon Council for Knowledge and Economic Development (2004–2005), the Board and the Managing Committee on the Colorado BioScience Association (2002–2004) and the Board for the Western Institute for Biomedical Research (1997–1999).

Chairman WU. Thank you, Mr. Pradhan. Dr. Butts.

STATEMENT OF DR. SUSAN B. BUTTS, SENIOR DIRECTOR, EXTERNAL SCIENCE AND TECHNOLOGY PROGRAMS, THE DOW CHEMICAL COMPANY

Dr. BUTTS. Chairman Wu, Ranking Member Gingrey, and Members of the Subcommittee, it is my privilege to address you on the topic of Bayh-Dole, the next 25 years. My name is Susan Butts, and I am the Senior Director of External Science and Technology Programs at The Dow Chemical Company. My group oversees, does external research collaborations around the world. I am also the Vice President of the University-Industry Demonstration Partnership, an organization operating under the auspices of the Government-University-Industry Research Roundtable, which is in the National Academies.

The Bayh-Dole Act is an important and pivotal piece of legislation that has produced many benefits. However, as you consider the next 25 years of Bayh-Dole, there are three key points to keep in mind. First, although the Bayh-Dole Act has enabled the licensing of federally funded technology from universities to industry, it has also created expectations for control of intellectual property that actually discourage research collaborations with industry.

Second, most foreign universities offer companies much more favorable rights to intellectual property arising from the research that they fund. This is causing companies to do more of their university research collaborations abroad. Both of these trends could have an adverse impact on U.S. competitiveness, since they will di-

minish U.S.-based collaborations, which can generate new knowledge, technologies, business opportunities, and jobs.

Third, small changes in the Bayh-Dole Act, and tax regulations to clarify the intent of Congress relative to the treatment of inventions resulting from industry-funded research, could significantly improve the climate for university-industry research partnerships in the United States.

I am sure that we will hear many different points of view in today's hearing. The important issue is not whether Bayh-Dole is good or bad, but rather, that it has taken the U.S. down a path that has diverged from most of the rest of the world, in terms of university-industry interactions. Some aspects of this path have been very beneficial. Other aspects have been detrimental. The challenge for our Nation is to put the United States on a new path that will fully engage our vast technology resources from industry, universities, and National Laboratories, to maximize U.S. competitiveness in technology and innovation.

Innovation is the translation of ideas into products. It happens in different ways and different technologies and industries. In my written testimony, I have tried to reflect issues and concerns that are broadly held across industries, but we should keep in mind that there are important differences. In industries like pharmaceuticals and chemicals, innovation is a discrete, long, and costly process. Products have a long lifetime, and business success is gained through exclusive access to key patent protected products and processes. In industries like information technology, innovation is a rapid, continuous process. Each product embodies many technologies and devices, products have a short lifetime, and business success is gained through rapidly getting the next product to market.

Pharmaceuticals and information technology define two ends of the innovation spectrum for technology-intensive industries. In order for university-industry collaborations to be productive and mutually beneficial, they must be flexible enough to accommodate the whole innovation spectrum. Globalization is a reality. U.S.-based companies must compete effectively in the global marketplace in order to stay in business.

Globalization also brings home the responsibility that government, industry, and universities share to solve the most serious challenges facing mankind, that know no national boundaries. Challenges like climate change and sustainable energy, food, and water. My employer, The Dow Chemical Company, has committed to meeting corporate sustainability goals to help address these challenges. We will have to make significant technology breakthroughs to meet these goals, and we want to partners with the best university researchers to do this. Unfortunately, the barriers that we experience in working with U.S. universities often cause us to seek out research partners with universities in other parts of the world.

I believe that the Bayh-Dole Act is fundamentally sound with regard to its stated purposes, but has gotten off-track in implementation, primarily through misapplication to research that is privately funded rather than government funded. This causes U.S. universities to impose their rights and obligations under Bayh-Dole to re-

search that is funded by industry profits rather than taxpayer dollars.

Clarification of the intent of Congress, and the laws and regulations that impact industry funded research at universities, could greatly enhance the flexibility that both parties have in dealing with foreground intellectual property, could speed the process to negotiate research agreements, and thus, foster more university-industry partnerships in the United States.

Thank you for your attention, and I would welcome questions.

[The prepared statement of Dr. Butts follows:]

PREPARED STATEMENT OF SUSAN B. BUTTS

Chairman Wu, Ranking Member Gingrey, and Members of the Subcommittee, it is my privilege to address you on the topic of Bayh-Dole—The Next 25 Years. My name is Susan Butts, and I am the Senior Director of External Science and Technology Programs at The Dow Chemical Company. My group oversees all of Dow's research collaborations with universities, independent laboratories, government laboratories, and government agencies around the world. Dow is the second largest chemical company in the world, and we spend over one billion dollars every year on research. Most of that funding is spent on internal programs but we also support almost 200 external sponsored research collaborations, research grants, and research consortium memberships. I am also the current Vice President of the University-Industry Demonstration Partnership, an organization operating under the auspices of the Government-University-Industry Research Roundtable which is in the National Academies.

There are three key points that I would like to make. First, although the Bayh-Dole Act has enabled the transfer of technology developed with federal funds from U.S. universities to industry it has also contributed to a contentious climate around the issue of intellectual property (IP) rights which discourages research collaborations between industry and U.S. universities. Second, most foreign universities, which do not have the IP expectations created by Bayh-Dole, allow industry research sponsors to own or control inventions resulting from the research that they fund. This much more favorable treatment of IP is causing companies to do more of their sponsored research abroad. Both of these trends will have an adverse impact on U.S. competitiveness since they will diminish U.S.-based collaborations which can generate new knowledge, technologies, and business opportunities. Third, small changes in the Bayh-Dole Act and tax regulations to clarify the intent of Congress relative to ownership or control of intellectual property resulting from industry-sponsored research could improve the climate for university-industry research partnerships in the United States.

The Bayh-Dole Act is an important and pivotal piece of legislation. It has successfully accomplished one of its primary stated purposes—to promote the commercialization of federally funded university research. There has also been, however, a negative and unintended consequence. Namely, that U.S. universities, in stark contrast with most foreign universities, have become substantially less attractive as research partners for companies. As U.S. universities increasingly focus on controlling intellectual property and maximizing their revenues from licensing inventions they have become more like competitors than partners to companies that sponsor research with their faculty and students. This is occurring at a time when global scientific challenges, such as climate change, renewable energy, health, and nutrition require collaboration like never before.

In 1980 when the Bayh-Dole Act was passed the Federal Government was the main source of funding for research and development in the United States so research partnerships with companies were neither common nor necessary for universities. Universities published their research results and companies used the published information to assist their internal research programs. Now, however, industry spends twice as much on research and development as the Federal Government so industry could be a significant source of research funding for universities (Figure 1).[1] More importantly, such research collaborations would benefit the U.S. economy by speeding the development of new products that draw on both company and university technology and capabilities. This is unlikely to happen, however, as long as companies and universities are at odds on how to treat intellectual property that comes from company-sponsored research. Although the amount of university research funding from companies has grown steadily over the last 25 years it still represents a small percentage of the total received by U.S. universities (Figure 2).[1]

In a speech given in the fall of 2006 Dr. John Marburger, Director of the Office of Science and Technology Policy, made the following observation about the necessity of looking beyond the Federal Government to find sufficient funding to sustain U.S. university research: "More likely in the foreseeable future is an increasing intensity of competition for a large and expanding but finite federal research fund by a growing number of research capable universities. . .. More promising is the prospect of increasing the share of research funding contributed by the states and by the private sector, particularly by industries that benefit from technologies that build on the scientific products of the universities. Unlike the Domestic Discretionary budget, the assets of the private sector do grow with GDP, and industrial investment in R&D has consequently increased much more rapidly than the federal contribution."[2]

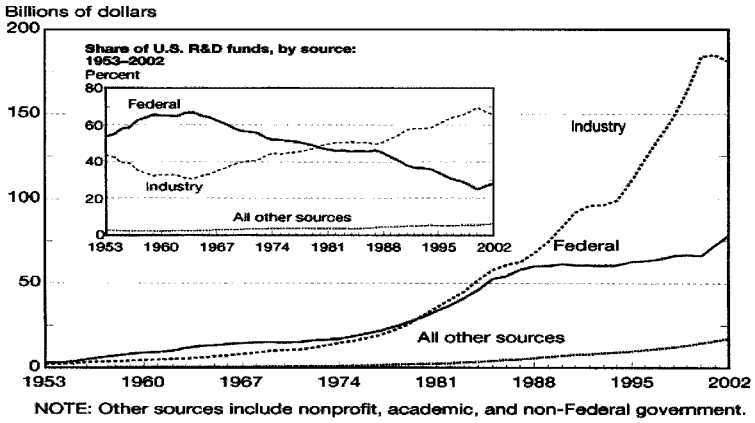


Figure 1

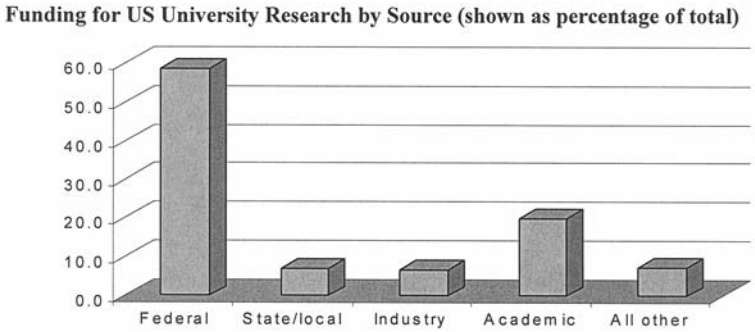


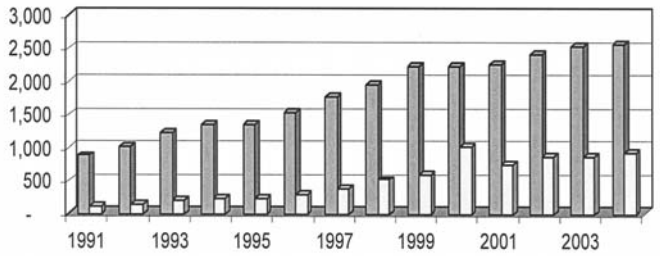
Figure 2

Impact of Bayh-Dole

Bayh-Dole recognized a fundamental reality—that companies are the primary engine for technology commercialization and the primary channel for getting new products to market for the benefit of society. Neither the government nor universities can or should fulfill those roles. So, in order to develop nascent inventions from the university and deliver them as new products to the market place companies are an essential partner. By giving universities the right to take title to inventions from federally funded research and the obligation to try to commercialize those inventions through licensing, the Bayh-Dole Act provided the legal framework to facilitate the transfer of technology from universities to industry. This has undoubt-

edly benefited the United States. Since universities were allowed to set licensing fees and royalties and to keep all the licensing revenue Bayh-Dole also created the expectation that universities should control intellectual property and generate income from their inventions. As financial pressures on universities have increased the prospect of filling the funding gap through licensing revenue is very attractive. However, although licensing income has grown steadily as university technology transfer offices have licensed significant numbers of inventions, the total net licensing revenues reported by universities to the Association of University Technology Managers are not sufficient to fill the research funding gap. In fact, the licensing income is only about one third of the total research funding that the same universities are receiving from industry (Figure 3).[3] Thus, it seems that the best interests of the universities will not be served by trying to increase licensing revenue at the expense of research funding from industry.

US University Licensing Revenue and Industry Research Funding (Millions of Dollars)



Key: Light bars represent net licensing revenue; Dark bars represent research funding from industry

Figure 3

Influence of Bayh-Dole on University-Industry Research Collaborations

Bayh-Dole has undoubtedly fostered some university-industry collaborations but it has had the unintended consequence of impeding many more.

Bayh-Dole has enabled licensing transactions and some new research to support the transfer of the inventions. For instance, when a company licenses a university invention that resulted from federal funding it may choose to engage the faculty inventor in follow-on research to further develop or refine the invention for commercial practice. This is more likely to happen when the licensee is a small company with limited internal research and development capabilities.

Bayh-Dole has not, however, fostered research partnerships—those in which a company is not seeking to license an existing university invention but, rather, to engage a faculty member and his or her students to perform research of interest to the company. In those research partnerships the company provides the funding for the research (including university overhead), frames the research problem, and may provide other resources to the university project such as company-generated research or testing results, proprietary technical, business or market information, noncommercial samples or prototypes, access to company facilities, and consultation with company researchers. In return, the faculty member and student(s) have an interesting real-world research problem to work on and usually the right to publish the research results. These company-sponsored projects thereby support the educational, research, and information dissemination missions of the university.

There is a fundamental difference between federally funded research and company funded research. In the former case the funding comes from tax dollars so it is reasonable to promote a use of resulting inventions in a manner that generally benefits society. That societal benefit comes in two ways: invention licensing income provides financial support for the university and successful commercialization of inventions brings new products to the public. The university, the licensee, and tax payers all benefit. In the latter case, that of company sponsored research, the research funding comes from the company's owners or shareholders and not U.S. taxpayers in general. Company profits pay for the research investment, and company

owners/shareholders expect this investment to produce a return which generally comes from a competitive advantage for its products in the market place.

U.S. universities have taken the position that virtually all privately sponsored research is at least "touched" in some way by federal funds and, therefore, subject to the Bayh-Dole Act. By this reasoning it then follows that the university, not the sponsor, should own and control any inventions resulting from the sponsored research and that the university should be free to license these inventions as it sees fit. This very broad interpretation seems to be in conflict with both the stated intention of the Act and the language of the implementing regulations. In fact, the policy and objective section of the Bayh-Dole Act lists, among others, the following two objectives: to promote collaboration between commercial concerns and nonprofit organizations, including universities and to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.[4] The section of the implementing regulation which defines its scope states: "To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology."[5]

Before beginning a company-sponsored research project the university and sponsor generally execute a research agreement that, among other things, determines how any inventions that may occur will be treated. As mentioned above U.S. universities generally claim ownership of inventions made by their faculty and students in the course of performing research sponsored by a company. The research agreement terms typically offered by U.S. universities give the sponsor a time-limited option to negotiate a license for the invention and require the research sponsor to pay patenting costs. The sponsor has to pay for the research and pay for the patenting without any guarantee that it can obtain a license at a reasonable cost. In fact, if the sponsor and university cannot reach agreement on the value of the invention and licensing terms then the university is free to license the invention to another company, even a competitor of the research sponsor. This is indeed a "nightmare scenario" for the company sponsoring the research because, although it framed the research problem and paid for the research activity, the resulting invention could give a competitive advantage to its competitor! Because of these risks and uncertainties many companies hope that no inventions result from their sponsored research at U.S. universities. This is an unfortunate situation since it limits the scope of the research partnerships and the potential benefit from them, for all parties.

For industries like my own (the chemical industry) patents are critical to business success. The cost of taking an invention from concept to commercial product is very high and the probability of success is low. It is not unusual for development and commercialization to take 10 to 15 years. Construction of a world-scale chemical plant costs hundreds of millions of dollars. Products and plants have a long life cycle. Most chemical companies are unwilling to make such a large investment unless they have the protection provided by ownership or exclusive control of the supporting product and process patents. They are also unwilling to make these investments if their licensing fees and royalty obligations make the profit margins too low.

Effects of the Increasing Globalization of Research

Global competition is an inevitable consequence of capitalism and free trade, two of the foundations of the U.S. economy. U.S. companies must produce products that are better or less expensive than those produced by competitors in order to stay in business. U.S. companies also want to access to foreign markets in order to grow. These and other factors, (fast, reliable, and inexpensive global telecommunications and air travel to name a few) have led U.S.-based companies to expand their research, manufacturing, and marketing assets abroad. This expansion leads naturally to the establishment of research partnerships with universities located in the same regions as the company's research or manufacturing facilities.

At the same time companies are finding that research partnerships with foreign universities offer a distinct advantage with regard to intellectual property use. Most foreign universities, in both the developed and developing world, readily provide the research sponsor with exclusive or controlling access to inventions resulting from the research. Such exclusivity comes through a variety of treatments of inventions ranging from outright assignment of ownership to the sponsor to joint ownership to granting of an exclusive license. In most cases, the exclusive access is provided in

return for payment of the cost of the research and the cost of obtaining the patent. In some cases, the company sponsor pays an additional, modest, predetermined fee.

Figures 4 and 5 provide data to support the observation that foreign universities provide more favorable intellectual property terms to research sponsors. In 2003 Dow compared the intellectual property terms from more than one hundred sponsored research agreements between Dow and universities around the world. Figure 4 shows that in 69 percent of agreements with U.S. universities the university took title to sole inventions (those made by faculty or students in the course of performing the research sponsored by Dow). In contrast, Figure 5 shows that in 85 percent of agreements with foreign universities sole university inventions were assigned to Dow or Dow was made a joint owner.

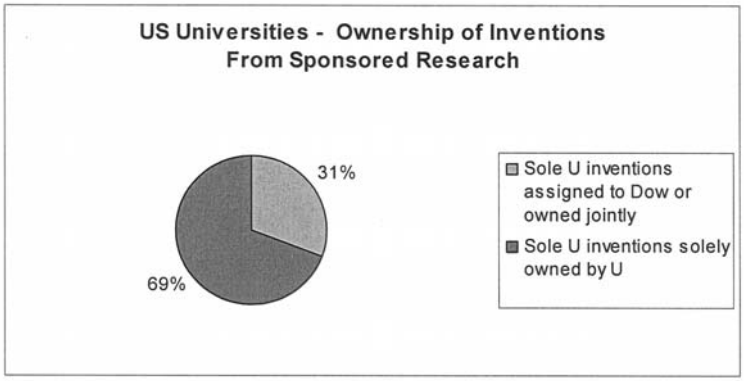


Figure 4

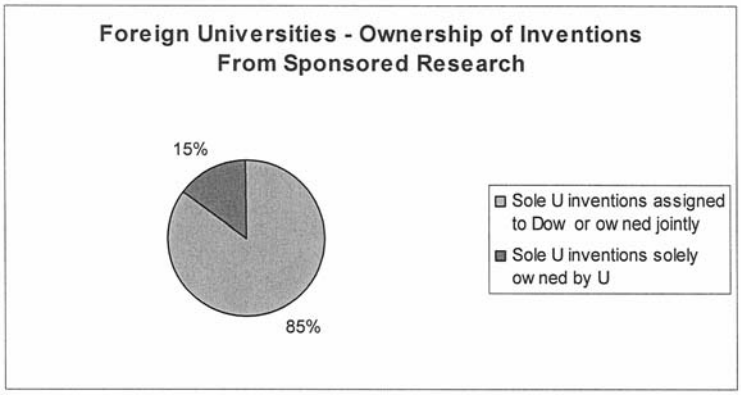


Figure 5

It has also been Dow's experience that it is much faster and easier to negotiate a research agreement with foreign universities. Not only does this allow research projects to get started in a timely manner but it also reduces the transactional costs associated with the negotiation. In 2002 Dow measured the average cycle time for executing a research agreement with U.S. universities. We found that, on average, it took over five months from the time that the Dow researcher and faculty member

finalized the research plan until both parties signed the research agreement. The most time-consuming step was negotiating the intellectual property terms. In some cases we were not able to reach an agreement, and we just walked away from the project. In contrast, when we set up agreements with universities outside the U.S. most negotiations were quite fast and easy, being completed in a few weeks rather than many months.

The high quality of research being performed at many universities outside the U.S., the favorable intellectual property terms that these same institutions offer to research sponsors, and the relative speed and ease of negotiating the supporting research agreements makes it increasingly attractive for companies in the U.S. to set up more of their research partnerships with universities abroad. At a recent meeting of the External Technology Directors Network, a working group within the Industrial Research Institute, members of the network conducted a straw poll to find out whether member companies were, indeed, increasing the amount of their sponsored research being done abroad.[6] Of the 23 companies represented at the meeting 17 responded that they are doing more of their sponsored research with foreign universities than they did in the past. Of the 17 who responded in the affirmative, nine agreed that either better intellectual property terms and/or ease of negotiating the agreements were major reasons for their decision to do more work with foreign universities.

Influence of Bayh-Dole on Academic Collaborations and the Broad Dissemination of Knowledge

Bayh-Dole has had both positive and negative influences on academic collaborations and dissemination of information. Academic collaborations are fostered by the fact that all universities have clear and equal standing with regard to their faculty's inventions that come from collaborations in which each party receives funding directly from the Federal Government. The situation is more complicated when there are joint inventions or when funding flows from one university to another since each party strives to maximize its rights to intellectual property.

Perhaps the most serious impediment to academic collaboration occurs when a university fails to make research results or materials available to the rest of the research community. Material transfer agreements between institutions have become very difficult to negotiate. Some universities have elected to patent and license research tools that result from federally funded research. It is hard to make a compelling argument that society is better served by limiting access of the research community to research tools developed with federal funding. Such tools have a limited number of potential users in the research community and don't have to be commercialized in order to be useful. Patent protection is not needed because little or no investment is required to make the tools available for others to use. Putting research tools into the public domain satisfies the intent of the Bayh-Dole Act with regard to public benefit. Generating income and limiting access appear to be the main reasons for universities to patent and license research tools.[7]

Changes in Bayh-Dole Legislation Needed to Promote U.S. Economic Development

U.S. competitiveness and, hence, U.S. economic development will be adversely impacted if no improvements are made in the climate for university-industry research and development partnerships. The U.S. economic engine cannot be fully engaged and functional if the three main components of the technology enterprise (Industry, Universities, and Government Laboratories) do not work together effectively to investigate science and translate technology into new products. U.S. companies with technology-based products will do more and more of their research collaborations with foreign universities. The potential impact on U.S. competitiveness of such a shift is well described in the report from The National Academies, *Rising Above the Gathering Storm*.[8] Many individuals and organizations, such as the University-Industry Demonstration Partnership, are working to lower the barriers to research collaborations between universities and companies in the U.S. but there are still some practices and expectations regarding intellectual property as well as some statutory and regulatory issues that are problematic.

The Bayh-Dole Act, largely through misinterpretation or misapplication, is offered as one of the main reason why universities must own inventions resulting from company-sponsored research and should have the freedom to license these inventions as they choose. This problem could be mitigated by the addition of language which further clarifies the intent of Congress relative to university research supported with private, rather than government, funding. In particular, clarification of circumstances under which private and federal funding of related research can exist simultaneously without Bayh-Dole rights and obligations being triggered would be

very helpful. It would also be very helpful to change some of the tax code provisions, mainly Revenue Procedure 97–14 (recently superseded by Revenue Procedure 2007–47) which creates a safe harbor for universities relative to their tax-exempt bonds only as long as they do not give preference in licensing foreground inventions to an industry sponsor of research. Finally, some of the economic pressures on universities which cause them to try to maximize their licensing revenue could be relieved by raising or eliminating the federal cap on overhead rates.

Although the focus of today's hearing is on how Bayh-Dole has affected university-industry relations it is worthwhile to remember that Bayh-Dole also applies to companies that receive research funding directly from government agencies. A white paper prepared by the Integrated Dual-use Commercial Companies (IDCC) organization makes the following observations and recommendations:[9] "Several aspects of the Bayh-Dole Act represent major barriers preventing most technology rich commercial companies from even considering performing R&D with the Government when there could be laboratory developments with Government funding with significant commercial application. Some of the concerns raised regarding the Bayh-Dole Act include the inability to keep a patentable invention a trade secret, the breadth of the Government-purpose license, march-in rights, and the broad definition of "subject invention," which includes inventions conceived (and possibly even patented) prior to entering into the funding agreement, but first actually reduced to practice under the funding agreement. Other concerns are the mandatory disclosure, election and filing requirements for subject inventions, which can potentially result in forfeiture of title to the inventions if the requirements are not timely followed. An additional concern is the Preference for U.S. Industry requirement, which prohibits the contractor from granting an exclusive license to use or sell a subject invention in the U.S. unless the licensee agrees that any product embodying the subject invention will be substantially manufactured in the U.S. These concerns have resulted in recommendations from both Government and industry that they be addressed."[10]

"Most of these industry concerns could be simply addressed by amending Section 35 U.S.C. § 210(c) to provide that if a funding agreement is made with a contractor that is subject to the Bayh-Dole Act (35 U.S.C. §§ 200–212), any rights of the Government or obligations of the contractor relating to patents described in 35 U.S.C. §§ 202–204, may be negotiated between the Government and the contractor to reduce such Government rights or contractor obligations, if the head of the contracting activity determines that the interest of the Government and the general public will be served thereby. This same right to negotiate reduced Government rights or reduced contractor obligations relating to patents would apply to those contractors that are large businesses and that are subject to the Statement of Government Patent Policy issued on February 18, 1983."[11]

In summary, the Bayh-Dole Act is an important piece of legislation that has produced many benefits. The unintended negative impact on research collaborations involving industry, universities and government can be mitigated through relatively minor changes in the law and related regulations.

References and Notes

1. National Science Board, *Science and Engineering Indicators 2004,* published by the National Science Foundation.
2. J. Marburger in a speech to the Council on Governmental Relations, Washington, D.C., October 26, 2006 on the topic of *Emerging Issues in Science and Technology Policy.*
3. From data in the *AUTM Licensing Survey—Fiscal Year 2004,* published by the Association of University Technology Managers.
4. See 35 U.S.C. § 200.
5. See 37 C.F.R. 401.
6. From a meeting of the Industrial Research Institute (IRI)-External Technology Directors Network (ETDN), Fort Lauderdale, FL, April 19–20, 2007.
7. See, for example, R. Eisenberg, *Science,* 299, 1018–1019 (2003).
8. N. Augustine et al., *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future,* The National Academies (2005).
9. IDCC, Integrated Dual-use Commercial Companies, was formed in 1991 by major commercial firms dedicated to improving the efficiency and effectiveness of Federal Government procurement and R&D interaction with commercial firms. For additional information on IDCC see *www.idcc.org*
10. See Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge,* 30 Pub. Cont. L. J. 225 (Winter 2001); Richard

N. Kuyath, *Barriers to Federal Procurement: Patent Rights,* 36 the Procurement Lawyer I (Fall 2000). Diane M. Sidebottom, *Intellectual Property in Federal Government Contracts: The Past, The Present, and One Possible Future,* 33 Pub. Cont. L. J. 63 (Fall 2003).

11. Corresponding changes for large business concerns would need to be made to the organic patent statutes applicable to DOE and NASA, 42 U.S.C. 2011, et seq. (DOE), 42 U.S.C. 5901–5915 (DOE), 42 U.S.C. 2451–2459 (NASA) and 42 U.S.C. 2471–2476 (NASA).

BIOGRAPHY FOR SUSAN B. BUTTS

Dr. Susan Butts is Senior Director of External Science and Technology Programs at The Dow Chemical Company. In this capacity she is responsible for Dow's contract research activities with U.S. and European government agencies and sponsored research programs at over 150 universities, institutes, and national laboratories worldwide. She also holds the position of Global Staffing Leader for R&D, with responsibility for recruiting and hiring programs.

Dr. Butts is active in a number of organizations that address issues pertaining to relationships between industry, universities, and government research laboratories. She is currently a Dow representative to the Council for Chemical Research, the American Chemical Society's Committee on Corporation Associates, and the Industrial Research Institute (IRI). She is also a member of the National Council of University Research Administrators (NCURA), the Association of University Technology Managers (AUTM), the American Association for the Advancement of Science, and Sigma Xi. Dr. Butts currently serves on the governing boards for the Council for Chemical Research and the Alliance for Science and Technology Research in America (ASTRA). She was a co-founder and member of the Steering Team for the University-Industry Partnership Project, an effort sponsored by the Government-University-Industry Research Roundtable (GUIRR) of the National Academies, NCURA and IRI with the goal of lowering the barriers to industry sponsored research at universities. This project led to the creation of a new organization, the University-Industry Demonstration Partnership (UIDP), which operates within GUIRR. Dr. Butts is the Vice President of the UIDP and will be President in 2008.

Dr. Butts holds a B.S. in chemistry degree from the University of Michigan and a Ph.D. degree in organometallic chemistry from Northwestern University. Before joining the External Technology group Dr. Butts held several other positions at Dow including Senior Resource Leader for Atomic Spectroscopy and Inorganic Analysis within the Analytical Sciences Laboratory, Manager of Ph.D. Hiring and Placement, Safety and Regulatory Affairs Manager for Central Research, and Principal Investigator on various catalysis research projects in Central Research.

Chairman WU. Thank you very much, Dr. Butts. Mr. Johnson, please proceed.

STATEMENT OF MR. WAYNE C. JOHNSON, VICE PRESIDENT, WORLDWIDE UNIVERSITY RELATIONS, HEWLETT-PACKARD COMPANY

Mr. JOHNSON. Good afternoon, Mr. Chairman and distinguished Members of the Committee. Thank you for the opportunity to speak with you today on the subject of Bayh-Dole, the next 25 years.

I am Wayne Johnson, Vice President of University Relations, Worldwide, from Hewlett-Packard Company. My focus is on bringing universities and industry together to work collaboratively, for mutual benefit and for our innovation system.

I have been working in this area for over 20 years, representing companies such Raytheon, Microsoft, and now Hewlett-Packard. For the past three years, I have been working on the cross-industry, cross-university efforts at GUIRR, the Government University Industry Research Roundtable, part of the National Academies here in Washington. I have been leading one of the efforts at BASIC, the Bay Area Science and Innovation Consortium in California, and I am a founding sponsor of the UIDP, the federal Uni-

versity Industry Demonstration Partnership, also here in Washington. The goal of these efforts has been to remove the barriers that prevent universities and industry from working together, and to understand deeply the partnership models and operating parameters that will work successfully, given the myriad of challenges that both parties face.

Personally, I care deeply about U.S. universities and their ability to work with industry. I believe that ability of these two types of partners to come together around important problems and interesting research areas is a very important part of our future, and our ability to be successful and to lead the world in innovation.

Now, you can hear me. I have three key points and two recommendations for you to consider. First, my key points.

My first point is that the information technology or IT industry does not believe in "home run patents." Last week, one of my colleagues went to a nearby office supply store, and purchased an HP Color printer, color copier, scanner, and photo printer all in one for $79.99. Today's products, such as PCs, PDAs, printers, and cell phones, et cetera, are sophisticated, complex aggregations of hardware, software, systems, and services. Each one contains literally hundreds of patented concepts and implementations. And yet, no single concept or implementation makes or breaks the success of the product. Each key concept can be designed around or implemented differently. Therefore, the sort of home run patents, which have high commercial value, rarely exist, and do not drive innovation in the IT industry.

My second point is, one of the key original goals of the Bayh-Dole legislation was to "promote collaboration between industry and universities." I am here to tell you today that unfortunately, it has had the opposite effect. One of my research colleagues has told me at HP Labs that he has been able to set up research collaboration with elite universities in Russia within a few days and just a few phone calls. Our experience in negotiating collaborative agreements with U.S. universities is that it can take as long as two years or more, if indeed, we ever reach such an agreement over IP rights. These types of situation have led to what we call a silent breaking, where many companies in our industry simply walk away, because it is too costly and takes too long to reach an agreement.

My third point is that while intellectual property rights, patents, and strong IP position have been critical to our success in the past, it is innovation and collaboration, together with strong relationships and interactions between U.S. universities and industry, that will drive our future success.

Our success depends on the ability of universities to cultivate and develop world class talent through high quality education of students, and this, in turn, depends on the relevant and challenging educational experiences between universities and industry. The shift away from collaboration is one of the reasons why the silent breaking represents such a threat to our long-term success in the IT industry and to the health of our innovation system in the United States. And Bayh-Dole in its present form does not address the particular issue of interaction, collaboration, and strong relationships.

Here are my two recommendations. My first recommendation is that we don't feel that Bayh-Dole should be changed, for two reasons. Bayh-Dole provides IP protection for industry and business models that depend on a few enabling key patents for competitive advantage, and as has been mentioned previously, certainly in the pharmaceutical industry. It also establishes a uniform approach to ownership and licensing of intellectual property, superior to the IPA process that it replaced.

In addition, my second recommendation is to launch a new focus on innovation, one that makes this country a hotbed of collaboration, one that highlights the differences between invention and innovation, and that understands that superior value can be created through innovation, one that enacts policies to bring innovation to the forefront, both for our industry's success and America's success for the next 25 years. When we look into the future from an IT company perspective, we believe that the focus on patents will wane over time, and many of the things that drive innovation, from our experience, are in the details, and those details are not about technology licensing.

Thank you for your attention and the opportunity to testify here today.

[The prepared statement of Mr. Johnson follows:]

PREPARED STATEMENT OF WAYNE C. JOHNSON

Introduction

Good afternoon Mr. Chairman and distinguished Members of the Committee. Thank-you for the opportunity to speak with you today on the subject of "Bayh-Dole—The Next 25 Years."

I'm Wayne Johnson, Vice-President of University Relations, Worldwide, from Hewlett-Packard Co. My focus is on bringing universities and industry together to work collaboratively, for mutual benefit and for our innovation system.

I've been working in this area for over 20 years, representing companies such as Raytheon, Microsoft, and now Hewlett-Packard. For the past three years, I've been working on the cross-industry, cross-university efforts at GUIRR (the Government University Industry Research Roundtable), part of the National Academies here in Washington. I've been leading one of the efforts at BASIC (the Bay Area Science and Innovation Consortium in California), and I'm a founding sponsor of the UIDP (the federal University Industry Demonstration Partnership, also here in Washington.) The goal of these efforts has been to remove the barriers that prevent universities and industry from working together, and to understand deeply the partnership models and operating parameters that will work successfully, given the myriad of challenges that both parties face.

Personally, I care deeply about U.S. universities and their ability to work with industry. I believe that ability of these two types of partners to come together around important problems and interesting research areas is a very important part of our future, and our ability to be successful and to lead the world in innovation.

Outline of Key Points and Recommendations

Key Points

Before getting into the details of my testimony this afternoon, there are three key points and two recommendations that I'd like for you to consider.

Please note the opinions expressed here are from an information technology industry perspective, and are not intended to reflect the issues and concerns of other industries such as Life Sciences, etc., which we understand to have very different needs.

1. We in the information technology ("IT") industry do not believe in "Home-Run" Patents
   - Today's products are sophisticated, complex aggregations of software, systems and services (such as the personal computer, PDA or cell phone)
   - Each one contains literally hundreds of patented concepts and implementations

- Yet no one concept or implementation "makes or breaks" the success of the product
- **"Home-Run" patents do not drive innovation in the IT industry**

2. One of the key, original goals of the Bayh-Dole legislation was. . .*to promote collaboration between industry and universities.* . .
   - **Unfortunately, it has had just the opposite effect of what was intended**
3. While intellectual property (IP) rights, patents, and a strong IP position have been critical to our success in past,
   - It is innovation, collaboration, and strong relationships and interactions between U.S. universities and industry that will drive our future success
   - **And Bayh-Dole, in its present form, does not address the particular issues of interaction, collaborations, and strong relationships**

Recommendations

1. At this time, we recommend that Bayh-Dole not be changed.
   - Bayh-Dole provides IP protection for industries and business models that depend on a few enabling patents for competitive advantage
   - It also establishes a uniform approach to the ownership and licensing of intellectual property, far superior to the IPA process that it replaced
2. In addition, we recommend a new focus on innovation—one that makes this country a "hot-bed" of collaboration
   - One that distinguishes the differences between invention and innovation, and that understands the superior value that can be created through innovation
   - And one that enacts policies to bring innovation to the forefront, both for our industry's success and for America's success during the next 25 years
   - When we look into the future from the IT industry perspective, we believe that the focus on patents will wane. Many of the things that drive innovation, from our experience, are in the details, and those details are not about technology licensing.

Innovation & the IT Industry Perspective

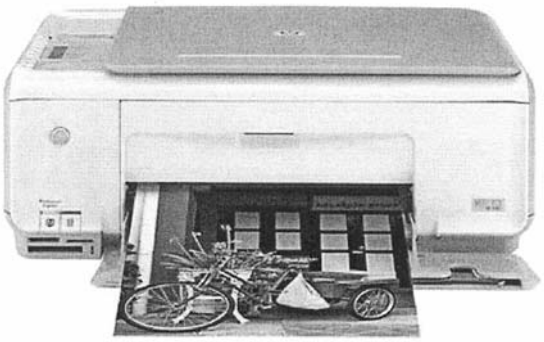
The information technology ("IT") industry has followed a unique evolution throughout the past five decades.

Initially, the efforts of university researchers and companies were largely decoupled, with universities focusing on basic research, and companies working to develop "stand-alone" products. Innovation efforts were typically focused on creating technologies that would enable new categories of products, such as printers, calculators, computers, etc.

As technology advanced and products grew more sophisticated in their capability, the focus of innovation moved to combining these products into systems. An example of such a system is the personal computer which integrates processors, memory, and video into an extremely useful, powerful, and low-cost system.

And as these systems became more advanced, they became linked together into networks, creating a widely available information infrastructure. The emphasis in innovation is now on how to create services that make sophisticated tasks both possible and pervasive, creating a whole new wave of communication and information capabilities enabling the Internet, cell phones, iPods, etc.

Innovation in today's world requires the combined efforts of multiple companies, partnering across multiple industries to bring a competitive offering to the customer. Even the seemingly simple printer shown here involves multiple research disciplines and numerous sciences in its creation, design, and development.



In this new model of product development, "goodness" is equated with the success of many varied players in the resulting ecosystem, all-the-while competing with each other to make contributions to and gain the loyalty of the end-consumer. Their primary mode of operation is innovating, creating more novel and unique value, and driving prices down so that more people can benefit from the products and services being offered. For example, printers that once only printed black & white text and sold for hundreds of dollars, can now print color documents and photographs, make color copies, and scan documents, all-in-one, and sell for $79.99. People using printing *services* enjoy the experiences of sharing photos with family and friends anywhere in the world, as their printer interfaces with the Internet and uploads their favorite photos automatically for sharing with others.

The pace of innovation in the IT industry is accelerated, marked by very rapid time-to-market. Product development cycles are 9–15 months and product life times are in the range of three to six months. The phrase that probably best characterizes this industry and its unrelenting pace of new value creation is "innovate or die."

The Myth of "Home-Run" Patents

"Home-run" patents are those which are key enablers for unique products or spawn whole new industries, and represent massive potential licensing revenue windfalls for a university. Some universities have built their technology transfer offices (TTOs) around the belief that the next "home-run" patent is imminent, eager to capture a significant windfall. Other universities have been driven by the fear of being known as the TTO that let the "big one" get away. This set of beliefs is reinforced by the universities' TTO focus on licensing revenue as a measure of their success.

These beliefs are driving the universities to behave as if the major, if not only, mechanism for transferring new knowledge is through patenting and licensing. However, there are many mechanisms for disseminating new knowledge out from universities, including student hiring, publications, conferences, informal exchanges, visiting researchers, etc.

For IT companies, the perspective about intellectual property is quite different. Most IT products involve the combined use of hundreds of patented ideas. Many of these patents are incremental advances and concepts for which there is no single patent that defines a key enabling technology. Due to the large number of patents in a typical IT product, companies will not pursue royalty-bearing licenses with universities. Also, the IP in IT products is unlikely to be clearly unique and defensible, since other approaches are generally feasible, making it difficult and expensive to protect. **For many IT companies, the role of IP is to accelerate product development, rather than to enable it.** It's not about the value of a single patent (since it is relatively easy to design around any IP that might present a problem); it's more about the exchange of ideas and collaborative research that builds out an ecosystem which utilizes the technologies being developed.

As a company in the IT industry, we don't believe in "home-run" patents, and we don't believe that they exist (for us). Innovation is driven by the knowledge that is created through collaboration and the flow of ideas, by working with leading research centers and doing good research, and by hiring well-educated students into the research and development activity.

Bayh-Dole: Its Goals and Results

As we have reviewed the original intent of the Bayh-Dole legislation, three of its major goals are identified as—

1. to promote the utilization of inventions arising from federally supported research and development,
2. to encourage maximum participation of small business firms in federally supported research and development efforts,
3. to promote collaboration between commercial concerns and nonprofit organizations, including universities

Promoting Industry-University Collaboration

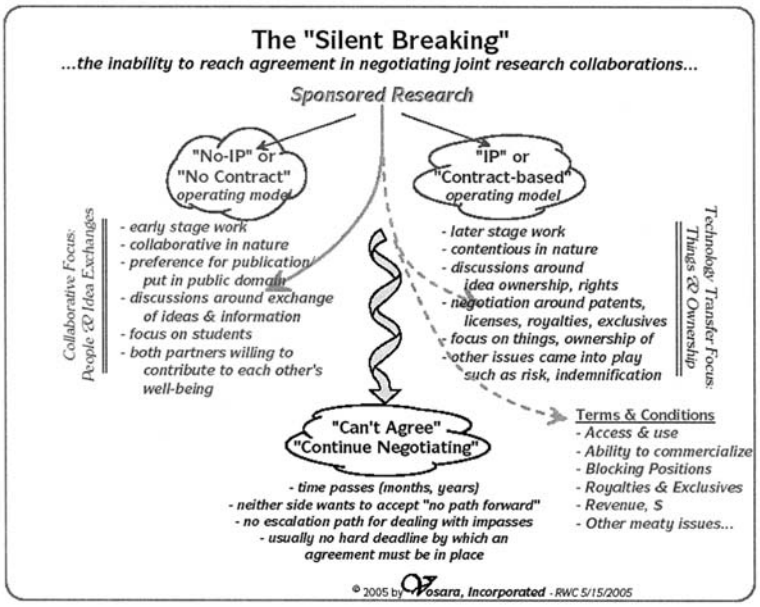
In this testimony, we will take an in-depth look goal #3 (above), from the perspective of the IT industry.

How well did Bayh-Dole do in terms of its objective to promote collaboration? From the results that have been observed over the past 10 years, we would have to give it a poor-to-failing grade. Unfortunately, much of what has actually happened has been exactly the reverse of what was intended, when the legislation was written.

1. Bayh-Dole has contributed to shifting the focus and attention of joint research towards rights, ownership, and the licensing of intellectual property, and away from collaboration, partnership, and innovation.
2. Bayh-Dole has accelerated the building of a bureaucracy—the technology transfer offices in U.S. universities. Since the inception of Bayh-Dole in 1980, more than 65 U.S. universities have put into place technology transfer offices as a way of dealing with the increasing emphasis on monetizing intellectual property, the belief in "home-runs," and the shortfalls in university funding.
3. The existence of these technology transfer offices has, in turn, constrained (not amplified) the flow of knowledge and research outward from universities. The TTOs have focused almost exclusively on patenting and licensing revenues, and in many cases operate independently of the industrial liaison offices, the sponsored projects offices, and other mechanisms that universities use to promote engagement and interaction with industry. One notable exception to this phenomenon is where the TTOs have been combined with Industrial Liaison Offices to provide a more comprehensive engagement model between universities and industry (e.g., the UC–Berkeley IPIRA model.)
4. The increased focus on rights, licenses, and revenues has strained the already challenging and tenuous relationships that have existed between U.S. companies and universities. This shift in focus towards "intellectual property" has made it more difficult for these two parties to work together. It has fueled mistrust, escalated frustration, and created a misplaced goal of revenue generation, which has moved the universities and industry farther apart than they've ever been.
5. The process of negotiating agreements that specify how to work together in joint research areas have turned into disagreements over IP rights and ownership, and **taken up to 2+ years to converge,** if indeed both parties ever come to mutual agreement. Often, both parties give up, disengage from the negotiation process, and resolve never to try and engage with each other again in joint collaborations.
6. The inability to reach agreement, and the frustration, mistrust, and damaged relationships over IP rights have contributed to a **"silent breaking,"** where companies decide that it's too costly and too much trouble to try and work with universities. Companies then **"walk away"** and find other partners such as the elite universities in Russia, India, and China, who are more flexible in their working arrangements, are easier to work with, and are more agile and speedy in their negotiations.
7. If effect, what Bayh-Dole has done, is rather than create a congressionally-mandated reason for universities and industry to work together for mutual benefit and increased societal benefit, is to organize a "shot-gun wedding," where both parties are trying to do the right thing, but it simply doesn't work because the focus is misplaced on rights, ownership, and revenue generation.

While the overall practice of collaboration has eroded significantly in the past decades, it's important to note that not all universities have jumped on the IP band-

wagon and focused on IP solely as a source of revenue for their institutions. In our experience there are some universities that can strike an appropriate balance between fostering collaborative relationships with industry, and at the same time managing the rights and patents associated with IP development. Universities such as Purdue, Georgia Tech, UC–Berkeley, and Stanford seem to know how to balance all of these needs, and still keep a focus on becoming the partners of choice for U.S. companies.



Innovation, Globalization, and New Interaction Models

While universities and the IT industry have been experiencing increasing relationship difficulties during the past decade, the world situation has been changing dramatically.

When Bayh-Dole was created, it was enacted to address a particular situation and need, at the time. Now, 27 years later, the U.S. IT industry (as well as others) is challenged with a new set of circumstances—the forces of globalization, rapid time-to-market, increasing sophistication of products and services, and the need for both rapid technological and market innovation.

With the Internet and the ready availability of global supply chains, we are experiencing an unprecedented "flattening" of the world and a "leveling of the playing fields" which before were thought to be the exclusive purview of U.S. industry. The expanded information and communications technology (ICT) infrastructure, together with the increased emphasis on science, technology, engineering, and math (STEM) education globally, has created a situation where literally anyone anywhere can create an innovative product or service, and bring it to market quickly. In this modern, interconnected world, new companies, new industries, and whole new ecosystems are created in a fraction of the time that it used to take for them in past to become established.

The "speeding up" of the world's rapid pace of development is requiring that we find new models and ways of working together, to match the accelerating pace of global innovation.

In light of this, we observe the following situations:

1. Today, most new information and communications technology (ICT) companies (even small ones of 5–10 employees) are structured to be "global," from the outset. One does not have to be a big company, to be a global company anymore. For example, every university graduate with entrepreneurial aspirations can start out their career, linking with fellow students from other

countries, and is enabled to access design, development, and manufacturing facilities on a global basis.

2. Global companies can work with anyone, anywhere on the planet, and are not constrained to working with university partners in a single country, region, or location. They can choose partners who have knowledge, ideas, insights, and interesting research to offer, and who are not constrained or slowed down by bureaucracies focused on rights, IP ownership, and licensing revenues.
3. As the need for speed and rapid innovation has increased, university TTOs have slowed down and impeded the process of collaboration, and made their institutions increasingly more unattractive and difficult to work with. This has, in turn, encouraged companies to find other university partners to engage with, typically outside the U.S. It has shifted the sponsorship of research, the vigorous multi-disciplinary interactions, and the flow of ideas to universities in other countries. In terms of innovation and the future of success of U.S. industry, this is a most distressing development.
4. The decreasing interaction and engagement of U.S. universities with companies threatens to reduce the relevance of their research and the quality of their students, and therefore erodes one of the major foundations of the U.S. national innovation ecosystem.

The Technology Transfer Model

While companies go in search of willing partners who are easy to work with on a global basis, universities find that they are becoming increasingly isolated from industry engagement, and are more reliant than ever on government funding and sponsorship.

Perhaps even more worrisome is that the focus on intellectual property of the past two decades has had the unintended effect of institutionalizing an engagement model which is now obsolete in the modern world.

In the old way of operating, research ideas were conceived of, developed, prototyped, and then shown to industry partners for evaluation, further engagement, and hopefully transferred into one or more product development efforts. Usually, universities worked independently during the early years of technology research, and then when they "had something" that was tangible and interesting, they went searching for industrial partners.

This research-then-transfer model (more commonly referred to as "technology transfer") worked well 20+ years ago when the pace of innovation was a lot slower than it is today, when globalization was relatively unheard of, and when the world was a lot less competitive in the drive to bring valuable products and services to market quickly. Back then, we were afforded the luxury of creating something first, and then searching for an application of what was hoped to be a "valuable technology."

Collaborative Engagement Models

As the pace of innovation has quickened, particularly in the past decade, the research-then-transfer model has been quietly rendered obsolete. Today, the development and engagement models of choice favor multiple partners from the outset, engaging in the free-flow of ideas, simultaneously envisioning many different applications for their work, and creating different types of products and systems that the technologies might be used in.

These new collaborative interaction models are inherently more parallel, more vigorous and engaging, and involve multiple partners (even competitors) working in tandem on their own ideas of what particular idea or innovation that will provide new value to the marketplace. They can't want for a single contribution to be researched, perhaps with a wrong or misguided target application in mind, and then have to redo the research later.

Some of the key points around innovation and interaction models are:

1. Technology transfer is an inherently serial process, takes too long, usually directs research along a single vector of target application, and runs the risk of missing the more useful applications of technology, when the work is at a "transferable stage."
2. The idea of "valuable technology sitting on the shelf" at major research universities is flawed. Much of the value coming out of the innovation process lies in the targeting of early stage ideas to target applications and uses of the technology. This is not where universities can engage from a position of strength.

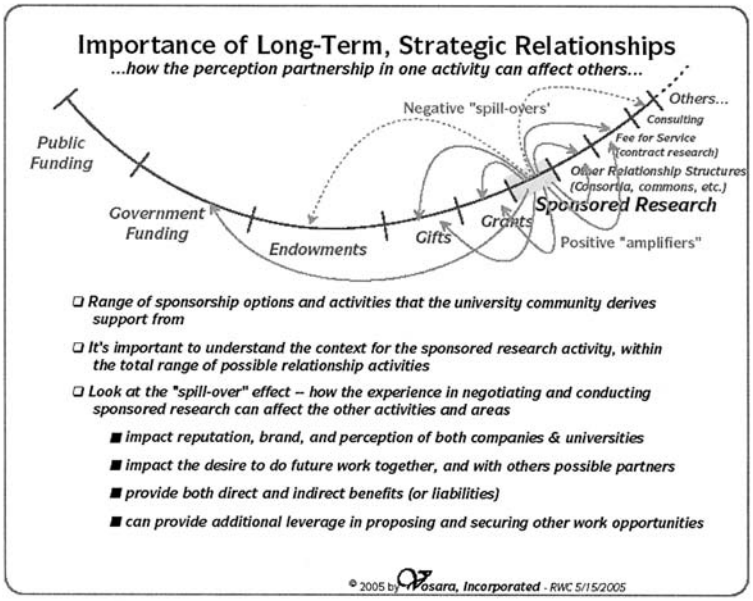
3. Technology transfer focuses institutions on "things"—rights, patents, licenses, etc. These are late-stage, after-the-fact indicators that something valuable has been going on between interested parties.
4. Collaborative models are more parallel, intensive, open processes that generate a flow of ideas, and calibrate directions and likely results quickly. They involve multiple research perspectives, and often result in a particular idea or concept being effectively utilized in multiple places, across multiple disciplines, and enabling multiple commercialization efforts to be undertaken simultaneously.
5. Collaborative models engage universities and industrial partners at the beginning of the process, there ideas are soft and malleable, and could go in a myriad of directions. With multiple partners present, concepts and ideas can be developed in many different directions, simultaneously from the beginning.
6. Collaborative models are more efficient—they minimize the risk of developing a research work on one particular line of application, and then finding out late in the process that the wrong path was chosen.
7. Collaborative models focus on people, capability development, the flow of ideas. They foster relationship-building, help to build trust, and avoid the traps of negotiating who owns what, and what monies should flow to whom, before the work is ever done.

This shift to more interactive and engaging research and development models favors the processes of rapid knowledge creation, the free flow of ideas and concepts, the parallel development of multiple target applications of an idea or technology. In this new model, no single idea or concept becomes the driving force behind compelling new value—it now takes a whole array of new ideas and concepts woven together in such a way as to make the new product or system revolutionary at the time it's interested. As we stated earlier, no single idea can be a "home run," and the value of a single patent without a whole series of others that complement it, is essentially trivial.

University-Industry Relationships

Another important consequence of becoming overly focused on IP, rights, and ownership, is the damage that is done to long-term industry-university relationships. Universities have a wide range of support needs. As mentioned earlier, the IP-focused negotiations which impede collaboration, and the escalating frustrations, mistrusts, and ill-will that result from not being able to reach agreement, have caused incredible damage to these relationships. Yet the damage goes far beyond the bounds of the sponsored research agreement itself.

In actuality, the funding that sponsored research generates for many universities, is usually only a very small portion of their total income. Yet the negative perceptions, the ill-will, and the memories that are generated from failed negotiations—the silent breaking, and the walk-away behaviors—have significant spill-over effects into other sources of sponsorship for the university. Long after a single negotiation has failed, the reluctance to participate in other areas of support such as gifts, grants, endowments, research contracts, consulting arrangements, and others lives on. The negative consequences to the universities on a long-term, aggregate basis dwarf any amount of money that could ever be recouped through IP licenses and royalties.



Summary

For the IT industry to be successful in the coming decades, we must distinguish between inventions (which take us quickly into IP rights, ownership, patents, and licensing discussions) and innovation which is the life-blood of the IT industry. We must recognize that there are different business models operating across different industry sectors, and while a strong IP position may adequately cover the needs of some industries, the need for a focus on innovation, collaboration, and new ecosystem development goes largely unaddressed.

To make the IT industry competitive, we need to begin by creating strong support for industry-university collaboration, and begin to put into place what I call Innovation 3.0—the next version of a rapid, vigorous, and healthy innovation environment.

We must help make U.S. universities the global partners of choice, in this new, global and "flattened" world, and shift the focus of attention back to people, the flow of ideas, and mutually beneficial interactions. Bayh-Dole, as it is presently written, does not accomplish this, but rather shifts attention away from people and ideas (the raw materials of innovation) to IP, rights, licenses, and the ownership of things.

Bayh-Dole also makes a dangerous leap, in that it confuses invention with innovation, and reinforces a language and a vocabulary solely around rights and ownership. These elements are late-stage artifacts of an obsolete technology transfer model, which runs the risk of putting America out of the loop of a competitive, global marketplace where value is created and true innovation takes place independent of any country, policy, region, or institution.

With Bayh-Dole and other legislation we've tried to address the protection of inventions through a strengthening of IP policy. It's time to do something for the other half of the equation—**Ignite Innovation, the life-blood of new industries and the foundation of economic development.**

And that time is now!

Thank-you for your attention, and for the opportunity to testify here today.

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BIOGRAPHY FOR WAYNE C. JOHNSON

Wayne C. Johnson is the Vice President for Hewlett-Packard Company's University Relations Worldwide, located at HP Laboratories in Palo Alto, California. He is responsible for higher education programs in research, marketing and sales, recruitment, continuing education, public affairs and philanthropy.

Johnson joined HP in 2001 from Microsoft's University Relations department where he managed Program Managers and administrative staff across a customer base of 50 tier-one universities. From 1967 to 2000, he held a variety of positions at the Raytheon Company in Waltham, Massachusetts, including National Sales Manager for Wireless Solutions, Manager of International Financing and Business Development, Manager of Administration and Strategic Planning for Raytheon's Research Division, and Manager of Program Development and Operations for Technical Services.

Johnson received his B.A. from Colgate University, Hamilton, NY and his M.B.A. from Boston College's Carroll School, Boston, MA. He was an Adjunct Professor of Management at Boston University from 1977 to 1999.

Johnson currently manages a worldwide organization of Program Managers and administrative staff working across 94 universities worldwide.

Johnson serves as a board member of:

- Anita Borg Institute for Women and Technology (ABIWT)
- MentorNet Advisory Board (MN)
- Industrial Advisory Board, the International Conference on Engineering Education (ICEE)
- Wentworth Institute of Technology (WIT)
- Alliance for Science and Technology Research for America (ASTRA)

His memberships include:

- The Glion Colloquium
- Olin College's President's Council-Chair
- Government-University-Industrial Research Roundtable (GUIRR)
- Association of American Colleges and Universities National Leadership Council (AACU)
- Accreditation Board for Engineering and Technology Industrial Advisory Council (ABET)
- Bay Area Science and Innovation Consortium (BASIC)
- University-Industry Demonstration Partnership (UIDP) Founding Sponsor

Chairman WU. Thank you very much, Mr. Johnson. Professor Lemley, please proceed.

STATEMENT OF DR. MARK A. LEMLEY, PROFESSOR OF LAW, STANFORD LAW SCHOOL; DIRECTOR, STANFORD PROGRAM IN LAW, SCIENCE, AND TECHNOLOGY

Dr. LEMLEY. Thank you, Mr. Chairman, distinguished Members of the Subcommittee. I am Mark Lemley. I teach at Stanford Law School. I want to make it clear that I am here speaking on my own behalf, and not Stanford's. In fact, I suspect I will say at least a few things that will horrify them.

Bayh-Dole fundamentally changed the way universities approach technology transfer, and you can see that best in the statistics. Universities obtain 16 times as many patents today as they did in 1980. Now, everybody is getting more patents, but still, universities' share of all patents in the United States is more than five times greater than it was before Bayh-Dole.

Universities license those patents for upwards of $1 billion a year. The effects of this surge in university patenting, I think, have been both good and bad. On the positive side, I think that the Bayh-Dole Act has had the effect, has achieved the goal, of encouraging university inventors to patent inventions, and to license patents to private companies that can make use of them. So, the risk that inventions were languishing in universities, that they were never commercialized, has I think been addressed in significant measure by Bayh-Dole. And particularly in the biomedical area, these university-private partnerships have been responsible for a number of significant breakthroughs, and I think we are going to hear about at least one in a moment.

On the negative side, universities, I think, too often look to the short run bottom line, how do I maximize my revenue from licensing fees, and setting their licensing priorities, not to the broader picture of how can I best improve technology transfer for the benefit of society. Particularly in the information technology industries we have just heard about, there is a sense that university patents are interfering with, rather than promoting the dissemination of technical knowledge to the world at large, that universities are filing lawsuits to try to restrict the use of this technology, and that they are adversaries, not partners, in the deployment of technology.

There is, in fact, the situation has gotten so bad that one information technology official has publicly referred to universities as "crack addicts," driven by "small-minded tech transfer offices addicted to patent royalties." Now, I don't think the situation is as bad as all that, or at least not as bad as all that most of the time, but the fact that there is this widely divergent view between different industries suggests that we have got an issue, or a problem we need to address, and the testimony here, the very different approaches we have heard so far, I think, is evidence of that.

The need for Bayh-Dole is greatest in the biomedical industry, where the FDA approval process, and the hundreds of millions of dollars, and the years of regulatory approval that are required to develop new drugs, mean that just coming up with an idea for a drug is only the very beginning of the process, and that if there isn't exclusivity associated with that drug, no one is going to take

it all the way through the regulatory environment. By contrast, in a field like computer software, exclusivity not only often isn't necessary, but it can actively interfere with the use of the technology.

The solution, I think, is largely in the hands of universities, rather than legislative response to Bayh-Dole. Universities need, I think, to take a broader view of their role in technology transfer. Technology transfer from universities ought to have as its goal maximizing the social impact of technology, not simply maximizing a university's licensing revenue.

Sometimes, that means patenting an invention and granting an exclusive license. That is going to be true in a lot of cases, in which there is a long, expensive commercialization process that has to happen after the invention has been made. Sometimes, it will mean patenting the invention but granting nonexclusive licenses to all comers. That is especially true of keystone or enabling technologies, the kinds of technologies that open up an entirely new field. So, university patenting was responsible for breakthroughs in chimeric DNA and in DNA manipulation, in monoclonal antibodies. Those patents were all licensed on a nonexclusive basis to all comers, and I think the industry benefited from that. If we decided that one and only one company can have control over recombinant DNA technology, or one and only one company can have control over monoclonal antibodies, I think the biotechnology industry would not be as vibrant and as diverse as it is today.

And sometimes, I think, promoting social technology transfer means foregoing patent protection altogether. So, universities have an obligation, a role, to try to figure out not just what maximizes the bottom line, but what actually is going to achieve the goal of commercialization.

The government has an important oversight role in this process. I think the Bayh-Dole Act contains various provisions designed to limit exclusive licensing of federally owned inventions, and to step in to require reasonable licensing of university owned inventions, so-called march-in rights in particular circumstances. So, my recommendation, at the end of the day, is not that we rewrite Bayh-Dole, not that we change it in fundamental ways, but that universities need to pay attention to the characteristics of the invention and the technology, and that if they don't, there is an oversight role for government to step in and make sure that the licensing occurs on the most reasonable and most favorable terms.

Thank you.

[The prepared statement of Dr. Lemley follows:]

PREPARED STATEMENT OF MARK A. LEMLEY

Summary of Testimony

The Bayh-Dole Act was enacted in 1980 in order to make it easier for universities to transfer technology to the private sector, and to solve the perceived problem of inventions made in universities languishing there, rather than being deployed to solve real world problems.

Bayh-Dole fundamentally changed the way universities approach technology transfer. Universities obtain 16 times as many patents today as they did in 1980, and their share of all patents is five times greater than it was before Bayh-Dole. They license those patents for upwards of $1 billion a year in revenue.

The effects of this surge in university patenting have been both good and bad. On the positive side, it seems clear that the Act has achieved its goal of encouraging university inventors to patent those inventions and to license those patents to pri-

vate companies that can make use of them. Particularly in the biomedical area, these university-private partnerships have been responsible for a number of significant breakthroughs.

On the negative side, universities have too often looked to the short-run bottom line in setting their licensing priorities, granting exclusive rights to breakthrough technologies to businesses that may not be best suited to exploit them for the benefit of society as a whole. Particularly in the information technology (IT) industries, there is a sense that university patents are interfering with rather than promoting the dissemination of technical knowledge to the world at large. The growing number of university-filed and university-sponsored patent lawsuits in the IT industries, many in association with non-practicing entities (or so-called "patent trolls"), has added to the sense in those industries that universities are often adversaries, not partners, in the deployment of technology.

The problem in my view is not with Bayh-Dole per se, but with the way it has sometimes been implemented without sufficient sensitivity to the very different characteristics of different industries. The need for Bayh-Dole is greatest in the biomedical industry, where the FDA approval process and the hundreds of millions of dollars required to develop new drugs means that few will see an idea through to fruition without the promise of exclusivity. By contrast, in a field like computer software, exclusivity not only isn't necessary but may actively interfere with the use of the technology.

Universities should take a broader view of their role in technology transfer. University technology transfer ought to have as its goal maximizing the social impact of technology, not merely maximizing the university's licensing revenue. Sometimes this will mean patenting an invention and granting an exclusive license. Sometimes it will mean granting nonexclusive licenses to all comers. And sometimes it should mean foregoing patent protection altogether. For Bayh-Dole to work as intended, universities must look beyond their short-run profit and think about what is best for society as a whole.

The government has an important oversight role in this process. Bayh-Dole contains various provisions intended to limit the exclusive licensing of federally owned inventions (35 U.S.C. § 209) and to step in to require reasonable licensing of a university-owned invention (35 U.S.C. § 203). To date, those provisions have not been used to exercise effective oversight over university licensing. But they could be. What is required, then, is not new legislation as much as greater vigilance on the part of both universities and federal funding agencies to ensure that university patenting serves its intended purpose and is not misused. Congress should exercise its oversight function to ensure that this happens, but it does not need to change the Act.

If Congress were to rewrite Bayh-Dole, the one change I would encourage is the removal of the provisions (such as 35 U.S.C. § 204) that discriminate against foreign businesses and international trade. They are the product of an earlier era of protectionism, and seem out of place in the global marketplace in which we find ourselves. Doubtless American universities have ample incentive to support local businesses; they should not be precluded from licensing their inventions to whoever can best provide the benefits of those inventions to the American consumer.

Are Universities Patent Trolls?[1]

MARK A. LEMLEY[2]

I. Complaints About University Patents

The confluence of two significant developments in modern patent practice leads me to write a paper with such a provocative title.[3]

A. The Rise of Patent Holdup

The first development is the rise of hold-up as a primary component of patent litigation and patent licensing. You can call this the troll problem if you like.[4] I prefer to think of it as the hold-up problem. But whatever we call the problem, it seems quite clear that more and more patent litigation is being filed, and significant money is being made, by non-manufacturing entities—entities that don't themselves actually make the product and in many cases don't actually engage in developing the technology very far at all. Many of these entities also engage in tactics that allow them to lay low and then take a mature industry by surprise once participants in the industry have made irreversible investments.[5] The holdup or troll problem is particularly significant in component-driven industries, notably information technology (IT), where the problem is compounded by the fact that a product developer such as Intel that must aggregate thousands of different inventions into its semiconductor chip is vulnerable to hold-up by any one of the thousands of inventors. Patent owners in those component industries can capture far more than the intrinsic value of their invention, because under long-standing patent law patent owners have the right not just to sue and get paid the percentage of the value contributed by their invention but to enjoin the sale of Intel's entire chip until it can design a new chip that avoids infringing that patent, something that might take years and require investing billions of dollars in a new fab.[6] These factors have combined to produce the growth industry of the new millennium: patent hold-up. Hundreds of companies are engaging in efforts to capture not just the value of what you contributed to as an invention, but a disproportionate share of somebody else's product.

B. The Rise of University Patenting

The second development in the last three decades is the massive surge in university patenting.[7] Universities obtained sixteen times as many patents in 2004 as in

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[1] © 2006 Mark A. Lemley.

[2] William H. Neukom Professor of Law, Stanford Law School; of counsel, Keker & Van Nest LLP. I am particularly grateful to a large number of people who read this and gave me comments, even though simply asking the question is anathema to many of them. In particular, thanks are due to David Adelman, Ann Arvin, Robert Barr, Linda Chao, Michael Cleare, Peter Detkin, Brett Frischmann, Carl Gulbrandsen, Rose Hagan, Joel Kirschbaum, Kathy Ku, Gary Loeb, Lita Nelsen, Alan Paau, Arti Rai, David Simon, and Janna Tom, and to participants in conferences at Washington University School of Law and the Licensing Executives Society/Association of University Technology Managers joint meeting for comments on this topic. Not only don't they necessarily agree with what I've said, in many cases I'm sure they don't. This is an edited transcript of a speech, and reads like it.

[3] So I don't give anyone a coronary, the general answer to the question in my title is no.

[4] The term "patent troll" was coined in the late 1990s by Peter Detkin, then assistant general counsel at Intel, to refer to patent owners who hide under bridges they did not build to pop out and demand money from surprised passers-by. I'll talk about some definitions of "patent troll" at the end of this paper.

[5] For discussions of this problem, see, e.g., Mark A. Lemley, Ten Things To Do About Patent Holdup of Standards (And One Not To), 48 *B.C. L. Rev.* 149 (2007); Mark R. Patterson, Inventions, Industry Standards, and Intellectual Property, 17 *Berkeley Tech. L.J.* 1043, 1048–51 (2002).

[6] On this problem and how it leads to settlements well in excess of the intrinsic value of the patent, see Mark A. Lemley & Carl Shapiro, Patent Holdup and Royalty Stacking, 85 *Tex. L. Rev.* _ _ {forthcoming 2007); Carl Shapiro, *A Model of Patent Bargaining With Holdup* (working paper 2006).

[7] For a discussion of the growth of university patenting and its potential risks, see DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT 4 (2004); John R. Allison et al., University Software Ownership: Trends, Developments, Issues (working paper 2006); Katherine J. Strandburg, Curiosity-Driven Research and University Technology Transfer, in *University Entrepreneurship and Technology Transfer: Process, Design, and Intellectual Property* 93 (Gary D. Libecap, ed., 2005).

1980,[8] and universities had 1000 times as many technology transfer offices.[9] In significant measure this is a result of the Bayh-Dole Act,[10] which not only permits but encourages university patenting of federally-funded inventions. But it is also a reflection of the growth in importance of patents more generally. Those university patents don't sit dormant; universities license them to companies for over $1 billion a year in revenue.[11] Patents are now a significant contributor to some university bottom lines. And importantly, more and more university patents are patents on the very earliest stages of technology. It is universities, perhaps not surprisingly given their role in basic research, who are patenting the basic building blocks in new technologies. We see this with particular force in nanotechnology, an area I have studied in detail.[12] Universities, which account for one percent of patents on average across all fields, account for 12 percent of all patents in nanotechnology, and more than two-thirds of what I identify as the basic building block patents in nanotechnology.[13] The other area in which university patents are significant is biotechnology, where they represent about 18 percent of all patents.[14] As a result, universities have met a much bigger role in patenting than they ever have before.

C. Are Universities Engaged in Holdup?

At the confluence of these developments is a growing frustration on the part of industry with the role of universities as patent owners. Time and again, when I talk to people in a variety of industries, their view is that universities are the new patent trolls. One even referred publicly to universities as "crack addicts" driven by "small-minded tech transfer offices" addicted to patent royalties.[15]

Why such a vehement reaction? One important reason is that universities are non-manufacturing entities. They don't sell products. I don't think that necessarily means they're bad actors. But it does mean that their incentives in dealing with the patent system align in many ways with those of private-sector patent licensing shops. One of the assumptions corporations in patent-intensive industries (such as IT or increasingly biotechnology) make about patenting is symmetry: that if a competitor sues you for infringement you can sue them back. That symmetry deters patent litigation in the industries in which it operates.[16] But that symmetry doesn't exist for non-manufacturing entities. Universities aren't going to cross license. They aren't going to trade their patents away in exchange for a cross-license, because they don't need a license to other people's patent rights.[17] Instead, they want money. And to an IT general counsel who deals with dozens of threats of suit every year, any patent owner in that position looks an awful lot like a patent troll. In short, there's definitely a sense among industry representatives that universities are greedy when it comes to licensing patents.

Compounding the perception of greed is that university patent licensing offices have strong institutional incentives to grant exclusive rather than non-exclusive li-

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[8] Before 1980, universities worldwide obtained about 250 U.S. patents a year. In 2003, they obtained 3933 patents, an almost sixteen-fold increase. See Bernard Wysocki Jr., College Try: Columbia's Pursuit of Patent Riches Angers Companies, *WALL ST. J.,* Dec. 21, 2004, at A1.

[9] Lorelai Ritchie de Larena, The Price of Progress: Are Universities Adding to the Cost?, 43 *Hous. L. Rev.* 1373, 1412 (2007) ("There were only 25 active technology-transfer office in the United States an the time the Bayh-Dole Act was passed. By the twenty-fifth anniversary of the Act, there were 3300").

[10] 35 U.S.C. § 200 et seq.

[11] Jerry G. Thursby & Marie C. Thursby, University Licensing and the Bayh-Dole Act, 301 SCI. 1052, 1052 (2003); The Big Ten: Universities That Made the Most Licensing Dollars Last Year, IP L. & BUS., Jan. 5, 2005, at 14 (estimating $1 billion in 2004); Bernard Wysocki Jr., Columbia's Pursuit of Patent Riches Angers Companies, *Wall St. J.,* Dec. 21, 2004, at A1, A12 (estimating $1.3 billion per year).

[12] Mark A. Lemley, Patenting Nanotechnology, 58 *Stan. L. Rev.* 601 (2005).

[13] *Id.* at 616 & Table 2.

[14] See David E. Adelman & Kathryn L. DeAngelis, Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate, 85 *Tex. L. Rev.* __ (forthcoming 2007), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=881842*

[15] Comments of Chuck Fish at the Fordham International IP Conference, April 22, 2006.

[16] See, e.g., John R. Allison et al., Valuable Patents, 92 *Geo. L. J.* 435, 474 (2004) (finding that semiconductor patents are litigated only one-third as often as other patents, and offering the symmetry of relationships as an explanation). To be sure, other factors, such as industry concentration and large patent portfolios, may play a significant role in causing disputes in this industry to be resolved without litigation. See Gideon Parchomovsky & R. Polk Wagner, Patent Portfolios, 154 *U. Pa. L. Rev.* 1 (2005).

[17] Theoretically universities could be sued for infringement, but they aren't—there is only one reported decision involving an infringement suit against a university between 1983 and 2004. See Tao Huang, The Experimental Purpose Doctrine and Biomedical Research, 11 Mich. *Telecomm. & Tech. L. Rev.* 97, 111–12 & tbl. 1 (2004). For reasons this might be true, see Rowe, *supra* note __, at 940–44.

censes, for various reasons. First, exclusive licensing royalty rates are almost always higher than non-exclusive rates. That's not surprising, since the licensee is getting more from an exclusive license than from a non-exclusive license. From the perspective of a tech transfer office focused on this quarter's bottom line, that higher royalty rate is hard to turn down. Second, the companies with which they are negotiating often want exclusivity.[18] They are especially likely to get it if the company in question is a faculty-organized startup.[19] Finally, exclusive licensees often pay the cost of patent prosecution, a relatively small savings but an immediate one that impacts the tech transfer office's bottom line. The result is that the overwhelming majority of university patent licenses are exclusive. In the nanotech licenses I studied (just a few dozen, admittedly), between 95 and 100 percent of the university licenses granted were exclusive.[20] One example from the biotechnology field of an exclusive license to an enabling technology is WARF's field-exclusive license to Geron of all stem cell patents, granted shortly before those stem cell patents became extraordinarily valuable because the Bush administration obstructed the development of new stem cell lines.[21]

In fact, however, this higher royalty rate may or may not translate into a higher revenue stream for the university. Whether it does depends on the nature of the technology being licensed. For certain basic building blocks—what I call "enabling technologies"—opening up licensing to many innovators who can develop different uses will generate substantial improvements, while giving an exclusive license to only one person will generate fewer improvements.[22] And exclusive licenses can block any development of a technology if the licensee doesn't deliver.[23] Even if in the long run non-exclusive licensing of many technologies actually increases university revenue, in the short run a university tech-transfer office seeking to maximize the amount of money that the office generates will tend to grant exclusive licenses. Exclusive licenses aren't necessarily bad—a point I discuss below—but they raise concerns about the effective diffusion of new technologies.

A final reason for industry concern about university patenting is that universities are increasingly enforcing their patents. Recent years have seen high-profile cases litigated to judgment by the University of California, the University of Rochester, Harvard, MIT, Columbia and Stanford, and suits filed by many other universities. One notable example is *Eolas Technologies v. Microsoft,*[24] in which the University of California licensed a software patent to a company that really does look like a patent troll however you want to define that term, and then shared with that company a jury award of $535 million against Microsoft.[25]

Universities, recognizing patent licensing and litigation as an important revenue source in the modern environment, have been active in politics, largely in alignment with the life sciences industries (from which most university patent revenue comes)

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[18] See, e.g., William J. Holstein, Putting Bright Ideas to Work Off Campus, *N.Y. Times,* Nov. 5, 2006, at 11 (quoting William R. Brody, president of Johns Hopkins University) ("Companies, on the other hand, want exclusive licenses.").

[19] Ritchie de Larena, *supra* note __, at 1415 (referring to "tacit favoring" of such companies).

[20] Lemley, *supra* note __, at 627; ETC GROUP, NANOTECH'S "SECOND NATURE" PATENTS: IMPLICATIONS FOR THE GLOBAL SOUTH 14 (June 2005), *http://www.etcgroup.org/documents/Com8788SpecialPNanoMar-Jun05ENG.pdf* (last visited Oct. 28, 2005). See also Allison et al., *supra note* __, at __ (discussing exclusive licenses of software patents by universities).

[21] See, e.g., Amy Rachel Davis, Patented Embryonic Stem Cells: The Quintessential "Essential Facility"?, 94 *Geo. L.J.* 205 (2005); Ryan Fujikawa, Federal Funding of Human Embryonic Stem Cell Research: An Institutional Examination, 78 *S. Cal. L. Rev.* 1075 (2005). Those patents are now under reexamination at the PTO, however, and WARF has significantly eased its licensing restrictions, particularly for academic research. For a discussion, see Antonio Regaldo & David P. Hamilton, How a University's Patents May Limit Stem-Cell Research, *Wall St. J.,* July 18, 2006, at B1.

[22] I have made this argument in detail elsewhere, see, e.g., Mark A. Lemley, Property, Intellectual Property, and Free Riding, 83 *Tex. L. Rev.* 1031 (2005), and I won't repeat it here.

[23] Rochelle Dreyfuss relates the story of Johns Hopkins' ill-fated exclusive license to Baxter for a patent that it didn't use. The exclusivity of the license prevented CellPro, which independently developed a commercial use for the invention, from licensing it from the university. See Rochelle Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface 5* (working paper 2005), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763688*

[24] 399 F.3d 1325 (Fed. Cir. 2005).

[25] *Id.* at __. A more recent high-profile case involved the Harvard-MIT patent successfully enforced against Eli Lilly for $65 million. See Brian Kladko, Ariad, research institutes win patent-infringement case against Eli Lilly, *http://boston.bizjournals.com/boston/stories/2006/05/01/daily48.html.* For documenting of other cases, see John R. Allison et al., *University Software Ownership: Hold-Up or Technology Transfer* (working paper 2006); Rowe, *supra* note __, at 936–37.

in opposing most of the effective pieces of draft patent reform legislation. Universities helped argue for eliminating from the 2005 patent reform bill any restrictions on both injunctive relief and continuation applications. The most recent version of the patent reform bill[26] also faced attacks from some universities seeking to eliminate the move to first inventor to file, which doesn't benefit them because they tend to file later than commercial entities, and eliminate the creation of prior user rights, which also don't benefit them since they aren't generally using the inventions. These university preferences shouldn't be surprising, at least if we view the university as a profit-maximizing entity rather than one concerned with the social good. Like other non-manufacturing entities, after all, universities are first and foremost intellectual property (IP) owners, not IP licensees.

The result is a felt sense among a lot of people that universities are not good actors in the patent system. Given the difficulty anyone has had in defining a patent troll, it is easy to move from that conclusion to the idea that universities are trolls too. I think it is worth questioning that leap. There is something going on here, but I'm not sure that it is reasonable to equate university patents with private troll behavior. The common refrain in complaints about patent trolls is that they are not contributing anything to society, but rather obtaining and asserting patents covering technology independently developed by defendants. The question remaining to be answered is whether the same is true of university patents. In other words, it's worth asking whether society needs or wants university patents at all.

II. Do We Need University Patents?

From the perspective of the university, one justification for university patents may be to fund universities. More money is better than less money, and the billion dollars a year in licensing is a substantial new revenue source for universities, most of which goes to research and some of which goes to education. If you think those things are under-funded in our society today, as I tend to believe, generating that additional revenue sounds useful in a way that paying for-profit licensing shops doesn't. But that additional revenue is not costless. It's money that comes out of industry pockets, and at least some of that money otherwise would have gone into industry research and development, or to selling better products, or to providing products more cheaply. So it's worth thinking about the costs of patents as a pure wealth transfer mechanism. And most economists would agree that if our goal is to adequately fund higher education, patent litigation is an inefficient way of doing so.[27] Further, there are some who claim that a culture of patenting imposes costs on the university or on academic research more generally.[28] University scientists focused on patenting may delay or even forego publication in favor of IP protection.[29] And there is a substantial literature on how the shift to university patenting has actually moved universities away from basic research and towards more applied research in ways that are arguably bad for society in the long run.[30] The risk is not so much that individual professors will change their research habits as that the departments that grow and the hiring slots that become available will go to those who engage in revenue-generating applied research. Of course, government and private foundation grants can come with conditions attached, and can also direct research to particular ends, so in practice they aren't perfect funding mechanisms either.

Why else might society need university patents? The classic justification for patents—creating incentives to innovate—arguably isn't nearly as important in the university context as in the private sector. I think it unlikely that university scientists would not do research or invent in the absence of patent protection. There are plenty of other incentives for university scientists to engage in research, including curiosity, academic prestige, and tenure and promotion. Further, university inventors are generally funded by grants or departmental revenue, must assign their rights

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[26] The Coalition Draft of H.R. 2795, 109th Cong., 1st Sess. (2005).

[27] A general tax is a cheaper method of wealth transfer than specific assessments. See, e.g., Alan J. Auerbach & Lawrence J. Kotlikoff, *Dynamic Fiscal Policy* (1987).

[28] See generally Jennifer Washburn, University, Inc.: *The Corporate Corruption of Higher Education* (2005).

[29] See Mowery et al., *supra* note __, at __. Margo Bagley has documented this problem and proposed giving university inventors more time to file patent applications after publishing articles in the hopes of eliminating it. See Margo A. Bagley, Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place, 47 *B.C. L. Rev.* 217 (2006).

[30] Mowery et al., *supra* note __, at __; Arti Kaur Rai, Regulating Scientific Research: Intellectual Property Rights and the Norms of Science, 94 *Nw. U. L. Rev.* 77 (1999); Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 *L. & Contemp. Probs.* 289 (2003); Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 *Yale L.J.* 177 (1987); Brett M. Frischmann, Commercializing University Research Systems in Economic Perspective: A View From the Demand Side, in Libecap ed., *supra* note __, at 155, 176–78.

to the university,[31] and don't necessarily see any tangible benefit from university patenting of their inventions. Now, this doesn't necessarily mean that patents have no additional effect. It may be that patents generate some revenue which is refunded to the researcher's department and supports further research, and even that the prospect of that additional funding motivates some research. But the contribution of patents to university incentives to innovate seems smaller than in profit-driven companies.

The final reason we might want university patents—and the argument that actually prevailed in the Congressional debates over Bayh-Dole—is the commercialization argument. Unlike the classic incentive story, commercialization theory argues that it is not so much the act of invention but the act of turning that invention into a marketable product that requires investment and therefore the exclusion of competition.[32] According to this theory, university inventions will languish and not be commercialized unless we give someone—initially the university, but presumably eventually a private company to which the right is licensed or transferred—control over the invention and therefore incentive to invest in developing and marketing it. This argument seems particularly strong with respect to university inventions, since we can reasonably expect those inventions involve more basic research, and therefore to be made at an earlier stage, than private inventions.

There is some debate as to whether the commercialization theory is actually true of university inventions. Mowery, Nelson, Sampat, and Ziedonis have a very interesting book in which they suggest that Bayh-Dole was based on concerns that were mis- or at least overstated. They argue that there was a good deal of technology-transfer without university patents in the decades before Bayh-Dole, and that even today there is plenty of university technology transfer that occurs in the absence of patents.[33] By contrast, the prevailing wisdom seems to be that university patents increase commercialization, and therefore that Bayh-Dole has been a success.[34] Certainly they increase commercialization deals between universities and companies,[35] though it is hard to know the extent to which that simply reflects the fact that once a patent issues the company in question needs a license in order to commercialize the technology.

My own view is that the validity of commercialization theory depends a great deal on the industry in question and the particular nature of the technology. In the pharmaceutical and biotechnology industries, where coming up with an invention is only the first step down a very long road of regulatory process that's going to take hundreds of millions of dollars and several years, the commercialization argument makes some sense. The university generally isn't going to engage in that regulatory process, and arguably we need to give somebody exclusive rights to induce them to make the regulatory investments that the university itself isn't going to make. We give the right to the university, but we do so expecting that they will transfer or exclusively license that right to a private company that will recoup the hundreds of millions of dollars they spend in clinical trials, product development, and mar-

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[31] See generally Corynne McSherry, *Who Owns Academic Work? Battling for Control of Intellectual Property* (2001).

[32] See, e.g., F. Scott Kieff, Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science, 95 *Nw. U. L. Rev.* 691 (2001); Edmund Kitch, The Nature and Function of the Patent System, 20 J. L. & Econ. 265 (1977); John F. Duffy, Rethinking the Prospect Theory of Patents, 71 *U. Chi. L. Rev.* 439 (2004); Michael Abramowicz, The Problem of Patent Underdevelopment, *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=873473*

[33] Mowery et al., *supra* note __, at __. Inferential empirical evidence for this is provided by Daniel Elfenbein, who shows that the majority of technologies developed at Harvard are licensed before the grant of patent rights, and often without a patent application. Daniel W. Elfenbein, *Publications, Patents, and the Market for University Inventions* 2, 4–5 (working paper 2005). See also Rebecca S. Eisenberg, Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research, 82 *Va. L. Rev.* 1663 (1996) (discussing ways in which patents do and do not promote commercialization of university research). One of the leading objections to university patenting comes from Katherine J. Strandburg, Curiosity-Driven Research and University Technology Transfer, in 16 *Advances in the Study of Entrepreneurship, Innovation, and Economic Growth: University Entrepreneurship and Technology* 97 (2005). By contrast, others—led by university organizations themselves—cite data claiming that Bayh-Dole has been an enormous success. See, e.g., Chester G. Moore, Killing the Bayh-Dole Act's Golden Goose, 8 *Tulane J. Tech. & Intell. Prop.* 151, 155–57 (2006). For an analysis of both the benefits and costs, see Siepmann, *supra* note __, at 230–38.

[34] See, e.g., Wendy H. Schacht, Congressional Research Service Report: *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology,* available at *http://www.ncseonline.org/NLE/CRSreports/07Jan/RL32076.pdf*

[35] Daniel W. Elfenbein, *Publications, Patents, and the Market for University Inventions,* working paper (April 30, 2006), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=739227*

keting.[36] Other industries might also have a long post-invention development cycle and therefore be good candidates for commercialization theory. That might be true of basic building block technologies like nanotechnology, where we expect a very long road between the development of the invention and the ultimate commercialization,[37] though it is likely too early to say for sure how nanotech will develop. In these industries, Bayh-Dole is probably a good thing.

On the other hand, I'm quite confident that central control is not necessary to produce commercialization in the majority of other industries.[38] Bear in mind that the commercialization story is at base anti-market: it assumes, contrary to centuries of economic learning, that ordinary profit motives will not produce efficient allocation of resources and that we need to vest exclusive control of a technology or market in one actor in order to get that efficient allocation.[39] Even if we think that's true in the pharmaceutical or biotechnology industries because of the regulatory barriers to entry in those markets, we should not conclude exclusivity is always or even generally required to encourage a company to bring a product to market.[40] In the IT industries, and even in industries like medical devices, there is no reason to believe that exclusive rights are necessary to encourage commercialization of the technology. It is true even in those industries that when an inventor has gotten to the point where she can patent something, there may still be development and marketing work to be done. But we get plenty of both in a competitive marketplace because the companies who engage in product development and marketing can reap enough of the benefits of that investment to make it worthwhile. And indeed we have seen an enormous number of technologies commercialized out of universities throughout the 20th Century without need of university patents. Think of the computer, the world-wide-web, search engines, relational databases, and any number of software programs.[41]

The need for university patents, in short, depends critically on the technology at issue. I think much of the industry frustration with the role of university patents stems from the failure of some university technology transfer offices to recognize and adapt to these technology differences. As noted above, technology transfer offices have strong incentives to maximize revenue from patent licensing. To achieve this, they have adopted the life sciences model, where exclusive rights and patents seem to make sense because of the regulatory delays, as their general approach to patent licensing. But they are increasingly using it in software and other information technologies.[42] The result is frustration on the part of industry counterparts in industries like computers or telecommunications that are more interested in freedom to operate than in exclusive rights over a new technology. It may also be frustration on the part of tech transfer offices; less than one percent of all university patent licenses generate over $1 million in revenue.[43] And efforts to commercialize the rest is what leads to a lot of the more worrisome patent licenses in cases like Eolas.

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[36] Interestingly, though, even industry players in the pharmaceutical industry sometimes lament university reliance on exclusive licensing. See Thomas J. Siepmann, The Global Exportation of the U.S. Bayh-Dole Act, 30 *U. Dayton L. Rev.* 236 (2004) (quoting Joshua Kalkstein, corporate counsel for Pfizer).

[37] Lemley, *supra* note _ _, at 628–29.

[38] Empirical evidence supports the conclusion that patenting reduces rather than increases technology diffusion overall. Murray and Stern find that patenting is associated with reduced citation to an academic publication associated with the patent. Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* (working paper 2005), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_*id=755701. Were commercialization theory true, it should be the opposite.

[39] See Mark A. Lemley, Ex Ante Versus Ex Post Justifications for Intellectual Property, 71 *U. Chi. L. Rev.* 147 (2004) (making this point).

[40] More and more property rights scholars seem to forget the benefits of a market economy. Michael Abramowicz, for instance, claims that we may not get efficient entry of Indian restaurants into particular neighborhoods unless we grant some sort of regional exclusivity. Abramowicz, *supra* note _ _, at _ _. Maybe he's right, but I doubt it. The market has worked pretty well in the past, and we should be reluctant to forego its benefits unless we're quite sure that the alternative will be better.

[41] For a detailed discussion of one example, Apache, see Jay P. Kesan & Rajiv C. Shah, Shaping Code, 18 *Harv. J. L. & Tech.* 320, 394–96 (2005).

[42] See John R. Allison et al., *University Software Ownership: Hold-Up or Technology Transfer* (working paper 2006) (documenting the growth in university software patenting).

[43] Jerry G. Thursby & Marie C. Thursby, University Licensing and the Bayh-Dole Act, 301 *Sci.* 1052, 1052 (2003) (0.56 percent).

III. Lessons From the University Patent Experience

A. Towards an Enlightened University Patent Policy

Universities should take a broader view of their role in technology transfer. University technology transfer ought to have as its goal maximizing the social impact of technology, not merely maximizing the university's licensing revenue.[44] A university is more than just a private for-profit entity. It is a public-regarding institution that should be advancing the development and spread of knowledge and the beneficial use of that knowledge. Sometimes those goals will coincide with the university's short-term financial interests. Sometimes universities will maximize the impact of an invention on society by granting exclusive licenses for substantial revenue to a company that will take the invention and commercialize it. Sometimes, but not always. At other times a non-exclusive license, particularly on a basic enabling technology, will ultimately maximize the invention's impact on society by allowing a large number of people to commercialize in different areas, to try out different things and see if they work, and the like.[45] Universities can still earn revenue from nonexclusive licenses, and for enabling technologies they might even maximize their revenue in the long-term by granting nonexclusive rather than exclusive licenses.[46] University policies might be made more nuanced than simply a choice between exclusive and nonexclusive licenses. For example, they might grant field-specific exclusivity, or exclusivity only for a limited term, or exclusivity only for commercial sales while exempting research,[47] and they might condition continued exclusivity on achievement of certain dissemination goals.[48] Finally, particularly in the software context, there are many circumstances in which the social impact of technology transfer is maximized either by the university not patenting at all or by granting licenses to those patents on a royalty-free basis to all comers.[49] Open source software development is one example, but hardly the only one.[50]

If we are to achieve the goal of maximizing the social benefit of a university invention to society, universities must first recognize their proper role in society and how that role affects patent policies. An important first step in that education process is to end the isolation of university technology transfer or licensing offices from the rest of the university.[51] If universities treat licensing offices as revenue generation devices, evaluated on how much money they bring in each quarter, the result

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[44] For a similar view, see Robert E. Litan et al., *Commercializing University Inventions: A Better Way,* NBER Working Paper (April 2007).

[45] See Lemley, Nanotechnology, *supra* note __, at __; Ted Sabety, Nanotechnology Innovation and the Patent Thicket: Which IP Policies Promote Growth?, 15 *Alb. L.J. Sci. & Tech.* 477, 510–12 (2005) (both making this argument).

[46] The key university patents on enabling technologies in biotechnology, issued to Cohen and Boyer for the creation of chimeric organisms and to Axel for methods of inserting genes into a cell, were licensed nonexclusively because of NIH requirements. See Wysocki, *supra* note __, at A1. They made enormous sums of money for Stanford, UC, and Columbia, arguably because, not in spite of, the nonexclusivity of the licenses. See Sally Smith Hughes, Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974–1980, 92 *ISIS* 541, 570 & n.77 (2001); Wysocki, *supra* note __, at A12. Amy Kapczynski has argued that open licensing may be profitable for universities more generally, not just with enabling technologies. Amy Kapczynski et al., Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, 20 *Berkeley Tech. L.J.* 1031, 1040 (2005). I am less persuaded by this broader argument.

[47] For examples of such approaches, including Stanford's and WARF's, see Ritchie de Larena, *supra* note __, at 1420.

[48] Stanford University has a relatively enlightened university technology transfer policy that uses all of these intermediate mechanisms. Conversations with Linda Chao, Stanford Office of Technology Licensing (May 2006). Stanford's official policy is at *http://otl.stanford.edu/inventors/resources/otlandinvent.html*

[49] For a general argument along these lines, see Brett M. Frischmann, An Economic Theory of Infrastructure and Commons Management, 89 *Minn. L. Rev.* 917 (2005). See Stanford Office of Technology Licensing Policies, *http://otl.stanford.edu/inventors/policies.html#research* ("Inventors may place their inventions in the public domain if they believe that would be in the best interest of technology transfer"). And some have argued for open licensing of university pharmaceutical inventions in the developing world. See, e.g., Amy Kapczynski et al., Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, 20 *Berkeley Tech. L.J.* 1031 (2005). By contrast, Arti Rai documents the difficulties scientists have had persuading universities to build an open source model for collaborative biotechnology research. See Arti K. Rai, "Open and Collaborative" *Biomedical Research: Theory and Evidence* 29, 35–36 (working paper 2005).

[50] For a useful step in this regard, see *http://www.kauffman.org/entrepreneurship.cfm?topic=innovation&itemID=662* (setting out principles agreed to by corporations and several major universities for making software inventions freely available).

[51] For a discussion of the various ways in which university tech-transfer offices are organized today, see Ritchie de Larena, *supra* note __, at 1413.

will be university patent policies that are not always or even often consonant with the ultimate public interest.[52] The problem is even worse if universities outsource their technology transfer functions altogether to private licensing shops.[53] If a university thinks of its role in society as a whole, if it treats patent licensing as one aspect of a broader technology transfer policy, it can and should develop more enlightened policies. A number of universities have taken significant steps in this regard, but more remains to be done.

B. Legal Constraints on Unenlightened Universities

If universities don't develop such policies voluntarily, society may have other mechanisms to ensure that university patents don't impede innovation. Federal funding agencies can play a role. The National Institutes of Health has at various times in the past imposed mandates requiring universities to grant certain types of licenses to their work.[54] The Bayh-Dole Act permits the government to exercise "march-in rights," requiring that particular patents be licensed on non-exclusive terms.[55] Alternatively, as universities become more and more vulnerable to patent infringement suits themselves,[56] private sector patent owners may be able to create some of the symmetry that drives cross-licenses in industries like semiconductors by obtaining patents that universities infringe and threatening to assert them against any university who sues them for patent infringement.[57] These measures might turn out to be necessary, but I'd like to see us try first to solve the problem not by imposing a solution, but by encouraging universities to take the first step in recognizing their social responsibility associated with their patents.

C. Broader Lessons: Who Is a Patent Troll?

Finally, I think we can learn something about the raging debate over who's a patent troll and what to do about trolls by looking at university patents. Universities are non-practicing entities. They share some characteristics with trolls, at least if the term is broadly defined, but they are not trolls. Asking what distinguishes universities from trolls can actually help us figure out what concerns us about trolls. One of the differences between universities and private licensing shops is that universities are by and large not engaged in hiding the ball, waiting until people have developed an industry and then popping up and demanding a disproportionate share of royalties based on irreversible investments.[58] There are occasional examples of that,[59] and they should be condemned, but it's not the ordinary case with a university license. Instead, most university licenses have a major technology transfer component. A nonexclusive patent license is effectively nothing more than forbearance from suit in exchange for money.[60] By contrast, most university licenses give the licensee not just the right to avoid a lawsuit, but also provide valuable know-how. Indeed, many also involve continued work by the inventor, particularly if the license is to a start-up and is exclusive. That sort of technology transfer is something we want to encourage for reasons Rob Merges has explained: granting IP rights allows us not to be constrained by a particular definition of the firm and forced do all of our innovation in house. It allows us to have markets for technology.[61] Markets for technology contribute more to society than markets for litigation rights.[62] University patent owners aren't trolls in my view when they contribute previously unknown

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[52] See Ritchie de Larena, *supra* note __, at 1416–17 ("One point that most technology-transfer managers agree upon is that it is not wise to judge a university's technology-transfer office solely on licensing income.").

[53] For example, the University of Colorado has outsourced much of its patent licensing to Competitive Technologies Inc.

[54] See Bernard Wysocki Jr., College Try: Columbia's Pursuit of Patent Riches Angers Companies, *WALL ST. J.,* Dec. 21, 2004, at A1 (noting that the NIH required Professor Axel at Columbia to license his fundamental patents on methods of inserting genes into cells nonexclusively and at a reasonable royalty).

[55] 35 U.S.C. § 209.

[56] See, e.g., Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002).

[57] There may be practical reasons why this last option is unlikely, however. See Elizabeth A. Rowe, The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment? 57 *Hastings L.J.* 921, 940–44 (2006).

[58] On this problem, see Lemley, *supra* note __; Lemley & Shapiro, *supra* note __.

[59] For a discussion of a submarine patent strategy employed by Columbia University, see Ritchie de Larena, *supra* note __, at 1417–18.

[60] See, e.g., Intellectual Prop. Dev., Inc. v. TCI Cablevision, 248 F.3d 1333, 1345 (Fed. Cir. 2001) (describing a nonexclusive license as nothing more than a "covenant not to sue").

[61] See Robert P. Merges, A Transactional View of Property Rights, 20 *Berkeley Tech. L.J.* 1477 (2005).

[62] See generally Ashish Arora et al., *Markets for Technology* (2001) (noting the contributions of technology markets).

technology to society, rather than just imposing costs on others by obtaining and asserting legal rights over inventions independently developed by others.[63]

In the abstract, I think we could successfully define patent trolls by distinguishing between cases in which non-manufacturing entities license only the right not to be sued from cases in which the patent owner actually engages in technology transfer. But that's only in the abstract. Were a court ever to announce such a definition, it would immediately be gamed. All true trolls would start passing on some mandatory know-how along with their patent licenses, in order to avoid being categorized as trolls.

What we ought to do instead is abandon the search for a group of individual companies to define as trolls. We shouldn't focus on the question of who is per se a bad actor. In my view, troll is as troll does. Universities will sometimes be bad actors. Nonmanufacturing patent owners will sometimes be bad actors. Manufacturing patent owners will sometimes be bad actors. Instead of singling out bad actors, we should focus on the bad acts and the laws that make them possible. We will solve the troll problem not by hunting down and eliminating trolls, but by hunting down and eliminating the many legal rules that facilitate the capture by patent owners of a disproportionate share of an irreversible investment. We should focus on reform of current continuation practice, which allows patent owners to hide the true nature of their invention until late in the process and facilitates their later claiming to have invented something they did not.[64] We should focus on reform of the willfulness doctrine, under which a patent owner can get treble damages from an independent inventor merely by telling them about the patent and which has the perverse effect of causing people to try to avoid learning of patents.[65] We should focus on reform of royalty calculation rules that give a disproportionate award of damages to patent owners in component industries because they don't adequately take account of the contributions of other aspects of the invention.[66] And we should take the opportunity presented by the Supreme Court's *eBay* decision[67] to craft intelligent standards for deciding when to grant injunctive relief. If we change the rules that make patent hold-up such an attractive revenue generator, we won't have to worry about the question of whether or not universities—or anyone else—are patent trolls. We will have eliminated the problem of opportunistic behavior that interferes with innovation, something we want to stop regardless of what we call it.

BIOGRAPHY FOR MARK A. LEMLEY

Widely recognized as a preeminent scholar of intellectual property law, Mark Lemley is a prolific writer, having published over 70 articles and six books, and an accomplished litigator, having tried cases before the U.S. Supreme Court, the California Supreme Court, and federal district courts. His major contributions to legal scholarship focus on how the economics and technology of the Internet affect patent law, copyright law, and trademark law. Professor Lemley has testified numerous times before Congress and the California legislature on patent, trade secret, antitrust, and constitutional law matters and currently serves as of counsel at Keker & Van Nest in their intellectual property and antitrust divisions. Before joining the Stanford Law School faculty in 2004, he was a Professor of Law at the University of California at Berkeley School of Law (Boalt Hall) and at the University of Texas School of Law, and served as of counsel at Fish & Richardson. He clerked for Judge Dorothy W. Nelson of the U.S. Court of Appeals for the Ninth Circuit.

Chairman WU. Thank you very much, Dr. Lemley, and I will not relay your comments to your colleagues at Stanford. Dr. Allen, please proceed.

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[63] Indeed, Jerry and Marie Thursby argue that the continued role of the inventor in technology transfer is critical to the success of university licenses. Jerry G. Thursby & Marie C. Thursby, *Are Faculty Critical? Their Role in University-Industry Licensing* (NBER Working Paper 2003).

[64] See, e.g, Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 *B.U. L. Rev.* 63 (2004). The Patent and Trademark Office has proposed to take significant steps to limit continuations, though whether the proposals will be implemented is uncertain at this writing. See United States Patent and Trademark Office, *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Distinct Claims,* 71 Fed. Reg. 48 (Jan. 3, 2006).

[65] See, e.g., Mark A. Lemley & Ragesh K. Tangri, Ending Patent Law's Willfulness Game, 18 *Berkeley Tech. L.J.* 1085 (2003) (identifying this problem and proposing changes to deal with it). H.R. 2795, pending at this writing, would make it much more difficult to plead willfulness.

[66] See Lemley & Shapiro, *supra* note _ _.

[67] eBay, Inc. v. MercExchange LLC, 126 S.Ct. 1837 (2006).

STATEMENT OF DR. MARK G. ALLEN, JOSEPH M. PETTIT PROFESSOR; REGENTS PROFESSOR, GEORGIA INSTITUTE OF TECHNOLOGY; CO-FOUNDER & CHIEF TECHNOLOGY OFFICER, CARDIOMEMS, INC., ATLANTA

Dr. ALLEN. Chairman Wu, Ranking Member Gingrey, and Members of the Subcommittee, my name is Dr. Mark Allen. I am a Professor of Electrical and Computer Engineering at Georgia Tech, and I am pleased to be here to address you today.

As we have heard, this hearing has focused on the next 25 years of technology transfers governed by the Bayh-Dole Act, and in order to comment on the next quarter century, I would like to focus on my past experiences as a researcher and transferor of technology, and what this, perhaps, has taught me. And I think that this experience also reflects upon some of the questions the subcommittee has asked.

Some years ago, I was sponsored in my Georgia Tech capacity by the Department of Defense on the topic of intelligent turbine engines. This was a university interdisciplinary research program administered by the Department of Defense, and my portion of the project was to develop a pressure sensor that could be used in particular locations in jet engines to allow optimal engine performance. I worked with a Ph.D. student, and we designed, fabricated, and tested a new type of pressure sensor that was small. It would operate in harsh environments, and able to be communicated with in a wireless fashion.

The results of my research were provided to the Department of Defense, and are currently being built upon by NASA, and in addition, the research results were patented by Georgia Tech, in accordance with the provisions of the Bayh-Dole Act. Conference publications, journal publications, and a Ph.D. thesis were all written on this work, and were all disseminated as an ongoing part of the academic research, and the patenting did not interfere with that in any way.

I began discussions a few years later with a medical doctor, who was interested in adapting new technologies to create the next generation of medical devices, and after several discussions, we noted that the pressure sensor that we developed for harsh environments in engines might also be applicable in another harsh environment, the human body.

We formed a company called CardioMEMS, dedicated to commercialization of this technology. CardioMEMS licensed some of the key patents, including the two cited from this DOD program, exclusively in a specific field, that of medical devices. Based on these patents, CardioMEMS engineers further developed wireless sensors to monitor aneurysms that have been repaired by physicians, and the sensors are used to provide information to the physicians, so they can monitor whether aneurysm repair is working.

The government funding provided by DOD, that was directed to the development of the sensor, was approximately half a million dollars, and today, CardioMEMS has received approximately $50 million in private equity investment, so that is a ratio of about $100 of private investment for each dollar of government investment. The company currently employs over 100 people. Its sensors are FDA approved, and in fact, we are cited in the 2005 FDA an-

nual report as an example of a device "that we believe will have a particular impact on patient care."

Having clear access to the intellectual property developed in the academic laboratory, through the mechanism of the Bayh-Dole Act, was the prerequisite for CardioMEMS' success, because as many of us know, in order to secure venture funding, it is necessary to have clear intellectual property rights to the inventions being developed.

Speaking more generally, the benefits of Bayh-Dole are numerous and well documented. One of the most significant contributions in the Act may be that it ensures nondiscriminatory access to and benefit from the technologies that result from our public investment in university research. This allows the creation of, in the United States, of new products, new companies, and new markets. In 2003, the President's Council of Advisors on Science and Technology affirmed the success of the Bayh-Dole Act, and noted that other nations are attempting to replicate this model.

Another significant benefit of Bayh-Dole, and one that we might think about in our discussions of industry-wide differentiation, is the flexibility of the law. By not constraining the use of Bayh-Dole, a variety of approaches, including exclusive and nonexclusive licensing, exclusive licensing in fields of use, such as the CardioMEMS example, which did not preclude further licensing in areas such as jet turbine engines, and also, the use of territories, universities and companies are able to tailor their agreements for specific industries, technologies, and applications, under the existing legislation.

Today, U.S. industry continues to face competitive pressures globally, and the need for basic research as the foundation of innovation still exists. While cultural differences sometimes strain collaboration between industry and academia, I firmly believe the Bayh-Dole Act has helped foster a new and highly successful era of collaboration, by establishing a uniform federal invention policy, encouraging universities to develop relationships with industry through commercialization of inventions, and establishing preference for manufacturing of products in the United States.

Based on the objective numerical successes of the Act, as well as my own personal experiences with CardioMEMS, I feel strongly we should not alter in any significant way the legislation that has been so successful, and that the rest of the world is using as a model of innovation.

In summary, thank you again for the opportunity to comment on my experiences, and on the topic of Bayh-Dole, and I would be happy to answer any questions.

[The prepared statement of Dr. Allen follows:]

PREPARED STATEMENT OF MARK G. ALLEN

Mr. Chairman, Ranking Member Gingrey and Members of the Subcommittee, my name is Dr. Mark Allen and I am pleased to be able to present testimony to the Subcommittee on the topic of Bayh-Dole—The Next 25 Years. I received the SM and Ph.D. degrees from the Massachusetts Institute of Technology (M.I.T.) in 1986 and 1989 respectively, and joined the faculty of the Georgia Institute of Technology[1] (Georgia Tech) after a postdoctoral appointment at M.I.T. Currently I am Regents' Professor of Electrical and Computer Engineering at Georgia Tech, with a joint appointment in the School of Chemical and Biomolecular Engineering, and hold the

[1] *http://www.gatech.edu*

J.M. Pettit Professorship in Microelectronics. Georgia Tech was founded in 1885 and is one of the Nation's top research universities, distinguished by its commitment to improving the human condition through advanced science and technology. Georgia Tech's campus occupies 400 acres in the heart of the city of Atlanta, where more than 17,000 undergraduate and graduate students receive a focused, technologically-based education. Georgia Tech also has satellite campuses worldwide. Georgia Tech's vision and mission is to define the technological research university of the 21st century, and educate the leaders of a technologically-driven world.

This hearing is focused on the next 25 years of technology transfer governed by the Bayh-Dole Act. In order to comment on the next quarter century, I will rely upon my past experience as a researcher and transferor of technology. This experience also reflects upon the questions the Subcommittee has asked of me.

In the mid to late 1990s and in my capacity as a Georgia Tech professor I was involved with a Multi-disciplinary University Research Initiative (MURI) program on Intelligent Turbine Engines. As defined by the Department of Defense, "The MURI program is a multi-agency DOD program that supports research teams whose efforts intersect more than one traditional science and engineering discipline. Multi-disciplinary team effort can accelerate research progress in areas particularly suited to this approach by cross-fertilization of ideas, can hasten the transition of basic research findings to practical applications, and can help to train students in science and/or engineering in areas of importance to DOD."[2]

The particular program was sponsored by the Army Research Office and was on the topic of "Intelligent Turbine Engines." My portion of the project was to develop a pressure sensor that could be used in particular locations in the engine to provide control signals to ensure optimal engine performance. Working with a Ph.D. student, we designed, fabricated, and tested a new type of pressure sensor that was (1) small in size; (2) capable of operating in harsh environments, such as high temperature; and (3) capable of wireless interrogation.

The results of my research were provided to the Army. In addition, the research results were patented by Georgia Tech[3] in accordance with the provisions of the Bayh-Dole Act. Conference publications[4], journal publications[5], and a Ph.D. thesis[6] were written and disseminated as an ongoing part of this academic research.

In the 2000–2001 timeframe, I began discussions with a medical doctor who was interested in exploiting microelectromechanical systems (MEMS)-based manufacturing technologies to create a new generation of medical devices. Wireless sensors, that could sense disease states from within the body, were a particular interest area of both of us; from his perspective as a clinician and from mine as an engineer. After several discussions, we noted that the turbine engine sensor developed for harsh environments under the MURI research program might also be applicable in another harsh environment, the human body. We formed a company, Cardiomems[7], dedicated to the commercialization of this technology. Cardiomems licensed key patents, including the two cited from the MURI project, exclusively in the field of medical devices. Based on these patents, Cardiomems engineers developed wireless sensors as monitors of endovascularly-repaired abdominal aortic aneurysms. The sensors are integrated with an external measurement antenna. A real-time waveform of the pressure environment of the excluded aneurysm is extracted and provided to the physician to diagnose the state of the aneurysm repair.

The government funding provided by the Army Research Office that was directed to the development of this sensor was approximately $500,000. To date, Cardiomems has received approximately $50 million in private equity investment, a ratio of approximately $100 of private investment for each $1 of government investment. Cardiomems currently employs over 100 people. Its wireless pressure sensors for aneurysm sensing were cleared for sale in the United States by the FDA in late 2005 and to date thousands of people have received them.

One of the key due diligence reviews prior to any private equity investment is a thorough review of the intellectual property licensed by the company, and it was clearly stated by investors that a strong intellectual property position would be a

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[2] *http://www.acq.osd.mil/ddre/research/muri/muri.htm*

[3] U.S. Patents 6,111,520 and 6,278,379.

[4] English, J.M.; Allen, M.G., "Wireless micromachined ceramic pressure sensors," *Technical Digest, Twelfth IEEE International Conference on Micro Electro Mechanical Systems,* pp. 511–16 (1999).

[5] Fonseca, M.A.; English, J.M.; von Arx, M.; Allen, M.G., "Wireless Micromachined Ceramic Pressure Sensor for High Temperature Applications," *IEEE/ASME J. Microelectromechanical Systems,* v. 11, no. 4, pp. 337–43 (2002).

[6] English, J.M., *"Wireless micromachined ceramic pressure sensors for high temperature environments,"* Ph.D. Thesis, Georgia Institute of Technology (2000).

[7] *http://www.cardiomems.com*

prerequisite for any investment. Without this strong position, enabled by licensing the critical technologies from Georgia Tech, in my opinion it would have been impossible for the company to have raised funding for this product. Due in part to the strong IP position the company holds as enabled by the Bayh-Dole Act, the medical community now has available a commercial device that has helped thousands of people, won multiple awards, and was cited in the 2005 annual report of the Food and Drug Administration as a device "that we believe will have a particular impact on patient care."[8]

To summarize this portion of my testimony, what these experiences have taught me is that the commercialization process has many challenges. By far the largest challenge is the development effort required to transform academic discoveries into useful, commercial, salable products (as I mentioned above, this effort at least for Cardiomems was in dollar terms approximately a 100:1 ratio), and includes not only further technical development, but also legal issues, raising funds, liability protection, and securing regulatory approval. However, before embarking on any of these additional challenges, and before raising the first dollar from private investments, Cardiomems negotiated for licenses to the intellectual property with the university holders. Having clear access to the intellectual property developed in the academic laboratory through the mechanisms of the Bayh-Dole Act was the prerequisite for Cardiomems' success.

Although I have spoken previously from my viewpoint as an academic researcher and given a single example of Bayh-Dole-enabled success, it is clear that the Bayh-Dole Act has had a broad and profound effect on academic technology transfer more generally. In the first twenty-five years after its passage, there was a ten-fold increase in academic patent portfolios according to statistics maintained by the Association of University Technology Managers. If, as some have said, innovation is the intersection of invention and opportunity, this wave of innovation created 5,000 new businesses, 3,641 new products, and generated 300,000 jobs.[9] Annually, U.S. research universities and institutions receive about sixty-seven percent of their research funding from the Federal Government).[10] Inevitably, simply because the vast majority of inventions in universities arise in the course of federally-funded projects, universities' obligations under Bayh-Dole will shape administrative systems for handling intellectual property, irrespective of the funding source.

In the State of Georgia the economic impact of technology transfer activities at universities is profound. Georgia Tech ranked 9th on the U.S. Patent and Trademark Office's List of Top 10 Universities Receiving the Most Patents in 2005 (April 6, 2006). In announcing the list, Jon Dudas, Under Secretary of Commerce for Intellectual Property noted that "America's economic strength and global leadership depend on continued technological advances. Ground-breaking discoveries and patented inventions generated by innovative minds at academic institutions have paid enormous dividends, improving the lives and livelihoods of generations of Americans." That certainly seems to be the case in Georgia. In our most recent fiscal year, Georgia Tech executed 42 licenses and options, most for more than one patent. In fiscal year 2006, ten new companies were formed based Georgia Tech technologies; between 2001 and 2006, that list includes 53 companies. Since 1999, companies from the Advanced Technology Development Center (ATDC)[11], a business incubator that is part of Georgia Tech's Enterprise Innovation Institute, have raised over one billion dollars in venture capital. In 2006, 10 of the top 25 largest venture capital deals in Georgia—including the two largest—went to ATDC companies, representing 21 percent of investments in Georgia.

The most significant contribution of the Act may be that it ensures non-discriminatory access to and benefit from the technologies that result from the public investment in university research. Small businesses receive preference under Bayh-Dole but the marketplace establishes the consideration for the license. As a condition of federal awards, universities are obligated to take steps to make nascent technologies available to the public by licensing them to entities that have the ability to bring them to the marketplace. Universities must ensure that licensees meet milestones for development of the technologies or products. Universities provide the government with a royalty-free right to use the technology for government purposes. Finally, in the relatively rare event that the university receives royalties under a license, its share of the funds may only be used to further research and the education of students. This reinvestment in research and education benefits both industry and

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[8] Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration, *2005 Annual Report,* pp. 1–4.

[9] Data from the Association of University Technology Managers: *www.autm.net*

[10] Association of University Technology Managers' 2005 U.S. Licensing Survey.

[11] *http://www.atdc.org/overview.asp*

the public through building research capacity in the public space and expanding the high tech workforce.

The impact of the Bayh-Dole Act varies across industry sectors. Biotechnology, medical device, and pharmaceutical companies typically must have the ability to obtain exclusive licenses to intellectual property. In this sector, new products tend to have fewer components. They also must meet expensive, time-consuming, but necessary regulatory requirements to bring a product to market. By comparison, in the electronics sector, where the long-term value of specific intellectual property is variable, access to a wide portfolio of patents may be necessary to develop a product. Product realization tends to be more rapid. Similarly, different licensing strategies may apply in dealing with small companies, in particular start-ups, than with larger companies. And, in a number of circumstances, the competitive advantage afforded through exclusivity may be absolutely critical to justify the risk undertaken by a company in developing a product from a promising early-stage university technology, as it was in the case of Cardiomems. As technology transfer within U.S. universities has matured over the past twenty-five years, this need for different licensing strategies across and within industry sectors has become widely recognized. Fortunately, the authors of the Act anticipated this need and provided universities with the flexibility to pursue exclusive or non-exclusive licensing strategies.

Challenges do exist in the relationship between American companies and universities. The primary cultural differences between them stem from their divergent missions and result from differences in their research agendas and positions on the dissemination of knowledge. In 2004, the National Academies of Sciences' Government University Industry Research Roundtable served as the neutral convener for a collaborative effort of the National Council of University Research Administrators and the Industrial Research Institute that would lead to an open dialogue about these cultural differences. It was hoped that the conversation would lead to new approaches that could respect the missions of higher education and private industry and their respective contributions to innovation. In April 2006, this group published *Guiding Principles for University-Industry Endeavors*[12] which examines the perspectives of universities and industries and identifies the common ground and the symbiotic relationship between American companies and universities. These *Guiding Principles* can serve as a roadmap for building collaboration and have the potential to foster stronger ties among those with common interests. However, an examination of this document reveals that the treatment of inventions that arise from federally-funded research at universities is not a factor in the relationship between industry and universities.

The Subcommittee asks about the possible effects of the globalization of research.

Universities in the United States have traditionally welcomed students from around the world. Faculty members have for many decades engaged in open collaborations in research and educational programs with colleagues in other countries. Universities have, therefore, had long experience in competing globally for talented students and faculty and competing globally in scholarship and intellectual output. For the last half of the twentieth century, the United States was undoubtedly the world's leader in science and technology. Even as European universities rebuilt following World War II, other nations' research institutions have emerged and grown along with R&D investment in those countries. Scientific and technological research as a global phenomenon has been studied intensively in recent years by a number of organizations including the National Academies of Sciences, The President's Council of Advisors on Science and Technology (PCAST), and the National Science Board.

The Committee on Science, Engineering and Public Policy of the National Academies stated in 2006[13], "Many international comparisons put the United States as a leader in applying research and innovation to improve economic performance". However, both this report and the PCAST report, *Sustaining the Nation's Innovation Ecosystems: A Report on Information Technology Manufacturing and Competitiveness*[14], noted that other nations are catching up to U.S. leadership in information technology research and development. In its *Science and Engineering Indicators 2006*[15], the National Science Board characterized the link between innovation and economic competitiveness by asserting that,

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[12] National Council of University Research Administrators (NCURA) 2006.

[13] *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Future.* National Academies Press, 2007.

[14] *Sustaining the Nation's Innovation Ecosystems: A Report on Information Technology Manufacturing and Competitiveness,* January 2004.

[15] *Science and Engineering Indicators 2006,* Volume 1, Chapter 4.

Increasingly, the international competitiveness of a modern economy is defined by its ability to generate, absorb, and commercialize knowledge. Although it is no panacea, scientific and technological knowledge has proven valuable in addressing the challenges countries face in a variety of areas such as sustainable development, economic growth, health care, and agricultural production. Nations benefit from R&D performed abroad, but domestic R&D performance is an important indicator of a nation's innovative capacity and its prospects for future growth, productivity, and S&T competitiveness.

This report also found that the majority of research and development in the world is still performed by a small number of wealthy nations but that, as in many sectors, emerging economies are investing increased resources in research. The National Science Board identified the following factors in assessing a country's R&D performance and innovation capabilities:

- The culture of cooperation between R&D performing sectors
- The ability of a country to train and retain its highly skilled scientists and engineers
- Strong intellectual property laws and a strong patent system
- Governmental, legal, and cultural restrictions
- The presence of a sophisticated, demanding, and wealthy domestic market for innovation
- The quality of research institutions (universities and government facilities) as quantitatively assessed by objective measures of research output and peer rankings
- Research infrastructure including facilities and instrumentation.

The Bayh-Dole Act is a key element in several of these factors. The Act is part of strong protections for intellectual property that arises from federally-funded research and helps ensure that entrepreneurs can find the sophisticated, wealthy, demanding investors and, ultimately, markets for new technologies. Bayh-Dole also contributes to the strength and quality of U.S. research universities. In 2003, PCAST affirmed the success of the Bayh-Dole Act and noted that other nations are attempting to replicate this model. As Senator Birch Bayh commented in a speech last year to the Licensing Executives Society, "It is no accident the rest of the world is copying the Bayh-Dole model. The European Union, Japan, China, India and many others hope to tap their own cutting edge university research to win the future economic race. We in the United States cannot afford to rest on our laurels." For example, Japan, clearly recognized as a world economic leader with a focus on technology markets, began implementing laws in the 1990's that contained provisions similar to the U.S. Bayh-Dole Act. Other countries throughout the world now recognize the importance of protecting intellectual property, having laws that allow their universities to assert rights in employee created intellectual property, and of benchmarking the system that resulted from the passage of Bayh-Dole. As Senator Bayh further noted, "When India decided that it wanted to start being a creator of technology and not an exporter of scientists to the West, it began protecting intellectual property."

Finally, the Subcommittee has asked what changes might be appropriate as we look forward to the next 25 years of Bayh-Dole.

The President's Council of Advisors on Science and Technology undertook a year-long study of the results of the federal investment in research and development. Their *Report on Technology Transfer of Federally Funded R&D: Findings and Proposed Actions*[16] was submitted to the Office of Science and Technology Policy on May 13, 2003. I commend this report, which offers a thorough analysis of technology transfer by a panel representing both higher education and industry, to the Subcommittee and have included it as an appendix to this written testimony. While PCAST made a number of recommendations to the Department of Commerce and others regarding education and implementation, their conclusion is:

"Existing technology transfer legislation works and should not be altered."

By almost any objective standard, the Bayh-Dole Act has been an exceptional success. More compelling than the 4,932 new licenses signed, the 527 new products introduced into the market or the 628 new companies formed in 2005 according to the AUTM's U.S. Licensing Survey are the individual technology realization stories captured in their The Better World Report first published last year. This report takes

[16] *Report on Technology Transfer of Federally Funded R&D: Findings and Proposed Actions.*

an in-depth look at twenty-five innovations derived from academic research that has had a dramatic impact on the world. Whether it is the story of Taxol® and the more than two million women worldwide who have taken the drug to fight ovarian and breast cancer, the SpeechEasy® device that has helped thousands of individuals affected with stuttering, Google™ and its more than 10,000 employees, or countless others, including the Cardiomems story, the success of academic technology realization is clear. This is a significant improvement from when intellectual property resulting from federally funded research was available to all non-exclusively and nearly 30,000 patents laid dormant.

Over twenty-five years ago, Senator Birch Bayh opened the hearings on the legislation with the following 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 No. 1 in international economic competition. In a number of industries we are no longer even No. 2. New incentives and policies are needed to reverse this trend."*

Today, U.S. industry continues to face competitive pressures globally. The need for basic research as the foundation of innovation still exists. And, while, cultural differences sometimes strain collaboration between industry and academia, the Bayh-Dole Act has helped foster a new and highly successful era of collaboration by establishing a uniform federal invention policy, encouraging universities to develop relationships with industry through commercialization of inventions, and establishing preference for manufacturing of products in the United States.

Based on the objective, numerical successes of the Act as well as my personal experiences with Cardiomems, I feel strongly we should not alter in any significant way the legislation that has been so successful, and that the rest of the world is using as the model of innovation.

Thank you again for this opportunity to comment on my experiences and the topic of Bayh-Dole. I am pleased to respond to any requests the Subcommittee may have for additional information regarding my testimony.

Attachment: *Technology Transfer of Federally-Funded R&D,* PCAST 2003.

THE PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY

Report on Technology Transfer of Federally Funded R&D

Findings and Proposed Actions

Overview

The President's Council of Advisors on Science and Technology (PCAST), through its Panel on Federal Investment in Science and Technology and its Economic Benefits, has reviewed two specific aspects of the government's investment in research and development (R&D). The first part of this review reported on the federal government's research portfolio, and can be found in PCAST's October 2002 Report: *Assessing the U.S. R&D Investment*.

This Report completes the second part of the R&D review, which focused on the value of federal research in maintaining the United States' economic leadership as it relates to the commercial use of technology developed with federal funding. Specifically, a study was conducted of the technology transfer mechanisms that encourage commercial developments, as well as the state of development of the research.

This review looks at technology licensing practices that have a very long and established history in the United States. Technology transfer practices are embedded in the earliest national defense research, activities of the Extension Services, especially the Agricultural Extension Services, and the preparation of scientific publications that date back nearly 100 years. The nation evolved rapidly during and after World War II[1] from one with very little technical development work or interest in intellectual property, to one leading a revolution in several technological disciplines.

[1] Howard W. Bremer. November 11, 2001. "The First Two Decades of the Bayh-Dole Act as Public Policy". Presentation to National Association of State Universities and Land Grant Colleges, Washington, D.C.

The increasingly sophisticated military demands of this era caused a dramatic increase in technological research, as it quickly became apparent that the government alone was not able to conduct the range and number of scientific projects needed to win a war. These priorities gave rise to a rapid evolution of government funded R&D contracts, which further proliferated with the commencement of substantial federal funding for disease related medical research in 1950.

However, in these early years there was only limited commercial interest by industry in federally funded inventions due to several factors. Most important, the government retained title to and ownership of most inventions, relinquishing title to the inventing organization only in unusual circumstances and making the inventions available to industry on a non-exclusive basis. These issues were compounded by the government's failure to develop a uniform patent policy, as well as the absence of any statutory authority giving agencies the ability to patent or license their inventions. Significant inconsistencies in the practices by a large number of agencies gave companies little incentive to invest in and develop products that were not properly protected and could be readily licensed and sold by competitors. As a result, the government accumulated an enormous backlog of unused federally funded and patented inventions, which numbered 25-30,000, only about 5% of which had been licensed to the private sector for commercialization.[2]

Although several incremental legislative initiatives were introduced over a number of years to facilitate the commercialization of taxpayer-financed research, the Bayh-Dole and Stevenson-Wydler Acts of 1980 and related follow-on legislation are credited as the first impetuses for a dramatic change in technology transfer practices in the United States. A recent study[3] provides evidence that additional factors, such as the increasing industrial commitment to technological R&D and a judicial trend to strengthening intellectual property rights, were also important contributors to the rapid rise in licensing activities commencing in 1980. Nevertheless, Bayh-Dole was in itself successful because it gave businesses and non-profit organizations, including universities, the right to retain title to federally funded inventions thereby providing an effective

[2] *Ibid.*

[3] David C. Mowrey, Richard R. Nelson, Bhaven N. Sampat and Arvids A. Ziedonis. 1999. "The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980" in *Research Policy* 30 (2001) 99-119.

conduit for the timely and broad distribution of government funded technology to the private sector. (The latter requires a *quid pro quo* set of obligations from universities to retain and administer such rights.) Provisions of Bayh-Dole are extended to the federal laboratories, large businesses conducting federally funded R&D, intramural federally funded R&D, the National Aeronautics and Space Administration, and the Department of Energy through a series of additional federal actions.[4]

The Bayh-Dole Act

The Bayh-Dole Act* is legislation that changed several practices to create a favorable environment for the transfer of government-funded inventions to the private sector for commercialization. The Act provided a uniform patent policy among the various governmental agencies that funded research and, most importantly, enabled businesses and not-for-profit organizations, including universities, to retain title to inventions made under federally funded research programs. The major provisions of the Act include:

- Non-profit institutions, including universities, and small businesses may elect to retain title to innovations developed under federally funded research programs;
- Universities are encouraged to collaborate with commercial enterprises to promote the utilization of inventions arising from federal funding;
- Universities are expected to file patents on inventions they elect to own;
- Universities are expected to give licensing preference to small businesses;
- The government retains a non-exclusive license to practice the patent throughout the world; and
- The government retains march-in rights.

*The legislation was enacted on December 12, 1980, as P.L. 96-517 (35 U.S.C. §§ 200-12) under the co-sponsorship of Senators Birch Bayh of Indiana and Robert Dole of Kansas.

The PCAST Panel held a series of industry and government hearings, as well as solicited written comment, looking at various aspects of the transfer of government-funded technology and its subsequent commercialization.[5] Testimony was heard in three separate briefings from experts

[4] The Trademark Clarification Act (1984), Executive Order 12591(1987), Stevenson-Wydler Technology Innovation Act (1980), National Aeronautics and Space Act (1958) and the Atomic Energy Act (1954) and Non-Nuclear Energy Research Act (1974).

[5] April 11, 2002, PCAST conducted hearings involving the Pharmaceutical Research and Manufacturers Association of America, Biotechnology Industry Organization and the Semiconductor Research Corporation. May 9, 2002, PCAST heard from the Association of University Technology Managers, Battelle Memorial Institute, the U.S. Department of Commerce and the NIH Technology Transfer Office. December 12, 2002, PCAST conducted a public hearing through the sponsorship of the Rand Science & Technology Policy Institute with presentations by the

representing industry and academic trade associations, research consortia, universities, government contracting research organizations, national laboratories and government agencies involved in the oversight of technology transfer, as well as its practice. The first two sessions gathered information on technology transfer resulting from the Bayh-Dole Act of 1980 and related legislation. The Panel looked more broadly at general technology transfer mechanisms in its third forum, a public session, on December 12, 2002. Plans for this meeting were published in advance in the Federal Register to encourage public discussion and comment from anyone who was interested. Written comment on the subject was also solicited from the venture capital community, which provides early stage capital to entrepreneurial technology companies largely involved in health care, biotechnology and information technology.

The Science and Technology Policy Institute[6] at RAND Corporation was asked to document technology transfer mechanisms resulting from federal legislation in order to provide a frame of reference for the hearings and a basis for PCAST's recommendations. The report, "Facilitating Technology Transfer of Federally Funded R&D,"[7] discusses five specific areas:

- An overview of the purpose and complex process of technology transfer;
- Legislation that governs technology transfer;
- Measuring the effectiveness of technology transfer activities;
- A summary of presentation and discussion themes from the December 12, 2002, public forum; and
- A process for identifying and documenting the best technology transfer practices.

Council on Government Relations, Massachusetts Institute of Technology, Hogan and Hartson, Sandia National Labs, General Electric and the Semiconductor Research Corporation.

[6] The Science and Technology Policy Institute is a federally funded research and development center sponsored by the National Science Foundation and managed by RAND that provides research and analysis for the White House Office of Science and Technology Policy and other federal agencies.

[7] Shari Lawrence Pfleeger, Mark Wang, David Adamson, Gabrielle Bloom, William Butz, Donna Fossum, Mihal Gross, Terrence Kelly, Aaron Kofner and Helga Rippen. January 2003. "Facilitating Technology Transfer of Federally Funded R&D", RAND Science and Technology Policy Institute, Arlington, VA.

Several of these topics are mentioned briefly in the recommendations made by this Report, though none of them will be discussed in detail. The Findings and Recommendations in this Report are those of the PCAST.

What is Technology Transfer*?

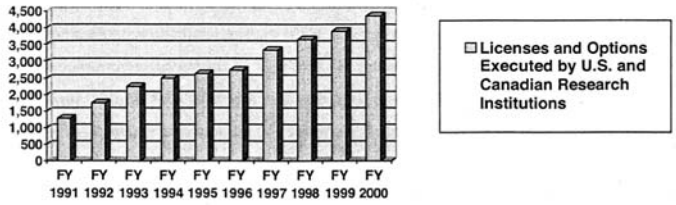
The term "technology transfer" tends to mean different things to different entities, generally giving flexibility to individuals and organizations within their practices. However, most broad definitions include:

- Technology—as an idea, practice or object resulting from research, as well as an embodiment of the technology;
- The movement of technology into a setting where it can improve a product or process in some way; and
- An entire process involving facilitators at different steps, including those who create the technology, those who incorporate the technology into a useful product, service, tool or practice, and those who further develop the technology for commercialization and use.

*Source: Pfleeger, *et al*, "Facilitating Technology Transfer of Federally Funded R&D," at note 7.

Summary of Findings

The transfer of government funded R&D involving technology to the private sector has grown significantly in the last two decades and today represents an increasingly important part of the overall industrial commercialization of technology (see graph below*). Equally important, the transfer of publicly funded technology is a critical mechanism to optimizing the return for this substantial taxpayer investment, particularly where other benefits are not measurable at all or are very long-term and therefore not measurable for years or even decades.



* Source: The Association of University Technology Managers (AUTM) Licensing Survey: FY 2000. No consistent, comparable data were collected prior to 1991.

The evolution of research from the laboratory into a setting where it can improve a product or process, or even become the basis of a new company, involves a number of different mechanisms and they vary in their effectiveness depending on the circumstances. Perhaps the simplest and least expensive is the publication and broad public dissemination of research results.

The publication of technical developments is a routine professional practice, particularly associated with university R&D. While its effects are difficult to quantify, publication is a form of technology transfer that has wide reaching consequences. Publication can be done exclusive of any effort at seeking protection of intellectual property rights, or it can be done in concert with such efforts. Using provisional patent filing processes allows researchers to publish, while protecting intellectual property rights. The majority of publications are not accompanied by any use of intellectual property protection. While the process of patenting and licensing inventions is employed by most technical fields, it is an expensive, time consuming process that has been most successfully employed for applications where there is a history of strong intellectual property protection and where the return on investment for the resources required to commercialize the invention consistently outweigh the risks of development failure. Such is the case for pharmaceutical applications of life sciences research discoveries, but it is less prevalent in other areas such as seed industry applications of plant agricultural research.

Other forms of technology transfer include, but are not limited to, Collaborative Research and Development Agreements (CRADAs), patents and licensing of intellectual property, as well as the direct transfer of technology. Furtherance of the commercialization process beyond an initial proof of concept can be enhanced through the activities of non-profit or commercial incubators that assist inventors in the early stages of business development. Government funded research performed by federal agencies, government-contracting laboratories, universities, private research institutions and industry utilize all of these technology transfer mechanisms, as well as others that tend to be more specialized depending on the area of application.

The process of commercialization of research outcomes, particularly government-funded inventions, involves a range of public and private entities, patent, copyright and trademark laws,

international and domestic issues, and sometimes competing agendas and interests. Those inventions often lead to new goods and services that benefit the public and, in some cases, to new businesses with attendant creation of jobs and new wealth. However, the end result of a successful research project with a proven idea is only the beginning of the commercialization process which includes development of a product that is market-worthy, the creation of a business plan, gaining access to capital to support further development, bringing the product to the production stage, and creating a business or a new/improved product or service within an existing business or industry. The large number of steps and players in the process create a journey that requires a sound knowledge base for the navigation to be successful.

Based on the hearings held by the PCAST Panel, it is apparent that those who attempt to participate in technology transfer activities come to the table from different backgrounds and histories. For example, according to the Association of University Technology Managers, over 2000 universities and colleges have patents of one kind or another. Yet only a small number of these are research universities with technology transfer offices and not all of these have developed high competencies in the process. In the business world, companies of varying size, with a history of dealing with technology transfer are more likely to be at ease with the process than many emerging companies with an idea that deserves consideration by the marketplace, but with little prior experience in the process. Equally, success in enabling technology transfer is not necessarily "better" within industry than universities—since there is much technology resident in both sectors that is never commercialized. Federal agencies have different cultures, ranging from those with a history of providing relatively open access to inventions (*e.g.,* the Department of Agriculture) to those that work within an industry segment that recognizes the need for protection of intellectual property in order to gain access to market capital (*e.g.,* the National Institutes of Health). The variety of players, ranging from very sophisticated to unsophisticated and from highly vested to less vested, all in the game at the same time, means that the field of play is complicated.

The key for the federal government is to find a course that can be followed routinely to serve the best interests of the nation for commercialization of research, but one that allows flexibility to accommodate "extremes" when appropriate, regardless of the nature of those engaged. At one

end, there are huge near-term financial markets at stake, such as those in the biotechnology area where billions of dollars are in play and nations are vying for prominence. If the U.S. does not shape its role in this sophisticated end of the spectrum carefully it could end up ceding dominance to other nations. In this case, the players are depending on the federal government to take a light hand so they can work within the existing framework that the U.S. pioneered over the past twenty years. On the other hand, there are important small market ideas, and emerging markets, that need to be nurtured where the players are not sophisticated and need guidance and support.

Although the present system is not perfect, the recent past demonstrates a record of reproducible commercial successes and creation of entirely new technology-based industries that are the envy of the world. So much have these accomplishments occurred singularly in the United States, that today there is widespread international interest in attempting to replicate this model. As a result, it is inevitable that the international assimilation of even just a few of the critical components could create new challenges to domestic competitiveness in commercial fields that have historically been dominated by the United States. *The role the government plays in this process has been and will continue to be vitally important to the future success of many technology-based industries, where basic research, technology transfer and the coordination of these activities are key factors.*

Recommendations

The PCAST review of technology transfer policies leads us to recommend:

1. Existing technology-transfer legislation works and should not be altered:

While it is unclear whether the Bayh-Dole Act of 1980 and its follow-on legislation largely facilitated the commercialization of a technological revolution or played a much more fundamental role (*i.e.*, provided the stimulus for the creation of commercial biotechnology), it is impossible to separate the two. This relationship is best documented for the life sciences, which today dominate technology transfer activities and have made commercial contributions leading to significant economic returns. The biotechnology industry and its numerous new companies are evidence of this. Other industries with different economics

have benefited from these practices, though with less dramatic results and often through different licensing relationships. Incremental improvements in established products or processes and increases in productivity are not as well documented or publicized as the transformational discoveries that launched the biotechnology industry.

Because of the heavy life-sciences contribution to numerous commercialization successes, the technology transfer practices for other industries appear more fragmented. In particular, the semiconductor industry has identified troublesome intellectual property licensing issues with universities in which it has sponsored research. These appear to relate to the variability and increased complexity of negotiating technology transfer agreements when industry provides funding for university research either in a three-way partnership with the federal government or in two-party collaborations with a university. However, we believe these differences are best addressed by improving the practice of technology transfer and by addressing differences among research areas rather than by altering the legislation. Finally, this is not to say that Bayh-Dole has caused the patenting and licensing of government-funded research to replace other important technology transfer mechanisms, such as publications and CRADAs, as well as direct transfer. All of these technology transfer tools complement one another, allowing flexibility in a rapidly changing environment that demands rapid adaptation for success and where other tools will surely emerge in the future.

2. ***Federal agencies, government laboratories and the Department of Commerce need to formalize their oversight of and accountability for technology transfer:***

Leadership that recognizes and embraces the importance and accountability of technology transfer must come from the highest government levels, including the President and Cabinet Secretaries. We recommend that the President request that all agencies specifically commit to technology transfer in their individual mission statements. The Technology Transfer Commercialization Act of 2000 has, in its requirement for annual agency reporting, provided a vehicle to account for progress in this area and the Commerce Department's first report is a good step towards that goal. The annual reporting process needs to be used as a mechanism to reinforce accountability for performance and viewed in the context of important short term

and long term progress objectives. This will only be achieved if senior administrative attention is devoted to reviewing and providing feedback on these reports.

We believe having the Office of Management and Budget clarify the importance of departmental reports and provide them to the Department of Commerce (DOC) would be the best way to achieve the desired outcome. This is particularly important in light of the different agency practices and attitudes, which show great variation in employee incentives/motivation for successful technology transfer, but still need to be aligned with one another. *This will only be accomplished by recognizing that the learning curve is steep for the successful practice of technology transfer, requiring considerable time (*i.e., *10 years or greater) and upfront investment to build internal and external competencies and consistent practices. However, DOC generally has few resources with which to manage its technology transfer responsibilities. While specific issues are addressed here and in each of the areas identified below, additional funding would give DOC the ability to respond to many of these concerns.*

3. ***Industry differences need to be recognized and practiced by institutions licensing government-sponsored technology, but made consistent within individual disciplines:***

Technology licensing conducted by life sciences research institutions has become very sophisticated in the last decade due to its high level of activity and commercial success. Today these technology transfer programs generally appear to be well received by licensees. In large part, this has occurred because most life sciences inventions are destined for development as pharmaceutical products, where the successful patenting of products is key to the long product development time frames and significant capital commitments. As a result, there is a template for technology transfer that has at least several consistent components that do not vary widely from transaction to transaction. In contrast, criticism arises more often for licensing practices for technologies having other industrial applications, such as those for selected segments of information technology, often because of competing interests or because the process is too slow to keep up with technology developments.

The value of intellectual property in these industries (*e.g.*, software, communications, semiconductors, etc.) is highly variable, ranging from entirely unimportant to moderately important. In these cases, the time to market is much shorter (measured in months to years, rather than many years for pharmaceuticals), and the international competition for manufacturing, as well as other factors, are much more important drivers of commercial success than for life sciences transactions. Templates for technology transfer for these industry applications are far different and much more diverse than for life sciences applications. The licensing of technologies for distinctly different industries should not be expected to occur within the same narrow parameters, although it is reasonable to assume they should all be successfully implemented under the same statute. Federal agencies should develop guidelines that allow for these differences, but at the same time insure a greater level of consistency for applications within each industry sector.

4. ***The Department of Commerce should document "Best Practices" for technology transfer, as well as refine a set of metrics to better quantify practices and their effectiveness:***

A set of documented "Best Practices" would serve a dual purpose in facilitating more rapid progress for institutions facing a new learning curve, as well as in setting expectations for first time licensees. The challenge is to align a series of models for varying industrial sectors with a wide range of differences in technology, market dynamics, intellectual property, etc. that are sufficiently specific to provide valuable guidance. Because the entire process is continuing to evolve and there is increasing global competition, identifying metrics to quantify program effectiveness is of increasing importance. Metrics need to take into account a wide range of steps in a highly complex process, as well as the ultimate product or service, but should not constrain the continued evolution or development of new technology transfer approaches. An example metric is the time to execution of a technology transfer agreement, which is increasingly important due to the growing length of time and related expense to conclude such agreements (see Recommendation 6 below). In addition, such measurements need to accommodate mission differences between the licensing institutions. For example, numerous universities are now seeing a meaningful contribution to the growth

of local economies as a direct outcome of their technology transfer activities and, as a result, their priorities are now more heavily weighted by interactions with their local constituencies.

The Technology Transfer Commercialization Act of 2000 provides a vehicle for the DOC to document best practices, although the issue of metrics is somewhat more complex and requires even greater interactions between DOC and the individual agencies. DOC's recent efforts with the Interagency Working Group on Technology Transfer is another good step towards reporting and refining both best practices and metrics. However, we would like to encourage further attention on behalf of DOC towards achieving these goals among all federal agencies and towards extending their reach to include all performers of federally-funded research— universities, industry, federal laboratories, etc.

5. ***The Department of Commerce should include "education" as a part of its technology transfer mission and task the individual agencies to disseminate related materials specific to their research and development programs:***

The practice of technology transfer would be better optimized as an "active" rather than a "passive" process, which would help both with the internal education process, as well as the external marketing. General educational materials need to be developed by DOC and tailored by the individual agencies to reflect specific R&D programs. This is particularly important where inventions have multiple applications and may need to be matched-up with commercial enterprises representing several industries. In addition, some agencies and government laboratories have worked with large contracting companies (*e.g.*, defense) where they have developed longstanding and successful relationships. New invention applications might be more rapidly developed and disseminated by companies that would not otherwise be known by the agency (*e.g.*, terrorism applications), where an active marketing effort would increase the interest from potential licensees and also increase the possibility of a return on investment. DOC could increase its education efforts without the addition of meaningful resources by taking responsibility for the education initiatives conducted through the Federal Laboratory Consortium.

6. ***Individual agencies and government laboratories need to provide regular transaction "process reviews" to reduce the complexity of, and time required to complete, technology transfer transactions:***

The time and expense required to conduct licensing activities under present circumstances is not inconsequential. For some, this is appropriate since the time to market is long term. For others, this is an issue that can lead to industry disenchantment. This is particularly true the first time a new form of agreement is executed by a relatively inexperienced licensing institution, requiring that organization to get up the "learning curve." As described above, much in the way of education can be done to minimize the pain and discomfort associated with new licensing activities. However, transaction complexity and managerial attention need to be reduced even for experienced and sophisticated organizations. Testimony provided for the PCAST Panel indicated that there are cases where the time required to complete the intellectual property process is an issue. While this is apparently not a problem in all areas, attention should be given to improving the efficiency of the process in instances where time is of the essence.

7. ***The Office of Science and Technology Policy should assist the new Department of Homeland Security in rapidly developing technology transfer policies and capabilities that meet the immediate and long-term agency needs:***

The Department of Homeland Security (DHS) has an immediate and pressing need to rapidly *acquire* numerous directed technologies to meet a broad range of security issues. This overall process is well documented, although the relatively slow historical timeframes for these activities will be inadequate, especially involving the patenting process. Once these technologies have been used to develop effective product prototypes, proprietary product information may also need to be recycled to the private sector for rapid product mass production and distribution. The national security issues and urgency will undoubtedly create additional barriers to universities and industry. The Office of Science and Technology Policy should work with DHS to create an environment that increases the likelihood of participation by the most successful and capable industrial organizations and universities, as well as insuring that the nation's pressing security needs can be met by experienced vendors.

The urgent need for DHS to access and acquire technology raises an important point with broader implications. Technology transfer should be thought of as not just flowing from government funded programs occurring in different agencies and universities to industry, but also from industry to universities/government. The bi-directional nature of technology flow is important to all of the federal agencies, government laboratories and universities and must be taken into account when evaluating the overall mechanisms, goals and effectiveness of technology transfer.

8. ***The Government should centralize information on technology transfer into a single, accessible location:***

Technology transfer has become a very broad activity today, with many U.S. and international participants, including the government, industry, universities, private research institutions and practitioners from many professional disciplines. There would be enormous benefits to aggregating available resources, information, education and contacts into a single location, which should be made available in an electronic format. The E-Government Task Force should assess the necessary requirements for providing such a site and most likely, provide for its implementation, whereas DOC should be responsible for the site's administration. The consolidation of these components would not only facilitate the access, administration, education, monitoring and efficiency of technology transfer activities with the government, but would stimulate further interaction and responsiveness from the private sector.

A central website would also facilitate the formation of much needed technology transfer databases and create additional interest in the study of this field. For example, it would be of interest to examine and track technology flows at a finer level of granularity than the gross measurements used today (*i.e.*, engineering, life sciences, etc.), which should prove to be more helpful in identifying important trends. In the context of a relational database, the use of "clustering" tools also could help to identify the emergence of new areas of research and

find new patterns in technology flows. These types of analyses would enable DOC to have a much improved base of information to guide national policy.

9. ***The Department of Commerce should study and assess the implications for technology development and transfer in a global environment, as well as the possible effects of emerging technologies:***

Research competition in many scientific disciplines is intensifying internationally and the electronic nature of communications is greatly expediting the distribution of information. This combination will most likely alter the geographical distribution of technological innovation from the way it has evolved in the past. DOC needs to document the growing international systems for technology transfer and their implications for U.S. competitiveness. In addition, U.S. industry will continue to use sources of international research as economically viable alternatives to domestic sources. Trends in these activities are important to identify to help both government and industry respond to potential technology transfer paradigm shifts in the future.

The "Innovation in America" roundtable series led by DOC is a constructive start on this topic, although that department's increasing interactions with industry and related trade associations, such as the National Venture Capital Association, will be an important and necessary part of assessing the interests of industry in going outside the United States to seek alternative sources of research. We strongly encourage these types of government/industry interactions. We also believe that the emergence of new technologies will alter the current practices of both domestic and international technology transfer. A growing interdependency of scientific disciplines for future technology development has already signaled the need for changes in technical education and training and this will likely impact the practices and complexity of patenting, licensing and other forms of technology transfer. We recommend that DOC expand its activities related to assessing and tracking emerging technologies so as to facilitate technology transfer opportunities.

10. Recent discussions about the availability of research tools that result from federally-funded research need to be monitored to insure that there is a balance in the protection of the commercial value of such inventions and assurance of access to these tools for further research and exploration:

Intellectual property remains a key component to the successful transfer and commercialization of all technology, but especially life sciences technologies. Over the last few years, the development of biological materials for use in research that may or may not also have significant commercial value has become an increasingly problematic junction for balancing the ability of researchers to freely (or at least affordably) exchange and use such materials with the rights of researchers to elect title to such inventions and license them for commercial use. NIH made a meaningful contribution to providing guidance on this topic through its December 1999 "PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES". The public discussion needs to be monitored, to either assist in sorting out complicated issues surrounding the bi-directional flow of materials used in research and/or to find new technology transfer mechanisms to deal with the changing landscape. This is a highly complex matter that has already received significant thought from many affected constituencies. A workshop may be appropriate for addressing the key policy implications.

A separate, but related issue that also requires close monitoring involves recent court decisions, pending litigation and resulting legislation that may have an impact on technology transfer, including technology that results from federal funding. A recent court case, Duke Univ. v. Madey,[8] has eliminated the experimental use exemption from claims of patent infringement for noncommercial university purposes. The court held that the experimental use exemption does not apply to research that furthers universities' "business objectives, including educating and enlightening students and faculty participating in these projects…In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate

[8] Duke Univ. v. Madey, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied,* 156 L.Ed.2d 656 (2003).

business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative."[9] While this decision appears to have its greatest impact on not-for-profit research institutions, a recent survey[10] of individuals involved in biomedical research shows that both commercial and non-commercial entities sometimes use patented research tools without a license, which they justify on the basis of a "research exemption." The outcome of this decision, whether judicial or statutory, could be an important factor in future technology transfer practices and, much like the case for research tools, would benefit from a public policy workshop.

Two additional factors are important in providing the proper context for this Report's recommendations. They are:

- ***Education and training:*** Technology transfer mechanisms in the United States have been quite successful and have created measurable economic benefit—to the admiration of the rest of the world—because there has been a wealth of talent in government funded research programs. Independent of successful mechanisms for transfer, this pattern cannot be expected to continue in the absence of strong technological education, training and a full "pipeline" of talent.

- ***Metrics and documentation:*** Because the process of technology transfer is complex, involving many steps and participants, it is very difficult to generate meaningful data to assess its effectiveness. For the same reasons, anecdotal data are readily available. We would encourage caution in interpreting anecdotal information on this subject and recommend the continued development and thoughtful study of technology transfer activities for the purpose of supporting sound policy decisions.

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[9] Duke Univ. v Madey, 307 F.3d at 1362.

[10] J. P. Walsh, A. Arora, W. M. Cohen, in *Patents in the Knowledge-Based Economy*, W. M. Cohen, S. Merrill, Eds. National Academy Press, Washington, D.C., in press.

BIOGRAPHY FOR MARK G. ALLEN

I. EARNED DEGREES

Ph.D., 1989, Massachusetts Institute of Technology, Microelectronics
S.M., 1986, Massachusetts Institute of Technology, Chemical Engineering
B.S.E.E., 1988, University of Pennsylvania, Electrical Engineering
B.S.Ch.E., 1984, University of Pennsylvania, Chemical Engineering
B.A., 1984, University of Pennsylvania, Chemistry

II. EMPLOYMENT

Regents' Professor, Georgia Institute of Technology—7/05–present
Professor (with tenure), Georgia Institute of Technology—7/99–present
Associate Professor (with tenure), Georgia Institute of Technology—7/94–6/99
Visiting Professor, Swiss Federal Institute of Technology—6/00–8/00
Visiting Professor, Swiss Federal Institute of Technology—6/98–9/98
Visiting Professor, Swiss Federal Institute of Technology—6/94–9/94
Postdoctoral Associate, Massachusetts Institute of Technology—5/89–9/89

III. RESEARCH INTERESTS

Professor Allen's research interests focus on the development and understanding of fabrication technologies for microelectromechanical and nanoelectromechanical systems.

IV. MOST RELEVANT PUBLICATIONS (SELECTED FROM APPROXIMATELY 200)

1. Frazier, A.B., Olson, C.S., Turner, S.P., and Allen, M.G., "Characterization of Graphite-Filled Polyimide Thin Films Using Micromachining Techniques," *International Journal of Microcircuits and Electronic Packaging,* vol. 17, no. 1, pp. 37–49, 1994.
2. Frazier, A.B., Ahn, C.H., and Allen, M.G., "Development of Micromachined Devices using Polyimide-Based Processes," *Sensors and Actuators A (Physical),* vol. A45, no. 1, pp. 47–55, 1994.
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4. Frazier, A.B. and Allen, M.G., "Uses of Electroplated Aluminum for the Development of Microstructures and Micromachining Processes," *IEEE/ASME Journal of Microelectromechanical Systems,* vol. 6, no. 2, pp. 91–98, 1997.
5. Taylor, W.P., Brand, O., and Allen, M.G., "Fully Integrated Magnetically Actuated Micromachined Relays," *IEEE/ASME Journal of Microelectromechanical Systems,* vol. 7, no. 2, pp. 181–191, 1998.
6. Seriburi, P.; Kercher, D.; Allen, M.G., "An Experimental Study of Microfabricated Spark Gaps: Wear and Erosion Characteristics," *J. Micromechanics Microengineering,* vol. 11, no. 3, pp. 165–74 (2001).
7. Kercher, D.S.; Lee, J.B.; Brand, O.; Allen, M.G.; Glezer, A., "Microjet cooling devices for thermal management of electronics" *IEEE Transactions on Components and Packaging Technologies,* vol. 26, no. 2, June 2003, pp. 359–66.
8. Chang, S.P.; Allen, M.G., "Capacitive pressure sensors with stainless steel diaphragm and substrate," *Journal of Micromechanics and Microengineering,* vol. 14, no. 4, April 2004, pp. 612–18.
9. Park, J.W.; Cros, F.; Allen, M.G., "Planar spiral inductors with multi-layer micrometer-scale laminated cores for compact-packaging power converter applications," *IEEE Transactions on Magnetics,* vol. 40, no. 4, pt. 2, July 2004, pp. 2020–2.
10. DiBiaso, H.H.; English, B.A.; Allen, M.G., "Solid-phase conductive fuels for chemical microactuators," *Sensors and Actuators A (Physical),* vol. A111, no. 2–3, March 2004, pp. 260–6.
11. Fonseca, M.A.; English, J.M.; von Arx, M.; Allen, M.G., "High temperature characterization of ceramic pressure sensors," *11th International Conference on Solid-State Sensors and Actuators, Digest of Technical Papers,* pp. 486–9, vol. 1 (2001).

12. Marquordt, C.; Allen, M.G., "Fabrication of micromechanical structures of titania and titanium with electrophoretic deposition," *11th International Conference on Solid-State Sensors and Actuators, Digest of Technical Papers,* pp. 616–19, vol. 1 (2001).
13. Yoon, Y.K., Allen, M.G., "A Pt heater/sensor microarray for distributed fluidic cooling assessment," *Micro-Electro-Mechanical Systems (MEMS). 2001 ASME International Mechanical Engineering Congress and Exposition,* 2001, pp. 669–75.
14. Choi, Y.; Kim, K.; Allen, M.G., "A magnetically actuated, electrostatically clamped high current MEMS switch," *Micro-Electro-Mechanical Systems (MEMS). 2001 ASME International Mechanical Engineering Congress and Exposition,* 2001, pp. 83–7.
15. English, B.A., Allen, M.G., and DiBasio, H.H., "Microcombustors Based on Controllable Solid Fuel Elements," *Proc. American Society of Mechanical Engineers Winter Annual Meeting,* vol. 5, pp. 725–733 (2003).
16. Yanzhu Zhao; English, B.A.; Yoonsu Choi; DiBiaso, H.; Guang, Yuan; Allen, M.G., "Polymeric microcombustors for solid-phase conductive fuels," *17th IEEE International Conference on Micro Electro Mechanical Systems, Technical Digest,* pp. 498–501 (2004).

V. HONORS AND AWARDS

1. Member, Tau Beta Pi (Engineering Honor Society), 1984
2. Member, Phi Lambda Upsilon (Chemistry Honor Society), 1984
3. Arthur K. Doolittle Award, American Chemical Society Division of Polymeric Materials: Science and Engineering, 1988
4. Georgia Tech Packaging Research Center, Research Faculty Award, 1996
5. Fellow, College of Relay Engineers, National Association of Relay Manufacturers, 1997
6. Georgia Tech College of Engineering Faculty Research Award, 2000
7. J.M. Pettit Professorship Georgia Institute of Technology, July 2001 (initial five-year term); renewed indefinitely 2005.
8. School of Electrical and Computer Engineering Sustained Program Development Award, 2002
9. Regents' Professorship, University System of Georgia, 2005.
10. Outstanding Leadership Award for Development of Graduate Research Assistants (for the period 2001–2003), Georgia Institute of Technology, 2005.

DISCUSSION

Chairman WU. I thank all of the witnesses for your very illuminating testimony, and now, we will turn to questions. And at this point, we will open for our first round of questions, and the Chair recognizes himself for five minutes.

Mr. Pradhan, you believe that Bayh-Dole has stimulated technology transfer, and also, done a reasonable job of encouraging productive university-industry partnerships. It appears from our panel of witnesses that this view is not universally shared, and I would like to give you and the other witnesses an opportunity to discuss this issue in this forum, and then, to drill down, and get a little bit more granularity on that discussion, about where the problems exist, and where they do not, whether it applies uniformly across different fields.

And Mr. Pradhan, let me turn it over to you, and then, we will do this first four minutes in a discussion format.

Mr. PRADHAN. Mr. Chairman, thank you. I do believe that there are more collaborations, effective collaborations that are occurring between universities and industry at this juncture than there have been before. My personal experiences in this have been very posi-

tive. At every institution that I have been at, the amount of industry collaborations has progressively increased.

I have been at Oregon Health and Science University for three years, and even in the three years that I have been there, the number of collaborations has doubled, and the amount of research funding changing hands has tripled. And this is across all sectors. We have effectively partnered with companies in the IT industry. We continue to effectively partner with companies for drug development, for clinical trials, and for basic research.

I think one of the fundamental aspects that one has to keep in mind are the different cultures that each industry brings to the table, and the culture of collaboration at a university. Intellectual property itself is not a stumbling block, in my opinion. Access to intellectual property is determined by the nature of the project. It is determined by what outcomes are being sought, and it is also determined by what relative contributions are made prior to the research project actually coming together between a company and a university.

So, I think the fundamental aspect of being pragmatic, and approaching this in a collaborative way, tends to alleviate a number of the problems that we have heard. It is true that you can't rely on patents in the IT industry to generate royalties. In fact, if you take a look at a printer or at a computer, there is upwards of 500 patented technologies that go into that. The price pressure for those in the marketplace is to keep the prices down, and——

Chairman WU. Arun, I am going to ask you to summarize your comments. I will extend the same courtesy to other members who are here. We will permit panelists to finish comments on the same question asked, but I am going to run over my first five minutes, but the prerogative of the chair, we will stay here as long as we need to to run through all of my questions in cycle.

Mr. PRADHAN. I will be brief. In summation, I think the problem are not insurmountable.

Chairman WU. Dr. Butts and Mr. Johnson, your comments, perhaps, and then, perhaps Dr. Lemley, you would like to clean up on this, and Dr. Allen, I don't mean to exclude you, if you have something you need after that also, please.

Dr. BUTTS. Yes, just a couple of thoughts to share. The growth in the number of partnerships is really a general phenomenon. In fact, as companies have moved from the old model of having the big, central research organization, to recognizing that it is more productive to use external resources, I think in general, the number of collaborations happening is increasing. So, not just between companies in the U.S. and U.S. universities, but around the world, in other sorts of collaborations. So, I don't think that is necessarily the best metric for the state of the relationship.

But I would also say that in negotiations, my experience has been that universities and companies are both trying to do the right thing for their institutions, and so, what they are trying to do is live by their expectations, or in some cases, of the universities' patent policies, that dictate how intellectual property should be handled.

And where we see the difficulty, often, is in the timeline. So, the difference in the university mission and the sense of time, versus

a corporate mission, and the sense of time. So, for instance, within Dow, our projects are all on a project timeline, with milestones and decision points, and when we spend five months negotiating an agreement, it may be that the research project, when it finally gets started, delivers its results too late to be useful. So, to me, it is a very important issue around how long it takes to reach agreement, even if we eventually get there.

Chairman WU. Thank you. Mr. Johnson, your comments.

Mr. JOHNSON. I have three of them. Well, one of the things that is, I think, apparent so far is that the IT industry is really different than some of the others that we have been talking about. In fact, you know, if you look at what we do as a practice, we actually cross-license even our own inventions to our competitors, otherwise, we don't have a product. So, I think in any kind of situation where you are dealing with a certain vertical industry, the universities, I think, need to take into account the fact that that is, you know, our expectation. Our time to market is three to six months. Our cost per unit keeps doing down, so to be competitive, we really need to do that.

I would also say that there is a difference between universities. I mean, I manage the entire strategic university portfolio across Hewlett-Packard, so I have an insight into a broad range of universities here and overseas. I think it differs between universities even in the U.S. We have universities where we are more able to negotiate these patents more quickly, or licenses, and ones that don't. So, I think to some degree, it is a function of the leadership and the strategic thinking of the university.

I would also comment that I don't think industry is blameless in this. There are some companies that haven't developed the right strategy, and don't understand the difference in cultures. If you don't figure out what the cultural differences are, you are not going to have a very good relationship, and you are not going to work quickly to get something done.

And I would say, from an IT industry perspective, the fact that we are a global, clearly a global activity, we need to go places where the technology, the localization, so we are constantly looking for opportunities to go somewhere else that we can get the work done as quickly as possible.

From a U.S. perspective, I don't think this is necessarily bad, but if we end up going only outside the U.S., it would clearly be. So, I think the issue of the global industries, and Dow, I think, is another example, we go where the information is, where the talented people are, and the ability to get the work done more rapidly.

So, I think all of those are factors that makes the IT industry somewhat different.

Chairman WU. Thank you for your comments, Mr. Johnson, and I think that something that you said triggered in my mind that perhaps one of the ignored factors in competitiveness for the long term is our visa policy, and we will hold hearings in the Science Committee on that issue later.

Dr. Lemley or Dr. Allen, any comments on this, and then, we will turn it to Dr. Gingrey.

Dr. LEMLEY. Well, so, I think that the most successful examples of university-private collaboration have been in what Mr. Johnson

called the home run patents, the very successful new inventions that can then form the basis of a product that is sold in the marketplace. Those are the ones where the patent needs to be turned into a product that is commercialized. They tend to be in the biomedical space, though there are exceptions to that.

And the problem comes about when universities take that lucrative licensing model for home run patents, and they try to apply it to the patent that is one component out of 500 in a product. There, not only are you having to deal with the other patents, but you have also got the problem, you have less need for this commercialization. You are not building a product around this patent. It is one piece in a much larger puzzle.

Dr. ALLEN. So, one thing that I heard from all of our panelists was that perhaps it is not so much changes in the Bayh-Dole legislation itself that is important, as it is education of some of the universities and technology transfer offices to these differences.

And we do have, within the current legislation, this flexibility available to us to do both kinds, the home run kind of licensing and the nonexclusive licensing to all comers. I, personally, as a researcher, have been involved in both, where appropriate, and I think that would be a good model, perhaps, for us to consider.

Chairman WU. We will return to this topic, but my time has expired long ago. Dr. Gingrey.

Mr. GINGREY. Mr. Chairman, thank you. And it really is a segue into my question, and I am going to address it first to Dr. Lemley, because he commented on it first.

You were talking in your testimony, Dr. Lemley, and you mentioned biotech and pharmaceutical companies benefit from patents due to the high R&D costs, and the lengthy process of commercialization. And I want to know, and we will start with you, and then, the other witnesses may comment, are you suggesting that Congress might consider creating product-specific or industry-specific patent regulations that are different? And we will start with you, Doctor.

Dr. LEMLEY. I think that is a possibility, though I would look at it as a last resort, in part, because it is very difficult to draw lines that cleanly divide technologies, so there are all sorts of examples. One that comes to mind immediately is bioinformatics, which is this interesting crossover of biotechnology and computer software in the service of trying to kind of mine and rationalize biotechnology data.

I do think it is a problem. I think it is a problem, the industry specificity, that we ought to try to solve at the university level. It is something that we could solve at the government level, if need be, though my preference would be, rather than industry-specific rules and legislation, having the PTO or some other agency with enough authority to make a case by case decision, that here is a circumstance in which we want to march in and require nonexclusive licensing.

Mr. GINGREY. I think, maybe Dr. Allen, you had mentioned something in your last comment, if you would like to pick up on what Dr. Lemley just said.

Dr. ALLEN. That is right, and I do agree that different industries, as I mentioned, do need different treatments, so to speak, but I

really don't believe that treatment at the level of legislation is required. I think it is more, perhaps, in the regulation and implementation or interpretation of the legislation where that might be most useful.

Otherwise, we will wind up with situations where companies are struggling to define their products in one area or another, in order to receive favorable treatment, perhaps, under certain differentiating patent rules or what have you.

Mr. GINGREY. Dr. Pradhan, and then, we will go to Dr. Butts and Mr. Johnson.

Mr. PRADHAN. I agree with Drs. Lemley and Allen. It is very hard to legislate patent policy by industry sector. In fact, the example that Dr. Allen used, where the original invention occurred for smart turbine engines is now being applied in healthcare, is very illustrative of how widely some university inventions can be applied, and from the university perspective, we actually cross a lot of industry sectors with any particular invention.

Dr. BUTTS. I am concerned that a legislative remedy that involved defining industries or technologies would only complicate the situation, and I would prefer to see more flexibility, so that individual companies and universities felt that they were freer to negotiate and agreement that made sense for the particular circumstances of the project.

Mr. JOHNSON. I would agree also with Susan's point on trying to figure out what industry specifically to add up and put in a certain column. I would, however, say that our typical interaction with a university, where we walk in to try to sponsor research, we are looking to find some of the best people in the world which are there. They have already done the research, that is why we know that they are there. We come in, we say we want to sponsor you with, say, $100,000, and the first comment out of the other side is well, it has got to be an exclusive license, and we own all the rights.

This idea that our major negotiating position is to have a nonexclusive, royalty-free license, especially when we are funding the research, we think that is reasonable. That is a win-win. So, even though Bayh-Dole provides for the possibility of both, I will tell you that the conversation, 90 percent of the time, does not go there. And that is what often takes the six months, nine months, a year, year and a half, 18 months, for us to get done. So, even though the flexibility is there, that isn't where the negotiation starts.

Chairman WU. Thank you, Dr. Gingrey. Let me follow up on that before I turn to a related topic.

Mr. Johnson, you said that when you come in with potentially $100,000 on the table for sponsored research, frequently the goal is to have a nonexclusive, royalty-free license from any resulting technology. I would like to hear from you, and perhaps some of the other folks who are familiar with university policy, what prevents that particular deal from working quickly, when there are potentially other revenue opportunities from that particular sponsored research?

Mr. JOHNSON. I think it starts out from the premise that the blockbuster patent or the pharmaceutical way of doing business is the best way to do business. I think there is an expectation there

will be more outcome or wealth for the university if that is the approach that is taken. I also think, based on our experience, that when we negotiate these things, it often ends up with an individual researcher, or an HP attorney, and the technology transfer office in the university, that no one has thought about the broader implications, both strategic and business, that need to be thought about as we are discussing this. So, our remedy, that we have worked on in California, which has actually moved in the right direction, is to move the whole conversation upstream, to understand why is a company coming to this university. Yes, it is about the technology, but typically, it is about a long-term strategic partnership.

At the Provost level, this conversation goes great. At the legal or lawyer level, it goes downhill quickly, and so, our remedy for that is really to get people engaged at a much higher level in understanding why the two organizations are coming together. That is often much more effective, and is the only effective way to get this to happen more quickly, so it is almost a conditioned response. Here is some money, oh, I want an exclusive license. You don't get the nonexclusive, royalty-free license, which is effectively what the IT industry does among itself. This isn't something new. This is how we build our industry. IBM, HP, Microsoft, we all cross-license.

Chairman WU. Thank you very much, Mr. Johnson, and we will let other folks comment on this, if folks have a comment, in one moment. Mr. Johnson, and this is related to the question of what works and what doesn't. In your written testimony, you list Purdue, Georgia Tech, University of California, and Stanford as institutions that perhaps do a better job of striking a balance to promote technology transfer. What is different in the practices among what you would characterize as successful institutions, versus some others that you negotiate with? And Dr. Allen, you referred to, we don't need legislation, we need better behavior, so let us circle in on what that, what the behavior is, and what the mechanisms might be for any potential improvements.

Mr. JOHNSON. So, I would say, generally speaking, that the licensing offices at those universities are staffed with some of the best people that we know in the university community. They are able to, there is a philosophy of staffing at that level, meaning very high level kind of capability. I would also say that as I mentioned before, that there is an understanding of the strategic partnership in all of those universities, all the way up to the President level, of what combining with HP means from their perspective. I would also say that we have been engaged in that process in all of those universities for maybe 10 or 15 years, so long-term strategic partnerships have been developed.

And in the case of Berkeley, recently, we have worked on this very long activity of looking at what are the strategic reasons that we are engaged with Berkeley, and then, we filter that all the way down into the licensing office. So, again, it is not a one decision, one license negotiation. It is done at a very high strategic level. And it seems that all of those universities more or less operate under those circumstances.

Chairman WU. Thank you. Arun, I believe you had some comment on this, or the prior exchange.

Mr. PRADHAN. This, as well as the prior exchange. I tend to agree with Mr. Johnson, with respect to establishing strategic alliances between universities and industry. However, taking the IT model and drilling down a little further, as you suggested, most universities would be willing to grant nonexclusive licenses, but oftentimes, where the communication breakdown occurs is that even in the cross-licensing realm, for example, universities need to be able to license other practitioners in the IT industry, if they are to derive revenue.

And so, there is an issue with respect to sublicensing rights that often comes up. A nonexclusive, irrevocable, royalty-free license that is sublicensable does nothing for an academic institution at that point. And it is hard to comment on the aspects of any one particular negotiation, but these are just some of the principles that we try to keep in mind as we move forward. Where if we understand what the needs are, and the company understands what the institution needs are, then we can often arrive at an amicable resolution.

Chairman WU. I want to let the other three witnesses comment on this particular exchange, and for the next five minutes that I have, Dr. Allen, you mentioned that statutory approaches may not be appropriate, but that perhaps a regulatory approach or something more flexible might work. What I have been racking my brain about since you made that comment is that we do not have an SEC, we do not have an FDA. We might not want to have any of those things in this particular arena, but I will save that for the next round of questions.

Do any of the other witnesses have comments on what Mr. Johnson and Mr. Pradhan have commented on?

Dr. BUTTS. I would like to comment on the options that are on the table in licensing, and actually, contrary to Wayne's experience, typically, when we are working with a university, what they are comfortable offering us is an option to negotiate a license to foreground inventions, with no certainty that we will be able to come to terms or no, really, indication of what we might have to pay to get the license. And for us, that is really the biggest problem. We would be happy often to have the exclusive, but it is a difficult decision for our management to justify, to go into a very open-ended situation, especially if we have contributed more than just money to fund the project. If we have provided background research results, we may be providing noncommercial samples or prototypes, plus input from our researchers. So, in that case, we have made a pretty significant investment, and having an open-ended situation is really very difficult for us to live with.

Chairman WU. Well, what Mr. Johnson said earlier makes me think that this course of dealing, a long course of dealing between a private entity and a university, helps establish some parameters, and it makes me think that, perhaps, if there were, shall we say, a range of reason, that if you were getting a license to license, that if one had a range of reason set of expectations, I mean, that is one of the problems, that there might not be that.

Do any of the other witnesses have a comment on this, before I turn to the next set of—please proceed.

Dr. LEMLEY. Just briefly, I think part of the problem is one of bureaucratic structure and incentives. If you are dealing with an office of technology licensing that is judged at the university by how much money it generates in licensing revenue at the end of the day, their incentives are different, and not necessarily aligned with the incentives of the broader university. And one of the things, I think, that distinguishes Mr. Johnson's more enlightened or easier to deal with universities, and I am delighted to see mine on the list, is that the relationship is a broader one. It is not just with a discrete office of technology licensing. It is with a broader group. It is with individual departments, and the office of technology licensing has an understanding that maximizing revenue is one goal, but it is not the only goal.

Chairman WU. And Dr. Allen, feel no compulsion to comment, but if you would like.

Dr. ALLEN. So, very briefly, I would just point out that of the vast majority of industry contracts that I have in my lab at Georgia Tech, they are either donations from industry, who have given money for support of students or what have you without any concern for intellectual property issues, or they are exactly the type of contract that are being discussed where, in consideration for the sponsorship of the research contract, a nonexclusive, royalty-free license is given for the foreground intellectual property.

So, I know it is possible.

Chairman WU. Thank you. Dr. Gingrey.

Mr. GINGREY. Mr. Chairman, thank you, and I hope my question is not the same question. I think when you got into your second five minute round, you may have touched on what I wanted to give Dr. Allen an opportunity to discuss. Georgia Tech is one of those that were mentioned, the five or six research universities that industry, whether it is Dow Chemical or Hewlett-Packard, has been fond of the relationship, if you will. I want to specifically ask Dr. Allen, because you mentioned some with Georgia Tech that moved a number of innovations from the lab into real commercial products.

What do you think are the characteristics of Georgia Tech that allow it to be so effective at this process?

Dr. ALLEN. I think that——

Mr. GINGREY. And like universities?

Dr. ALLEN. Yes, of course. I believe that one of the things that Georgia Tech has always had a history of is a long relationship with industry, a relationship that has been focused on being able to do the applied end of engineering research in terms of a broad spectrum, so we certainly have our basic science departments, but we span a broad spectrum all the way to applied engineering, and even to work that is done not with students, of course, but work for the government, which is kept classified.

As a result, I think that there has been a value, placed on the faculty, or the faculty have felt that there is value in commercialization, so in, and it is certainly not a universal sentiment. Some faculty feel that commercialization is something that should be left to others. I believe at the universities that are cited by Mr. Johnson, there is a feeling that commercialization is part and parcel of what at least the engineering faculty are supposed to be

doing. In some sense, it is a final validation of the engineering research that we are doing, if at the end of it, someone is willing to pay for using that particular product.

I also think that one of the things that we don't do at Georgia Tech is that we don't look to the value of licensing revenue as adding to a huge percentage of the industry income. And I hesitate to read these numbers into the Congressional Record, because I am doing them from memory, but I believe that annually, the Georgia Tech does about $80 million of industry research, which represents about 21 percent of Georgia Tech's total research budget, and of that, about 1 percent is revenue from licensing.

And so, if you look at these numbers, and say well, I am going to double the licensing revenue, perhaps, and cut the industry contracts by a factor of two, I don't think that anyone at Georgia Tech would be very happy with that. So, I think that that is another piece of what we do, is to make sure that the technology licensing is serving the industry contract piece, rather than the other way around.

Mr. GINGREY. Any other comments from witnesses? Yes, Dr. Butts.

Dr. BUTTS. I would like to make a comment. I think what we are seeing at an institution like Georgia Tech is very enlightened leadership around the whole process of working with industry, and the recognition that quickly coming to an agreement is really beneficial to both parties, and that both benefit more by doing that than by either one holding out to try to get the best possible deal. So, I think institutions where there is a recognition that this is a good thing, to have these research projects go forward, and have these collaborations occur, and all the benefits that come from those, including opportunities for students and things, is worth not worrying about, perhaps, losing a little bit on the financial side.

Mr. GINGREY. Mr. Chairman, thank you, and I will yield back, and look forward to the next round.

Chairman WU. Thank you very much. Dr. Allen, you refer to perhaps regulatory oversight, and Dr. Lemley, you refer to, essentially, important Congressional oversight function in making Bayh-Dole and technology transfer in general work a little bit better. What kind of oversight do you all have in mind, and I would like to have the other witnesses comment on this, to the extent that you all have some thoughts on this also. Dr. Lemley or Dr. Allen.

Dr. ALLEN. I think oversight can be performed at many levels, and one of the ones that comes to mind immediately to me is whether or not, and I almost hesitate to use this term, the trade association, if you will, or perhaps, the Association of University Technology Managers, might not be a place where there is peer pressure based oversight to make sure that these sorts of favorable intellectual property provisions that we have talked about, are implemented in the appropriate places. I think that that is certainly a place to start, rather than, perhaps, immediately leaping to Congressional oversight.

There is a motion to do this. My understanding, we heard mentioned earlier the *Nine Points to Consider* of the AUTM, and perhaps, that is a place that we can start, and build upon within the university community.

Dr. LEMLEY. Mr. Chairman, what I was referring to in my testimony is something that is already in the Bayh-Dole Act, Section 203 of the Patent Code, which leaves open the possibility that federally funded inventions that are patented and licensed under Bayh-Dole, are subject to what are called march-in rights, in circumstances in which the agency doing the funding determines that the invention is either not being licensed appropriately, or has been licensed exclusively to someone who is not, in turn, commercializing it. That provision, I think, gives the government, and the agencies who are most directly responsible for funding the invention, a decent amount of discretion and power to solve problems as they arise, at least in theory.

It has, in practice, never been used. Perhaps that is because we have never run into one of these situations, but I think it may also be that there is a bit of unnecessary timidity on the part of the agencies to be the first one to actually exercise this right.

Chairman WU. Well, Dr. Lemley, since you are speaking, let me invite you to continue. Stanford did some interesting nonexclusive licensing, starting, I believe, in the late '70s and maybe early '80s. The shape of our biotechnology industry would be very, very different had those licenses been exclusive, rather than nonexclusive. To the extent that you are familiar with the history, can you tell us how Stanford, or the tech licensing folks at Stanford, went about the university's decision to make those nonexclusive, and therefore, broadly practicable licenses?

Dr. LEMLEY. As I understand it, and this is secondhand, my understanding, in particular, of the licensing of the licensing of the Cohen-Boyer patents on DNA, which were the fundamental California and Stanford patents, was that they were nonexclusive, and available to all comers, in significant part because the National Institutes of Health required that they be, or at least, strongly encouraged it. This was in the time prior to Bayh-Dole, so there weren't rules with respect to university patenting that were across the board. Individual government departments set up their own rules, and the National Institutes of Health strongly encouraged nonexclusive licensing.

I don't know, I wasn't around, and I haven't talked to the people at Stanford at the time, whether that is something they would have done anyway in the absence of that government encouragement.

Chairman WU. I am afraid I am showing that I am getting long in the tooth. I was a student hanging around during those days, but of course, I didn't know any of that was going on. Actually, there were some professors, saying that they had something interesting, but they didn't think that there would ever be any commercial value to it.

Following up on that, if we do have, in some respects, a divide between some of the life sciences and some of the chemical compounds, and let us just say, call it the world of electronics and software, where there is a lot of cross-licensing, and cycle times are a lot higher, would a parallel approach, where individual agencies that are grant-giving agencies, have some more leeway, and have some more influence over setting up some guidelines for tech licensing, would that be helpful to some of the problems that Dr.

Butts and Mr. Johnson, you all have experienced from, you know, sitting from your perspective. And Arun, we will get you your chance to comment on that, too.

Dr. BUTTS. Actually, our problems don't really occur when we try to license inventions that came from federal funding. I think we understand how that process occurs. It is more when we want to invest in the research, and make sure that we understand what rights we will have to the resulting intellectual property. And I think it would be hard, there, for the federal agencies to have very much constructive impact.

In fact, my belief is that Bayh-Dole really shouldn't apply in cases where the company is funding that research, and I think what would be helpful is a clarification that that really was not the intention of Congress that Bayh-Dole would apply to every research project going on in the university, regardless of the source of funding.

Chairman WU. We will come back to that in the next round. Mr. Johnson or——

Mr. JOHNSON. So, I have—well, I have a different industry, but I would say that the whole issue around the understanding of this as an issue needs to get raised. You know, we have done work for three or four years at GUIRR, under the National Academies. I think there needs to be a National Academy level discussion about what the needs of these two industries are, and that people would better understand what good approaches would end up with, when we would go about this.

I just think the conversation ends up at the wrong level. Our work in the Bay Area, we found there were a lot of belief systems that operate below the radar screen, that basically make people feel that this is a money-maker, and in fact, when you look at our industry, it is not. So, it is a lose-lose. So, I think a discussion needs to go on at some place. Maybe the National Academies would be the right place, but some convening power, where everybody would really understand what the issues are here. It is really a lack of understanding.

Chairman WU. We are starting that conversation today, but you are right. We may need to take it somewhere else. Mr. Pradhan, if you have any comments, and then, we will flip it back over to Dr. Gingrey.

Mr. PRADHAN. Just a very brief comment that, as Dr. Butts suggested, that the role of federal agencies is not necessarily to determine what happens to inventions from industry-university collaborations. That actually falls on different shoulders, and has to do with tax laws and what is defined as unrelated business income tax. And so, there are multiple issues, as always, that come into a decision-making process, and it is not just one regulation or one set of policies or the other.

Chairman WU. Thank you. Dr. Gingrey.

Mr. GINGREY. I was discussing with my staff, earlier today, in regard to preparation for this hearing, and I asked them a question, and I think that they satisfactorily answered my question, and I know that you will do the same. So I already anticipate the answer, but it may be that some of the people that are in the room today would like to hear this question. The Federal Government,

through its various and sundry programs, sponsors research in our public and private colleges and universities across the country, and it is not an insignificant amount of money, whether it is coming through the National Science Foundation's budget or wherever. And then, one of these home runs occur.

My question to them was, how does the taxpayer, that is generating all this revenue, the $3 trillion or so that we seem to spend every year, how do they get reimbursed? Why don't they have an exclusive license or a royalty position in regard to one of these home run discoveries? And I would just like to hear you comment on that, and your general impression of maybe a misperception in regard to that, and we can start from my left to right with Dr. Pradhan.

Mr. PRADHAN. Thank you, Mr. Gingrey.

It is—every invention that gets licensed out of an academic institution needs substantial development that needs to happen, and there is an issue of taking the revenues from that licensing and reinvesting it, and universities have effectively done that, so any amount of income that comes in is reinvested into the system. Bayh-Dole requires that we share those revenues with the inventors, which we do, and then, we reinvest a majority, if not all of it, into the research and education enterprise, and the training enterprise of the university. So, I think that the public has a net benefit that arises from that.

Dr. BUTTS. I think the foundation behind Bayh-Dole is that the public benefits, because the product gets into the marketplace, and you know, the question, I think you were raising is, is that fair, because the company that gets the license gets a lot of benefit, but I think that was really the concept, that in order to get products into the marketplace, you had to provide a business benefit, so that companies would take the risk and make the investment to do it.

Mr. JOHNSON. I guess I would similarly. I think, you know, the ability for companies like Hewlett-Packard to create jobs, and to create new industries in the United States, where people pay taxes, and have, you know, a viable economic sense of being, is really a result of this. I think innovation is the key to our world economic competitiveness, and this sort of research allows us to stay ahead of the curve. You know, everybody else in the rest of the world has really benchmarked us, China, India, Singapore, they have taken our best practices, they have gone off, and now, they are competing, and they are competing very well.

So, I think the degree to which we can benefit U.S. companies in the U.S., creating jobs, is really the way this gets paid back.

Dr. LEMLEY. Everything that the three witnesses have just said is true, but of course, it is true only in the circumstances in which we wouldn't have gotten the commercialization of the invention that was federally funded without Bayh-Dole and university patenting. If we had a circumstance in which we would have gotten the technology to the public without the patenting, and they would have paid less money for it, then the public is contributing money, but they are not getting the full benefits of it. And that, I think, is why there is a greater opportunity or role for the government to have this occasional oversight, to make sure that the results, the

fruits of federally funded inventions aren't locked up unfairly, or in ways that might damage public health.

Dr. ALLEN. I have a slightly different view than my four colleagues. I think that it is very rare that the home run invention is worked on and available in the academic laboratory, to the point where it is ready to be lifted directly from the laboratory and put into commercialization. I quoted what turns out to be relatively inexpensive factor of $100 of private investment required for every dollar of public investment, and I heard quoted, The Economist, $10,000 of private investment for every dollar of public investment.

Certainly, it is true that this is going to be industry specific, but I think that unless we have the capability of exclusive access to some of these home run patents, we will never get through, in my particular case, the regulatory hurdles associated with a new medical device. And I would point out as well that the companies that are commercializing these are not only benefiting themselves, but also, all of their employees, all of the new jobs that are created, and so forth, a very important factor.

Mr. GINGREY. And I thank all of the panelists. And obviously, the more jobs, the more people pay in taxes, the multiplied effect of that, making our country more globally competitive, and I hope, if we have another round, that I will get an opportunity to come back, and maybe ask the question about that global competitiveness as well.

Thank you.

Chairman WU. Dr. Gingrey, I can guarantee you another round.

I understand, Dr. Lemley, that you may have a flight this afternoon, and we want to be sensitive to your schedule. And so, I think that I have one further inquiry, based on comments that you made earlier, and I think I, and the rest of the committee would dearly appreciate your sticking with us as long as you possibly can.

You mentioned that one of the challenges, one of the opportunities or challenges, is to get universities to take a broader view of their role in society, and in tech transfer, to maximize all of the different roles, which a major research university should be playing in our society. What are some of the things that can be done, culturally, within a university, or statutorily, or through financing mechanisms, to encourage that kind of shift? What are some of the things that might be helpful in reorganizing the tech transfer function within a university, to try to serve that broader societal function?

Dr. LEMLEY. It is an important question, and I want to start by confessing a fair bit of ignorance, so I will offer some suggestions, but there are people far more qualified than I to talk about the kind of organizational structure of universities.

But I think one thing that clearly can be done is the kind of best practices benchmarking among universities that we have heard discussed here today. If it is, in fact, the case that from the industry's perspective, there are some universities that are perceived as hard to deal with and others that are perceived as easier to deal with, and that as a result, university collaborations with private sectors are flowing to those universities, then I think there is an opportunity for a trade association, like AUTM, to sit down and figure

out what does make that work, do that kind of best practice benchmarking.

The other thing I would suggest, with respect to the organization of the universities is that the more isolated the technology transfer office is from the mainstream life of research in the university, the more likely I think we are to see the kind of short run, profit maximizing mentality that I was concerned about. And so, anything you can do to build the technology transfer office more clearly into the Vice Provost for Research or whatever the departmental structure is, to make sure that those technology transfer offices are rewarded not just by how much money did you get, but also, by some other measure of number of collaborations or university satisfaction, and probably, I think, also, the sort of logical endpoint of that is to discourage what I have seen some universities from doing, which is to entirely outsource the function of technology transfer to a private company, that is just in the business of holding and licensing university patents.

Chairman WU. Before we broaden that discussion to the rest of the panel, let me ask you, Dr. Lemley, is there a problem with the metrics? Because one of the easy things to do when you are running a business or running any kind of enterprise is to count dollars, and you know, sometimes, you just count what you can count, and then, you wind up with a metric that doesn't serve anyone well.

Is there a problem with metrics in this arena?

Dr. LEMLEY. Yeah, I think there is, because as Mr. Johnson indicated, in the information technology industries, a lot of the value of patents to private companies comes not in the form of revenue that they generate, but in the form of cross-licensing or freedom to operate, and that is the sort of value, those inventions have the sort of value that easily gets lost if all we are counting is what is the percentage of the royalty, or what is the total number of dollars that are coming in at the end of the day.

Chairman WU. Do any of you have suggestions about alternative metrics, or as a best practices suggestion? Arun?

Mr. PRADHAN. Thank you, Mr. Chairman.

AUTM has been engaged in an effort to look at the metrics and surveys that currently get published in the AUTM licensing survey. Just as a brief point of history, the licensing survey began in the early '90s, as a means of benchmarking institutions with each other, to take a look at what activities were being performed by the respective technology transfer offices.

Seventeen years later, the role of technology transfer, as we have heard in this panel and in this discussion, has changed. We participate much more in economic development. We participate much more in strategic alliances. The models for industry, the models for the way that industry does business, have changed, and over the last year, our Vice President for Metrics and Surveys has been engaged in an activity with the funding from the Kauffman Foundation and others, to review what additional measures need to be looked at, what outcomes need to be looked at, not just activity.

Chairman WU. Mr. Johnson.

Mr. JOHNSON. You know, I think it comes back, so you get what you measure, and if you are measuring licensing income, then peo-

ple will be eager to do that. I think that is 90 percent of what is at the difficulty of the licensing offices that we have trouble negotiating with. One of the major a-ha moments that I had in our work out in the Bay Area centered around, when I finally realized that the average amount of industrial or sponsored research is somewhere between 5 and 7 percent of the total research or the university budget, depending on how you define it.

In the cases that have been mentioned previously, Georgia Tech, and MIT would be another example, their amount of industry funding is on the order of 20, over 20 percent. So, again, you see the difference in philosophy of engaging as a strategic partner, where that is a viable outcome of the work that faculty are supposed to be doing. It is part of the mission statement, but in the case of the average, it is 5 to 6 percent, so you might ask well, what else could you measure? Well, companies give money in many ways. There are grants that go without any licensing requirements at all. There is philanthropy. There are gifts from companies. If you measure all the places along this continuum, you can see that if you pick one specific area that generates 5 percent, it might impact all of the others. And the others are actually much bigger, so in the cases that work, Berkeley would be a good example, the Provost there has actually pulled the industry sponsored research and the licensing office together, and they are measured on the net outcome of both. So, I think that is a best practice. That has actually substantially reduced the amount of time that we take to negotiate with UC Berkeley.

Dr. BUTTS. I agree there are two ways to win, then, either to secure a license, or to have a sponsored research agreement. So, I certainly feel that having, because there are typically two separate offices in universities that deal with those things, so if you have both technology transfer and sponsored programs reporting to the same person, then there is the ability to measure that bigger impact, whether it is in money coming in for research or money coming in for licensing. So, I definitely feel that that is what distinguishes some of the universities that are easiest to work with.

Chairman WU. Thank you very much. Dr. Gingrey.

Mr. GINGREY. Mr. Chairman, thank you.

I want to have Dr. Pradhan comment a little bit about the *Nine Points,* in regard to licensing university technology. Because I think in his written testimony, that is a very interesting concept. But before that, I want to turn to Dr. Butts and Mr. Johnson, and ask this basic question.

What are the reasons your companies, maybe Mr. Johnson feels more strongly about this, Dr. Butts, than you do, that it is easier to deal with foreign universities, and seek partnerships there? Where is there such a roadblock, as it seemed that Mr. Johnson had a lot of heartburn over? Let us cut to the chase on that, and tell us what the problems are, and maybe Dr. Pradhan can say how the *Nine Points* recommendation could solve those problems.

Mr. JOHNSON. Well, I think if you look at the reasons why companies actually do research overseas, it is many faceted. Matter of fact, referenced in my testimony is the Thursby study called "Here or There," sponsored under GUIRR, and with Kauffman, about why do we actually go to do this. So, part of the answer around why

the fact that our competitors out there, these are governments driving university investments, as I have said before, have benchmarked us, have looked at our best practices, and by the way, I don't think they think Bayh-Dole is a best practice, per se. I think what they are looking at is the level of investment, the encouragement of engineering graduates in the technology field of science.

So, when we go there, they are eager to collaborate. They are eager to compete. We have significant presences in all those countries, manufacturing and R&D. We go there for access to talent, the access to the resources provided, and the marketplace that we are trying to sell in. So, it is a combination of factors as to why we are there in the first place. Then, when we get there, and we develop the partnerships, we find that this eagerness allows them to want to participate with Hewlett-Packard or Microsoft or IBM. They really move rapidly to complete the research agreements. And it is not really encumbered by any of the issues that we find in the U.S.

So, we are there for certain purposes that are strategic to our company, and then, the ease of doing business is much better, and then, we run into the roadblock in the U.S. at some places, so the natural answer is to go there instead of here.

Dr. BUTTS. Well, I welcome the chance to address this question, because I would like to mention something that hasn't come up in our discussion today, and that is that useful inventions are rare outcomes from sponsored research at universities. So, in fact, one of the reasons why foreign universities are easier to collaborate with is that what they really want is the partnership. They would like to have the funding for their research, and they would like to have the opportunity for their faculty and students to work with companies who are providing interesting problems for them, and recognize that the chances, let alone a home run invention, but even just an invention that is useful, are small.

So, I think that what we see outside the U.S. is that there is a heavy focus on the value of the research partnership, and all the benefits that flow from that, and very little concern about what if there is a patent. So, the whole approach outside the U.S. is different, and it is really focused on the research and the partnership, and not on potential value of investments that might come from the research.

Mr. GINGREY. Dr. Pradhan.

Mr. PRADHAN. Thank you, Mr. Gingrey. The *Nine Points* document is something that establishes consistent guidelines across institutions. It is meant to be flexible. It is meant to promote licensing approaches, as the introduction suggests, for comparable technologies, and does vary considerably from industry sector to industry sector.

What it does establish are the protection of certain core values that a university, or an academic institution has. For example, the right to publish. For example, the making research tools broadly available across industry sectors, as well as to other institutions. The right to practice the licensed technology, and allow other academic institutions to practice that technology, as well.

So, then, extrapolate that to also successful practices, and working with companies on research. In terms of using similar approaches, which is taking a look at things by, sector by sector, pre-

serving rights to use it ourselves, and then, moving forward. So, I think it starts the process of consistent implementation of Bayh-Dole.

Chairman WU. Thank you, Dr. Gingrey.

I would like, in a few minutes, to turn to whether some of the *Nine Points* would be basis for more of a guideline focus. Now, we have just spent some time talking about changes that one might make in the university enterprise. I would like to focus now on the phenomenon of going overseas with sponsored research, and to what extent is this driven by sort of, if you will, free market hunger for collaboration, and to what extent are there sometimes, I just read about this at times, if you want to sell airplanes in certain places, there is a co-production requirement at times. Are we facing some of those issues in sponsored research, as we look at Russia, China, India, or some other places around the world? Do we run across that kind of conversation?

Dr. BUTTS. We have not encountered that, Chairman Wu. In fact, our research with universities is often so far upstream that it is not really tightly linked to our manufacturing, so I think the issue comes up more when companies want to market, sell, or manufacture in a foreign country. For the most part, our research is really driven by the more fundamental side, and so, we have not encountered those sorts of requirements.

Mr. JOHNSON. I would say we encounter those from time to time, and I think it is more about if you fall into the role of corporate responsibility, being a good corporate citizen. If you are HP, and you are only selling in that country, and they have a broader objective, we want to be their partner, their long-term partner.

Chairman WU. So, it may not be expressly said, but it is one of the, perhaps, understandings of life.

Mr. JOHNSON. It is implicit that you are investing, I mean, the best partnerships, and this includes the supply chain business, the success of supply chains.

Chairman WU. Please proceed.

Mr. JOHNSON. The success of supply chains is sort of not throwing it over the wall and asking people to come up with the lowest price. It is investing in your other, in the other ecosystem. So, I think that is true in countries around the world. I also would tell you that there are many countries coming to us with research investments, laboratory facilities, saying please come here, we want HP or Microsoft or IBM to be part of this.

And there is a third situation that I can cite in Brazil, where the tax law gives an incentive to work with universities. Instead of paying taxes, we are allowed to invest as a tax nonpayment, to pay it into research that we fund and we direct inside university systems. So, I mean, that is a win-win. We didn't pay tax, but we funded research inside a university. So, we have an extensive amount of university research in Brazil, but it was an incentivization through the tax system, as one example.

Chairman WU. Does anybody else want to comment on this factor, before we move on?

There was some mention of Tax Code issues, and I want to ask about that, and then, Arun, I want to turn to you for other potential barriers to tech transfer. There was some mention of tax

issues, the treatment of bonds that are used to finance buildings and limitations on unrelated business income.

For those who choose to or want to, can you address that issue for me briefly, clearly?

Dr. BUTTS. I would like to give it a try. I will do my best. I am not a tax expert, but as you have already mentioned, many universities use tax exempt bonds to finance building facilities, and in order to preserve the tax exempt status of the bonds, they have been given a safe harbor by the IRS with regard to doing collaborative research. And basically, as long as they stay within that safe harbor, they know that their bonds are protected.

And the safe harbor is actually, from an industry standpoint, pretty small, and it says that you cannot give preference to a research sponsor in licensing foreground inventions, and that for universities to stay in that safe harbor, they have to be careful that they are making sure that they can show that they are licensing an invention at a fair market value. If you don't know what the invention is, it is hard to show that if you agree up front what the invention is going to cost, that it is a fair market value. So, that provision really makes it extremely difficult for a company like mine to have the assurance that we would like that we are going to be able to execute a license that we feel is done at a reasonable cost, if the university has to stay in that safe harbor.

Chairman WU. Anyone else wish to address that issue, before we—Mr. Pradhan, I believe that in your written testimony, you mentioned that there are some barriers to technology transfer. Can you, can we come back to that, and address what barriers you are talking about, what can be done to eliminate some barriers, whether they are real or perceived, what federal statutes there might be, what State statutes there might be?

Mr. PRADHAN. Thank you, Mr. Chairman.

I think some of the real barriers are exactly what we have referred to here. The Tax Code, for example, is a potential barrier in effective collaborations and licensing. There are perceived barriers with respect to positions that a particular entity might take in the negotiation process, and are attributed to Bayh-Dole. I don't think that a negotiation is anything more than that. It is a negotiation, and also, from my perspective, from my personal experience in working with companies, and we have discussed this a little bit, when you are able to sit down with them and articulate to them some of the issues with respect to, for example, the tax laws, the business model, that would derive benefit for an academic institution versus, so, for example, nonexclusive, royalty-free licensing versus exclusive licensing, that those barriers tend to go away.

So, at the end of the day, one of the most effective means of achieving success is education, but not only at the academic institution level, but also, at a company level. I think we understand some of the issues that relate to us. We are not as cognizant of some of the issues, as they relate to companies. And the flip side of that is also true, that they understand some of the issues that are very important to them, but don't completely understand the issues as they relate to academic institutions.

So, in very brief summary, I think it is a matter of educating both sides, with respect to effective means of establishing licensing partnerships, as well as research partnerships.

Chairman WU. Thank you very much. I think I heard most of that, but the rest of it, I will read from the written record. My apologies to you all, or perhaps you will be relieved. We do have a series of seven or eight votes coming up, and I think that the right thing and the humane thing to do is to recess the panel in about ten minutes.

A couple of you have obliquely, or perhaps a little bit more than obliquely, referred to issues where despite the fact that research may be privately funded, that the direct research is privately sponsored research, that there is a line drawing challenge in negotiating with universities, and that this is probably a challenge on both, for both parties, but what a university takes title to, versus what is, shall we say, sponsored research uncontaminated by federal funds. For those who choose to address this issue, can you illuminate the outlines of that issue a little bit more for the Committee?

Dr. BUTTS. I would like to address that issue. I think that we see a whole range of ways of looking at how Bayh-Dole should apply, and one that I frequently hear from universities is the statement, if one federal dollar touches your project, then Bayh-Dole has to apply. And I think in reading the implementing regulations that that clearly was not the intention, and that what you really need to do is look at the statement of work for the program that is being funded privately, and if, in fact, it is not overlapping with any work that is being funded by the Federal Government, then I think Bayh-Dole should not apply.

But I think there is some concern in the university community about not doing something that will cause difficulty with their federal sponsors, so the easy answer is take a very broad interpretation, and say because we have so much federal money in our laboratories, there is no way that your project cannot somehow be, can run without being impacted by federal dollars.

Mr. JOHNSON. I agree with Susan's comments. It is sort of a mine, yours, or ours kind of thing. I mean, this ought to be just common sense, but when you look at the complexity of looking at prior background IP across, say, the entire University of California system, to determine whether they have looked at, and you have made sure that any possible connection to your research has been identified, it is a daunting task by itself.

So, if you are making a bet on this, and you have got a large institution, and there is all this uncertainty, then what do you do? And that, again, causes a breakdown. So, it is more common sense that well, this is fundamentally mine, or mostly yours, and I am just trying to buy into it. Those are the sort of conclusions we would like to make rapidly, but this thing overhangs it, and it is difficult.

Chairman WU. Would legislative clarification be helpful in this arena?

Mr. JOHNSON. I will go out on a limb, and say I think it might be, in this particular case, just because, you know, the idea, as Susan pointed out, just touching something. I mean, the Federal

Government funds just about every kind of research that I know, so I am sure I am going to touch some of it. So, some clarity there, I think would be helpful.

Chairman WU. Other viewpoints on that particular question?

Mr. PRADHAN. I think it would be possibly a wrong path to go down, and provide legislative oversight along those lines. I think the issue is more of——

Chairman WU. Do you agree that there is an essential problem here?

Mr. PRADHAN. Yes, I do, but I don't think it is rooted in Bayh-Dole. I think it is rooted in value allocation of what has, or going to be created. I think it is also based on the relative contributions that the two parties, or the three parties make to whatever occurs.

It is a question of access, and it is a question of control, and——

Chairman WU. Mr. Pradhan, then, at what relative contribution would you say this is sponsored research, privately sponsored research, and not subject to, shall we say, Bayh-Dole contamination, and at what percentage would you say that this vests in the university?

Mr. PRADHAN. I don't think—sorry.

Chairman WU. Please proceed.

Mr. PRADHAN. I don't think universities take, or all universities take the position of Bayh-Dole contamination. I don't believe that that is an issue here. We take a position, where we have our faculty, who are our employees, and by policy, need to assign to universities intellectual property that is created as a result of their work. If the issue is, then, assignment of that intellectual property back to a particular company for further development, yeah, we need to take a look at that carefully, and sometimes, we do, for example, in clinical trials that we conduct, take into account what is being brought to the table by the company. That is a model that we can effectively use for other means, as well.

Chairman WU. My apologies, Mr. Pradhan, but because there is a vote clock ticking, I would like to move the discussion along, but let us come back, perhaps, you all have some written—things that you would like to submit in writing.

As I was reviewing this issue, one of the questions that developed in my mind, for Dr. Butts and Mr. Johnson, we could address this legislatively, but it seems to me that going into the relationship of sponsored research, that to the extent there is an issue here, if it is not taken care of by the relationship, that a private entity, a sponsoring entity, could get representations and warranties, and an undertaking from the university. You can already tell that, you know, I am the kind of guy that you don't like to get involved in technology licensing, but you could get those reps and warranties from the university, that this is sponsored research. Why doesn't that take care of it up front?

Dr. BUTTS. I just think that the issue of being able to clearly define when are federal dollars involved and when are they not is difficult, and I have had people say to me, well, in order to do what you are suggesting, Mr. Chairman, this faculty member would have to move into a different building and work in a separate laboratory, so that there was basically no federal funding in the area, which I think is really more than the Act requires, but it is that level of

certainty that I think many people want to have, in order to make sure that they are not somehow failing to meet the obligations under Bayh-Dole.

So I think, you know, some clarity about is it really that necessary to totally segregate the research, or is there a way that federal dollars and industry dollars can be funding separate projects, and still be, not have Bayh-Dole apply, I think would be very helpful.

Chairman WU. Dr. Allen.

Dr. ALLEN. Briefly, I think that this is a very important point. I think it is, in some sense, almost independent of Bayh-Dole. I think if industry comes to my laboratory to do some research, part of the reason is because I have built up, or I, by extension, Georgia Tech, have built up over the years expertise in an area that is very valuable to that particular industry.

And so, I do agree with you, Mr. Chairman, that the way to solve the issue of who is contributing 1 percent, or 99 percent, or whatever it is, to the ultimate collaboration, is one to be negotiated between the private parties, as opposed to bringing in the Bayh-Dole situation.

Chairman WU. Perhaps you all are relieved, but I apologize for needing to bring this hearing to a close. It would not be fair to you, or to the other attendees, to recess for seven or eight votes, and then to come back.

I do feel that we have just barely scratched the surface of this very important, large topic. It is my intention to return to this subject, and to try to get it right, rather than to get it fast, and sometimes, one of the most difficult things to do around this institution, do nothing. And we will consider carefully what the right things are to do for the next generation of Bayh-Dole, which will affect, I believe, several future generations of Americans.

I did not have a chance to discuss some of my experiences, either with domestic universities or, in particular, with foreign universities, and whether the challenge is changing American conduct, or whether the challenge is in, perhaps, developing standards for conduct elsewhere in the world. We will return to these subjects.

If there is no objection, the record will remain open for additional statements from members, and I do hope that we will be able to ask you all questions, and that you will continue to help us in our consideration of these issues.

Without objection, so ordered. The hearing is now adjourned. Thank you all very, very much.

[Whereupon, at 3:12 p.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Arundeep 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

Questions submitted by Chairman David Wu

Impact of Federal Statutes

Q1. Several witnesses commented in their testimony that Bayh-Dole is only one of several federal statutes that play a role in shaping the interactions and relationships between universities and industry. What are other important statutes, and how, if in any way, do they discourage technology transfer, and industry-sponsored university research? Do you see bright line rules which would help universities lower the perceived risk of the loss of non-profit status or federal research funding?

A1. The impact of the Bayh-Dole Act on research and university-industry interactions has been much more positive than negative. Comments made by my colleagues on the panel seem to imply that the Bayh-Dole Act discourages university-industry research relations. This is erroneous.

University-industry relations encompass a variety of relationships, such as collaborations, multi-party consortia, material transfers, government-university-industry partnerships, sponsored research agreements, and licensing arrangements. Each relationship is defined by a set of complex issues of which patent ownership (the issue addressed by the Bayh-Dole Act) is one. Other issues relate to research conducted in tax-exempt bond financed facilities; valuation of inventions that have yet to be created; the nature of the industry sector; and, the desire of companies to negotiate payment of the full burden of expenses associated with research (reimbursement of Facilities & Administrative costs). In addition, the mission of a company typically focuses on generating revenue through commercialization of products and is fundamentally different from that of a university that focuses on research, education and public service. The Bayh-Dole Act remains supportive and flexible to allow universities to address these issues and the financial support of a particular university research laboratory.

One of the other panelists raised the impact of the federal rules governing tax-exempt bond financing. While these rules present limitations to pre-determining the value for a future unknown invention, they do not change the fundamental principles of universities to retain ownership of their technology, determine appropriate values for commercial use of federally-funded technology, and ensure that these public assets are appropriately developed for maximum utilization to benefit the public. Therefore, any changes to such laws would not alter significantly the university-industry relationship.

Even without the issues created by tax-exempt bond financing, there are real problems in establishing a value for technology that is yet to be created, as neither the company nor the university know the actual market for the technology or what further development will be necessary to bring the technology to market. Further, trying to pre-value the unknown inventions would create greater contention between the respective parties as each party would have an incentive to value unknown inventions at either extreme of the spectrum. As I have stated in my prior testimony, the issues are mainly based on the cultural distinctions between the different industry sectors and that the nature of the transaction is a negotiation which needs to be conducted in good faith.

In addition, the Stevenson-Wydler Technology Innovation Act (15 U.S.C. 3710 et seq.) provides the basis for federal agencies and laboratories to enter into Cooperative Research and Development Agreements (CRADAs). CRADAs encourage technology transfer from federal laboratories (including some managed by universities and some in collaboration with universities) to the private sector.

In summary, I do not believe that federal statutes play a significant role in discouraging university industry research relations. Rather the opposite, federal statutes encourage and require such beneficial relationships. In addition universities would and do accommodate industry's desire to know the commitments for research collaborations and follow-on licensing to the extent that we reasonable can.

Impact of State Laws

Q2. You noted in your testimony that since 2005, 19 states have launched initiatives targeting innovation by investing in university R&D—including R&D incentives

and tax incentives for the private sector to partner with universities. How do State laws shape the university-industry collaboration environment? Do these laws pose any additional barriers, beyond those created by some federal statutes, for university-industry collaboration? Please explain.

A2. Most State laws are flexible to encourage university-industry collaborations in various fields of research. Very few states have enacted legislation that requests a share of the licensing income and/or require that technology developed be first licensed to local companies or be the basis of start-up companies in the name of economic development. Where such State laws and regulations exist, they may pose obstacles in venturing with out-of-state companies and leveraging State and federal funds together. On the other hand, States laws that provide R&D tax credits to corporations who fund research in the state encourage these important research investments.

The initiatives that I have outlined in my written testimony and other initiatives of which I am aware, do not limit the interactions of universities to local and regional economies. The initiatives capitalize on the ability of universities to retain ownership of intellectual property, function as engines for economic growth in the region, and partner with companies across a wide range of disciplines. I am not aware of any of these State laws creating additional barriers for university-industry collaboration.

Overseas University-Industry Collaboration Trends

Q3. Industry witnesses expressed concern that policies at some universities are discouraging university-industry cooperation, and, as a result, companies are turning to conduct sponsored research overseas. How are universities tracking these international developments and how are universities responding? Are there changes to the Bayh-Dole statute that are needed to respond to these developments?

A3. Policies at universities protect academic freedom, education of students, integrity of the research enterprise, and utilization of research results for the public benefit and do not discourage university-industry research collaborations. The issue is one of negotiation and a meeting of the minds to achieve a mutually beneficial arrangement. Companies expand overseas due to pressures of globalization, not merely because U.S. universities are hard to deal with. As Mr. Johnson indicated in his testimony, there are multiple factors that are taken into consideration; for example, building R&D centers and working with overseas universities often are a response to penetrating overseas markets. To blame U.S. universities for companies outsourcing R&D to foreign universities is deceptive. The relatively few firms that assert that U.S. universities are difficult to work with claim that overseas universities are willing to agree to different terms than U.S. universities, but overseas universities have different histories, interests and drivers.

The approach of U.S. industry in chasing "easy" foreign universities strikes me as the same short-sightedness that led to the concerns that resulted in the Bayh-Dole Act. In addition, most major foreign universities either have or soon will have policies similar to U.S. universities. Many countries are investing heavily in their universities to entice companies to establish bases there and to benefit from subsidized research. As foreign universities gain more experience they will recognize the importance of intellectual property in preserving the integrity of their research programs as well as the damage generated by giving away all of their valuable intellectual property for quick revenue enhancement. These universities will become less likely to assign away ownership of invention rights that are critical to continuing their research, ensuring that graduating students and collaborators can continue to utilize their research results, attracting future research funding, and maximizing utilization of their technologies in multiple fields of use. We are in fact seeing these trends in Singapore, Taiwan, and Japan. AUTM is partnering with universities and individuals, who are very interested in seeking to replicate U.S. models of technology transfer in these countries and others.

It also remains the case that, some countries' observation of international agreements and intellectual property rights is limited at best. Trying to enforce agreements for example in China, India and other countries is challenging and costly.

In fact, many multinationals are coming from overseas to U.S. universities! Foreign-based multinational firms are building R&D centers near U.S. universities and entering into long-term collaborations. Further, these relationships are established on terms that both companies and the U.S. universities find acceptable! The companies tell us our terms are different than they encounter with universities overseas, but they understand the issues of academic freedom, advancing research, protection

of students, intellectual property rights, and that this is the way that business is done in the U.S. and they see the advantages.

I would also like to point out that Dr. Gary Schuster, Provost and Vice President for Academic Affairs at Georgia Institute of Technology, testified in the July 26, 2007 hearing before the House Committee on Science and Technology on the impact of globalization of R&D and innovation on American universities. Dr. Schuster stated that many foreign companies are establishing research collaborations with U.S. universities.

According to the National Science Foundation's 2006 Science and Engineering Indicators, from 1997 to 2002, R&D investments made by foreign firms in the U.S. grew faster than R&D investments made abroad by U.S.-based multinational corporations. During 2002, while U.S. affiliates of foreign companies accounted for 5.7 percent of the total U.S. private industry value, R&D conducted by U.S. affiliates of foreign companies accounted for 14.2 percent of the industry R&D conducted in the U.S. This demonstrates that the process of globalization is at work with companies investing and seeking collaborations in other countries and that, foreign companies are able to successfully enter into research collaborations with U.S. universities.

Taken with the 28,000 active licenses in the U.S. between companies and universities last year to develop useful products, the many more R&D agreements in place between companies and U.S. universities indicates an enormously active research enterprise. Even companies espousing that U.S. universities are hard to deal with have active, sizable research partnerships and licensing programs with U.S. universities.

In summation, policies at universities do not discourage university-industry partnerships; the Bayh-Dole Act plays a minimal role in these types of collaborations; most universities would like to establish ties with industry, but not at the expense of becoming "company shops"; and companies would like to access the expertise at the U.S. universities. An example of a common negotiation is that most universities would be happy to grant non-exclusive licenses to companies in the IT sector, as long as the universities retain the ability to offer additional non-exclusive licenses. However, the company's request for non-exclusive licenses is often accompanied with the right to sub-license, no payments towards patent expenses, and the license is irrevocable. Under such circumstances, if the university were to grant such a license, it would not be fulfilling its obligation as a steward of public resources and further, would be entering into a relationship that was not mutually beneficial.

So I am concerned and deeply puzzled by the continuing profile given to the erroneous viewpoint that U.S. universities are hard to deal with, which is contrary to the facts and appears strictly based on anecdotal evidence.

Foreign Legislation

Q4. We hear that other countries are copying Bayh-Dole. What are the goals of the legislation in countries which have passed similar laws? Have differences in goals lead to different metrics for universities in technology transfer and university-industry collaboration? Are there changes to the Bayh-Dole statute that are needed?

A4. The objective of the countries that are also emulating the Bayh-Dole Act is to quite simply duplicate the astounding success of the Bayh-Dole Act in their own territories. The effect of these new changes overseas is too nascent to assess their impact at this time, especially in achieving the respective objectives established by different countries. One likely outcome will be more consistent treatment and collaboration between faculty and students across the globe. As policies enabling collaboration are regularized to respect research teams' contributions to the public, university-owned intellectual property is likely to be treated more similarly, as has been achieved with intellectual property laws. This is likely to enable faster validation of early-stage university technology, and easier entry into foreign markets for U.S. companies.

I do not believe any changes to the Bayh-Dole Act are required at this time to address this issue.

In the Public Interest

Q5. Dr. Lemley, in his testimony, said universities should take a broader view of their role in technology transfer, maximizing the social impact of technology. And you included in your testimony the March 2007 white paper, In the Public Interest: Nine Points to Consider in Licensing University Technology. *How could technology transfer and university-industry collaboration be conducted to*

better serve the public interest? What might the impact be on industries with different business models?

A5. The most effective technology transfer occurs when both parties understand each other's needs and arrive at an arrangement that is mutually beneficial. Negotiations and discussions between the parties should not be confused with legislative, regulatory or policy issues. Most universities do take a broad perspective when entering in to a research relationship or a licensing transaction and remain cognizant about different industry clusters and respective business models. Some of the challenges that universities address during a research negotiation include cultural differences between the academic and corporate environments, ownership of university-developed intellectual property, licensing rights to such intellectual property, background rights, confidentiality and publication rights, tax issues, export control (under certain circumstances), and access to research materials.

The public interest is served best when universities enter into research relationships that are consistent with the university mission of research, education and public service. This includes retaining ownership of technology that the university develops and consistently ensuring that technology is transferred to the commercial sector in many different ways—through education, training, source of employees, and licenses to intellectual property. Part of the obligations under the Bayh-Dole Act requires universities to ensure that inventions are diligently developed for the public benefit. This requires negotiation of terms for diligent development of federally-funded technology as well as terms that permit universities to terminate licenses where appropriate utilization is not taking place.

The "Nine Points" document serves as a guide for universities to ensure that the public interests are taken into account and that any arrangement between the university and a potential licensee is effective in the utilization of the licensed technology. A number of the points articulated in the document are currently part of policy and/or widely practiced. This document consolidates these issues into a succinct guide that provides a perspective on why such issues are important and need to be considered. We hope that the *Nine Points* white paper helps our industry collaborators to understand better the academic environment.

Small Business Perspective

Q6. In the hearing we discussed both university and large corporation perspectives on the impact of Bayh-Dole. How do you think the experience of small business with Bayh-Dole differs from that of large corporations? Please distinguish between experiences you think are unique to individual industries from experiences you believe are common to all small businesses.

A6. Many of the Nation's large corporations have significantly reduced their efforts to engage in fundamental research and development. The *Economist* recently observed, "Companies tinker with today's products rather than pay researchers to think big thoughts." Therefore, a significant number of large firms are not themselves as engaged in early-stage research, and therefore the Bayh-Dole technology transfer process, as are small businesses. The issues related to this move away from early stage research have very little to do with the nature of university-industry relations and more so with the need for these large corporations to continually meet targets established by Wall Street, reduction of costs and overheads, and the introduction of the next version of the product at a faster pace.

Small businesses, in contrast, are a vital part of the Bayh-Dole technology transfer process. $42 billion was spent on R&D in U.S. academic centers in 2005. With the support of Bayh-Dole, universities transferred this technology primarily to small businesses. In a majority of these relations, venture capital and angel investors facilitated this process by providing "risk capital" to facilitate this process. In 2006 alone, venture capitalists made over 3,400 investments and angel investors over 51,000 in small businesses, and together investing over $50 billion in small businesses.

In return, small businesses make good stewards for the transferred technology. The Small Business Administration recently said that "small firm innovation is twice as closely linked to scientific research as large firm innovation on average, and so substantially more high-tech or leading edge." More notably, the same SBA study observed that small businesses are necessary to "maintain the diversity in our country's innovative capacity which is a source of economic strength over the long-term." That is because small business bring new, high-risk technologies to market, they invest in new business methods and models, and they provide competitive pressure on large corporations.

Therefore, it is my understanding that the small business perspective on Bayh-Dole is fundamentally different than a large corporation. Small businesses see the Bayh-Dole Act, partnerships with universities, and other sources of federal research as vital to their future business objectives and they act accordingly. Large corporations, in contrast, invest proportionally less in university collaborations, recognizing that, in anything, Bayh-Dole may represent a source of competitive threat to an existing product or technology's incumbent position.

Best Practices

Q7. During the hearing, the witnesses discussed a number of best practices which improved university-industry collaboration on industry sponsored research. Please summarize, in priority order, your top recommendations to improve collaboration on industry sponsored research.

A7. It is obvious that there cannot be a single set of "Best Practices." In fact, the term "Best Practices" implies a singular approach to a situation, which as we are discovering is untrue. Even within the industries represented by the other co-panelists (information technologies and chemicals), there is a wide spectrum of what each seeks in their respective interactions with universities. Each technology and university-industry collaboration represent unique sets of circumstances that must be carefully considered to ensure a mutually beneficial relationship to all parties. This leads to a negotiation of either a simple or complex set of issues to determine the respective rights and obligations of the parties under either a research agreement or an appropriate license agreement. The same issues and drivers that apply to the case for negotiating license agreements can be extrapolated to negotiations in university-industry research collaborations. It is this search for a singular set of Best Practices which often blocks effective collaborations, as the circumstances regarding early-stage research vary greatly.

The following recommendations to improve collaboration on industry sponsored research would apply equally to companies as well as universities:

1. Understand the culture and needs of the other party.
2. Be aware of federal and State regulations that might play a role in the nature of the relationship.
3. Don't negotiate the Facilities & Administrative rate associated with the project.
4. Avoid pre-valuing intellectual property that has not yet been created.
5. Negotiate separately the licensing rights to any background intellectual property.
6. Ensure that companies as well as the faculty are aware of issues related to conflict of interest.
7. Recognize that universities must continue to maintain their academic principles and are not serving as a hired company laboratory when participating in a research collaboration.
8. Recognize that industry sponsored research is not a source of "un-obligated money," i.e., faculty need to be aware of the expectations of the company when entering into a research relationship.
9. Operate with an open mind, in good faith and on a reasonable basis to arrive at mutually beneficial arrangements on issues concerning intellectual property; publications; and confidentiality.

Federal Government Oversight

Q8. The Federal Government has an important oversight function for Bayh-Dole to insure that university patenting serves its intended purpose and is not misused. What specific oversight do you recommend, including oversight by individual agencies funding federal research at universities?

A8. One of the initial purposes of the Bayh-Dole Act was to ensure a streamlined and uniform federal policy across all federal agencies with respect to inventions arising from federally funded research. Differing policies by individual agencies were ineffective, confusing and administratively burdensome. It is extremely important for the Federal Government to provide strong and consistent oversight and implementation of the Bayh-Dole Act in order to continue the enormous success of the Bayh-Dole Act into the next 25 years.

Over the years, a few agencies have needed clear guidance on the proper implementation of the Bayh-Dole Act as they have strayed from the standard clause and

established regulations. With the recent passage of the COMPETE Act and expected elimination of Technology Administration in the Commerce Department, it is unclear who will assume the oversight function of the Bayh-Dole Act. Because much of the Commerce Department is focused in other areas and Commerce organizations, such as NIST, is specifically designed to function as a national research laboratory that also funds research, a more appropriate placement would be the Office of Science and Technology Policy (OSTP) which has a broad policy focus to ensure consistent implementation across all federal agencies and laboratories. We encourage Congress to transfer oversight function to such an office.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Susan B. Butts, Senior Director, External Science and Technology Programs, The Dow Chemical Company

Questions submitted by Chairman David Wu

Impact of Federal Statutes

Q1. Several witnesses commented in their testimony that Bayh-Dole is only one of several federal statutes that play a role in shaping the interactions and relationships between universities and industry. What are other important statutes, and how, if in any way, do they discourage technology transfer, and industry-sponsored university research? Do you see bright-line rules which would help universities lower the perceived risk of loss of non-profit status or federal research funding?

A1. In addition to Bayh-Dole there are two other important federal laws and regulations that impact technology-related interactions between universities and industry: the Internal Revenue Code of 1986 (and the clarifying Revenue Procedure 2007–47), and the cost principles, specifically the cap on university overhead, described in OMB Circular A21 Section G.8. Each of these impacts the university-industry relationship in a different way which I will explain below.

There is a key distinction that I want to make before addressing the specific laws and regulations. This is the distinction between situations in which university inventions result directly from research that is funded by the government versus research that is funded by industry. In the former case no company has a vested interest in the invention so the university should take the commercialization path most likely to get the invention into use for the public good. In the latter case the company that sponsored the research has made an investment and should have preference in using patentable inventions that result from the research. Industry sponsored university research is different by nature and important to U.S. competitiveness. In contract to federally funded basic research in which projects are proposed by faculty members and competitive grants are awarded based on the funding agency's judgment of technical merit, industry funded research projects generally are framed by the sponsoring company based on its knowledge of the technology and market and are intended to answer a scientific question or solve a technical problem that may ultimately lead to a new or improved product or manufacturing process.

In my opinion, the most significant legislative barrier to university-industry research collaborations is the understandable concern that universities have regarding their non-profit status and the tax-exempt status of their bonds. The Internal Revenue Code of 1986 sought to prevent companies or individuals from deriving private benefit from or making private use of non-profit institutions and tax-exempt bonds. I am not qualified to comment on the specific language in the tax code or how to interpret it. However, there is a concern on the part of universities that giving preference to a industry research sponsor in licensing inventions resulting directly from the research funded by the sponsor may constitute private use and, therefore, endanger their non-profit status as well as the tax-exempt status of any bonds used to finance the facility in which the sponsored research was conducted. Revenue Procedure 2007–47 (which recently superseded Revenue Procedure 97–14) creates a safe harbor regarding tax exempt bonds. It sets forth conditions under which a research agreement does not result in private business use under the IRS Code of 1986. Section 6.02 in the Revenue Procedure describes these conditions for corporate-sponsored research as follows: ". . .if any license or other use of the resulting technology by the sponsor is permitted only on the same terms as the recipient would permit that use by any unrelated, non-sponsoring party (that is, the sponsor must pay a competitive price for its use), and the price paid for that use must be determined at the time the license or other resulting technology is available for use. Although the recipient need not permit persons other than the sponsor to use any license or other resulting technology, the price paid by the sponsor must be no less than the price that would be paid by any non-sponsoring party for those same rights."

This safe harbor is problematic for companies that wish to sponsor research. First, it provides for no credit toward the cost of the license to be given to the sponsor for the investment that the sponsor made up-front in the research. This investment includes not only the funds provided to pay for the research project but also other contributions such as proprietary information (technical or business) used to frame the research problem, use of company-developed noncommercial materials or proto-

types, and use of results of related research and testing performed by the sponsor. Second, the university alone determines the competitive price or market value of the license. It has been our experience that universities tend to overvalue inventions, and it is in the interest of the university technology transfer office to make the royalty as large as possible. Third, and most problematic for many potential sponsors, is that they cannot have any assurances before entering into the research agreement that they will be able to have reasonable access to inventions that may occur nor that they can prevent these inventions from being licensed to a competitor. It is very difficult for a potential industry sponsor to justify the business risk involved in sponsoring research on the terms specified in Revenue Procedure 2007–47.

Since these regulations are peculiar to the United States they contribute to the pressure for potential industry sponsors to take their research projects to foreign universities. I believe that the barrier to university-industry research collaborations created by the IRS Code and clarifying revenue procedures could be significantly lowered by amending the tax code and regulations to allow the university to include licensing terms (such as royalty rates or caps for field-specific licenses) in the sponsored research agreement without incurring the private business use penalties as long as the research otherwise satisfies the university's non-profit mission (e.g., the research results will be published, the research provides an educational opportunity, etc.). Such a change would not obligate universities to include such terms in industry-sponsored research agreements but it would allow them to do so without jeopardy to their non-profit and tax-exempt status. Such pre-licensing terms would then be subject to university policy and negotiation under appropriate circumstances. This would not give an unreasonable private benefit to industry sponsors and would level the playing field relative to universities in the rest of the world.

The second barrier to technology transfer and industry sponsored research is actually an indirect barrier stemming from the cap on the overhead rate that universities can charge on their federally funded research projects. The federal overhead cap as proscribed in OMB Circular A21 Section G.8 (facilities and administration (F&A) costs are limited to 26 percent of the modified total direct costs) has been in place for more than a decade and is insufficient to cover the actual F&A costs that universities now incur. Since the cap was first imposed universities have been subject to numerous additional federal requirements relating to health and safety as well as homeland security (e.g., tracking foreign students and complying with export control laws). This shortfall in government funding for real costs creates a funding gap that universities have to make up from other sources. One source is licensing revenue. This leads many technology transfer offices to seek to maximize royalty income even though it may jeopardize the relationship with potential industry licensees and research sponsors. I believe that the basis for the federal overhead rate cap should be re-evaluated and that F&A charges against research grants and contracts should reflect reasonable costs for administration, including federally-mandated compliance programs.

Impact of State Laws

Q2. Mr. Pradhan noted in his testimony that since 2005, 19 states have launched initiatives targeting innovation by investing in university R&D—including R&D initiatives and tax incentives for the private sector to partner with universities. How do State laws shape the university-industry collaboration environment? Do these laws pose any additional barriers, beyond those created by some federal statutes, for university-industry collaboration? Please explain.

A2. State initiatives generally have a positive but limited impact on the university-industry collaboration environment. The impact is positive because the incentives generally promote collaborations but limited because the incentives usually pertain only to companies which have research and/or manufacturing operations within the state. The initiatives typically are directed toward creating new technology that will ultimately lead to new jobs in the state. This is understandable since the funding for these initiatives comes from the State's tax payers. While these initiatives will foster more local research collaborations they are unlikely to have a significant impact on innovation since they fail to take into account the global character of research and development. Large companies will choose to work with the best research partners around the world, not the closest ones and successful new products will come from the most competitive, market aligned technology.

Foreign Legislation

Q3. We hear that other countries are copying Bayh-Dole. What are the goals of the legislation in other countries which have passed similar laws? Have differences

in goals led to different metrics for universities in technology transfer and university-industry collaboration? Are there changes to the Bayh-Dole statute that are needed?

A3. It is true that a number of countries have implemented (e.g., Japan) or are contemplating (e.g., India) legislation similar to the Bayh-Dole Act. They generally have the same purpose as Bayh-Dole, namely to facilitate transfer of government funded university technology to businesses for development and commercialization but the exact mode of operation reflects national circumstances and priorities. The U.S. is unusual in that the Federal Government was the largest source of research funding when Bayh-Dole was enacted, and it is still the main source of research funding for universities. In some other parts of the world industry is a more significant source of funding for university research, and the nature of the relationship between universities and industry is more symbiotic, less competitive. The universities see their role to be education and research and industry's role to be employment and innovation. It is still the norm outside the U.S. that universities assign title to subject inventions (those arising from the sponsored research project) to the sponsor since it is the sponsor's role to develop and commercialize the inventions. I have not yet seen an adverse impact on university-industry research collaborations due to Bayh-Dole-type legislation in other countries since the legislation is focused on transfer of government-funded technology rather than industry sponsored research, and research partnerships with industry, especially large or multinational corporations, are seen as desirable and prestigious.

I am not aware that other countries have established new or different metrics for technology transfer. The U.S. is still considered to be the leader in moving university technology out to the marketplace so most countries that enact Bayh-Dole-type legislation will likely use the same metrics that have been established in the U.S., namely, number of licenses granted and amount of licensing revenue generated. This could be counterproductive to university-industry research collaborations since it focuses attention on licensing activity rather doing research and than getting new technology to market. In my answer to Question 5 below I have provided some suggestions for more appropriate and meaningful metrics.

I believe that there are many positive features of the Bayh-Dole Act and that minor changes could alleviate the barriers that it has posed to university-industry research collaborations. The Bayh-Dole Act was intended to promote the licensing of inventions made with federal funding by universities to businesses for subsequent development and commercialization. It recognizes the critical need for a company to have a secure position with regard to the university's intellectual property in order to risk making the large investment needed to develop the invention and bring it to market. Bayh-Dole provides sufficient flexibility in the various ownership and licensing options to accommodate a wide range of business models and industry sector needs. These options range from the university retaining title to the patent and granting a royalty-free nonexclusive license (which is often preferred by industry sectors such as information technology) or a royalty bearing exclusive license (which is preferred by the pharmaceutical industry as long as the royalty is reasonable), to actual assignment of ownership of the invention to a company with permission of the federal funding agency. Bayh-Dole does not require universities to patent discoveries that can best be used for the public good by putting them into the public domain through publication nor does it require universities to charge the highest royalty that the market will bear. Thus, Bayh-Dole is a sound piece of legislation that reasonably addressed the key problem at the time of its enactment: that the U.S. public saw little benefit from federally funded university inventions because industry would not invest in developing and commercializing inventions that were held in the public domain. Bayh-Dole has had a negative impact on university-industry relations when taken beyond its intended and stated purpose, namely, when used as a means for universities to try to generate the maximum licensing income which makes successful commercialization of inventions less likely and when it is applied to privately funded (rather than federally funded) research which discourages such private funding. The latter impact could best be addressed by Congress clarifying that the Bayh-Dole Act (and the rights and obligations of the university there under) does not apply when private (e.g., industry) funds pay for a specific research program. Such a clarification would not obligate universities to change the way they deal with intellectual property from industry-sponsored research. It would, however, allow those institutions that value industry partnership to have more flexibility and a wider range of options regarding ownership and licensing of foreground intellectual property and, thus, attract more research collaborations with industry.

Preference for U.S. Industry Requirement

Q4. Dr. Butts—You commented on the "Preference for U.S. Industry requirement" in Bayh-Dole (35 U.S.C. § 204), and say that concerns about this restriction have resulted in recommendations from both government and industry that this be addressed. How do you think this requirement should be changed and what would be the potential impact?

A4. My comment was made specifically in reference to the application of Bayh-Dole to direct government funding of industry research. However, the same issues can occur when federally funded university inventions are licensed to companies. The preference for U.S. industry requirement stipulates that any product embodying the subject invention will be substantially manufactured in the U.S. This is problematic to companies that have global markets or foreign affiliates or subsidiaries. A company may not be able to satisfy global demand at a competitive cost if most manufacturing must occur in the U.S. This could be due to a lower cost of raw materials or labor outside the U.S. or to a high cost of shipping manufactured products to other parts of the world. For example, the extremely high cost of natural gas, a primary feedstock for petrochemicals in the U.S., makes commodity chemicals produced in the U.S. very expensive relative to those produced in other parts of the world.

I believe that U.S. preference in manufacturing should be removed or made a negotiable term rather than a requirement. This change would make it more attractive for companies with foreign markets and operations to work with the Federal Government to develop new technology that could benefit the U.S.

In the Public Interest

Q5. Dr. Lemley, in his testimony, said universities should take a broader view of their role in technology transfer, maximizing the social impact of technology. And Mr. Pradhan included in his testimony the March 2007 white paper, In the Public Interest: Nine Points to Consider in Licensing University Technology. *How could technology transfer and university-industry collaboration be conducted to better serve the public interest? What might the impact be on industries with different business models?*

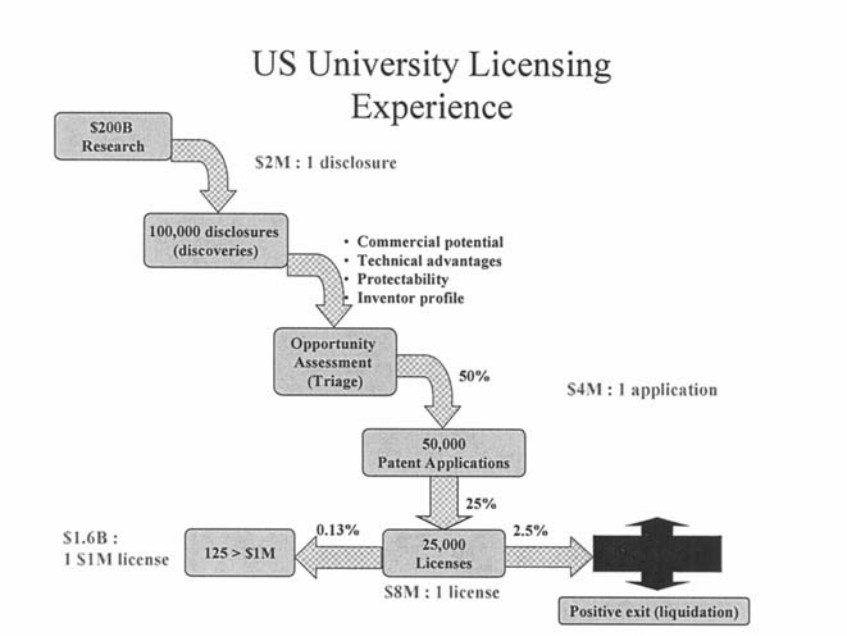
A5. I agree with Dr. Lemley's statement but I do not believe that the *Nine Points* document provides a reasonable approach for doing this. The *Nine Points* document was written by representatives from eleven large U.S. research universities and the Association of American Medical Colleges. As the preamble points out, it reflects certain shared perspectives that emerged from their brainstorming about university technology licensing. It has a very strong focus on medical- and life sciences-related research and licensing of inventions to companies that manufacture pharmaceuticals or medical devices. The Nine Points document does not address other areas of technology, such as the physical sciences or engineering, nor does it include input from the companies that receive the licenses for university inventions. The perspective is one-sided and fails to recognize the business needs of the commercial companies that must take the risks and make the sizable investments needed to develop and commercialize the university invention. In contrast, the Bayh-Dole Act is enlightened in its recognition that industry must have a reasonable assurance of right to practice and competitive advantage, which may require including exclusive licensing, in order to make the investment needed to bring a technology to market.

Going back to Dr. Lemley's comment that universities should take a broader view of their role in technology transfer, maximizing the social impact of technology, I believe that it is important to recognize the difference between transfer of existing technology that resulted from federally funded research on the one hand and industry-sponsored university research which may or may not produce useful results, let alone patentable inventions, on the other hand. Different approaches are needed to encourage the two activities and maximize the social impact. No "one size fits all" approach will work.

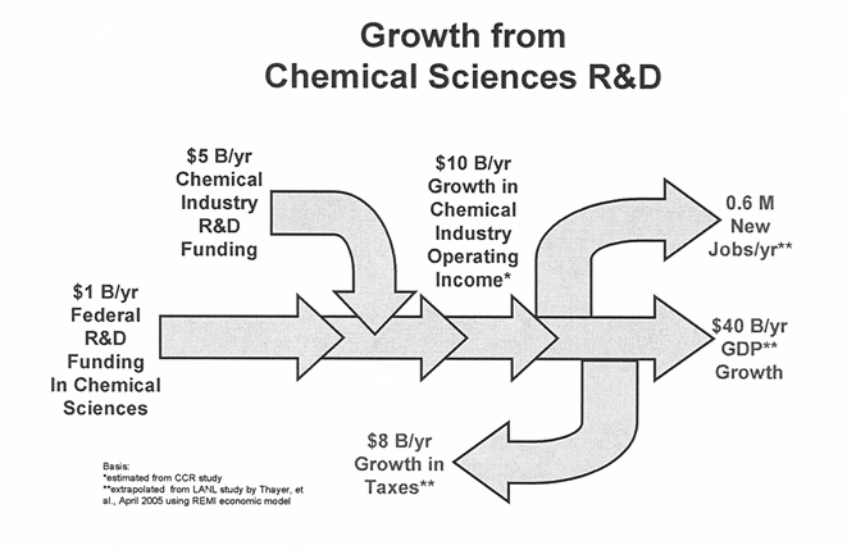
In the first case, technology transfer from federally funded research, judicious patenting and licensing of useful inventions that need protection for commercial development is appropriate. But where does the societal benefit come from? Is it from maximizing licensing revenues for the university or from getting new products to market? Many universities concentrate on the former but the greater benefit to society comes from the latter. This suggests that different metrics are needed to support and promote the most beneficial outcome. It is better to measure inventions in commercial practice since this reflects the real societal benefit rather than to measure number of licenses or amount of licensing revenue since both can occur without successful commercialization of the invention. The down side of measuring the number

of inventions in commercial practice is that the time lag between licensing and commercialization may be years or even decades depending on the amount of technology development required. A more immediate and meaningful metric than number of licenses is the percentage of university inventions for which one or more licenses have been issued. A higher percentage would indicate that useful inventions have been patented and that the licensing terms are reasonable.

In the second case, industry-sponsored university research, the societal benefit comes primarily from the opportunities provided by the research interaction on a real-world problem between faculty and students and the industry researchers. Such interactions can grow and lead to other benefits such as employment for graduates and gifts from the company. The amount of research funding from industry sponsors is an appropriate and immediate metric. There is no guarantee that the research effort will produce useful results and a patentable invention is a rare outcome. Fewer than five percent of the university research programs that my company has sponsored have produced an invention worth patenting. This low success rate is common for early stage research. Data from the Association of University Technology Managers Annual Licensing Surveys shows that, over a ten year period of time, member universities reported receiving $200 billion in research funding (from all sources) and filed 50,000 patent applications. This corresponds to a ratio of $4 million of funding to each patent application.



On the other hand, the U.S. realizes considerable benefit when industry builds on the foundation of research performed at universities. Two recent studies sponsored and published by the Council for Chemical Research (*www.ccrhq.org*) show the annualized research investment and returns for the chemical sector in the United States. The Federal Government invests about $1 billion in research in the chemical sciences at universities and national laboratories and companies in the chemical sector invest an additional $5 billion in their own research programs. Together, these investments yield $40 billion of growth in GDP and $8 billion in tax revenue for the Federal Government.



Small Business Perspective

Q6. In the hearing we discussed both university and large corporation perspectives on the impact of Bayh-Dole. How do you think the experience of small business with Bayh-Dole differs from that of large corporations? Please distinguish between experiences that you think are unique to individual industries from experiences that you believe are common to all small businesses.

A6. There are several differences between large and small companies, regardless of industry sector, that can affect the impact of Bayh-Dole. The first is that small companies have fewer research assets (employees, facilities, equipment) and, therefore, less capability to perform all steps in the process from idea generation to development of a new product ready for commercial manufacturing and sales. This makes them more dependent on external research and intellectual property sources, including universities, than large companies are. The second is that small companies are often less able to support interactions with distant universities so they are more likely to work with local universities. The third is that small companies usually have fewer existing products to generate income so failure of even one new development effort could put a small company out of business. This, also, can make them more dependent on university partners for continuing research and development since the company cannot afford to walk away from a line of research in which it has invested heavily. Large companies, by contrast, develop many new product ideas in parallel. Their existing product lines provide profit to fuel the development of new products. They can, and do, abandon product concepts that do not meet technical or commercial milestones and targets. They cut their losses and redirect their research investments. Successful new products have to recover their own development costs as well as the costs of the failures. While large companies value collaboration with universities they usually have other options for achieving their goals and can walk away from prospective collaborations that are too risky or do not meet their business needs. They can do the work in-house, they can contract the work out to a private research laboratory, or they can find a capable research partner at another university somewhere else in the world. The net result is that small companies are more negatively impacted when universities are not responsive to their needs. One complaint that I hear from my colleagues in small companies is that U.S. universities take too long to negotiate licensing and research agreements and hold out for terms that are unfavorable to the company. Although both of these difficulties are damaging to the company's business opportunities it may have no other good alternative.

Best Practices

Q7. During the hearing, the witnesses discussed a number of best practices which improved university-industry collaboration on industry sponsored research. Please summarize, in priority order, your top recommendations to improve collaboration on industry-sponsored research.

A7. Best practices need to take into account the needs and constraints of both universities and industry. A recent project sponsored by the Government-University-Industry Research Roundtable (GUIRR) in the National Academies brought together high level representatives from a range of industry sectors, types of universities, and various federal funding agencies to suggest ways to lower the barriers, particularly those involving intellectual property, to university-industry research collaborations. The project team produced a document called *Guiding Principles for University-Industry Endeavors* (available at *http://www.uidp.org/UIDP_PUBLICATIONS.html*) which describes three principles that should be followed in order to promote win-win interactions. These principles require looking beyond individual transactions toward the benefits of longer-term partnerships. The three guiding principles are:

#1 A successful university-industry collaboration should support the mission of each partner. Any effort in conflict with the mission of either partner will ultimately fail.

#2 Institutional practices and national resources should focus on fostering long-term partnerships between universities and industry.

#3 Universities and industry should focus on the benefits to each party that will result from collaborations by streamlining negotiations to ensure timely conduct of the research and the development of the research findings.

It is also important to recognize the circumstances leading to each research collaboration, the nature of the proposed project, and the contributions that each party makes to project. This is difficult to do when standardized templates are used for research agreements and when negotiations are policy based rather than principle based. The new University-Industry Demonstration Partnership (*www.uidp.org*), which is operating under the auspices of GUIRR, is developing a negotiation and education tool that will guide prospective partners through set of questions relating to the facts and circumstances of each project in order to identify reasonable terms and conditions for the research agreement. This consideration of circumstances and contributions is particularly important when it comes to dealing with foreground intellectual property that may result from the industry-sponsored project. If the sponsor is making a large contribution (funding and other resources) or has significant background intellectual property then the standard U.S. university research agreement terms are typically not acceptable to the industry sponsor.

Federal Government Oversight

Q8. The Federal Government had an important oversight function for Bayh-Dole to insure that university patenting serves its intended purpose and is not misused. What specific oversight do you recommend, including oversight by individual agencies funding federal research at universities?

A8. I believe that a light touch is best in the area of oversight so as not to add unnecessarily to the administrative burden on universities. A constructive approach would be for each agency to state its intentions about how technology developed with its funding should be licensed and used. The NIH has provided such guidance in the past.

Only some of the problems with university-industry interactions are due to government laws or regulation. Other problems stem from university and company policies or practices and cannot be fixed through legislation or governmental oversight.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Wayne C. Johnson, Vice President, Worldwide University Relations, Hewlett-Packard Company

Questions submitted by Chairman David Wu

Impact of Federal Statutes

Q1. Several witnesses commented in their testimony that Bayh-Dole is only one of several federal statutes that play a role in shaping the interactions and relationships between universities and industry. What are other important statutes, and how, if in any way, do they discourage technology transfer, and industry-sponsored university research? Do you see bright line rules which would help universities lower the perceived risk of the loss of non-profit status or federal research funding?

A1. There appears to be a complex interaction between the Bayh-Dole legislation, tax-free municipal bonds, the IRS federal tax code, and perhaps other legislation that leads to differing and uncertain interpretations of what can and can't be done. I call it "a perfect storm" of things that are working against our efforts to collaborate. This complex confluence of laws, tax-exempt statuses, exemptions, and obligations, causes universities to take a conservative approach and declare that most, if not all, of the industry-sponsored research, should come under the Bayh-Dole umbrella. While I'm not an expert in this area, I believe that Susan Butts painted a pretty vivid picture of some of the challenges presented by this in her testimony. Although there are many challenging areas, I would like to briefly elaborate on three examples to illustrate some of the problems.

Fair-market value and the inability to license up-front: One of the major sticking points arises because universities feel that they cannot determine (and hence license) the fair-market-value of a future invention up-front, essentially before the work has begun. Rather, they propose to their industry partners who sponsor research with them, to provide only an option to negotiate for a license later in time, once the IP is created and its fair market value has been determined. This means that, in the best case, the industry partners who sponsor various research activities are not assured access to the inventions that they are funding. They are relegated to having only an option to negotiate later (sometimes even a time-limited option) for a technology license, which could in fact be declined. In the worst case, a company could even be prevented from using a technology that they funded and developed, while the university shops it around to competitors, at a later date, presumably when the value is higher because the sponsoring companies have invested time and money building products and services that utilize the technology. Still, an even worse situation occurs when patent aggregators ("patent trolls") buy-up these licenses and then prevent companies from bringing their own products to market—in effect holding them "hostage" after significant investment has been made. In these situations, Bayh-Dole is not only having a chilling effect with respect to university-industry collaboration, it is also discouraging investment and partnership in the very technologies that we desire to bring to market, for public benefit.

Staying within the IRS-allowed safe-harbor: We've been told that, in order to preserve their tax-exempt status and stay within allowable guidelines for tax-exempt municipal bonds, industry sponsorship of university research must stay below a certain threshold. (sometimes only five percent, sometimes only 10 percent of a building or facility is allowed for private use.) That threshold limits industry participation, and reduces the amount of sponsored research that the university can perform in these buildings. This immediately puts joint collaborations into the positions described above, discourages industry participation (other than philanthropic), has a chilling effect on collaborative research, and prevents us from architecting the types of partnered experiences that enrich the faculty, produce well-educated students and give them a good experience of industry and universities working together.

Intersection of concerns: When we look at this from a higher-level, it doesn't make sense in aggregate form, and causes immense frustration to industry. On one hand, we have tax-exempt bonds which lower the cost of building university buildings and facilities—a good move. We want private sector participation, so that the universities don't become islands unto themselves, and provide rich, relevant experiences for researchers and students—another desirable outcome. And then we immediately get into an argument about whether or not we can work together and do work in a particular lab that sits within a building or facility. I'm wondering if there's a way

to clarify all this into an "acceptable use policy" and provide operating parameters that foster and encourage a collaborative environment.

Avoiding contact and seeking-out neutral territory: When an industry researcher literally "comes onto campus" for the purpose of interacting and collaborating with their university counterpart, there is a built-in conflict of interest that comes about. When researchers are hired by companies, they usually assign to the company they work for the IP rights to works that they create, while employed there. On the university side, there are laws that require universities to own the resulting IP that is developed in buildings that are built with tax-exempt funds. One of our researchers jokingly indicated that whenever he wants to have a technical conversation with any of his university colleagues, he invites them off-campus to Starbucks which, in effect, creates a kind of neutral "de-militarized zone" for collegial and collaborative discussions to take place. Here again, the collection of laws, practices, and boundary conditions we are faced with make it very difficult for universities and industry to collaborate, which is exactly what me must do in order to ensure a successful future.

To summarize, across the Nation, university technology transfer offices and willing industry partners struggle greatly to determine what they can and can't do, in the face of this increasingly complex set of laws and obligations at the federal, State, and municipal levels. Whether it's the laws themselves, the perception of what is required, or simply the inability to determine what can work for both sides, is irrelevant. What is relevant is that these types of situations (of which I have described only four above) create a bureaucracy that makes it extremely difficult to work with American universities on research of mutual interest and benefit. What can take as long as two years to never to negotiate in a research agreement with an American university, is achievable in a matter of days with universities in Russia, China, and other countries (ref: Stan Williams testimony, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Science, Technology, and Space, Hearing on Nanotechnology, September 17, 2002).

Impact of State Laws

Q2. Mr. Pradhan noted in his testimony that since 2005, 19 states have launched initiatives targeting innovation by investing in university R&D—including R&D incentives and tax incentives for the private sector to partner with universities. How do State laws shape the university-industry collaboration environment? Do these laws pose any additional barriers, beyond those created by some federal statutes, for university-industry collaboration? Please explain.

A2. I am not directly aware of any State laws that have been passed addressing these issues. However, I am aware of State funded program initiatives which began five or six years ago in California. These included the major institute programs that provided matching funds with the private sector, using an RFP process that picked the "best of the best." HP has participated in several of these institutes, including CITRIS (Center for Information Technology Research in the Interest of Society) and CNSI (California NanoSystems Institute). These types of investments are exemplary, and they are directly tied to the states becoming more competitive, as well as the U.S. becoming more competitive. I think that those ought to be emulated. Furthermore, this work needs to be a combination of State and federal programs that will be successful in making us competitive, and one without the other doesn't make sense. If we are talking about laws around R&D incentives, I would be all for them.

Foreign Legislation

Q3. We hear that other countries are copying Bayh-Dole. What are the goals of the legislation in countries which have passed similar laws? Have differences in goals lead to different metrics for universities in technology transfer and university-industry collaboration? Are there changes to the Bayh-Dole statute that are needed?

A3. A number of countries, such as Austria, Canada, Denmark, France, Germany, Ireland, and Spain, are considering or have enacted policies with respect to innovation and intellectual property. While the goal of Bayh-Dole was to transfer ownership for publicly funded inventions from the U.S. Government to universities, the goal of the policies in these countries is to change employment laws for university professors. They are no longer exempt from laws that give employers the IP generated by their employees—this new focus is on the retention of IP ownership for the benefit of the universities.

Governments in countries such as Germany, Sweden, and Japan have initiatives to encourage the formation of technology licensing organizations in universities. In Brazil, their law is even stronger—it requires (compels) universities to either form an agency to deal with IP or to use one established by another university. Their intent is to foster innovation and maintain R&D inside a productive environment, in order to provide for Brazil's technological autonomy and industrial development.

Goals in other countries are driven by the belief that the U.S. university system has a big impact on our innovation economy. They are copying our policies without completely understanding our context. For example, UK universities like Oxford and Cambridge are not as well-funded, so having the universities own and license IP does not make sense. Some people like David Mowery of Stanford have postulated that uninformed emulation of Bayh-Dole could be counterproductive in other countries, because a focus on licensing as the primary channel for technology transfer can have a chilling effect on the other (multiple) channels for moving knowledge and technology out into society.

Although many university TTOs in the U.S. use gross licensing revenue as a measure of success, developing countries like Brazil and Mexico are having difficulty applying this metric. These countries invest less in R&D overall, with much of their investments typically accomplished through government funding. The lack of private sector investment in R&D in developing countries makes it much more difficult for TTOs in those countries to derive revenue through the licensing of technology. Instead, Brazil is using as a metric the number of patents and publications generated by a researcher.

In discussions in Europe that I've had two years ago in the Glion colloquium, the practices that are similar to Bayh-Dole that have been transferred seem to be impacting the ability to do technology transfer in a negative fashion. Most every company that attended that consortium (Nestle (USA), DuPont (USA), HP (USA), Hoffman-Laroche (Switzerland), Fraunhofer-Gesellschaft (Germany)) indicated that technology transfer had become more complicated as a result of U.S. "best practices" that center around Bayh-Dole. I do not know any specifics of Bayh-Dole being implemented in Russia, India, or China—which have significant interest by the major private sector area—but my work in other countries leads me to believe that this is not the case.

In the Public Interest

Q4. Dr. Lemley, in his testimony, said universities should take a broader view of their role in technology transfer, maximizing the social impact of technology. And Mr. Pradhan included in his testimony the March 2007 white paper, In the Public Interest: Nine Points to Consider in Licensing University Technology. *How could technology transfer and university-industry collaboration be conducted to better serve the public interest? What might the impact be on industries with different business models?*

A4. First, let me address the "Nine Points to Consider" document. As I understand it, this was a document prepared by university vice-provosts for research, research officers, and licensing directors for university technology transfer offices (TTOs). Its purpose was to help TTO staff understand the cumulative impact of their actions over time—such as exclusive licensing, improvements, research tools, etc.—and how certain types of actions can reduce the university's future flexibility and freedom to operate. If not chosen wisely, actions taken in the present by TTOs could, in some cases, paint the universities into a corner which would be hard to remediate later.

The "Nine Points" document was not put forward as, nor was it intended to be, a solution to the challenges in negotiating university-industry collaborations, yet others have offered it as such.

Because the "Nine Points" document is one of the few tangible expressions of detailed parameters having to do with technology licensing, it is being broadly used in ways beyond what was intended. I would like to point out that there are several examples of contract terms and parameters in this document (as it presently stands) that are simply unacceptable to industry and could not be used as a basis for successful negotiation, neither in IP-focused cases, nor in collaborative exchanges.

What is needed, from a collaborative viewpoint, is an equivalent set of guidelines—let's call it "Points to consider in fostering collaboration and knowledge transfer via multiple parallel paths." There is a whole spectrum of ways that knowledge and information moves outward from universities; licensing is just one of them. Consider the impact of publishing, open source development, participation in conferences, participation in professional societies, U–I collaborations, consulting. For decades, it has been widely recognized that the best method of knowledge transfer is students—highly educated, well prepared students that move to industry and

other career destinations and utilize their knowledge for societal benefit. And this is in keeping with the core mission and primary focus of the university—to produce highly educated students.

What we are experiencing now is a shift in focus away from knowledge and people (students) to licenses and things ("technology that is presumably sitting on a shelf") for which it is possible to maximize revenue through technology transfer offices. Our experience is that the goal of maximizing revenue is getting in the way of increasing the transfer, dissemination, and utilization of knowledge and information (for public benefit), and at the same time, taking us away from the core mission and purpose of education.

In considering the original question, "How could technology transfer and university-industry collaboration be conducted to better serve the public interest?" I would submit that the metrics are currently inappropriate and misguided. This has been written about by several authors in various papers. They observe that university TTOs are acting as if driven by a patent mentality, and a maximization of revenue objective. Yet what is needed is a flow of knowledge and ideas out to the public through multiple avenues (again, technology licensing is only one), and an understanding of the benefits of working collaboratively at multiple levels across the university-industry space.

Even in the case of technology licensing and "deals," the current metrics are still misguided. As has been pointed out in the literature, it would better serve our collective interests if TTOs were to maximize the number of deals that they do (with a goal of maximizing the amount of technology transfer), rather than maximizing the revenue that can be gotten from the smallest number of deals. The dynamics that support revenue maximization (as opposed to transfer maximization) force the TTOs into the role of "gate-keepers" that slow the flow of knowledge and information, which is again, directly in conflict with what Bayh-Dole was intended to achieve. One research vice provost (whom I have a lot of respect for) tells his staff repeatedly that, "the worst deal that we can make is 'no deal,'" thereby emphasizing the whole picture of multiple contributions to society, and a focus away from revenue maximization of a single deal.

From my point-of-view, Dr. Lemley's point is extremely well taken. There is a much broader role that universities can play. The revenue objective is taking us away from solid and productive university-industry relationships and interactions, away from knowledge transfer and collaboration, and is putting us on a dangerous path of "go-it-alone"—which is, again, the opposite of what Bayh-Dole was trying to achieve. In terms of licensing, the lure of revenue maximization is amplifying the "home run" patent mentality, which mostly applies to the pharma and bio-tech industries. Studies have shown that, if one removes the university licensing revenue received from pharma and bio-tech "home run" patents, most university TTOs do not even recover enough revenue to cover their own administrative costs. So, in effect, what is happening is the dream of "home run patents" and revenue maximization is being chased by a bureaucracy that slows the transfer of knowledge and information, and erodes industry relationships and partnerships, that should be the cornerstone of our society. Further, it forces a "one-size fits all" treatment of intellectual property using the pharma and bio-tech models across all university-industry negotiations. On the industry-side, it feels like we are trading the bio-tech and pharma industry for all others, and ignoring information technology, information sciences, software, new media, clean energy, etc., who do not rely on the "home-run" patent mentality.

Small Business Perspective

Q5. In the hearing we discussed both university and large corporation perspectives on the impact of Bayh-Dole. How do you think the experience of small business with Bayh-Dole differs from that of large corporations? Please distinguish between experiences you think are unique to individual industries from experiences you believe are common to all small businesses.

A5. From a background perspective, intellectual property plays a key role for entrepreneurial businesses, particularly in their early stages of development where start-up capital is being sought. Venture capitalists and other funding sources feel more confident about investing in a company which has a defensible IP that can contribute to a distinctive advantage, than they do in funding companies with competencies that are un-established, unproven, and perhaps easily duplicated. Even if their patents are not yet granted, but still applied for, intellectual property ownership gives them an added measure of credibility when seeking financing.

Since most of my career has been doing work involving larger companies and universities, I don't have the additional perspective to comment beyond this.

Best Practices

Q6. During the hearing, the witnesses discussed a number of best practices which improved university-industry collaboration on industry sponsored research. Please summarize, in priority order, your top recommendations to improve collaboration on industry sponsored research.

A6. From my experience, let me first say that the overarching theme of best practice is to understand that it is a long-term strategic multilevel partnership that develops the best results. I've been working in the university-industry space for many years, and have found that companies and universities need to understand this as a basis for everything they do.

Second, universities and companies need to set an appropriate high-level context and value the collaborative relationship more than they do any single activity or opportunity, utilize their interpersonal networks to advantage, and value research support as highly as license revenue. These higher-level philosophies or operating parameters give valuable guidance to individuals and departments acting on behalf of the institution or company, in this space. We also need to recognize that there are multiple paths for universities to get their knowledge and information transferred for societal impact.

Third, I would recommend that we follow the Sponsored Research Interaction Process (SRIP) which was developed under BASIC (the Bay Area Science and Innovation Consortium). While the typical negotiation begins at a difficult entry point—emphasizing draft agreements which quickly lead to polarized positions, the SRIP model starts with the leadership of each organization committing to the relationship and the negotiating team focusing on the collaborative intent and the building of a shared understanding. Our experience in using this process yields a 10X improvement in negotiating a collaboration agreement—from 20+ months to two months! The essence of the SRIP model is:

- *Build a team.* Convene teams with the appropriate members on both the university and industry sides. Each team member should have a clearly identified role. Have a lead person in each team accountable for getting to timely agreement. Have the principals and negotiators meet face-to-face to build relationships and enhance rapport.
- *Set expectations.* It should be possible to get to agreement with 1–2 face-to-face meetings, a couple of phone calls, and a final closing meeting, all in a few days, spread over 3–4 weeks. Instill in the team a sense of urgency. This activity shouldn't drag on, nor should it be overly burdensome or time-consuming.
- *Work from the big picture (model).* Set goals at the right level to gain agreement, and establish metrics (such as the total amount of research funding) that reflect relationship-level thinking and not just transaction-level thinking.
- *Utilize a process that the team commits to use (secure "buy-in").* Secure strong sponsorship and commitment to making it work. Educate all team members about the process that they will use to communicate.
- *Work the process creatively.* All concerned must be prepared to offer creative insights for working through tough problems and navigating impasses.
- *Have an escalation path.* When stuck, leaders must elevate reasoning to a higher-level of intent, focusing on the broader collaborative relationship and how the planned research work will benefit both industry and university.

Federal Government Oversight

Q7. The Federal Government has an important oversight function for Bayh-Dole to insure that university patenting serves its intended purpose and is not misused. What specific oversight do you recommend, including oversight by individual agencies funding federal research at universities?

A7. I think that we ought to have a clear understanding of whether the goals of the legislation are being met, from a technology transfer point of view. Two key goals of the Bayh-Dole legislation are to promote the utilization of inventions arising from federally supported R&D, and to promote collaboration. Is it really accomplishing these goals? In aggregate, or only in specific situations? How would we know?

While we've not been recommending changes to the legislation, many times throughout my testimony, as well as in the testimony of others, we've indicated that the exact opposite of what was intended to happen, is what has happened. This legislation didn't get put into place yesterday. It's 27 years old, and we've had plenty

of time to figure it out. The results we have now are the results we're likely to have in the future. If it were up to me, I would focus on developing metrics to ensure that the intent of the legislation is being met. In industry, we understand the importance of having a closed-loop mandate for organizations—including a goal/objective statement, a set of operational parameters, and a set of metrics to ensure that things stay on track.

In the world arena, knowledge exchange and collaborative engagements/partnerships are now the norm. They are supplanting technology transfer as the contemporary operating model for accomplishing joint work. Technology-transfer, and the operating model that lies beneath it, made sense 30 years ago. It is now obsolete in the IT, information sciences, and software industries. The properties of this operating model are such that it yields results that are poorly targeted, takes too long in development, misses out on important opportunity windows, encourages go-it-alone approaches, engages single (vs. multiple stakeholders), does not have a collective amplifying effect on innovation, nor does it support the development of broad ecosystems of value delivery. Our industry has moved beyond the technology-transfer paradigm, more into the collaborative arena with multiple industry partners working with multiple universities, for both individual and collective benefit.

We know, anecdotally, that Bayh-Dole has broadly hurt collaboration, and in the best of cases, at least made it more difficult. We also know that, in many cases, Bayh-Dole has brought to the forefront a university focus on licensing, at the expense of the other forms of knowledge transfer and relationship development, not the least of which is the education of students. Within this licensing focus, we've seen that universities have been focused on maximizing revenue from the few patents that have high potential value (the "home-run" patents, typical of the pharma/bio-tech industry), and not the aggregate portfolio of technology that could be transferred and gotten "out-there" for public benefit. They've been optimizing for a return of total revenue, and not maximizing the total transfer of a portfolio of technology (which, again, was what was intended by the legislation.)

The goals of Bayh-Dole were right for the time. If we had also created the companion metrics when the legislation was written, I believe that we would have avoided many of the traps and pitfalls, and would now know with certainty where we are, and how much we've fallen short of the original intent.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Mark A. Lemley, Professor of Law, Stanford Law School; Director, Stanford Program in Law, Science, and Technology

Questions submitted by Chairman David Wu

Impact of Federal Statutes

Q1. Several witnesses commented in their testimony that Bayh-Dole is only one of several federal statutes that play a role in shaping the interactions and relationships between universities and industry. What are other important statutes, and how, if in any way, do they discourage technology transfer, and industry-sponsored university research? Do you see bright line rules which would help universities lower the perceived risk of the loss of non-profit status or federal research funding?

A1. I do not know of other federal statutes that discourage technology transfer and industry-sponsored university research. One set of federal statutes and regulations that bear on this issue involve government procurement, and particularly Department of Defense procurement. Because the DOD often develops inventions in the course of designing specifications for private companies to supply, DOD regulations governing IP ownership and technology transfer are critically important.

Impact of State Laws

Q2. Mr. Pradhan noted in his testimony that since 2005, 19 states have launched initiatives targeting innovation by investing in university R&D—including R&D incentives and tax incentives for the private sector to partner with universities. How do State laws shape the university-industry collaboration environment? Do these laws pose any additional barriers, beyond those created by some federal statutes, for university-industry collaboration? Please explain.

A2. State laws generally are aimed at encouraging, not discouraging, university research and development and university-private sector partnerships. But they can occasionally raise issues. For example, the State of California has funded stem-cell research by public initiative. Part of that initiative requires that inventions developed through State funding be licensed in a way that benefits the State of California. While this makes sense given the State funding, it may impose barriers to broad licensing of the results of that research to private companies outside California, depending on how the law is interpreted.

Foreign Legislation

Q3. We hear that other countries are copying Bayh-Dole. What are the goals of the legislation in countries which have passed similar laws? Have differences in goals lead to different metrics for universities in technology transfer and university-industry collaboration? Are there changes to the Bayh-Dole statute that are needed?

A3. Foreign countries are generally seeking direct foreign investment in research and development. While some foreign countries that pass Bayh-Dole type legislation may be particularly interested in the results of their own funding, my impression is that more commonly they are seeking to eliminate any perceived barriers that prevent multinational companies from investing in university research in their countries and licensing the resulting innovations on an exclusive basis.

Preference for U.S. Industry Requirement

Q4. You recommend in your testimony removing provisions in Bayh-Dole which discriminate against licensing university inventions to foreign businesses (35 U.S.C. §204). Would you please explain your recommendation and its potential impact?

A4. I am a believer in free trade, particularly in IP. I think that in the modern, globalized world, there is no reason to prevent universities from licensing their technology to the company or companies best positioned to maximize its impact in the world. Sometimes—usually—those companies will be local, but not always. If no good local alternatives are available, universities should not have to choose an inferior licensing deal simply to encourage local manufacture.

It is possible that eliminating section 204 will encourage some licensing to move offshore, but I think any such effect is likely to be minimal. And even if that hap-

pens, it will be offset by the benefits to American consumers of having university technology licensed more efficiently, and by the possibility that American companies can license technology from foreign universities.

In the Public Interest

Q5. You recommended in your testimony that universities should take a broader view of their role in technology transfer, maximizing the social impact of technology. And Mr. Pradhan included in his testimony the March 2007 white paper, "In the Public Interest: Nine Points to Consider in Licensing University Technology." *How could technology transfer and university-industry collaboration be conducted to better serve the public interest? What might the impact be on industries with different business models?*

A5. I believe the nine points Mr. Pradhan offered are a sensible place for universities to start in achieving what I believe must be their overarching goal: to maximize the beneficial social impact of new technology. Taking that goal seriously will, I suspect, mean that licensing will look different in different industries. In particular, I think it likely that exclusive licenses will make sense primarily in the biomedical and nanotechnology industries, which require a lot of time and effort to turn an invention into a marketable product acceptable to regulators. By contrast, I think exclusive licenses in the information technology industries would be quite rare under this approach.

Small Business Perspective

Q6. In the hearing we discussed both university and large corporation perspectives on the impact of Bayh-Dole. How do you think the experience of small business with Bayh-Dole differs from that of large corporations? Please distinguish between experiences you think are unique to individual industries from experiences you believe are common to all small businesses.

A6. I believe the effect on small businesses is bound up with the industry-specific nature of the best practices I just noted. Small businesses that are started around a university invention usually want exclusive licenses to develop and practice that invention. Under the approach I outlined, this will likely be common in some industries but not others. On the other hand, an exclusive license benefits only one business, large or small, and disadvantages all others. Small businesses who do not need to invest large sums in making an invention marketable will benefit from a non-exclusive license, because they will all be free to compete to make the invention.

Best Practices

Q7. During the hearing, the witnesses discussed a number of best practices which improved university-industry collaboration on industry sponsored research. Please summarize, priority order, your top recommendations to improve collaboration on industry sponsored research.

A7. My top three priorities for university best practices are: (1) adopt as a goal maximizing the social impact of the licensed technology, not short-term revenue. (2) structure and reward university licensing offices as part of the broader mission of technology transfer, and not on their short-term bottom line. (3) avoid exclusive licenses unless necessary to bring the technology to market, and if exclusive licenses are necessary, set benchmarks and required practices to ensure that the licensee is effectively commercializing the technology and not merely interfering with the ability of others to do so.

Federal Government Oversight

Q8. The Federal Government has an important oversight function for Bayh-Dole to insure that university patenting serves its intended purpose and is not misused. What specific oversight do you recommend, including oversight by individual agencies funding federal research at universities?

A8. I believe granting agencies should require reports on patents produced as a result of their grants, to whom those patents were licensed, and under what conditions. They should also require that those licenses be made public. They should monitor progress under the license periodically, and should have a mechanism to field and evaluate complaints about the licensee if the licensee is interfering with the implementation of the licensed technology. If necessary, agencies should be will-

ing to exercise their march-in rights under section 203 to revoke an exclusive license or compel broader licensing on reasonable terms.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Mark G. Allen, Joseph M. Pettit Professor; Regents Professor, Georgia Institute of Technology; Co-founder & Chief Technology Officer, CardioMEMS, Inc., Atlanta

Questions submitted by Chairman David Wu

Impact of Federal Statutes

Q1. Several witnesses commented in their testimony that Bayh-Dole is only one of several federal statutes that play a role in shaping the interactions and relationships between universities and industry. What are other important statutes, and how, if in any way, do they discourage technology transfer, and industry sponsored research? Do you see any bright-line rules which would help universities lower the perceived risk of the loss of non-profit status or federal funding?

A1. The relationship between universities and industry is broad and multifaceted. Interactions range from universities providing a highly skilled workforce for U.S. companies to private industry support for the mission of universities through philanthropy. University research is just one part of that relationship and even that is highly variable depending on the nature of the research problem. Some research problems center on fundamental inquiry, some build on background intellectual property developed by one or both parties over an extended period of time, and some are simply short-term tactical problems—just to name a few. In many cases a program of research will proceed over a long period of time and be funded by the U.S. Government, private industry, and non-profit organizations that fund research. The Council on Governmental Relations and the National Council of University Research Administrators have both published documents identifying the many federal statutes that control university research in all these circumstances. I will not attempt to re-address those here but will mention the area of law and regulation affecting university technology transfer that is most often cited after the Bayh-Dole Act, the tax code.

I am not an expert in tax law. It is my understanding that the general framework for the treatment of tax exempt organizations that perform research and transfer technology is that such institutions, since they benefit from public investment by virtue of their tax exempt status, must take steps to ensure that the public benefits from the results of the research, including patents, by making them available on a non-discriminatory basis. When universities take title to intellectual property that results from research, regardless of the sources of funds for that research, and licenses it to an entity that has or can attract the resources necessary to develop it into a new product, good or service, it seems to me it meets that test of public benefit. Exclusive licensing may be necessary for early stage technologies that require significant investment and require long lead times to ensure that investors have incentive to develop the technology. Non-exclusive licensing is a valid approach in industries, such as some sectors of information technology, where cross-licensing is common and the life of technologies is relatively short. The ability of universities to accept funds from industry and once the research is conducted license technology to industry on reasonable market-based terms does not seem to be impeded by the tax code.

The roles and importance of the most common modes of technology transfer, the education of students and the publication of research findings, should not be overlooked or underestimated. Students that graduate from the leading research institutions in the United States carry with them to their eventual employers in private industry a wealth of know-how gained from their participation in research. Similarly, the robust body of peer-reviewed literature in each discipline is a primary mode of dissemination of research results both to industry and the public. The tax code supports these important modes of technology transfer. Two of the purposes for which university research may be considered to be in the public interest are the education of university students and undertaking research that will be published in treatises, theses, or other forms available to the public. Taken together with a third purpose, discovering a cure for a disease, the tax code supports the mission of research universities in serving the public including all sectors of private industry.

Finally, the tax code anticipates that research will be undertaken by tax exempt organizations such as universities to aid a community or geographic area in attracting or retaining industry. This is consistent with the mission of research and technology transfer by universities. The existence of major research universities is an often-cited reason for the success of localities where high-tech industries have blos-

somed. This is likely to result from a combination of the availability of exciting new technologies based on federally-funded research and accessible to industry because of Bayh-Dole, a highly educated workforce, and closely available research facilities to address industry's questions through sponsored research and collaboration with top scientists and engineers.

Impact of State Laws

Q2. Mr. Pradhan noted in his testimony that since 2005, 19 states have launched initiatives targeting innovation by investing in university R&D—including R&D incentives and tax incentives for the private sector to partner with universities. How do State laws shape the university-industry collaboration environment? Do these laws pose any additional barriers, beyond those created by some federal statutes, for university-industry collaboration? Please explain.

A2. States have a legitimate interest in promoting strong interactions between universities and private industry for continued economic development including creation of new ventures and building new or existing industries. As noted above, strong research universities are correlated with development of high tech industries. For example, in my home state the Georgia Research Alliance (GRA), a public-private collaboration between the State of Georgia and private industry, has for a number of years fostered innovation through support for research in Georgia's universities. GRA achieves its goals through strategic investments at the state's leading research universities in eminent scholars, research laboratories and equipment, national centers for research and innovation and technology transfer programs. The support through endowed chairs and funds for equipment has been invaluable in expanding the research capabilities of institutions in Georgia. GRA supports technology transfer by matching research funds for translational research. Translational research occurs at the critical stage of technology development between the laboratory and the working prototype or demonstration of market feasibility.

State governments provide significant support for State universities. Some State universities are State agencies or units of State government and subject to the statutes and regulations that apply to such agencies. State governments may seek to ensure that tax-payers in the state benefit from the State's investment in research infrastructure. Benefits to tax-payers may take the form of economic development, new products or services, increased research revenue that ultimately furthers the university's public benefit mission, or revenue from intellectual property that can be reinvested in research and education at the university where the discovery was made. The treatment of intellectual property contemplated by Bayh-Dole addresses the needs of State government to ensure public benefit and reinvestment in research and education.

University requirements based on State laws that lead to protracted negotiation of research agreements with industry are not generally laws that deal with intellectual property matters. Rather, those cited by industry as impediments are most often issues surrounding indemnification provisions, dispute resolution, or open records. When a State agency is one of the parties to an agreement, it is probably reasonable for laws that apply to State contracts to be accommodated.

Foreign Legislation

Q3. We hear that other countries are copying Bayh-Dole. What are the goals of the legislation in countries which have passed similar laws? Have differences in goals lead to different metrics for universities in technology transfer and university-industry collaboration? Are there changes to the Bayh-Dole statute that are needed?

A3. I do not have detailed knowledge of the specific foreign initiatives or legislation referred to in this question so it would be inappropriate for me to speculate beyond my experience in this area. However, I have also noted that in visits to universities in other countries, specifically Japan, Korea, and Switzerland, that the American model of university-based intellectual property creation, protection, and licensing is being held forward as a model to be duplicated.

In the Public Interest

Q4. Dr. Lemley, in his testimony, said universities should take a broader view of their role in technology transfer, maximizing the social impact of technology. And Mr. Pradhan included in his testimony the March 2007 white paper, In the Public Interest: Nine Points to Consider in Licensing University Technology. *How could technology transfer and university-industry collaboration be con-*

ducted to better serve the public interest? What might the impact be on industries with different business models?

A4. I agree that universities should be mindful of the public interest in their research, education and technology transfer activities. *In the Public Interest: Nine Points to Consider in Licensing University Technology* enumerates the tenets of licensing in the public interest as articulated by the signatory universities. However, licensing generally involves patented intellectual property or software protected by copyright. Technology transfer also takes place at universities in many other ways including the education of undergraduate and graduate students, publication of research findings in peer-reviewed publications, continuing education programs, symposia and seminars. Balancing these modes of dissemination of new knowledge is critical to maximizing the social impact of research. The following practices in the conduct of university-industry collaborations particularly tend to serve the public interest:

- Contractual assurance that researchers are able to freely publish research results. Allowances for brief delay so that patent protection can be obtained do not impede this practice.
- Supporting graduate student research as part of the collaboration.
- Encouraging the exchange of university and industry scientists and their participation in symposia and seminars.
- Encouraging a number of companies to support research in university research centers focused on problems in a particular industry or technology area such as the Engineering Research Centers funded by the National Science Foundation which requires that universities recruit industry members for the center.

Patented intellectual property and copyright software are often best brought into public use by commercial entities that develop technology and the market for it. There are numerous examples of new drugs, medical devices, telecommunications technologies, and information technologies that resulted from university research that have changed or even saved the lives of Americans. Licensing of such technology serves the public interest. Milestone and diligence provision in the license ensure that the companies that license such technologies take the steps necessary to bring the technology to the marketplace. Common license terms further protect the public interest. By reserving the right to practice such technology in research and permit other universities and non-profits to do so, universities ensure that further development can take place. Granting exclusive rights to a defined field of use in a license encourages development and application of a transformational technology in more than one industry. These and similar license provisions help in finding the balance between broad access to technology and maintaining the value of the business opportunity for licensees.

Small Business Perspective

Q5. In the hearing, we discussed both university and large corporation perspectives on the impact of Bayh-Dole. How do you think the experience of small business with Bayh-Dole differs from that of a large corporation? Please distinguish between experiences you think are unique to individual industries from experiences you believe are common to all small businesses.

A5. Bayh-Dole is particularly valuable to small businesses in the United States. Often lacking the infrastructure and funds to fully exploit in isolation their inventions, small businesses rely on partnerships with noncompetitive institutions such as universities that have more infrastructure, expertise, and resources. Bayh-Dole helps ensure that intellectual property can be created and protected during this process. In many small business enterprises, especially in the medical and pharmaceutical arenas, the ability to protect the intellectual property created in a small business-university research partnership (as opposed to allowing it to proceed into the public domain) is essential to future funding and success of the business, as I mentioned in my previous testimony. In other areas such as telecommunications, where freedom to practice is often as important as exclusivity, universities can still utilize the Bayh-Dole mechanism to nonexclusively license intellectual property to multiple small businesses, ensuring that the commercial potential of the federally-funded research is not lost.

In addition to pre-existing small businesses, Bayh-Dole provides impetus for the creation of small companies based on university-owned intellectual property. In my experience, such spinouts are either based on university-owned inventions pre-

viously created using federal funding (and are therefore direct beneficiaries of Bayh-Dole), or are created with the willing participation of industry sponsors of the research. In the latter case, the originally-sponsoring industrial concern will typically accept an equity stake in the new small business, usually in return for an initial investment. It is typical that the new company's intellectual property relies on background intellectual property held by the university and created with federal funding. The Bayh-Dole act allows this important background property to be both protected as well as licensed to the new concern.

Finally, Small Business Innovative Research (SBIR) grants and analogous directed federal funding are an essential resource for the creation and support of small businesses. Often, for the infrastructure, expertise, or other reasons cited above, small businesses will partner with universities in the performance of these grants. Bayh-Dole acts as a 'regularizer' allowing straightforward negotiation between federally-funded small businesses and universities while simultaneously preserving the abilities of both parties to protect the produced intellectual property essential for future company growth.

Best Practices

Q6. During the hearing, the witnesses discussed a number of best practices which improved university-industry collaboration on industry sponsored research. Please summarize, in priority order, your top recommendations to improve collaboration on industry sponsored research.

A6. The relationship between universities and industries is best facilitated by recognition and understanding of the respective missions, needs, and intents of both parties. Universities exist to create and transfer knowledge through their educational and research programs. Companies focus on improving products and processes in order to enhance shareholder value. In many cases these interests are aligned and synergistic. Both parties serve the public best when new products, services, cures for diseases are made available to the public and that often leads to profitable business and economic growth. In the area of human resources, universities provide an educated workforce and leaders in science, technology and business while the private sector creates jobs and opportunities for those highly skilled workers. Research needs and technology transfer practices may vary from discipline to discipline and among industry sectors. A best practice exists when these differences in mission and role in society are recognized and valued in the university research relationship.

Practices that enhance understanding and improve the research relationship between universities and industries have been documented several times. Most recently, the Council on Governmental Relations published a brochure, *University Industry Research Relationships,* which is available from that organization and discusses the context and models for collaboration. The National Academies of Sciences convened, under the auspices of the Government University Research Roundtable, a group of companies and universities to examine the research relationship between academia and industry. This group formed the University-Industry Demonstration Partnership (UIDP) the purpose of which is to nourish and expand collaborative partnerships between university and industry in the United States. After much discussion about the missions, values and constraints of both parties, the UIDP published a document entitled *Guiding Principles for University-Industry Endeavors.* That document is available on their website at *http://www7.nationalacademies.org/guirr/Guiding_Principles.pdf.* Best practices might be summed up in terms of finding common ground and alignment of interests. As COGR states in *University Industry Research Relationships,* "many successful relationships between universities and industry have been implemented and many involve the parties reaching compromises regarding intellectual property that satisfy the requirements of both parties."

Federal Government Oversight

Q7. The Federal Government has an important oversight function for Bayh-Dole to insure that university patenting serves its intended purpose and is not misused. What specific oversight do you recommend, including oversight by individual agencies funding federal research at universities?

A7. It is my understanding that the oversight focal point for Bayh-Dole has been shifted within the Department of Commerce to the National Institute of Standards and Technology. I believe the Department of Commerce should re-elevate the oversight function to the Secretary's level or other high-level position to insure the nec-

essary attention to oversight within the Department and a high profile for the Bayh-Dole issues within the business and university communities.

Appendix 2:

Additional Material for the Record

AAU *Association of American Universities*
AAMC *Association of American Medical Colleges*
COGR *Council on Governmental Relations*
NASULGC *National Association of State Universities and Land-Grant Colleges*

August 8, 2007

The Honorable David Wu
Chairman
House Science and Technology Subcommittee on
Technology and Innovation
2338 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Phil Gingrey, M.D.
Ranking Member
House Science and Technology Subcommittee on
Technology and Innovation
119 Cannon House Office Building
Washington, D.C. 20515

Dear Chairman Wu and Ranking Member Gingrey:

On behalf of the Association of American Universities, the National Association of State Universities and Land-Grant Colleges, the Council on Governmental Relations, and the Association of American Medical Colleges, we are writing to thank the subcommittee for its interest in and attention to the role of universities in contributing to U.S. economic competitiveness, and for the recent hearing, "The Bayh-Dole Act (P.L. 96-517): the Next 25 Years." Given that the testimony and discussion from the hearing will provide a basis for any further deliberation by the subcommittee on this topic, we submit for the record these additional comments.

Our organizations unequivocally affirm the statements made by subcommittee members and the witnesses on the success of Bayh-Dole as a catalyst for innovation and its substantial contribution to U.S. economic growth and competitiveness over the past 25 years. In his testimony, Arundeep Pradhan of the Oregon Health & Science University cited several key indicators that are worth revisiting. According to the Association of University Technology Managers (AUTM), over the past nine years approximately 3,600 new products have been introduced as a direct result of university research in a broad array of fields including medicine, public safety, food and agriculture, new materials, semiconductor devices, education, and communications; 527 new products were introduced in 2005 alone. Since 1980, more than 5,000 companies have been started based on university research, contributing to the creation of more than 260,000 new jobs. There are many examples of recent university-led innovation,[1] including

[1] See COGR, *21 Questions and Answers About University Technology Transfer*, http://www.cogr.edu/. Also, AUTM, *Better World Report*, http://www.betterworldproject.net/reports.cfm.

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National Association of State Universities and Land-Grant Colleges • 1307 New York Ave., NW, Suite 400, Washington, DC 20005 • (202) 478-6040

the start-up medical device firm, CardioMEMS, founded by hearing witness Mark Allen of the Georgia Institute of Technology. This record of economic growth recently motivated the National Governors Association to reaffirm its support for Bayh-Dole.[2]

We note that, significantly, all of the witnesses testified that they see no need for major legislative changes to Bayh-Dole, and that current issues could be addressed in the implementation of Bayh-Dole's existing provisions or by strengthened government oversight. Unquestionably, difficulties can arise in establishing research relationships between universities and U.S. industry. The concerns expressed in the hearing focused largely on intellectual property practices as an impediment to some university-industry collaborations. However, other overriding aspects of academic culture—and academic freedom—enter into all university arrangements, and directly or indirectly may contribute to the challenges encountered by some commercial firms in these negotiations. Such issues include freedom to publish (including the ability to publish negative results), sustaining an open environment for faculty and students conducive to training new scientists and workers, management of conflicts of interest, honoring philanthropic commitments, and generally safeguarding an institution's academic mission.

The occasional inability of industry and academic institutions to conclude a negotiation does not necessarily indicate a weakness of the system. Most universities, we believe, correctly focus on technology transfer as a public benefit and, consistent with the provisions of Bayh-Dole, work to see that the development of new technologies is not held back by either academic institutions or by industry.

Numerous successful academic-industrial collaborations have been established over the past 25 years and others continue to arise, spanning many industrial sectors and fields of research. We believe that the issues highlighted by some of the witnesses regarding impasses they have encountered in specific circumstances must be viewed with this in mind. This is not to diminish the potential significance of the witnesses' experiences, but we offer a caution that attempting to remedy problems encountered in a few situations may create problems for many other collaborations, most of which appear to work successfully. It also is important to keep in mind that the provisions of the Bayh-Dole Act itself do not directly address mechanisms for industry-university collaborations, nor should they.

Several witnesses commented that university technology transfer to industry appears to work more smoothly for pharmaceuticals and biotechnology than other industry sectors. We are not certain that this distinction is as pronounced as implied in some of the statements at the hearing. However, it is the case that university technology licensing offices tend to have the most experience with these areas of research (as life sciences receive the largest share of federal support for university research). To the extent that this observation is valid, it may support our view that the majority of existing difficulties can be attributed to the technology-transfer learning curve for universities and companies alike.

Near the end of the hearing, industry witnesses expressed the view that the Bayh-Dole Act inadvertently creates expectations among universities that industry should assign them intellectual property rights resulting from industry-sponsored research, contrary to industry preference. These witnesses also noted that federal tax issues may arise if universities pre-commit rights to technologies based on research conducted in facilities supported with tax-exempt debt financing. They suggested that these issues might need clarification. Even absent Bayh-Dole or tax concerns, universities are usually not at liberty to

[2] National Governors Association, Policy Position EDC-04.5.4, July 24, 2007, http://www.nga.org/portal/site/nga.

assign patent title or ownership rights because such actions might prevent continuation of important lines of research and have an adverse impact on faculty or students. There also is potential for conflicting obligations because university laboratories typically are supported by multiple sponsors, including federal, state, and local governments, philanthropic foundations, their own endowments, and commercial and non-profit organizations, all of which contribute to university research. We do not believe that amending Bayh-Dole or federal tax law could safeguard these academic concerns or resolve the issue of assigning ownership rights to a specific company when several sponsors may have contributed to the new technology. While assertions were made at the hearing about the behavior of institutions in other countries with which some U.S. firms seek collaborations, it is not clear that practices of those institutions have relevance for U.S. universities. Rather, our sense is that more nations are adopting policies similar to Bayh-Dole. Moreover, we are not aware of any data that support assertions that adverse negotiations with U.S. universities are causing industry to "off-shore" research and development (R&D) that otherwise would be performed at U.S. institutions.

We agree that, to the extent real deficiencies are encountered in technology transfer, universities and their federal and industry partners have the ability and bear the responsibility to optimize the process and protect the public's interest. In the spirit of protecting the public good, several academic organizations convened recently to develop a white paper on best practices in licensing, "In the Public Interest: Nine Points to Consider in Licensing University Technology," which was published in March. [3] Among other elements, the paper affirms that university licenses should not excessively restrict other areas of R&D and should protect, in drug development for example, the interests of vulnerable populations and developing countries. In the months since the participating organizations developed these principles, additional universities and associations (including AUTM) have signed on to the document. Other academic coalitions, or AUTM, may develop similar statements of good practices and related resources to help academic institutions strengthen their professional capacities for negotiations with industry (e.g., helping to minimize unwarranted variances in academic licensing practices that may contribute to perceived difficulties). The university community and industry also have made several efforts to develop common frameworks for collaboration. These include activities undertaken by the Business-Higher Education Forum and, more recently, the University-Industry Demonstration Partnership. The cultural differences between universities and industry, given their different missions, make these activities particularly challenging. However, the dialogue has been ongoing and, as noted, there are many examples of successful collaborations.

In conclusion, we believe that by focusing specifically on programs and mechanisms that promote industry-academic-federal collaborations, and by continuing to champion increased funding for the National Science Foundation and other federal science agencies, the subcommittee and the full committee have the best opportunity to promote the next generation of innovation. In our view, these approaches provide more productive alternatives for encouraging innovation and U.S. competitiveness than changes to the proven, successful structure of the Bayh-Dole Act itself. We note especially Chairman Wu's opening statement that the subcommittee also will hold a hearing on the Stevenson-Wydler Act, which will examine the progress of industry collaborations with federal laboratories. We look forward to that discussion.

[3] Available at AUTM, http://www.autm.net/ninepoints_endorsement.cfm.

We are, again, grateful to the subcommittee for its consideration of these views, and would gladly respond to questions or provide other assistance as requested.

Sincerely,

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President
Association of American Universities

Peter McPherson
President
National Association of State Universities
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Darrell G. Kirch
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STATEMENT OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

Summary

The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide the perspective of its members on the Bayh-Dole Act. BIO represents over 1,100 companies, universities and research institutions using biotechnology to research and develop cutting edge health care, agricultural, industrial and environmental products and applications.

The biotechnology industry is one of the most R&D-intensive and capital-focused industries in the world. The industry is primarily made up of small companies that are unprofitable and that lose billions of dollars annually. 'bet it holds the promise for a cutting edge cure for Alzheimer's, drought resistant crops, or the next alternative energy source. With over 1,400 companies, many of which spun out of university research, the U.S. leads the world in biotechnology R&D. In 2005, the U.S. biotech industry spent $20 billion on research and development, and since its inception roughly two decades ago, has put into the hands of the public more than 300 biotech products, including lifesaving and life-enhancing health care treatments, and hundreds of diagnostic tests. The industry has already developed dozens of insect-resistant crops and environmentally friendly industrial applications.

All of this accomplishment has occurred despite the decades-long development time, massive investment needs, and complex regulatory process the industry must face before bringing its products and applications to market. The Milken Institute, in a 2006 report entitled "Mind-to-Market: A Global Analysis of University Biotechnology Technology Transfer and Commercialization,"[i] identified five key factors that contribute to the successful commercialization of university biotechnology research: a consistent and transparent national innovation policy that recognizes intellectual property protection and promotes entrepreneurial capitalism; the availability of funding and venture capital; biotechnology clusters not restricted by geographic borders; robust university technology transfer mechanisms; and patents and licensing.

The U.S. system of commercializing scientific discoveries has made it the world leader in the area of biotechnology in large measure because it takes into account the factors identified by the Milken Report. However, this was not always the case. Indeed, rapid commercialization of scientific discovery did not fully come about until the enactment of the Bayh-Dole Act in 1980. Prior to enactment of this legislation, publicly-funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public. There was little incentive for businesses to undertake the financial risk to develop a product. The result was that only five percent of publicly-funded discoveries were ever developed into new or improved products.[ii] The Bayh-Dole Act allowed universities and research institutions to patent and retain title to their inventions. Moreover, the Act allowed for flexibility in licensing of publicly-funded inventions without excessive government intervention. The motivation to license the technology in expectation of royalty payments was created. This provided a necessary impetus for the transfer of publicly-sponsored research to the private sector, thereby dramatically stimulating the commercialization of Federal Government-supported research. The result, among other things, is the existence of innovative new therapeutics, diagnostics and tools, industrial processes and agricultural products for the benefit of society.

From the perspective of the biotechnology industry, over the past 25 years the Bayh-Dole Act has accomplished more than its goal of turning publicly-fielded research into useful, commercial products. It has also served as a basic tool for economic development and job creation in the United States. In its policy statement on July 24, 2007, the National Governors Association recognized the import of Bayh-Dole and university technology transfer as catalysts for innovation and R&D.

The Bayh-Dole Act has become a template for innovation and economic development for other enterprising countries such as India and China. The Milken report shows that, while universities in the United States have clearly set the standard in commercializing research, other countries, particularly in Europe and Asia, have recognized the role of universities in spurring the biotechnology industry. The study suggests that, in order for the U.S. to maintain its leadership in innovation, it must continue to field research and university technology transfer offices, encourage the transfer of innovative research to the private sector, and ensure strong intellectual property (IP) protection.

BIO applauds this committee's oversight of this critically important Act to ensure that the next 25 years of Bayh-Dole provide even greater benefit to the American public and the world community. In its oversight capacity, this Committee should carefully consider how pioneering policies like the Bayh-Dole Act have helped to cre-

ate the biotechnology industry and U.S. leadership in this area, as well as the broader economic and societal benefits from the Act.

The Role of Patents in Biotechnology

In BIO's view, efficient technology transfer is intricately linked to strong IP protections and free market incentives. In the context of the Bayh-Dole Act, patents serve as the legal instrument used in the transfer of technology, information and know-how. Commercializing an invention in the biotech sector is a lengthy process requiring significant amounts of capital, often in the hundreds of millions of dollars. While government funding and research is critical in biotech R&D, substantial additional financing from the public and private capital markets is required to actually take the product from the idea stage to one that can be used by the public. Let's take as an example a typical health care-related biotech discovery. A researcher, typically in a publicly-funded laboratory, discovers a gene whose presence is only found in a particular type of cancer. The researcher also determines that the presence of this gene signals the presence of a quantifiable amount of a particular protein. Translating this initial discovery into a therapeutic application can take decades and hundreds of millions of dollars. However, it is at this early stage when the promise of a therapy is on the horizon that the researcher can seek patent protection on the various aspects of the discovery. By way of a patent, the researcher can generate interest in the further development of this potential new product by, for example, out-licensing the invention, or forming a spin-off company focusing on the R&D of this early-stage discovery. In both cases, the patent is the asset that creates a forward trajectory for the project. In the former case, an interested company partner would, among other things, review the strength and scope of the EP protecting the early-stage discovery to determine the worth of the investment. In the latter case, the IP generates the interest of institutional investors, venture capitalists, or other partners encouraging the creation of an early-stage company. In any event, the early-stage, publicly-funded discovery is now on its way to development. Of course the road to development from this point is long and torturous, and often fraught with set backs, but the transfer of technology is complete and the wheels are set in motion.

From this point on, patents play a significant role in investment of capital in the biotechnology markets. Investors measure opportunities in the biopharmaceutical and pharmaceutical sector through potential sales of the drug/product, the market exclusivity prospect through patent protection, other forms of marketing exclusivity (such as orphan drug exclusivity), or other means to gauge the strength and predictability of patent protection.

The ancillary benefits of this ecosystem to the economy in the form of jobs, tax revenue and new companies should not be overlooked. According. to the Association for University Technology Managers' (AUTM) annual report[iii], the Bayh-Dole Act continues to create hundreds of companies and tens of thousands of new jobs annually. Virtually every state has a biotechnology center or initiative.

If the major policy objective of the Bayh-Dole Act is to use the patent system to promote the commercialization and utilization of inventions arising from federally-supported research or development, then the biotechnology sector is an exemplary measure of its success. The Bayh-Dole Act provides the environment for biotechnology companies to take the risk of investing in biotechnology R&D. It provides the lure of market exclusivity as the incentive for companies to work 'in cooperation with public institutions. There is little misunderstanding of the primary obligation that companies have under Bayh-Dole to *commercialize* the licensed technology. This point is solidified by the statute's provision that failure to commercialize a licensed federally-funded invention can be the basis for government march-in rights.

While BIO believes that the Bayh-Dole Act is working quite well, there are ways to ensure that maximum benefit is continually derived from its provisions. As an example, BIO urges that the patent system should be kept strong and predictable. Congress is currently considering patent reform legislation that, iii its current form, could negatively impact commercialization of publicly-funded research by undermining the strength, value, and predictability of patent protection. This would, in turn, make it much less likely that companies and venture capital companies would invest in risky, cutting-edge research, resulting in publicly-funded research sitting on laboratory shelves. BIO recently testified before the Senate Judiciary Committee about its views on patent reform, and the university technology transfer community has weighed in with similar concerns.[iv]

In addition, consistent and transparent implementation of the Bayh-Dole Act, together with a cataloguing of "best practices" and successful partnerships, would provide more efficient transfer of technology. Congress should consider funding studies

that would aid in the identification and compilation of such best practices and identify how best to support the technology transfer offices in their overall mission.

In this spirit, BIO cautions against policies that would weaken market incentives through excessive government intervention. We can point to lessons learned in the 1990s in studying the Bayh-Dole Act. Concerns that health care reform proposals from the early 1990s could lead to price controls led to serious perturbations in the market for biotechnology investment. The impact of potential price controls on the biotechnology industry was immediate and powerful. The capital markets crashed and investment in biotech research nearly dried up.

A similar result occurred in 1999 when President Clinton and Prime Minister Blair were cited in the press as supporting the notion that certain classes of patented genetic information should be freely available to all at the time the human genome was "unraveled." Despite a clear correction by the President the next day, it took six months for the biotechnology capital markets to recover.

In both cases, a threat to free-market protection and undermining intellectual property rights drove investors away froth biotechnology research. The Bayh-Dole Act was designed to facilitate the transfer of publicly-funded research to the private sector for further development and commercialization. The careful balance set forth in the Act has been hugely successful. We have learned from history that excessive government intervention can disincentivize biotechnology companies from undertaking the huge risks to bring innovative products and services to all Americans.

Conclusion

The legislative framework of the Bayh-Dole Act has worked well over these 25 years. The House Committee on Science and Technology is to be commended for undertaking this examination of the Bayh-Dole Act. BIO appreciates the opportunity to provide insight into the impact of Bayh-Dole on the biotech industry and to describe the nature of the industry and its contributions to the improvement of the human condition. BIO's members are strong supporters of the Bayh-Dole Act, which has opened the door to the creation of many biotechnology companies that have developed important advances and cutting-edge solutions to some of the world's most intractable problems. We caution against policies that would weaken market incentives through excessive government intervention. We urge Congress to continue its far-sighted approach to innovation as it continues oversight of the effective implementation of the Bayh-Dole Act.

Endnotes

i Mind to Market Study. *http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=576&cat=ResRep*

ii Association for University Technology Managers, Annual Report, 2003

iii Association for University Technology Managers, Annual Report, 2005

iv BIO's patent reform statement. *http://bio.org/ip/domestic/20070606.asp*

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