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

HEARING CHARTER
"Bayh-Dole – The Next 25 Years"
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 US 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 sizeable 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 FY2005[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% 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%), small companies (50.2%), and large companies (30.9%). 37% 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% of the income and five universities received over 45% 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.

[1] *AUTM U.S. Licensing Survey FY2005.* 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.

[3] Arti K. Rai and Rebecca Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine, 66 *Law and Contempory Problems"* 289, 2003

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

- 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]

[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;