KANSAS LEGISLATIVE RESEARCH DEPARTMENT

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March 20, 2013

To:

House Committee on Health and Human Services

From: Iraida Orr, Principal Analyst

Re:

SB 199 - Funding

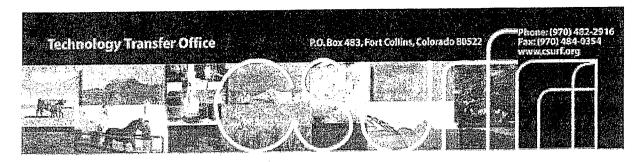
A request was made during the House Committee on Health and Human Services hearing on SB 199 regarding whether the state would receive any proceeds from the adult stem cell therapy research addressed by the bill. An inquiry subsequently was made as to whether there was any precedent allowing some of the proceeds of research projects to go to the State General Fund. Information was requested as to any instances where a portion of the research proceeds would go to the state if state funds are allocated to the research project, or in cases where no state funds are provided.

A representative of the University of Kansas, Office of Public Affairs, provided a response stating knowledge of no instance where the State General Fund receives moneys from any research activities. The representative provided direction to federal restrictions commonly referred to as the Bayh-Dole Act (Act) governing university research and commercialization.

Information is enclosed from the Colorado State University Research Foundation and the Association of University Technology Managers providing a brief history, description, and benefits of the Act.

Enclosures

IVO/rc



What is Bayh-Dole and why is it important to Technology Transfer?

In 1980, the Bayh-Dole Act (PL 96-517, Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies funding research. As a result of this law, universities retain ownership to inventions made under federally funded research. In return, universities are expected to file for patent protection and to ensure commercialization upon licensing. The royalties from such ventures are shared with the inventors; a portion is provided to the University and department/college; and the remainder is used to support the technology transfer process.

From a historical perspective, there was a need for reliable technology transfer mechanisms and for a uniform set of federal rules to make the process work. It was tough for the federal government to transfer technologies for which it had assumed ownership. In 1980, the federal government had approximately 30,000 patents of which only 5% led to new or improved products. Many patents were not being used as the government did not have the resources to develop and market the inventions. Thus, Bayh-Dole gave universities control of their inventions.

Prior to Bayh-Dole, fewer than 250 patents were issued to universities per year. In FY 2000, there were over 330 U.S. and Canadian institutions and universities engaged in technology transfer. Technology transfer has helped to spawn new businesses, create industries and open new markets. In fact, core technologies, likely to spark new industries, often result from university patents. University-industry collaborations have helped to move new discoveries from the lab to the marketplace faster and more efficiently than ever before -- ensuring that products and services based on federally funded research reach the public.

The reason that the Bayh-Dole act is so instrumental to university technology transfer is that it speeds up the commercialization process of federally funded university research and helps new industries to develop quicker. Examples range from Stanford's Cohen-Boyer patent on the basic gene splicing tools - to the Axel patents, from Columbia University which provided a completely new process for inserting genes into mammalian cells to make protein. Bayh-Dole has also enabled laboratory advances to become a significant factor in U.S. and Canadian industrial growth. The Bayh-Dole act is also vital to the university as a whole. University gross licensing revenues exceeded \$200M in 1991 and by 1992 that number had risen to \$250M. In FY 2000, U.S. and Canadian institution and universities Gross Licensing Income is reported in the AUTM survey at \$1.26 Billion.

COGR University Technology Transfer: Questions and Answers, October 1999

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Government

Bayh-Dole Act

Bayh-Dole Act

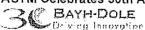
Enacted on December 12, 1980, the Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs. This legislation was co-sponsored by Senators Birch Bayh of Indiana and Robert Dole of Kansas. The Bayh-Dole Act was especially instrumental in encouraging universities to participate in technology transfer activities.

The Act is "perhaps the most inspired piece of legislation to be enacted in America over the past half-century," according to The Economist. "Innovation's Golden Goose," an opinion piece published in the Dec. 12, 2002, edition the respected publication, states: "Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

Major provisions of the Act include:

- Non-profits, 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 concerns 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
- The government retains march-in rights.

AUTM Celebrates 30th Anniversary of Bayh-Dole



December 12, 2010 marked the 30th anniversary of the Bayh-Dole Act. This legislation changed fundamentally the way America develops technologies from federally funded university research and effectively secured the country's leadership position in innovation. AUTM joined forces with the Association of American Universities, BIO, the Association of Public and Land-grant Universities and the American Council on Education to celebrate the Act and communicate its value. The Bayh-Dole Act 30th Anniversary Event was held Dec. 1 at the Washington Convention Center.

The first half of the event included remarks from original congressional sponsor of the

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Act, Sen. Birch Bayh. Other notable speakers included Sharon Barner, Deputy Director, USPTO and William Kirwan, Chancellor of the University System of Maryland. Patient advocate Betsy de Parry spoke of her diagnosis of an incurable form of follicular non-Hodgkin's lymphoma in 2002, de Parry talked about the life saving treatment, radio immunotherapy (RIT), that was co-developed at the University of Michigan. "It was the Bayh-Dole Act that enabled them to turn their discovery into a life-saving treatment that has given many lymphoma patients back their futures," said de Parry.

de Parry presented awards for Outstanding Contributions to American Innovation to Senators Bayh and Dole. Michael Connor, partner, Alston & Bird, accepted the award for Sen. Dole, who wasn't able to attend the event.

Sen. Bayh presented The Driving Innovation Award to Howard Bremer, Ralph Davis and Norm Latker for their work in drafting the Bayh-Dole Act. The Bayh-Dole 30th Anniversary Award was presented to Joseph Allen for his work over the past 30 years as a champion for the Bayh-Dole Act.

"Without Senator Bayh's and Senator Dole's foresight and commitment to this great nation, not only would the technology transfer profession exist as it does, but countless companies and products like Flumist, the nicotine patch, once-a-day HIV medication and the HPV vaccine might also not be here to help countless lives in our nation and around the world," said AUTM President Ashley Stevens, D. Phil. (Oxon), CLP.

Former Rep. Jim Greenwood, CEO of BIO (Biotechnology Industry Organization) moderated the second half of the event, a panel discussion among business, university and policy leaders which included Sharon Barner, Deputy Director, USPTO; Sen. Bayh; Betsy de Parry, Patient Advocate; William E. Kirwan, Chancellor of the University System of Maryland; and Bart Newland, Biogen.

AUTM also launched a Web site, www.B-D30.org. The site provides links to articles and videos on the Act, its history, current news and more. The site includes examples of technologies and products that originated from federally funded university discoveries. Read more.

A celebration of the 30th Anniversary of the Bayh-Dole Act was held Dec. 9 at the United States Patent and Trademark Office. Read the remarks of USPTO Director David Kappos here.

Bayh-Dole Talking Points

Over the years, various groups have expressed support or questions about the Bayh-Dole Act. The AUTM Public Policy Committee has tried to compile some of that information into one document of talking points that you may wish to use when speaking with senior university management, legislators, the media, and the general public. We recommend adding another page that highlights the specific successes generated by your organization and have provided some ideas on what you could include.

- Bayh Dole Talking Points (Adobe PDF File)
- Customize This Template for Your Institution (Microsoft Word Document)
- AUTM Letter to Department of Commerce (PDF File)
- Kaufmann Letter to Department of Commerce (PDF File)
- Case Western Response to Harvard Business Review (PDF File)

Learn more about Bayh-Dole

Senate Committee on the Judiciary for the October 24, 2007 hearing "The Role of Federally-Funded University Research in the Patent System".

- Statement submitted by the Association of University Technology Managers
- Testimony presented by Charles F. Louis, Vice Chancellor for Research, University of California, Riverside
- Testimony presented by Elizabeth Hoffman, Executive Vice President and Provost, Professor of Economics, Iowa State University

House Committee on Science and Technology, Subcommittee on Technology and Innovation, for July 17, 2007 Hearing on "Bayh-Dole – The Next 25 Years"

 Testimony presented by Arundeep S. Pradhan, Director, Oregon Health & Science University, and President-Elect, AUTM

House Committee on the Judiciary, Subcommittee on Courts and Intellectual Property for July 13, 2000 Oversight Hearing on "Gene Patents and Other Genomic Inventions"

 Testimony presented by James A. Severson, President, Cornell Research Foundation, and Past-President, AUTM

The Bayh-Dole Act: Important to the Nation, Important to Vermont

Learn the latest on the Bayh-Dole Act from a Congressional Research Service report for Congress published in March 2012.

Other countries with similar Bayh-Dole legislation:

- Brazil
- China
- Denmark
- Finland
- Germany
- Italy
- Japan
- Malaysia
- Norway
- · Philippines
- Russia
- Singapore
- South Africa
- · South Korea
- · United Kingdom

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The Bayh-Dole Act: Important to our Past, Vital to our Future

"Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980... More than anything, this single policy measure helped reverse America's precipitous slide into industrial irrelevance." Economist Technology Quarterly, Dec. 14, 2002

American academic centers performed more than \$40 billion in research in 2005. Most of this was basic research where cutting-edge discoveries are most likely to occur. It is precisely this long-range research that U.S. industry has discontinued, focusing on shorter range applied research. Linking these two complementary sectors together provides a key competitive advantage to the U.S. economy and U.S. competitiveness in a global marketplace.

But it wasn't always this way...

1970's Query: Are Our Best Days Behind Us?

- Double-digit inflation and double-digit unemployment;
- Industrial heartland becomes the Rust Belt;
- Experts predict loss of the U.S. lead in high technology to Japan and Germany;
- U.S. universities performing R&D, but few inventions commercialized.

Before enactment of Bayh-Dole in 1980, discoveries made on campus with federal funding lay fallow because the federal government embraced a policy of taking title to all such inventions and licensed them on a non-exclusive basis. The vast majority of university inventions are very early stage discoveries that require substantial investment to be developed into products. Thus, with the inadequate protection against competition afforded by a non-exclusive license, companies could not justify investing the significant amounts of time and money necessary to turn them into products. At the time the Bayh-Dole Act was passed in 1980, the federal government held title to approximately 28,000 patents, of which fewer than 5% were licensed to industry for development of commercial products according to the GAO report "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities," issued on May 7, 1998. This meant that billions of dollars invested by American taxpayers in cutting-edge research were not being effectively utilized.

According to the Congressional Research Service report "The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology" (Dec. 8, 2006) more than anything, the certainty of ownership of intellectual property has contributed to the success of the Act.

The Bayh-Dole Act: It's Good Policy.

- Allows universities and small companies to own inventions they make with federal funding.
- Funding agencies can use these discoveries royalty-free for their own purposes.
- Universities are allowed to partner with industry to translate research results into products benefiting the public.
- Preference is given to small businesses and to those making products in the U.S.
- Resulting university licensing income is invested in more research, rewarding university scientists and supporting technology transfer offices.
- Operation under the Act keeps the inventors actively engaged in the technology transfer process which is critical for companies to enable products for public use.

It's Good for the U.S. Economy:

- The U.S. is the leader in basic and applied research and is a leader in applying research and innovation to improve economic performance.
 - The Gathering Storm, National Academy of Sciences, (Feb. 2006).
- University research helped create whole new industries, such as biotechnology, where the U.S. enjoys a leadership role.
- Since enactment, more than 5,000 new companies have formed around university research results -- the majority located in close proximity to the university.
- University patenting has exploded from just 495 issued patents in 1980 to 3,278 in 2005.
- In 2005 alone, universities helped introduce 527 new products to the marketplace. Between 1998 and 2005, 3,641 new products were created.
- University technology transfer creates billions of dollars of direct benefits to the U.S. economy every year.
- According to the former President of the NASDAQ Stock Market, an estimated 30% of its value is rooted in university-based, federallyfunded research results, which might never have been commercialized had it not been for the Bayh-Dole Act.

It's Good for the Public:

Significant benefits for public health and well being are derived from technologies developed under the Bayh-Dole Act, such as:

- Synthetic penicillin
- Hepatitis B vaccine
- Citracal calcium supplement
- Cisplatin and carboplatin (cancer therapeutics)
- Human growth hormones
- Treatments for Crohn's disease
- Avian Flu vaccine
- Clean water technologies

In the meantime, academic research remains strong:

Researchers in the United States lead the world in the volume of articles published and in the frequency with which these papers are cited by others. U.S.-based authors were listed in one-third of all scientific articles worldwide in 2001.

- The Gathering Storm, National Academy of Sciences, (Feb. 2006).

And It's Good for Our States:

- "Numerous studies have shown that anchors of fast-growing, technology-oriented economies are major research universities interacting with a robust technology oriented private sector... Studies by the U.S. Department of Commerce's Office of Technology Policy and others have found that all areas of technology-based economic development in the U.S. have strong concentrations of both university and private research. A Milken Institute study found that research centers and institutes are "undisputedly the most important factor in incubating high-tech industries."
 - State Science and Technology Institute
- University patenting contributes to the most consistent measure of technological advances. According to a study cited in the 2005 Annual Report of the Federal Reserve Bank Cleveland, patent activity within a state may be the most important indicator of per capita income. "For example, patents might be a proxy for success in commercialization of technology."

Every state is a real beneficiary of the Bayh-Dole Act!

But We Can't Take Future Success for Granted...

- The United States has already entered into an era where we face new challenges to our technological competitiveness.
- Our international competitors are taking aggressive steps to leap frog our model by combining their own cutting-edge university research with low cost manufacturing.
- This is no time to weaken the Bayh-Dole Act!

CONCLUSION

"The Bayh-Dole Act (Public Law 96-517) has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefited the economic and trade policies of the United States."

 Sense of Congress resolution passed by the U.S. House of Representatives on December 6, 2006