

The Bayh-Dole Act: It's Working

In the United States, much of the research performed at universities is funded, in part, by U.S. government agencies. Sometimes university research yields a discovery that has commercial potential or the potential to improve lives. When this happens, highly specialized university employees known as technology transfer professionals, begin a complex process to protect that discovery and turn it into a product or service. Sometimes this is done by licensing the discovery to an existing company. Sometimes, a university will create a new company—or "startup"—to produce the new product. University research is incredibly important not only for advancing science, but also for helping the United States maintain its competitive edge. Technology transfer is vitally important for maximizing the benefits of research. Technology transfer is good for our economy—helping to create new jobs, products and companies. Technology transfer is possible in the United States, through legislation called the Bayh-Dole Act.

The Bayh-Dole Act, passed in 1980, represented a fundamental change in U.S. government innovation policy. It provided ownership and title to any invention made in whole or in part with federal funds 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 established a federal policy that was uniformly applied to all U.S. government agencies, while also providing the first statutory authority for the government itself to obtain, own and license patents. Prior to its passage, it has been documented that nearly 30,000 technologies were sitting on government shelves with no plan for development.

The Bayh-Dole Act is as fully viable today as it was when passed in 1980. The technology transfer process has been refined over time and the professionals who work in the field continue to respond to new markets and market forces. It is an evolving system that adapts. The Bayh-Dole Act is good for the U.S. economy—helping the United States maintain its competitive edge—and it spurs job creation.

Since 1980, American universities have spun off more than 4,000 companies. According to recent survey data by the Association of University Technology Managers (AUTM), in fiscal year 2012 alone, \$36.8 billion of net product sales were generated and startup companies started by 70 academic institutions employed 15,741 full-time employees.

The Bayh-Dole Act is good for our national economy and also good for state and local economies. The majority of startup companies born from university technologies are located in the university's home state.

Thanks to the research conducted at U.S. universities, and to technology transfer, over the past 30 years, 153 new FDA approved vaccines, drugs and/or new indications for existing drugs were discovered through research carried out in public sector research institutions, consisting of

93 small molecule drugs, 36 biologics, 15 vaccines, 8 in vivo diagnostics and 1 over-the-counter (OTC) drug.¹ This would not have been possible without the Bayh-Dole Act.

Altering the Bayh-Dole Act could have devastating consequences to this country's leadership position in basic and applied research and our leadership position in commercializing university discoveries.

Under the Bayh-Dole Act

- Universities and small companies are allowed to own inventions they make with federal funding.
- Funding agencies can use these discoveries royalty-free for their own purposes.
- Universities are encouraged 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 United States.
- Resulting university licensing income is invested in more research, rewarding university scientists and supporting the cycle of invention.
- 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.
- •The United States is the global leader in basic and applied research and leads in applying research and innovation to improve economic performance.
- University research helped create whole new industries, such as biotechnology, where the United States upholds a leadership role.
- Since enactment, more than 4,000 new companies have formed around university research results -- the majority located in close proximity to the university.
- In 2012 alone, 591 new products originating from university research were introduced to the marketplace by companies.
- 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 percent of its value is rooted in university-based, federally funded research results, which might never have been commercialized had it not been for the Bayh-Dole Act.

¹ The Role of Public Sector Research in the Discovery of Drugs and Vaccines, New England Journal of Medicine: authors: Ashley J. Stevens, D.Phil (Oxon), Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D., January, 2011.

Prior to the enactment of Bayh-Dole:

- The United States experienced double-digit inflation and double-digit unemployment.
- Experts predicted that the United States would lose its lead in high technology to Japan and Germany.
- U.S. universities performed R&D, but few inventions were commercialized.
- 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 percent were licensed to industry for development of commercial products2. This meant that American taxpayers were not getting the full benefit from the billions of dollars invested in cutting-edge research.

About AUTM

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe. To learn more about AUTM visit <u>www.autm.net</u>.

² GAO report "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities," issued May 7, 1998.