Impact of Bayh–Dole Act on Scientific Research

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What was Bayh–Dole Act?

When it comes to research patent, The Bayh–Dole Act continues to generate heated debate. Senators Birch Bayh and Bob Dole, a Democrat and a Republican, sponsored this piece of legislation as an amendment to the Patent and Trademark Act in 1980.

Prior to 1980, the technology transfer from federally funded research at American universities had been chronically slow, prompting complaints that government bureaucracy was stifling technological advancement. More fervent critics argued that America was on the verge of "industrial irrelevance," unless the system was overhauled.

Aim Was to Make a Streamlined Process

Prior to Bayh–Dole, sclerotic bureaucracy notwithstanding, the Government asserted full ownership of patents based on research it funded, and granted non-exclusive licenses to those patents. For corporations, that stipulation was unacceptable to the extent that federally funded research breakthroughs were criticized as being "tainted" by government money.

The Bayh–Dole response to this problem was an amazingly simple bipartisan solution. Universities were granted the right to claim title to any inventions funded with federal research funds. The only major stipulations were a time limit in which to claim that title, and an escape clause for the government to deny the claim in advance of the funding in the case of "a determination of exceptional circumstances." This solution was applied to all government research funding agencies.

Advocates of the Act argued that it removed all barriers to research commercialization in one fell swoop, but critics were unhappy that no commitments to additional funding were included in the legislation.

Unexpected Consequences



Universities were quick to capitalize on the new arrangement by creating offices of technology licensing (OTL), and there is plenty of data to back-up the financial benefits of Bayh–Dole. For example, university licensing revenues increased from only \$7.3 million in 1981 to over \$3.4 billion in 2008.

As an example of this night-and-day transformation of the relationship between the government and universities, consider the story of the invention of the Gatorade sports drink. The inventor, Dr. Robert Cade, at the University of Florida, was a recipient of National Institute of Health (NIH) funding in his department. After it was discovered in 1967 that he had used \$42 of NIH grant money during the development of the Gatorade formula, the government claimed ownership and took him to court. The University of Florida also claimed its share of the rapidly increasing revenues for the product. Fortunately, everything was eventually settled through licensing and royalty agreements.

By comparison, in 2008, Northwestern University booked licensing revenues of over \$800 million from the drug Lyrica that had been invented at Northwestern and licensed to Pfizer with no litigation on the part of the government.

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Critics of Bayh–Dole argue that the dramatic increase in the potential for commercialization of academic research has come at the cost of less foundational <u>basic</u> research in favor of incremental applied research.

In addition, the collaborative environment of the traditional academic campus has been replaced by highly secretive research that takes place behind locked door to protect pending patent applications.

The taxpayers who fund much of this research, it is argued, see no return on this investment other than the opportunity to take advantage of these new discoveries at full retail price. So, is it a case of Faustian bargain then? The debate on the relative merits of Bayh–Dole Act is still on, even after 35 years.

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