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Bayh-Dole: A Model for a New Congress



By Former Sens. Birch Bayh

and Robert J. Dole

W ith a new, closely divided Congress taking office, many wonder if the resulting partisan friction will grind the ability to solve important national problems to a halt. However, this need not be the case. With appropriate leadership partisan frictions can

Former Sen. Birch Bayh is a partner in the Washington office of Venable LLP. He represented the state of Indiana in the Senate from 1963 to 1981 and authored the Bayh-Dole Act of 1980, introducing it with Sen. Robert J. Dole (R-Kan.). He also authored the 25th and 26th Amendments to the U.S. Constitution (presidential and vice presidential succession, and the 18 year-old vote). Dole, who was senator from 1969 to 1996, and a member of the House from 1961 to 1969, is special counsel with Alston Bird, Washington, D.C. also be channeled, boiling seemingly intractable problems down to the nub, revealing constitutionally inspired solutions agreeable to both parties.

With this in mind, it is highly appropriate that we just marked the 30th anniversary of the landmark Bayh-Dole Act. The bill we cosponsored passed after an historic election shifting control of one body of Congress from Democrats to Republicans. And the similarities don't stop there. In 1980, the United States was in the midst of a serious economic recession causing many to speculate that our best days were behind us.

Despite this backdrop, an overwhelming bipartisan majority enacted a law later described by the *Economist Technology Quarterly* as follows:

"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 helped reverse America's precipitous slide into industrial irrelevance."

We demonstrated an important lesson: When laws can only pass with bipartisan support there is an opportunity for well-conceived, fundamental changes propelling the nation forward when it may seem to be hopelessly bogged down.

That was the case as we untangled long established government policies which denied the public full benefits from thousands of patents developed by billions of federal research dollars languishing in agency files. Our seemingly unlikely partnership worked because our bill incorporated principles for rights to patents laid down by the Founding Fathers that unfortunately had been forgotten over time.

Before the Bayh-Dole Act, the complete impact of our nation's unmatched university and federal laboratory research system was effectively divorced from the economy while innovative small companies became reluctant to accept federal R&D contracts. The reason: the government took ownership of federally funded inventions away from their creators, making them freely available to all. While this policy was a real boon to foreign competitors, it devastated domestic innovation.

The federal government has a legitimate role funding basic research which private industry simply will not do. Government-sponsored research is where fundamental breakthroughs are most likely to occur *potentially* creating revolutionary discoveries and new industries changing the world.

However, "potentially" making discoveries is not enough. Unless these early stage inventions are actually taken out of the lab and developed into new products, they just remain interesting theories or patents drawing dust. Transforming these discoveries from scientific papers into products is the role of the private sector.

We found that not a single new drug had been commercialized when the government owned the patent. More than 28,000 federally funded inventions were wasting away on agency shelves with fewer than 5 percent licensed for development. The reason was not hard to uncover. Government effectively destroyed the value of these patents by ignoring the importance of the entrepreneur as recognized by President (and inventor) Abraham Lincoln who said patent ownership adds "the fuel of interest to the fires of genius." Unfortunately, for federally funded inventions the fuel was removed from the fire.

Government-funded inventions are a long way from being products. Typically, for every dollar invested in research, ten, or many more dollars, are needed for development. This development burden is borne by our private sector, particularly small entrepreneurial companies. If the discovery is a new drug, development costs increase exponentially, requiring an average of \$1.2 billion over more than a decade to reach patients. Even then, there is no guarantee of success. Without adequate patent protections, the risk will not be taken.

Almost immediately, the Bayh-Dole Act reversed this destructive course. We mandated that universities and small companies owned their inventions made with federally funded research. We put in place market driven incentives for universities and federal laboratories to form partnerships with industry, while emphasizing the need for domestic development. We required universities to share royalties with their inventors and to use their remaining funds to support additional research. Government agencies can also use these discoveries if necessary in the performance of their missions.

And we did not create any new federal bureaucracy.

We put Lincoln's formula to work, and the results were spectacular. Under Bayh-Dole more than 7,000 new companies sprang from university inventions. Despite the recession, universities launched almost 600 new companies last year—that's two companies created every working day.

More than 8,000 new products have resulted. Because of Bayh-Dole the nicotine patch, Google, once daily HIV medication, the Honeycrisp apple, the V-chip, PSA tests, and the world's first cancer vaccine are benefitting people around the world. In the past week, we just learned of a revolutionary new blood test derived from federally funded research with the potential to spot a single cancer cell among billions of healthy ones with "the potential to transform care for many types of cancer, especially breast, prostate, colon and lung."

Academic inventions created 279,000 new jobs, and at least \$187 billion to the U.S. gross national product between 1999 and 2007. Unlike the disastrous previous policies, under Bayh-Dole more than 150 new drugs, vaccines, and in vitro devices are protecting public health here and abroad. The U.S. biotechnology industry developed from university-industry partnerships under the law. No other country comes close to these achievements.

Bayh-Dole proves our political system still works. All that's needed is the right leadership.