

Bayh-Dole: Don't Turn Back The Clock

By Senator Birch Bayh*

Speech of Birch Bayh at the Licensing Executives Society 2006 Annual Meeting, New York, New York Tuesday, September 12, 2006

After a quarter century of what by most objective standards has been an exceptional success, the Bayh-Dole law is under increasing attack today. Most of the attacks have come from individuals who have little experience with the comprehensive nature of how the law is implemented. They do not know what Bayh-Dole does and does not do, and why certain features were incorporated into the law. Equally important, these nay-sayers have no appreciation for the factors that motivated our efforts to develop this legislation in the first place. Most unfortunate of all, these modern-day experts in technology transfer apparently do not understand the basic factors upon which our nation's free enterprise system is based.

Bayh-Dole didn't just happen. Although both of these Senators provided leadership, let me emphasize that our success depended upon countless individuals who had a working knowledge of university research, patent law and basic economic motivators.

Permit me to give you a behind the scenes view of the genesis of Bayh-Dole. This is important because the better we understand the process which led to this law, the better we are able to deal with today's critics. First, a basic premise on which we, as Americans, have relied.

Historically, American economic success has depended upon our ability to develop creative and innovative minds whose ideas serve as the catalyst for business and industry. Free and open competition has resulted in generation after generation of increasingly sophisticated technology. With this innovation came new products followed by more and better paying jobs, increased family incomes and opportunities for home ownership. We had problems, but we were the envy of the rest of the world.

Unfortunately, we had begun to take our quality of life and our economic dominance for granted. By the early 1970's, America began to lose its technological advantage:

- We had lost our number one competitive position in steel and auto production. In a number of industries we weren't even no. 2.
- The number of U.S. patents issued each year had declined steadily since 1971.
- From 1973-1978, the number of patents granted to non-citizens had increased 35%.

- Investment in research and development over the previous 10 years had been dormant.
- American productivity was growing at a much slower rate than that of our free world competitors.
- Small businesses, which had compiled a very impressive record in technological innovation and which had provided most of the new jobs, were receiving a smaller percentage of Federal research and development money.
- The number of patentable inventions made under federally supported research had been in a steady decline.

The bottom line of these alarming economic indicators was that the United States was losing its technological edge. Frankly, the problem was so enormous and complex I doubted if there was anything I could do. It seemed hopeless and I assume that most of my colleagues shared my frustration. I felt like Moses in the wilderness and doubted if the "Man upstairs" would send down a lightning bolt.

The first step out of the wilderness began with a call to my office in the summer of 1978 from Ralph Davis, head of technology transfer at Purdue University. Like Indiana and many other universities, Purdue was making cutting edge discoveries from research funded by federal dollars. But Ralph said that the Government's policy that prohibited universities from owning these patents and leasing them to businesses killed the incentives necessary for innovative companies to fully develop these new ideas. If a company couldn't own the patent, it would not invest in developing it.

I asked Joe Allen, one of my legislative staffers, to check this out. He discovered that although the U.S. government owned approximately 28,000 patents, less than 4 percent were licensed to industry. The others were gathering dust at the Patent and Trademark Office. All those new ideas were gathering dust. The taxpayers

**Birch Bayh is a former Senator from Indiana who co-authored the Bayh-Dole Act, which revitalized the nations patent system and helped create the biotechnology industry by spawning a whole generation of scientist-entrepreneurs. Currently, Senator Bayh is a partner in the Washington, D.C. law firm of Venable LLP. E-mail: bbayh@venable.com*

were getting nothing.

Next, Joe and I met in my office with Ralph Davis and two of his associates, Howard Bremer, Director of the University of Wisconsin Alumnae Research Foundation, and Norman Latker, Patent Counsel at HEW. The collective vision of these three individuals was critical to our success. After hours of thinking through the problem, our meeting resulted in the drafting of legislation designed specifically to take advantage of the innovation found on campuses and the entrepreneurial skills of small businesses. I asked Bob Dole, the Senator from Kansas, to join in and the battle began. While Bob and I didn't always see eye to eye, we did agree that the United States could no longer afford to waste billions of dollars on university and small business research with no return on the investment.

The legislation was straight forward and easy to understand. Universities and small businesses would retain ownership of the ideas they developed through government funded research. They could license such patented ideas to industry at large for commercialization and would receive royalties. The inventors, usually professors, also received a share of the royalties if they assisted in developing the patent to market.

The Bayh-Dole bill was introduced and the legislative journey began. It was far from a cake walk. As could be expected, there were several hurdles in our way.

First, Senator Russell Long, Chairman of the powerful Senate Finance Committee, told Joe Allen, "This is the worst bill I've ever seen." Senator Long believed if the taxpayers funded any of the research, the government should have total ownership of the ideas produced. He believed he was protecting the taxpayer. But the Long theory ignored the fact that many of the resulting inventions were at a very embryonic stage of development. They required substantial expenditures before they actually became a product or applied system of benefit to the public.

Senator Long was one of the most influential members in the Senate. Among 100 equals, Russell Long was more equal than the others. He was a good friend and I had hoped to get his support. But, he'd made up his mind, he was protecting the taxpayers. The task of getting Bayh-Dole would be uphill all the way.

The second hurdle was Admiral Hyman Rickover, father of the nuclear navy. He called me at home one evening and came straight to the point. "Senator, that patent bill of yours threatens to destroy the nuclear navy. You must withdraw it immediately." He demanded to testify, and echoed Senator Long's opposition.

"In my opinion, government contractors—including many small businesses and universities—should not be given title to inventions developed at government expense... These inventions are paid for by the public

and therefore should be available for any citizen to use or not as he sees fit.

"I was able to develop nuclear power systems for the navy without having had to give up property rights."

Bayh-Dole provides that the Navy and other governmental entities will have first call on patents developed by government research if they are needed. In addition, it should be understood that the nuclear navy was developed by utilizing tax dollars in its development. Private investment was not necessary for development. More to the point, the Rickover logic ignores the fundamental economics of bringing an idea or product to market from the private sector. It is estimated that for every dollar's worth of academic research which leads to a patent, it requires \$10 to \$10,000 (sometimes close to \$1 million) of private capital to develop it and bring it to market. Far from getting a free lunch, companies that license ideas from universities often wind up paying over 99 percent of the innovation's final cost, without which the idea would have no value.

Nevertheless, there they stood, Senator Long and Admiral Rickover. A long tough battle would follow.

We were able to overcome such formidable opposition by relying on our allies on the campuses across the country and by developing strong support among the small business community nationwide. We organized task forces composed of individuals from both groups (universities and small businesses) and directed them to talk to their individual Senators and Congressmen. They did just that. Don't let anyone tell you that determined individuals can't make a difference.

To illustrate the power of this combination of citizens, I remember one afternoon when I was at my desk on the Senate floor, and an excitable Joe Allen came bounding up to report some good news. "Senator, we just got two more sponsors. Senators Kennedy and Thurmond just signed on."

Well, getting Ted Kennedy and Strom Thurmond to agree on anything was an achievement, but I couldn't help but kid Joe by asking, "Joe, are you sure this bill makes sense?" Bayh-Dole passed the Senate by the vote of 91 to 4. Those dedicated individuals had made a difference.

The Bayh-Dole bill moved to the House of Representatives. Rep. Bob Kastenmeier of Wisconsin was Chairman of the House Judiciary Subcommittee with jurisdiction over patents and trademarks. Congressman Kastenmeier was sponsoring a Carter Administration bill which was a more traditional measure for patent law reform. Our team went to work and through Howard Bremer's efforts, individuals at the University of Wisconsin explained to Rep. Kastenmeier the benefits to be derived from Bayh-Dole. In addition they pointed out to the Congressman the positive impact Bayh-Dole could

have in his district. In a matter of days, we agreed to join Congressman Kastenmeier's legislation and Bayh-Dole in one package which quickly passed the House and was sent back to the Senate for its concurrence. Congressman Kastenmeier's leadership was crucial to our success. Once again, a few individuals made a difference.

This was not the end of the story. 1980 was an election year. With Members anxious to go home and campaign, Congress recessed, planning to come back after the election for a lame duck session to take up the Budget Bill and certain other bills. Bayh-Dole was one of those. The Senate needed to agree to changes made to the bill in the House.

When Congress reconvened for the lame-duck session, as a result of the Ronald Reagan landslide, 12 Democratic Senators had been replaced by Republicans. The people of Indiana had said, "Bayh, stop making law and start practicing it." On January 3, I would be out of a job.

But, Bayh-Dole was paramount on my mind. The lame-duck session would be short, with only a few days for us to finish our task. What would Senator Long do? Our campus and small business allies had been communicating with their Senators, but Senator Long had put a hold on our bill. If he persisted, the rules of the Senate would enable him to stop us.

While we were wondering, on the last day of the 1980 session, Senator Long's legislative director cornered Joe Allen on the Senate floor and asked, "Does Senator Bayh really wanted that crazy patent bill?" Joe's answer was an emphatic yes.

Later that afternoon, I got a phone call from my friend, Russell Long. After commiserating with me at length over the outcome of the election, he paused and said, "Oh, by the way, Birch, take the vote on that damn patent bill. You've earned it. We'll miss you in the Senate." Click.

Now, fast forward 25 plus years. Here are what some of the critics are saying. I purposefully omit any attribution to avoid embarrassing the authors of such short-sighted and ill-founded criticism.

1. Universities and their researchers should not be entitled to financial reward because they are not manufacturing anything. Response: This suggests that the ideas (that is, the intellectual property) has no value. This is as ridiculous as suggesting that the manufacturing process has no value. Bayh-Dole recognizes that the idea alone has no value. It is designed to create the incentive for entrepreneurs to invest in the idea and provide the development capital necessary to create a valuable product out of the idea. The marriage of intellectual property and its developmental partner is the basis of Bayh-Dole's success.

2. Bayh-Dole creates the incentive for universities and researchers to ignore their search for knowledge and to be motivated like "crack addicts" driven by "small minded tech transfer offices" addicted to patent royalties. Response: Wow! Such conclusions can only come from those who have no familiarity with the dedication of our universities and their faculties to spread knowledge and have no understanding whatsoever of what motivates those who devote their lives to science and the educational process.

I well remember the testimony of Dr. Leland Clark, of the Children's Hospital Research Foundation. Dr. Clark's obsession was finding practical solutions to improve the lives of the children and adults facing cancer and serious burns. Here's what he told the Senate Judiciary Committee in strongly endorsing the Bayh-Dole bill and describing the mindset of researchers and the role of the few who also became inventors:

"The point is, as part of the mental process which leads to an invention, the inventor often envisions possibilities for application which are not immediately evident to others. The inventor's personal persistence and confidence is often the deciding factor which carries the idea forward and prevents the invention from being set aside or ignored."

3. Researchers/inventors should not share in the royalties granted universities for licensing the product of their research. Response: Bayh-Dole specifically requires a university to reach an agreement with its researcher/inventor so that he or she would continue to assist in the development of the idea until it reached the public. Prior to Bayh-Dole, the researcher/inventor would patent the invention, write a paper for publication in a reputable publication, and return to his laboratory for more research. The idea gathered dust; the public suffered. In addition, Bayh-Dole says to the inventor, "Write your paper, receive recognition among your peers, follow your idea until it is developed so that individuals and society benefit from it."

4. Industry alliances are tainting university research away from basic toward applied research. Response: A National Science Foundation study found no evidence of such a shift.

5. Bayh-Dole has adversely impacted the publication of scientific papers by academia. Response: The U.S. remains by far the leading source of science and engineering publications.

6. Here's the real zinger. There should be no exclusive licenses. They should be made available to all. This criticism is heard repeatedly. Response: Without protection, business and industry will not expend (risk) the large amount of capital necessary to get an idea to the marketplace. It was this same philosophy that resulted in the 28,000 patents drawing dust that Joe

Allen discovered in the PTO in 1978. This sounds so simple, so equitable. The taxpayer pays for the research and makes the results available to everyone. Yet to follow this course of action would turn back the clock of history. It reminds me of the admonition given to us long ago by noted philosopher and historian George Santayana who said, “Those who fail to learn from history are doomed to repeat it.” Will we never learn? Or, as another noted philosopher Yogi Berra observed, will we have “déjà vu all over again?”

There are other criticisms of Bay-Dole, equally lacking in merit. They constitute a relatively small clique who, by repeatedly using one another as an authority, appear to represent a large segment of learned opinion in the U.S. This is not the case.

Enough attention to the criticism, after 25 years a successful law should have produced tangible results. Here’s what *The Economist* had to say in 2002:

“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 to reverse America’s precipitous slide into industrial irrelevance...”

“The Bayh-Dole Act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers got a piece of the action.

“Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies on their own.”

Let’s review some statistics from the most recent Association of University Technology Manager’s survey. Under the provisions of Bayh-Dole:

- 137 non-profit institutions introduced 567 new commercial products through their licensing agreements in FY 2004.
- 185 institutions have introduced 3,114 new products through licensing since 1998.
- 16,871 invention disclosures were reported, up 8.8% over the previous year (about 250 university inventions were disclosed in 1980, the year prior to Bayh-Dole).
- In 2004, 462 new companies were formed, based on academic research (an increase of 23.5% over the previous year).
- 67.8% of university licenses went to small businesses.

But these are just statistics. Consider the new products benefiting not just the United States, but

the world: Cisplatin Citracal, a new treatment for Crohn’s disease; recombinant DNA technologies; the nicotine patch; better monitoring of diabetes patients; techniques to reduce infant respiratory deaths; 3-dimensional surgery technologies; new crops; and even the Google search engine all sprang from university research. There are many others.

So here is my challenge to the members of LES who know much more than I will ever know about this very sophisticated area. Where are we? The hard fact is that we are in danger of losing the larger philosophical war unless we explain to policy-makers and the general public why protecting intellectual property is important not only economically, but also ethically. Also, we need to understand that hidden in some of the attacks on Bayh-Dole is a veiled assault on our country’s patent system.

Our patent system and Bayh-Dole provide incentives and rewards for successful risk-taking. We should be proud of this and bold in its defense. We shirk this responsibility at great risk.

Look at the hard fact: We have allowed our critics to dominate the public forum for too long, thinking that the fallacies of their arguments are transparent. This is a dangerous assumption and one that if left unchecked will undo us. This can happen literally overnight. Legislation in the form of “patent reform” is pending in Congress at this very moment. If it should pass, it would do irreparable harm to our economic growth and our ability to provide sophisticated solutions to the problems which face our society.

We hope that someone else will step into the breach since most normal people do not enjoy conflict, particularly when their integrity and motives may well be attacked. But, to my friends of LES, unless we pick up the gauntlet, no one else will. We cannot remain complacent. This is true of us as individuals and true of the United States of America. We must remember how Edward Gibbons concluded his great volume, *The Decline and Fall of the Roman Empire*: “All that is human must retrograde if it does not advance. Nations, like individuals, are either moving forward in life or moving backward. We are never standing still. The ethical creation of wealth is the real challenge facing the world today.”

Previously I have tried to convey the impact that a few dedicated citizens can have on our country’s legislative process. If Ralph Davis, Howard Bremer, Norm Latker, and Joe Allen can harness the effort which provided us with Bayh-Dole, certainly those of us who are faced with basically the same challenge a generation later should be willing to stand up and be counted today!

Let me repeat, if we don’t do it, who will? ■