Enacting Bayh-Dole

By Joseph P. Allen

There is a tide in the affairs of men
Which taken at the flood, leads on to fortune;
Omitted, all the voyage of their life
Is bound in shallows and in miseries.

Julius Caesar by William Shakespeare

We caught the tide-- but just barely. That the Bayh-Dole Act passed was amazing. That it passed in a lame duck session of Congress with its principal author defeated, the US Senate changing hands, and a sitting president thrown out, was a miracle. Even then success was not assured. The bureaucracy was waiting to undermine the implementing regulations. Yet the new law survived, strengthening the economy while improving public health and well-being.

Success depended on slipping through a narrow window of opportunity. In **Julius Caesar,** Brutus hesitates and is swept away. Fortunately, we launched and caught the tide. This is my "staff's eye view" of how it happened.

In 1978 I was on Senator Birch Bayh's (D-IN) staff when Purdue University asked for a meeting. Our general counsel invited me to sit in. Purdue had several promising government funded inventions taken away under existing federal patent policies. They explained that taking early stage inventions from their creators, making them widely available through non-exclusive licenses doomed the technology's development. Confirming Purdue's observation was Howard Bremer of the Wisconsin Alumni Research Foundation and Norman Latker, the National Institutes of Health (NIH) patent counsel. They added that NIH had a very successful policy granting patent ownership to inventing universities, but it was being abolished by the Carter Administration. Would Senator Bayh look into this matter and consider introducing legislation allowing universities and small companies to own inventions made with government support?

The economy was then in a tailspin. Combining double digit inflation with double digit unemployment created the "Misery Index". The federal government funded 50% of U.S. research, but few inventions made it to the marketplace. The Department of Defense routinely granted patent ownership to major contractors, but not to universities or small companies. Yet these very entities are the most likely to make breakthrough discoveries. Instead, universities

and small companies had to petition to own their discoveries. The procedure was slow and cumbersome. The answer was frequently "No."

We learned that Senator Robert Dole was also looking at the problem. This raised an interesting possibility. Senator Bayh was a liberal Democrat and Senator Dole a conservative Republican. Both served on the Senate Judiciary Committee. Both reached the same conclusion: patent incentives must be restored to the federal R&D system. They were happy to work together to make that happen. The political combination of Birch Bayh and Bob Dole was formidable. Together they bridged the partisan divide.

A draft bill was introduced in late 1978 to get comments from interested parties before the bill was re-introduced the next Congress. We asked the Comptroller General of the United States, Elmer B. Staats, to conduct a study of the federal patent policies then in place. Staats knew the subject well. He had the clout to get data from reluctant agencies how effectively taxpayer-supported R&D was being commercialized.

As Congress reconvened, we held a press conference showcasing university inventions at risk. The inventors explained that medical discoveries would not alleviate human suffering unless they were turned into products. This would not happen when government destroyed the incentives of patent protection. The event got great press coverage.

The next day the **National Inquirer** called. "Is it possible the cure for cancer is being delayed?" I replied that anything is possible, but that was hardly likely. For weeks I glanced nervously at the checkout counter to see if a headline screamed *"Government Hides Cure for Cancer."* Luckily, the story didn't run.

Our hearings that spring went very well. The Comptroller General confirmed that the government's patent policies were not working. He showed that petitions for patent ownership took up to 18 months to process. Approximately 28,000 inventions had piled up, and less than 5% were ever licensed.

University and small business witnesses told how detrimental the current policies were to American innovation. The Carter Administration had not taken a position on the bill so they did not testify. However, Admiral Hyman Rickover ("The Father of the Nuclear Navy") appeared under full steam.

Rickover was a staunch believer that whatever the government funded should be freely available. Experience in the nuclear industry showed that patents were not critical to development, he said. Rickover and Sen. Bayh had a lively debate on the merits of the patent system. The Admiral deeply believed in his view. He also had a close ally in Congress—Senator Long of Louisiana.

Russell Long was the son of the legendary Huey ("The Kingfish") Long. Sen. Long chaired the powerful Senate Finance Committee overseeing tax policy. He reportedly replied when asked about a pending tax reform provision: "If I have to explain it, we'll be here all day. Just vote Yes."

Sen. Long greatly admired Admiral Rickover, sharing his views on government patent policy. Long was not someone you crossed lightly. We hoped that limiting our bill to universities and small companies would avoid his wrath if we got to a full Senate vote. Universities and small companies were the crux of the problem anyway. But first we had to get out of the Senate Judiciary Committee.

The next step was the Committee "marked up." This is when the Judiciary Committee reviews the bill, makes any amendments, and then votes it up or down. If approved, the bill proceeds to Senate consideration.

The Committee had the most liberal Democrats and conservative Republicans in Congress. But the political alliance of Bayh and Dole, with support from the universities and small businesses was our secret weapon.

One day Chairman Ted Kennedy (D-MA) and Ranking Minority Member Strom Thurmond (R-SC) independently called to be co-sponsors. I made a bee line to the Senate chamber to give Senator Bayh the good news. Mischievously looking up from his reading glasses he said: "Are you sure this bill is ok?'

Shortly before the Committee vote in December 1979, we were visited by the Carter Administration. They had sat on the bill for a year. I was astounded when they asked that we stop while they developed an alternative approach. I replied we had waited long enough as Congress was already half over. The Administration would make their presence felt -- to our dismay.

The Judiciary Committee unanimously approved Bayh-Dole, reporting it to the full Senate.

We were now at a point of great peril. We continued to hear from Admiral Rickover. He was also prodding Senator Long to get involved. We would soon know if Rickover had succeeded or not.

The actual hit came from an unexpected direction. Giving up on dissuading us, the Administration moved to the Senate Commerce Committee. They developed a rival bill geared toward large contractors, arguing that these companies performed the majority of federal R&D. Senator Bayh met with Senators Stevenson and Cannon. He argued that universities and small companies were those suffering most from the current policies, that they were the ones most

likely to make breakthrough discoveries with federal funding, and the alternative approach was not politically feasible. Bayh's views were rejected.

Before debate on Bayh-Dole began in February 1980, all Senate offices received a "Dear Colleague" letter from Commerce Committee. They intended to amend our bill to include big business. Senator Bayh and Dole replied with a rebuttal letter. Both sides worked the phones hard lining up support.

The next day showed who had the votes. After a lively debate, we handily beat back the amendment. However, just as the vote concluded, Senator Long emerged. He was not a happy man. As Stevenson and Cannon fled, Senator Bayh whispered "Great, they're leaving me to clean up their mess."

I had a good relationship with Wiley Jones on Senator Long's staff. Senators Long and Bayh also got along very well. Wiley and I agreed not to sandbag each other. Long feared that Bayh-Dole was a "Trojan horse" limited at first, but later expanding to include big business. Sen. Bayh pledged to fight such efforts. But the Commerce Committee had waved a red flag before a very powerful bull. When he charged, you knew it.

Senator Long's seat was directly behind Sen. Bayh. As a staffer, I was sitting beside my boss. Senator Long soon brought further consideration of Bayh-Dole to a screeching halt, muttering to us: "This is the worst bill I've seen in my life."

Long told the presiding officer that he had several amendments to the bill. It became obvious that the debate would take much longer than the Senate leadership had allocated. We had to pull Bayh-Dole from the floor.

Under the rules, one Senator can greatly complicate consideration of a bill. They can object to it being scheduled. They can drag out debate offering endless amendments, or use parliamentary maneuvers like the filibuster.

As the 96th Congress got closer and closer to election day, non-essential bills were severely limited on the time allotted for debate. Three precious months were spent working behind the scenes with Senator Long's office to re-schedule Bayh-Dole. In late April 1980 we succeeded--again pledging to oppose any attempts to broaden it.

The bill passed the Senate 91-4. Sen. Long voted no.

Meanwhile, the House was also looking at federal patent policies. Consideration began in the House Science and Technology Committee, then onto the House Judiciary Committee. The end of the Congress was rapidly approaching. The Carter Administration gained support for their approach. The House bill included big business.

The reaction was predictable. On September 24, 1980 Senator Bayh received a public letter from Sen. Long: "I am adamantly opposed to the House bill. I urge you to join with me in taking whatever steps are necessary to prevent this monopolistic provision from being included in the final form of any patent policy legislation."

Two days later, Bayh replied: "I will offer an amendment to bring any House passed patent policy into conformity with that already passed by the Senate, which as you know is strictly limited to universities and small businesses."

And there things stood on Election Day, 1980.

The election of 1980 was similar to 2010. Jimmy Carter was initially viewed as a political outsider who would change Washington. Political missteps, an economy spiraling downward, and the Iran hostage crisis ate away his support. Americans felt that it was time to clean house. Carter lost to Reagan. Birch Bayh lost. The Senate went to Republican control for the first time in decades.

However, Congress had recessed without enacting a budget so a lame duck session was necessary. This provided a glimmer of hope for Bayh-Dole. But Senate policies for bringing up non-budgetary bills were strict: they must pass unanimously.

The House combined several patent related provisions into one bill, including their version of patent policy. The bill manager was Rep. Robert Kastenmeier of Wisconsin. Through informal negotiations, we made it clear that we could not accept this approach as evidenced by Senator Long's letter. The House would not back down. We stopped talking. However, the University of Wisconsin was a large part of Kastenmeier's district. And they backed Bayh-Dole.

One afternoon I received a call from Bruce Lehman (later PTO Commissioner). Bruce was Representative Kastenmeier's staffer on their bill. Bruce offered a deal. They would include our patent policy if we would accept the rest of their omnibus bill. I ran it by Senator Bayh. He gave the green light. The House would pass the bill with Bayh-Dole included. We would then pass their revised bill without any changes. However, if even one Senator objected, we were sunk.

I contacted the Senate Majority Leader's office to schedule a vote as soon as the House acted. The Majority and Minority leaders then alert their respective members to see if anyone objected. Congress was adjourning any moment when the final parts of the budget were completed.

I received a call. We would not be scheduled because a Democratic hold had been placed on our bill. Under the procedures, any Senator can anomalously "hold" legislation blocking consideration. I checked with Wiley Jones. He said Long had not placed the hold.

There was another likely candidate: Senator Stevenson. He had developed rival legislation that would become the Stevenson-Wydler Act. Stevenson, like Bayh, was leaving Congress. I went looking for his staffer, Steve Merrill.

Finding Steve in the Senate cafeteria, we had a direct conversation. I said that two could play this game. If the hold wasn't lifted on Bayh-Dole anything with Sen. Stevenson's name would have a similar hold —and they would not even have to guess who had done it.

Shortly the hold was removed. However, the Majority Leader's staff said because of Senator Long's interest; they had to call his office as well.

Minutes later my phone rang. It was Wiley Jones. "I have two questions for you. One is from Senator Long and one is from me." He asked if Senator Bayh really wanted the bill. I said that he did. Wiley then asked if it would be better for me not to pass the bill so I could find a new boss and have a job next year. Moved by his thoughtfulness, I replied it was now or never for passing Bayh-Dole. He said "OK," and hung up.

Senator Long immediately called Senator Bayh. "Birch, you can pass your damn patent bill-- and I'm really going to miss working with you."

I ran to the Senate chamber. It was in chaos. Staff fought to get bills scheduled while there was still time. In the confusion, I found the Majority Leader's staffer. We would be up in 10 minutes, but if we weren't ready, too bad.

I called for Senator Bayh. He was at a press conference and would take 20 minutes to return. My heart sank. I looked around the Senate cloakroom. There stood Senator Dole!

Running over I explained our dilemma. Senator Dole said "Follow me," and went out on the Senate floor. I handed him the statement I had written for Senator Bayh, he read it, and asked for the vote. On November 21, 1980 Congress passed H.R. 6933 including the Bayh-Dole Act. We had done it-- or so we thought.

As Bayh-Dole was moving through Congress, agency opposition centered in the Department of Energy (DOE). DOE is a large funder of nuclear weapons research and very sensitive on how their technology is developed. Over the years DOE amassed a large staff reviewing patent petitions. They rightly saw Bayh-Dole as a threat to their job security.

After Congressional passage, legislation moves to the President's desk for signature. The Constitution says:

> *If any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like manner as if he had signed it,* ***unless the Congress by their adjournment prevents its Return, in which case it shall not be a law.*** (Article I, Section I, emphasis added)

Congress had adjourned so the President could "pocket veto" Bayh-Dole by simply ignoring it. We heard that DOE was working the White House against the bill. As days ticked by without the President's signature we became increasingly alarmed.

Our ally in the fight was the Office of Advocacy in the Small Business Administration. Headed by Milton Stewart (later founder of INC magazine), they supported Bayh-Dole over the Carter Administration proposal. Milt had worked with Stuart Eizenstat, Carter's chief of staff, organizing a very successful small business conference before the election. Deftly countering DOE, Stewart cleared the roadblocks.

On the very last day President Carter signed Bayh-Dole into law.

But it was still in jeopardy. Any law is only as effective as its implementing regulations. With Sen. Bayh gone and the new Reagan Administration not in place, DOE had a golden chance to torpedo the regulations.

While Bayh-Dole held the general principle that universities and small companies making inventions with federal support could own them, we stipulated that in "exceptional circumstances" the agency could provide otherwise. Congress envisioned situations where government agencies were actually developing the technology, or where national security concerns prevailed. The Department of Energy launched their assault using this provision. They tried to exempt broad categories of research from the law.

Luckily, we had a capable person in place guiding the regulations. Norman Latker as NIH patent counsel realized that unless universities were allowed to own and manage federally funded discoveries, inventions were unlikely to ever be developed. Norm developed a highly successful administrative policy that worked for years until the Carter Administration decided to roll it back—and fire Latker.

Instead, Bayh and Dole got Norm relocated and placed oversight of the new law under him. His boss was Dr. Bruce Merrifield, Assistant Secretary of Commerce in the new Reagan Administration-- a great stroke of luck.

As an entrepreneur, Merrifield immediately understood the importance of Bayh-Dole. He strongly backed Latker in his fight with DOE, alerting the White House of the importance of the new law to an ailing economy. Eventually, President Reagan issued an Executive Order giving his support to Bayh-Dole.

In 1982, I began working in Dr. Merrifield's office overseeing Bayh-Dole's implementation.

We stopped a State Department agreement with Japan giving visiting scientists rights to inventions made in US universities and federal labs. When State protested, the issue was taken to the President's Economic Policy Council, where we prevailed. The agreement was renegotiated bringing it into line with Bayh-Dole. We developed a standard intellectual property rights clause for agreements with other countries. We also protected Bayh-Dole in free trade agreements. We worked closely with Congress protecting the law and extending its provisions. The Federal Technology Transfer Act allowing federal laboratories to develop "cooperative R&D agreements" (aka CRADAS) was one result.

Steve Merrill, formerly of Senator Stevenson's staff, is now with the National Academy of Sciences. Their new report **Managing University Intellectual Property in the Public Interest** addresses the Bayh-Dole Act. While supportive of the law and its benefits, the report concludes that Bayh-Dole failed to establish an effective oversight function. This is not accurate.

As shown above, when the oversight function was staffed by those knowledgeable and supportive of the law, it was highly effective. Deborah Wince-Smith, who succeeded Bruce Merrifield as Assistant Secretary of Commerce, was an untiring defender of Bayh-Dole.

Unfortunately, support for overseeing Bayh-Dole waned in the Clinton Administration. The Department's Advanced Technology Program was exempted from Bayh-Dole. The oversight function was downgraded until it landed at the National Institute of Standards and Technology. As a laboratory, NIST cannot insure interagency compliance with Bayh-Dole, or halt international agreements.

Bayh-Dole was enacted and thrived because a small band recognized its potential benefits for the United States. Its future depends on having new hands willing to pick up that banner.