Latker, Carole (NIH/NIGMS) [E]

From: Maureen Adams [AdamsM@browdyneimark.com]
Sent: Wednesday, March 04, 2009 1:13 PM
To: Latker, Carole (NIH/NIGMS) [E]
Subject: FROM JOE ALLEN FOR MR. ALTKER - FW: My papers on Bayh-Dole
Attachments: Bayh-Dole to FTTA, submitted version to AUTM Journal.doc

Please let Mr. Latker know I am sending two cases by Fedex for delivery tomorrow, Thursday, March 5. The deadline for response is March 24, 2009.

It's awfully quiet around here without Mr. Latker :-)

Maureen

From: Joe Allen [mailto:jallen@allen-assoc.com]
Sent: Wednesday, March 04, 2009 11:29 AM
To: Karen Hersey; Jon Cavicchi
Cc: Norman Latker; Howard Bremer
Subject: My papers on Bayh-Dole

Boy, this turned out to be more of a task than I thought. I organized my papers and put them in bundles corresponding to the various stages of our adventures. I wrote up an explanatory introduction to each bundle so, hopefully, they are easier to track.

While this is a pretty good paper trail, unfortunately, while going through them, I realized how much I didn't keep. I'll contact Sen. Bayh and see what he did with his papers when he left office and how you could go about reviewing them, if you're interested (please let me know if you are). I'm not sure how they are organized.

Now I need to find an appropriate box and I'll call UPS for a pick up. I ask that you copy the papers and return the originals to me.

In 2007, the AUTM Journal asked me to write something about the tech transfer legislation enacted after Bayh-Dole. I just learned this week that it finally came out. It's attached. I also want to send you an excellent article Ashley Stevens wrote after interviewing me on the story behind the story in passing Bayh-Dole. Now that I need it, I can't lay my hands on it, but asked Ashley to send me another copy which I'll pass along to you.

Joseph Allen
President
Allen & Associates, Inc.

740-484-1814
304-280-2259(cell)
60704 Rt. 26 S.
Bethesda, OH 43719
www.allen-assoc.com

97-4374

A Long, Hard Journey: From Bayh-Dole to the Federal Technology Transfer Act

A constant series of Congressional actions between 1980 and 2000 directly link the evolution of federal patent policies from universities straight to the federal laboratory system. Congress consciously modeled federal laboratory policies on the 1980 Bayh-Dole Act.[1] Senator Dole even tried expanding Bayh-Dole to cover the federal laboratory system in 1984.

That this did not happen and there are now separate statutes for universities and most federal laboratories was an accident of political history. Because this history is largely lost, many practitioners see the university technology transfer system and the federal laboratory system as similar but unrelated.

This article demonstrates that the Federal Technology Transfer[2] Act truly is the son of Bayh-Dole in the fullest sense.

Comment [EWG1]: Citation?

It also demonstrates that a key driver in the development and implementation of a comprehensive patent policy was the existence of an effective Executive branch oversight office. That this oversight function is now absent raises serious questions about the future of the U.S. technology transfer system that has done so much to restore American competitiveness by linking the best research minds in universities, federal laboratories and industry.

Prior to 1980, management of federally funded inventions was covered under a mish mash of conflicting statutes, agency policies and presidential directives. Normally the federal government took ownership of inventions created under its funding, making them available to all non-exclusively. Because creators and potential developers of these inventions lacked the authorities and incentives of patent ownership, most such discoveries languished on the shelves of government agencies. This lack of return on taxpayer investment, coupled with a serious decline in U.S. competitiveness led Senators Bayh (D-IN) and Dole (R-KS) to introduce legislation in 1978 to begin the overhaul of federal patent policies.

Hearings on the bill revealed that at least 20 different patent policies existed across the government, with some federal agencies having conflicting policies in various programs. Normally universities and contractors whose inventions were taken by their funding agencies could petition to have patent ownership rights restored to them. Such actions frequently took between 18 to 24 months to process. This did not imply that the result was necessarily favorable to the inventor. Obviously, such uncertain ownership coupled with serious delays in decision making made commercialization difficult.

A very successful administrative policy of the National Institutes of Health granting patent rights to universities with technology transfer offices was terminated by the Carter Administration. NIH planned to revert back to the federal ownership model then prevalent.

This action led several universities to approach Senators Bayh and Dole separately asking them for a legislative solution establishing for the first time a uniform patent policy to encourage the commercialization of billions of dollars of federally funded R&D.

The result was the introduction of the University and Small Business Patent Procedures Act seeking to "cut through this sea of red-tape" in the words of Senator Bayh. Because the unusual partnership of a liberal Democrat and a conservative Republican addressing what was becoming a pressing competitiveness issue made such a strong political impression, the bill was quickly nicknamed "Bayh-Dole."

While the initial debate on the Bayh-Dole bill focused on patent ownership by universities and small businesses, Congress was also developing a framework for more effective management of federally-funded R&D in general. The key principles were the decentralized management of inventions by their creators, rewards for public sector inventors along with funding more research in their facilities and the utilization of the incentives of the patent system to encourage industry to assume the risks of subsequent commercial development.

Because of the unique role that universities and small businesses have in fostering innovation, the Bayh-Dole legislation focused on this element. However, it also provided authority for licensing all government owned inventions. The fact that the government rarely found licensees for more than 28,000 patents "gathering dust on the shelves" was a rallying cry for Bayh-Dole supporters.

Many of these inventions came from federal laboratories either operated by the government or its contractors. To address this problem, Sections 207- 210 of the bill authorized the federal agencies to apply for patents and license them non-exclusively or exclusively as necessary for commercial development. These provisions were the genesis for the subsequent overhaul of patent policies for the federal laboratory system.

During the Senate Judiciary Committee's deliberations, the legislation's scope began to broaden in other ways as well. Early on Sen. Howard Metzenbaum (D-OH) asked Senator Bayh to expand coverage of the bill to nonprofit research organizations like the Battelle Memorial Institute. Senator Bayh was happy to make this change as it comported with the intent of the bill and Senator Metzenbaum was thought to be one of the most likely opponents of changing the old patent policies of putting inventions freely into the public domain. Subsequently, Sen. Metzenbaum joined as a co-sponsor of the bill.

Large companies were also closely following the Senate Judiciary Committee debate. Because many big defense contractors were allowed to own resulting inventions under

Department of Defense (DOD) administrative polices, General Electric (G.E.) requested that Senator Bayh insert a provision stating that passage of Bayh-Dole was not intended to undercut DOD practices. If such language was accepted, G.E. pledged that it would not block passage of Bayh-Dole even though competing legislation by the Carter Administration and Senator Stevenson (D-IL) was pending focusing on big business while also providing coverage to universities.

Given such an offer from G.E., Senator Bayh inserted the following provision into the bill:

> *Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on August 23, 1971.*

Thus, even in its original "pure" form, Bayh-Dole expanded the definition of non-profit organizations beyond universities, assured large companies that they would not lose existing protections under agency administrative policies and created statutory guidelines for the management of inventions made by federal laboratories.

The Bayh-Dole Act also provided flexibility to agencies such as the Department of Energy to extend the provisions of the law to its laboratories managed by non-profit organizations. Thus, Section 202, Disposition of Rights, states that patent rights will be left with non-profit organizations, but that:

"*a funding agreement **may** (emphasis added) provide otherwise when the funding agreement is for the operation of a Government owned research or production facility.*"

Note that the language leaves the door open for an agency to grant such rights if it is disposed to do so. This provision set the stage for the next Congressional action expanding patent policies to federal laboratories.

There were three basic schools of thought opposing Bayh-Dole:

(1) One was the "public interest" philosophy that Government funded technologies should be put in the public domain, freely available to all;

(2) Another was a belief that large companies were more important than universities or small companies in driving the economy and should be the real focus of any new policy;

(3) There was opposition to the decentralization of technology management out of Washington, D.C. This belief was particularly strong at the Department of Energy (DOE).

To understand the motivation of DOE, it is important to review its nature. Despite the name, the agency is home to the laboratory system that developed the atomic bomb in World War II and devotes a large percentage of its R&D to weapons related research. The resulting culture emphasized protecting national security through close control of its technology. Thus, it is easy to see why some in DOE viewed the decentralized approach of Bayh-Dole as a serious threat to its established culture.

Like most agencies, DOE had a policy of requiring case by case petitions for ownership of inventions made by its contractors or grantees. The Comptroller General of the United States, Elmer Staats, testified that it could easily take from 18- 24 months for such requests to be decided. Such delays were, of course, normally fatal to commercialization efforts.

While muted at the hearings on Bayh-Dole, as the bill gained momentum in Congress, DOE became more active behind the scenes opposing it. Eventually the resistance at DOE became a serious threat to the bill.

When the Bayh-Dole Act was finally enacted in a "lame duck" session of Congress, it was widely rumored that DOE was working behind the scenes urging President Carter not to sign it. Since Congress had adjourned its session, by simply not the signing the law it was effectively "pocket vetoed." Frantic efforts were launched by the Small Business Administration to the White House urging the President to sign Bayh-Dole. Finally, on the last day before it would expire the bill was signed into law.

At the same time it was approving Bayh-Dole, Congress also passed additional legislation encouraging the commercialization of federally-funded R&D. The Bayh-Dole Act falls under the legislative jurisdiction of the Senate and House Judiciary Committees. The Senate Commerce Committee and the House Science and Technology Committee authored the Stevenson-Wydler Act.[3] This legislation also passed in the closing days of the 96th Congress.

This bill sought to establish "Cooperative Research Centers" to encourage university-industry collaborations, required federal laboratories to establish an "Office of Research and Technology Applications" to promote technology transfer and gave Congressional recognition to the Federal Laboratory Consortium for Technology Transfer which had been established informally to help trade best practices among the agencies.

However, the Stevenson-Wydler Act did not remove many of the legal barriers preventing federal laboratory technologies from being commercialized. The incoming Reagan Administration declined to fund the "Cooperative Research Centers" authorized in the bill, preferring the Bayh-Dole decentralized technology management approach empowering universities to commercialize their own inventions.

Fighting to Implement Bayh-Dole

However, this did not mean that the fledgling Bayh-Dole Act was out of the woods by any means. Just because a law is enacted does not necessarily mean it will be implemented as Congress intended. Creating the necessary regulations instructing the federal agencies how to apply the various provisions of Bayh-Dole were critical to its uniform application. If undermined by the bureaucracy, the regulations could provide sufficient loopholes to undo its intent.

With Senator Bayh defeated in the 1980 election, the Senate going from Democratic to Republican control, the defeat of an incumbent President and the incoming President's team not firmly in place, there was plenty of opportunity for mischief. What next ensued was a two year battle over the initial regulations and with continuous bureaucratic skirmishing over the next five years.

That the original intent of the law was preserved in the regulations was only because there was a strong oversight entity insuring that the intent of Congress was met. This operation was headed by Norman Latker, former patent attorney for the National Institutes of Health. Mr. Latker was intimately familiar with the problems in the old government patent policies having seen first hand at NIH that unless universities were allowed to manage their inventions, taxpayers were not likely to see research turn into products improving public health and well being.

The impetus of the Bayh-Dole Act was the administrative program Latker established allowing universities to retain patient ownership of NIH funded inventions. Not only did the Carter Administration overturn this policy, it also sought to fire Latker. Mr. Latker only remained a federal employee due to the strong intervention of Senators Bayh and Dole. Subseqently, Latker moved to the Office of Federal Procurement Policy (OFPP). Because of his presence there, Bayh and Dole placed the regulatory authority for the new law at OFPP. That this confidence was well placed was soon borne out.

Because he understood both the language and intent of Bayh-Dole and the ins and outs of bureaucratic infighting, Latker was able to go toe to toe with DOE over the implementing regulations. Without this strong policy oversight, Bayh-Dole would have been smothered at birth under the very red-tape it was designed to remove.

One significant fight was over DOE's attempted to use the "exceptional circumstances" provisions of the law (exempting title to universities in extraordinary circumstances) to exclude any technologies listed under export control regulations from the law. Since the list of such technologies is very large, this would have seriously eroded the impact of Bayh-Dole creating a dangerous precedent for other agencies to follow. Norm Latker was able to fight off DOE with assistance from Senator Dole's office which closely followed the implementation fight.

In addition to fighting the regulations, DOE made it clear that it had no intention of using the discretion under the law to allow its university operated federal laboratories to manage their inventions. Thus, the discretionary nature of the original statute was an insufficient carrot for change. Policy makers reached for the stick.

In the first term of President Reagan, it became apparent that something significant was occurring under the Bayh-Dole Act helping the U.S. to restore its competitiveness. In 1983, the President asked David Packard to report how to get similar results from the federal laboratories. The report said:

Comment [EWG2]: Citation?

> The ultimate purpose of federal support for R&D is to develop the science and technology base needed for a strong national defense, for the health and well-being of U.S. citizens, and for a healthy U.S. economy. Federal laboratories should recognize that they are an important part of the partnership with universities and industry in meeting this goal. A strong cooperative relationship must exist between federal laboratories, universities, industry and others of the laboratories' research results.
>
> Federal laboratories have traditionally felt that they are part of the government, committed to its highest service, and totally dependent on it for support. They perceive industry as an awkward partner with a different value system. Although the degree of interaction with universities and industry varied among the laboratories visited, the Panel feels that this interaction could be increased at all federal laboratories.

President Reagan accepted the Panel's recommendation and issued a patent policy memorandum to all federal agencies instructing that "to the extent permitted by law" policies regarding the ownership of all federally funded research should be treated under the principles of the Bayh-Dole Act. It was felt that such language would spur DOE to overhaul its centralized management practices.

Comment [EWG3]: Citation?

This was not the case.

Expanding Bayh-Dole to Cover University Operated Federal Labs

Senator Dole was growing increasingly frustrated by continued resistance at DOE. As it became apparent that legislation would be needed to compel change, Dole introduced a bill specifically including federal laboratories within the coverage of Bayh-Dole. This time DOE was openly opposing these efforts.

Finally fed up with an agency defying Administration policy, on August 24, 1984 Senator Dole wrote a letter to the Office of Management and Budget with a copy to Vice President Bush. It said:

Comment [EWG4]: Citation?

> I write to call your attention to the existence of continuing opposition within the Department of Energy to the implementation of the President's new policies regarding contractor ownership of inventions developed under federal research and development contracts...
>
> The Administration and I have been seeking to establish the concept of

> contractor ownership of all Federally funded inventions by law. Legislation proposing contractor ownership and repealing DOE's authority, which has been used by the agency to generally retain ownership, has been endorsed in a Cabinet Council Resolution, three letters from the President's Science Advisor to congressional committee chairmen, and OMB approved testimony before House and Senate committees during the current and previous session. In spite of this clear position, DOE staff have recently been trying to influence Congress to exclude DOE from... the current bills providing for changes in the law needed to implement an agency-wide contractor ownership policy.

The 1984 Dole bill amended the Bayh-Dole Act to give federal laboratories the authorities to manage their inventions on the same basis as the original law provided for universities and small businesses.

The bill was approved by the Senate Judiciary Committee with little debate. The night before full Senate passage, DOE sent an Assistant Secretary to try to dissuade Dole from proceeding to passage. Summoning Department of Commerce representatives to a late night showdown with DOE, Dole's staff made clear they had no intent of backing off.

The bill was passed unanimously the next day and sent to the House of Representatives. However, since the House companion bill was more limited, a compromise was reached as the Congressional session ground to an end. The final law extended the provisions of the Bayh-Dole Act to university operated federal labs with exceptions for DOE "naval nuclear propulsion or weapons related programs." The other provisions of the Dole bill covering the remaining federal laboratories were dropped, leaving resolution of this issue to the future.

Another important part of the Dole bill was maintaining a strong Executive branch oversight function for the expanded Bayh-Dole Act. The Department of Commerce in the Reagan Administration had formed a new technology policy office recruiting Norman Latker as their patent policy expert. Ironically, the Department strongly opposed Bayh-Dole in the Carter Administration, but the new organization under the leadership of Assistant Secretary Bruce Merrifield warmly embraced the law and its philosophy. Thus, Senator Dole moved oversight authorities for the law from the Office of Federal Procurement Policies to the Commerce Department.

Commerce was given statutory authority to notify the head of any federal agency if it believes "that any pattern of determinations is contrary to the policies and objectives of this chapter." If agencies still did not comply, Congress authorized the issuance of additional regulations bringing them into line.

This meant that the Department of Commerce was charged with insuring that all federal agencies applied the law uniformly as Congress intended.

Son of Bayh-Dole, the Federal Technology Transfer Act

It quickly became apparent that without specific authorization, federally owned and operated laboratories were not going to be able to implement Bayh-Dole type systems.

As we have seen, the Bayh-Dole Act allowed the federal government to license its inventions on a more effective basis. Government inventors were also receiving a percentage of resulting royalties under administrative policies. However, the Office of Personnel Management ruled that such royalty sharing for federal inventors would no longer be permitted since there was no specific legislative authority for them.

When the new Congress reconvened in 1985, Senator Dole left the Senate Judiciary Committee to become Senate Majority Leader. This was the Committee with oversight for the Bayh-Dole Act.

Senator Slade Gorton (R-WA) picked up the mantel for a uniform technology transfer policy in the Senate. However, Senator Gorton was not on the Senate Judiciary Committee. His staff re-worked the provisions of the old Dole bill covering federally owned and operated laboratories as an amendment to the Stevenson-Wydler Act. That law fell under the jurisdiction of the Senate Commerce Committee where Gorton served.

Since Stevenson-Wydler also dealt with federal technology management, it was a good fit for expanding technology transfer policies to the remaining federal laboratory system. However, the political reason for this tactical decision was not widely appreciated. To the casual observer it appeared that Congress was creating a new system for federal laboratories separate from Bayh-Dole. Thus, the common heritage of the two systems in the Bayh-Dole Act was eclipsed.

A fortuitous event paralleled the introduction of the Gorton bill. The success of the Bayh-Dole Act interested regional leaders in aggressively incorporating their publicly funded research institutions as drivers for local economic development. In what was being called the "Rust Belt" of America the economy was in particularly bad shape.

Peoria, Illinois is the home of Caterpillar tractor that due to stiff foreign competition was laying off workers. Community leaders identified complimentary university/ federal laboratory biotechnology research that could be the basis for forming an important new research consortium. The problem was that the local federal laboratory lacked the legal authorities to participate.

This led Peoria city leaders to visit the Department of Commerce to discuss the situation. Informed that the discarded provisions of the 1984 Dole bill were required to achieve their goal, the delegation next met with their Congressman Bob Michel (R-IL). Rep. Michel was the House Minority Leader and was well respected on both sides of the aisle. Michel pledged to help secure passage of new legislation. This interest brought an important new ally into the fight to extend the missing legislative authorities to federally-owned and operated laboratories.

Soon legislation titled the Federal Technology Transfer Act was pending in the House and Senate allowing federally owned and operated laboratories to license their inventions and conduct cooperative R&D with industry. Since the legislation was originally intended to fall under the Bayh-Dole Act it incorporated decentralized technology management with the local federal laboratory director as the key decision maker. The law also stipulated that royalties to the lab should be used to defray technology transfer costs, fund new research and reward federal inventors. It also gave a preference to partnering with small companies and those who would manufacture resulting products in the U.S. as is the case under Bayh-Dole.

With the impact of university technology transfer growing before its eyes, Congress did not have the same philosophical debate over whether or not public/private technology partnerships were good policy or not. That they were essential to the nation's future prosperity was now a given. Instead, a small group of large companies was concerned that sharing royalties with government inventors represented a dangerous precedent that might be extended to their own employees. Countries like Germany had laws controlling how industrial inventors must be rewarded. Some companies feared that the pending bill was a dangerous precedent for rewarding employed inventors that must be neutered.

These companies succeeded initially in removing the royalty sharing provisions from the House bill. They also tried to persuade Department of Commerce Secretary Malcolm Baldrige to reign in his staff from supporting the Senate bill. Baldrige rejected these overtures.

The Senate and House staff eventually resolved the differences in the bills restoring royalty sharing for government inventors. A provision was included requiring the Comptroller General to report back to Congress on the royalty sharing programs of the various agencies along with recommendations for improving them.

The new bill became the Federal Technology Transfer Act of 1986 (FTTA). The FTTA is essentially Bayh-Dole for federally owned and operated laboratories.

The 1986 law says that agencies **may** permit directors of government-owned and operated labs to enter into cooperative research and development agreements and negotiate licenses for inventions made in their facilities. The overall authority was made permissive because of opposition from NASA that it did not want to operate under the new statute, preferring its existing authorities of the 1958 Space Act.

The FTTA requires that agencies share royalties with their inventors and allows them to pay administrative costs associated with technology transfer. The majority of remaining dollars goes back to the individual laboratory to fund more research or to reward other employees associated with the project.

Preferences are given to small businesses and to companies manufacturing resulting inventions in the U.S. as is the case under Bayh-Dole.

Agency headquarters have 30 days to approve or modify an agreement but must give a written explanation for any changes.

To track agency use of the new law, Congress charged the Department of Commerce with assisting other agencies develop and share models and to report to the President and Congress every two years on how the Act is being utilized.

President Reagan made the new law the centerpiece of Executive Order 12591[4] (which remains the guiding document on federal technology transfer policies) making clear that he expected all agencies to use these new authorities. Thus, the President said that the heads of federal agencies, to the extent permitted by law, **shall** delegate the authorities of the Federal Technology Transfer Act to the directors of its government-owned and operated laboratories.

Covering All Federal Labs, Providing New Tools for Partnerships

DOE continued to insist that it still lacked clear legislative authority to implement the President's Executive Order to many of its contractor operated laboratories. Because of the importance of DOE laboratories such as Sandia and Los Alamos to New Mexico, Senator Domenici (R-NM) decided to intervene. He pushed through Congress an amendment to the Federal Technology Transfer Act in 1989.

Sen. Domenici included government-owned, contractor operated (GOCO) laboratories under the FTTA. He also added language permitting laboratories to keep information "that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party" that is generated under a cooperative R&D agreement (CRADA) exempt from release under the Freedom of Information Act for up to 5 years. This provision underscored how far Congress had come from the old policies essentially putting federally funded R&D into the public domain without regard to impact on subsequent commercialization.

The law also signaled a shift in Congressional attention. The emphasis was moving from providing authorities to partner with U.S. industry to an insistence that federal laboratories effectively use the technology transfer tools Congress had provided.

This is illustrated in the next step in our journey. Vocal companies began complaining of the difficulty in completing agreements with the laboratories in a timely manner to Congress. These concerns led Senator Jay Rockefeller (D-WV) to introduce legislation amending the Federal Technology Transfer Act to assign **title** to any resulting inventions under a CRADA to the industry partner because:

Comment [EWG5]: Citation?

> I believe that this ability by the Federal Government to claim a right of ownership to intellectual property developed jointly with American companies has inhibited the establishment of cooperative R&D agreements and has retarded the

commercialization of federally supported technology developments. This view is shared by the many research-intensive U.S. companies we contacted.

Rockefeller added:

> The bill we are introducing today eliminates this option by directing Federal laboratories to ensure that the private sector is assigned title to any intellectual property arising from a CRADA…
>
> This provision, in addition to putting technology in the commercial sector where it can be commercialized, will greatly speed up the negotiations of CRADAS. Under current law, the most time-consuming, and often deal-breaking, part of the negotiation between Federal laboratories and the potential research partners is over the ownership, assignment, licensing, restriction, etc. of the intellectual property rights. Our bill eliminates this obstacle. (7)

In the House, Representative Connie Morella (R-MD) had the National Institutes of Health and the National Institute for Standards and Technology as major drivers of the economy of her district. She also wanted the laboratories to be more aggressive in developing cooperative R&D agreements with industry, but felt that wholesale assignment of title went too far. She was concerned that a company might not be interested in-- or even capable of -- commercializing an invention in all its possible fields that could span many markets. Because of the early stage nature of federal R&D, unexpected applications for a technology could easily arise that might be neglected by a one size fits all approach. Representative Morella felt that improving licensing was a better approach.

The result was an amendment requiring the laboratory to insure "that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement…" This approach was acceptable to the Senate and enacted into law. (8)

Continuing her interest in spurring on federal laboratories to maximize the commercialization of their research, Rep. Morella authored the Technology Transfer Commercialization Act of 2000.[5] The intent of new legislation is laid out in the "Findings" section of the bill. In passing this legislation, Congress again recognized the link of Bayh-Dole to the FTTA, with clear guidance on how the tools should be applied:

> *The Congress finds that-*
>
> *(1) the importance of linking our unparalleled network of over 700 Federal laboratories and our Nation's universities with United States industry continues to hold great promise for our future prosperity;*
> *(2) the enactment of the Bayh-Dole Act of 1980 was a landmark change in United States technology policy, and its success provides a framework for removing*

bureaucratic barriers and for simplifying the granting of licensees for inventions that are now in the Federal Government's patent portfolio;
(3) Congress has demonstrated a commitment over the past 2 decades to fostering technology transfer from our Federal laboratories and to promoting public/private sector partnerships to enhance our international competitiveness;
(4) Federal technology transfer activities have strengthened the ability of United States industry to compete in the global marketplace; developed a new paradigm for greater collaboration among the scientific enterprises that conduct our Nation's research and development- government, industry, and universities; and improved the quality of life for the American people, from medicine to materials;
(5) the technology transfer process must be made "industry friendly" for companies to be willing to invest the significant times and resources needed to develop new products, processes, and jobs using federally funded inventions; and
(6) Federal technology licensing procedures should balance the public policy needs of adequately protecting the rights of the public, encouraging companies to develop existing government inventions, and making the entire system of licensing government technologies more consistent and simple.

Demonstrating her concern that it was simply taking too long to license federal patents, Morella cut through a Gordian knot of required public notices. The Bayh-Dole Act requires federal agencies to place notices in the Federal Register whenever they want to license other than non-exclusively. A second notice is required when the agency had selected a potential licensee. Taken together, these two notice periods could easily take five months to complete. The Morella Act authorized agencies to combine both notices in one posting for as short a time as 15 days. Thus, the agencies are now able to significantly reduce the amount of time they must spend on public notifications.

The law made clear that Congress was clearly expecting to see results from its legislative actions. The Morella bill required agencies to report annually on their technology transfer programs, including how many patent applications they filed, how many patents were issued, how many inventions were successfully licensed, how much income they generated, how many licenses were non-exclusive or exclusive and "the time elapsed from the date on which the license was requested by the licensee in writing to the date the license was executed."

Ironically, just as the federal laboratories received unprecedented authorities to transition their technologies from the bench to the marketplace, the oversight function at the Department of Commerce was fading away. Beginning in the Clinton Administration, Commerce re-organized the Technology Administration (where federal technology management oversight resided) and interest in federal technology transfer policy seemed to wane.

Next, the Department of Commerce exempted its own Advanced Technology Program (ATP),[6] designed to promote high risk technology partnerships, from the Bayh-Dole Act. When enacting the ATP program, Congress wanted to ensure that U.S. companies were the program's main beneficiaries. Thus, it included language that ownership of resulting

intellectual property would vest in businesses incorporated in the United States. The Department of Commerce took this to imply that Congress meant to exempt the program from the Bayh-Dole Act, brushing aside arguments that this was not the case.

The Commerce Department did not object when the Department of Defense created "other transactions" than grants or contracts for funding research to be exempt from Bayh-Dole. In fact, in its report, **Effective Partnering,** the Department of Commerce urged agencies to use "where available, 'other transactions' or comparable authority permitting the greatest possible flexibility" in R&D partnerships. Another recommendation was: "Where appropriate, use the "exceptional circumstances" authority of the Bayh-Dole Act to permit industry to own or control the rights to inventions resulting from federal funding, including inventions of subcontractors." (11)

A precedent was being set away from the goal of creating uniform patent policies across the agencies.

As the years passed, the Bayh-Dole oversight responsibilities slipped from a policy office to the Commerce general counsel responding to specific questions on interpreting the statute. Finally, in 2007 the Bush Administration and Congress agreed to abolish the Technology Administration at Commerce all together. It appears that Bayh-Dole and FTTA oversight will remain a very diminished function of the Department..

This does not bode well for preserving a **policy perspective** on the goals of the laws and subsequent agency practices. Time will only tell how this turns out.

Here ends our journey through a 30 year revolution in U.S. technology policies. It has taken us from a time when the linkage between federally funded R&D and the development of new products benefitting the health and well being of American taxpayers was virtually non-existent to a time when the U.S. model for fostering public-private partnerships between the best and brightest minds in universities, federal laboratories and industry is recognized world-wide. But it is unclear how this achievement will be maintained.

Perhaps the **Economist Technology Quarterly (TQ)** in a 2002 editorial puts the issue in the best perspective. Here's how the piece is introduced: "The *reforms that unleashed American Innovation in the 1980's, and were emulated widely around the world, are under attack at home.*"

Comment [EWG6]: Citation?

TQ summarized the contribution of the university and federal laboratory system this way:

> Remember the technological malaise that befell America in the late 1970's? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in reverse. An exhausted Soviet Union threw in the towel. Europe sat up and started investing heavily in America. Why the

sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.

Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

Before Bayh-Dole, the fruits of research supported by government agencies belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

Less quoted, but just as insightful, are **TQ's** words of warning for the future:

There has always been a fringe that felt it was immoral for the government to privatize the crown jewels of academic research. Why, they ask, should taxpayers be charged for goods based on inventions they have already paid for?

That is easily answered. Invention, as TQ has stressed before, is in many ways the easy bit. A dollar's worth of academic invention or discovery requires upwards of $10,000 of private capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99% of the innovation's final cost...

Whatever the merits of their case, suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, not plucking for the pot.

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[1] The Bayh-Dole Act of 1980 (Patent and Trademark Law Amendments of 1980, Public Law No. 96–517) now codified as 35 U.S.C. §§200-212. Regulations for implementing the Bayh-Dole Act are found at 37 C.F.R. §§ 401.1-401.17.

[2] Public Law 99-502 amending the Stevenson-Wydler Technology Innovation Act of 1980, P.L. 96-480

[3] Stevenson-Wydler Technology Innovation Act of 1980 (Public Law No. 96–480).

Report of the White House Science Council's Federal Laboratory Review Panel, May 20, 1983, p. 11

5 Senator Robert Dole to Frederick N. Khedouri, Associate Director, Natural Resources, Energy and Science, Office of Management and Budget, August 24, 1984

[6] Executive Order 12591, Facilitating access to science and technology, 52 Fed. Reg. 13,414 (Apr. 10, 1987).

[7] Statement of Senator Jay Rockefeller introducing S. 1537, the Technology Commercialization Act of 1993, October 7, 1993, Congressional Record, p. S. 13284

8 Public Law 104-113

9The Technology Transfer Commercialization Act of 2000 (Public Law No. 104–113). now codified as 15 U.S.C § 278n

10Federal Register notice, **Advanced Technology Program,** August 2, 1993, p. 41069.

11 Effective Partnering: A Report to Congress on Federal Technology Partnerships, U.S. Department of Commerce, Office of Technology Policy, April 1996, p. 15.

12 Innovation's golden goose, The Economist Technology Quarterly, Dec. 14, 2002