Bayh-Dole: Don’t Turn Back The Clock

By Senator Birch Bayh*


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 number 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 percent.
- 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 lightening 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 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 cakewalk. 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.

Nevertheles, 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, twelve 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 shortsighted 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 idea (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 Bayh-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 hot-beds 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 percent 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 percent over the previous year).
- 67.8 percent 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?”
In December 2002, the normally stiff upper lip English weekly The Economist gushed:

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.

The savior of America? Heady stuff indeed.

So, what is all the hoopla about? What on earth is Bayh-Dole? Why is Senator Birch Bayh remembered not for his substantial role in fundamentally changing U.S. society—he authored the 25th and 26th amendments to the Constitution (respectively, changing the rules for the Presidential and Vice Presidential succession and lowering the voting age to 18) and Title IX, the law which, by changing how women are treated in college athletics, transformed women’s role in society—but instead, for an obscure law which changed the way universities manage their patents?

The Act’s very name takes us back to what today, just thirty years later, feels like a bygone era of bipartisanship. Back in those distant days, a Republican and a Democrat would decide that something was important to do, would jointly author an act, would bring their colleagues into a coalition to discuss and amend it, and eventually it would be passed. Some of the U.S.’s greatest pieces of legislation were born this way.

The Background to the Act

The Act was born of desperation. To quote The Economist again:

Remember the technological malaise that befell America in the late 1970s? 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 retreat. An exhausted Soviet empire 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.

At its heart, therefore, Bayh-Dole was a competitiveness and economic revitalization initiative. It was intended to reconnect academic research and innovation to the mainstream economy after three disastrously controversial cases in the mid 1960s (concerning, respectively, Gatorade, 5-fluorouracil and the phenylketonuria test) in which the government asserted ownership of patents based on research it had funded. This resulted in a Chinese wall being erected between academic and corporate research. Research was literally described as being “contaminated” by federal funding because of the government’s licensing policies—the government would only grant non-exclusive licenses to patents it owned. It will be important to remember its origins later in this commentary when we start to look at the criticisms of it.

What is the Act and isn’t the Act?

The Act was remarkably simple. It gave institutions the unambiguous right to claim title to inventions made with federal funding. The funding agency couldn’t deny the request unless it had made a “determination of exceptional circumstances” in advance. Disclosing the invention and claiming title had to be done within defined time limits. A single set of rules governed all funding agencies.

There were remarkably few rules and conditions. The institutions had to:

- Grant licenses to the patents rather than assign their title to them;
- Disclose the government’s interest in patent applications and notify the government before abandoning any patent application;
- Share the income they received with the inventors—how much to share was left up to individual institutions;
- Use any residual income retained by the institution for research and education;
- Grant a royalty-free non-exclusive license to U.S. Government for its own use;
- Require licensees to manufacture products in the U.S. that were to be sold in the U.S.; and
- Give preference to small businesses.

As a final safeguard, the government retained the

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2. In the case of 5-fluorouracil, just $120 of reagents were erroneously charged to a grant out of a $500,000 project funded by Roche. However, the government still took title to the patents.
right to grant a compulsory license in the public interest if the invention was not being practiced.

The Act provided no new funding for these new commercialization responsibilities, a topic we shall return to later. On balance this was probably a positive at the time, since there was no need for the Act to be periodically reauthorized when new funds were appropriated. There was therefore no opportunity for the provisions of the Act to be tinkered with and institutions have been able to make long term investments in implementing the Act. As a result, a body of licensing expertise and practical experience has been developed within academia over the past thirty years.

Was Bayh-Dole that miraculous? Well, Birch Bayh’s laconic co-sponsor, Bob Dole, once dryly observed that it sounded like an advertisement for bananas! The Act is in fact massively misunderstood. It’s not about whether professors at research universities should work on real world problems—they have been ever since Boston University gave an obscure professor of Vocal Physiology and Elocution—Alexander Graham Bell—a year’s paid leave of absence in 1875 so that he could apply his understanding of sound waves to electricity, thereby creating the telephone.

It’s not about whether professors at research universities should apply for patents if their work on real world problems results in something useful—like any lone inventor, they need to get patents on their inventions if they hope to attract the funding necessary to develop them. Bell’s two patents are arguably the most valuable patents the world has ever seen.

And it’s not about whether professors’ inventions should be developed—if course their inventions should be developed if they’re truly useful.

Rather, the Bayh-Dole Act is quite simply about who should own and manage academic inventions and who should share in the fruits of their success. Before Bayh-Dole, inventions made with federal funding, which accounts for 70 percent or more of the research funding at universities, were owned by the government, which as noted above, believed that no single company should benefit from research that had been publicly funded and so would only grant non-exclusive licenses to the patents. While certainly a high minded and well meaning principle, what it meant in practice was that the first company brave enough to take a license to an academic invention and make the substantial investment needed to prove that the technology worked could then expect to see other companies get a license on the same terms without having to assume a similar financial risk. Not surprisingly, this was an unattractive proposition and by 1978, the government had acquired 28,000 patents this way and had licensed fewer than 4 percent of them. Another major problem was that, the government had no relationship with the inventor, whose active involvement is invariably needed to successfully transfer an embryonic academic technology to a company for development. The government couldn’t guarantee a prospective licensee that the inventor would approve of them as a licensee and would collaborate with them to develop the technology.

The Institutional Ownership Model of Academic Inventions and its Alternatives

Bayh-Dole gave ownership of inventions back to the universities that created them and gave universities the freedom to negotiate license terms that would encourage development. Essentially, it created the “institutional ownership model” of academic inventions.

In the UK, the National Research and Development Corporation was set up in 1949 to ensure that the UK would never again miss out on the commercial benefits from a scientific breakthrough like penicillin, which had been handed over to the U.S. during WWII. The NRDC held a monopoly on British academic inven-

3. {Bruce, 2000 #89}; Bell owned his patents himself, what we will later describe as the “Professor’s Privilege” model of academic invention ownership, and Boston University did not benefit financially from its generosity to Bell in providing him with a year’s salary so that he could invent.

4. Bell’s intellectual predecessor in creating the modern era of instant communications—Samuel Morse—was also a professor, but a professor of Arts and Design at New York University and his invention of the telegraph cannot be attributed to his academic expertise.

5. The term “university” should also be read to include teaching hospitals and non-profit research institutes.

6. In the ultimate insult, the UK even had to pay royalties to Andrew Moyer, the USDA staff scientist who developed the submerged fermentation method. Under practices in the 1930’s and 1940’s, federal labs didn’t take out U.S. patents, but their employees could take out non-U.S. patents in their own names!
tions, but when Margaret Thatcher realized it had failed to recognize and capitalize on major British public sector inventions such as the hovercraft and monoclonal antibodies, she abolished its monopoly in 1987 and started the UK down the same pathway of institutional ownership as the U.S. had adopted.\(^7\)

Given that the government’s ownership of academic patents clearly didn’t work, what are the alternatives to the Bayh-Dole institutional ownership model of academic inventions?

The only alternative is to let professors own their inventions themselves—the so-called “professor’s privilege,” which was historically the predominant model in Europe and the rest of the world outside the U.S. and the UK.\(^8\) Observing the long term success of the institutional ownership model in the U.S. and UK, European countries started changing over to the institutional ownership model in the mid-1990’s, and Sweden is now the only major European country where the professor’s privilege model is still in place.

The professor’s privilege model has numerous drawbacks, including:

- Younger faculty frequently can’t afford to pay for patent protection, in which case their inventions will go unprotected and undeveloped;
- The vast majority of professors are outstanding at identifying the practical applications of their science and how to develop them, but are frequently not good businessman;
- Since academic patents generally have multiple inventors, often at different institutions, reaching agreement on who will manage the invention will complicate and delay commercialization;
- There are substantial private inurement issues and conflict of interest concerns with allowing publicly funded laboratories to operate for the personal benefit of professors. For instance, how will the professional development needs of postdoctoral fellows and graduate students be safeguarded?

The institutional model has therefore become the norm in the developed world and is now spreading to the developing world, with Brazil, India and South Africa having adopted it.

**The Impact of Bayh-Dole**

So, what have been the impacts of Bayh-Dole?

First, after 1980, universities responded and started creating offices of technology licensing (“OTL”), albeit at a somewhat slower pace than might have been expected. Only twenty three universities had OTLs prior to Bayh-Dole. Starting in 1983, the rate of creation increased dramatically and today, all major research institutions have an OTL.

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The level of basic technology transfer activity—invention disclosures, patent applications, patent issuances, licensing—has increased steadily too. The Association of University Technology Managers (“AUTM”) has conducted an Annual Licensing Activity Survey since 1991. Figure 1 shows how key measures of activity have increased since the inception of the Survey.

Universities have used a diverse pattern of commercial arrangements. Existing small companies (i.e., companies with 500 employees or fewer) account for 50 percent of licenses, while large companies account for 35 percent of licenses. Spin-out companies—newly created companies formed specifically to commercialize a particular academic technology—account for 15 percent of licenses. These proportions have held fairly constant for a number of years.

There has been an increasing trend towards non-exclusive licensing and in FY2008, non-exclusive

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8. Even in the UK, the Universities of Oxford and Cambridge followed the professor’s privilege model, following Oxford’s disastrous experience in the 1920’s in a fraud case resulting from a professor’s invention of a new way to extract sugar from beet. Oxford started moving away from this model as soon as Thatcher abolished the NRDC’s monopoly, while Cambridge only started around 2003.
licenses accounted for 56 percent of all licenses issued. Licenses to spin-out companies and to potential drugs, where substantial investments will be required, are almost always exclusive.

The income earned by universities from licensing has increased substantially, from $7.3 million in 1981 to $3.4 billion in 2008. Paradoxically, however, despite this high level of income, technology transfer is still a money losing proposition for most universities. Two factors account for this:

1. Income is highly concentrated in a few “big hits.” 24 percent of the $3.4 billion in income reported in 2008 was reported by Northwestern University, which had discovered Lyrica, licensed it to Pfizer and monetized part of its royalty stream in 2008. City of Hope Hospital, which has patents on key techniques for producing monoclonal antibodies, reported 12 percent of the total, and Memorial Sloan Kettering, Children’s Hospital of Philadelphia and the University of California system reported the next 16 percent. The final 47 percent was shared among the remaining 180 respondents to the Survey; and

2. The majority of the income that is generated—typically 60-80 percent—is distributed to the inventors for their personal benefit and to the inventors’ laboratories and colleges to be spent on research (both of which the Bayh-Dole requires) to incentivize them to participate in the technology transfer process. Only a small portion is used to offset the costs of technology transfer.

As a consequence, a recent study showed that, in 2006, 52 percent of U.S. institutions spent more on technology transfer than the entire income they generated from the activity, while only 16 percent kept enough of the income they generated to cover their costs. This is probably inevitable—ninety five percent or more of the economic impact of technology transfer is outside the university, in the private sector, reflecting the enormous private sector investment usually needed to take an embryonic academic technology from the laboratory to the marketplace. And this is reflective of technology transfer professionals’ priorities—finding the best method for getting science into the public’s hands. However, to 84 percent of university presidents, their technology transfer operations showed red ink. University presidents normally don’t like to see red ink—every professor, every degree, every program is expected to support itself—“Every tub must stand on its own bottom” is an ancient proverb that is famously associated with Harvard’s philosophy of financial management.

Back in 1980, the sponsors of the Act were concerned that the results of America’s publicly funded scientific research were not benefiting the public from either a quality of life or an economic development standpoint. This has changed dramatically over the past 30 years:

• As early as 1992, stories started to appear in the business press talking about how regions anchored by research universities were becoming centers of high tech job growth.

• 154 FDA approved drugs have been brought to market since 1980 which were discovered in whole or in part at U.S. public sector research institutions.

• From 1990—2008, 9 percent of all drugs approved by the FDA, and 21 percent of the most innovative drugs approved by the FDA, were based on discoveries at public sector research institutions.

• As shown in Figure 3, the rate at which public sector researchers started discovering these drugs stepped up significantly in 1980, the year Bayh-Dole was passed.

• In 2008, worldwide sales of these drugs was estimated to be $103 billion.

• Well known products such as the Web browser, email programs that can attach documents, the V-chip, hollow optical fibers, the nicotine patch, the PSA test, Google, the Honeycrisp apple, cochlear

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14. At first blush, the drop off since the early 1990’s might be interpreted as indicating that this was a relatively brief “bubble” phenomenon; however, these are the dates of discovery of drugs that subsequently received FDA approval, and owing to the long lead time of developing a drug, many drugs discovered since then are still working their way through the clinical testing and FDA approval process. Figure 2 shows that drugs discovered through public sector research are still being approved by the FDA at a healthy rate.
implants, lightning detection technology, the Hib vaccine, improved guardrail systems and cell phone technologies all have their roots in university research.15

• From 1980-2008, 6,652 start-up companies were formed and 3,381 of these companies were still operating at the end of 2008.16
  o 72 percent of these companies had their primary place of business in the institution’s home state.
  o Every state, except Alaska, has had at least one start-up company formed as a result of licensing technology from university research.
  o In 2008 alone, 595 new start-up companies were formed—11 every week.
  o In a study of just 100 university spin-outs, total employment at 81 of the companies was 167,000, and total revenues at just 31 of these companies were $95 billion in 2008.
• Another study found that from 1996 to 2007 university licensed products created over 279,000 jobs17 and that academic technology transfer contributed as much as $187 billion to U.S. GDP between 1996 and 2007.18
  o 76 percent of biotechnology companies have a license from a university.
  o At least 50 percent of current biotech companies got their start as a result of a university license.20
  o These biotech companies represented over 1.42 million jobs in 2008.21
  o The bioscience sector represents an employment impact of 8 million jobs, with 5.8 jobs created for every new bioscience job.22

**Figure 2. NDA Approvals Of Drugs Discovered Through Public Sector Research**

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18. ibid.
19. ibid.
20. BIO, *BIO 2009 Member Survey “Technology Transfer & the Biotechnology Industry.”*
22. ibid.
Are There Downsides?

These examples show that Bayh-Dole has certainly delivered the economic benefits that were hoped for. But has the law of unintended consequences also come into play? Have there been bad effects? After all, just three years after its euphoric 2000 article, *The Economist* ran another article titled “Bayhing for blood or Doling out cash?” in which they started to identify some of the issues with the Act, based on the strident criticisms of a coterie of academics who have made a living criticizing Bayh-Dole and attributed negative consequences to it.

The most serious of these are that:

1. Bayh-Dole has changed the nature of academia;
2. It has shifted the focus of research away from ground breaking, fundamental research to incremental applied research;
3. It has instilled a culture of secrecy on campus; and
4. The public good has not been protected.

Fortunately, there is an equally vigorous industry of academic economists who have applied rigorous economic methodologies to study technology transfer.

Their findings show that academic entrepreneurship benefits rather than harming the academic enterprise. For instance:

- In a long term study covering a number of universities, Jerry and Marie Thursby found that only 6 percent of faculty are frequent invention disclosers, while two thirds never disclose anything in their entire careers. They also found that despite a tenfold increase in the level of disclosures over the course of their study, there hadn’t been a shift from basic to applied research.

- Blumenthal had found that faculty members receiving industrial funds had more peer-reviewed articles published in the previous three years, participated in more administrative activities in their institutions or disciplines, and were more commercially active than faculty members without such funding.

• Shane found that professors who’d started companies raised twice as much grant funding to support their academic research as professors who’d not started a company.26
• Lowe found that the publication rate of professors who started companies went up five years before they started the company and that this elevated rate continued for five years after they started the company. He also found that professors who started companies were more than ten times as likely to be superstars (as measured by citations to their papers) than their peers who had not started companies.27
• Sauermann et al. found that life sciences and engineering professors who patented a lot did so because they wanted to change society.28

Those who assert that patenting academic inventions introduces a culture of secrecy on campus totally fail to understand the patenting process. The very essence of patenting is that the inventors are required to make full and complete disclosures of their inventions, so that others can build on them, in return for being given a period of exclusive use of the invention. Since 2001, even U.S. patent applications have been a matter of public record—previously patent applications were confidential until the resultant patent was issued, so transparency has increased even further.

Applying for patent protection on an academic discovery creates an additional, parallel track for communicating the scientist’s research results—their discoveries are published in academic journals in the normal way and presented at scientific conferences and freely disseminated to the scientific community, while, in addition, intellectual property is created from the discoveries which can then be licensed to a company for commercial development.

Particularly since 1995, with the availability of provisional patent applications31 in the U.S., patenting and publishing are entirely compatible and the one will not delay the other. Academic exclusive licenses routinely reserve the rights to pursue basic research for all academic institutions.

American academics have embraced this freedom. Fiona Murray at MIT studied publications in *Nature Biotechnology* from 1997 to 1999 and identified that for just under 50 percent of the papers, there was a corresponding issued U.S. patent, a phenomenon she termed the “patent-paper pair.”30 A more recent study looked at the life sciences publications in 6 months of *Science and Nature*, journals that do not tend to favor scientific discoveries that have commercial potential as *Nature Biotechnology* undoubtedly does, and found that 32.7 percent of the biomedical research articles surveyed in the study were associated with underlying patent applications31—17.9 percent directly covered the research disclosed in the scientific publication, while 11.7 percent related to an enabling technology that was utilized in conducting the research.

Finally, some critics have asserted that universities are only interested in the financial gain that can result from licensing technologies and ignore social considerations. It’s important to remember that Bayh-Dole was passed for economic development reasons, and as we have shown above, it has admirably fulfilled this mission. A recent study showed that maximizing financial gain only accounts for around 10 percent of the driving forces and motivations of TLO’s.32 The profession has started formulating ethical practices, such as “In the Public Interest: Nine Points to Consider in Licensing University Technology,”33 and the “Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies” to ensure availability of university-discovered drugs at affordable prices in the developing world.34 Currently AUTM is developing guidelines for the licensing of genetic tests, an emotionally charged area of medical practice.


29. A provisional patent application can be as little as a scientific manuscript or a grant application with a cover sheet. A provisional application is not examined and must be converted to a regular utility application within a year or it is abandoned.


One of the biggest problems in technology transfer is the “Valley of Death”—the difficulty in finding sources of private capital to fund the earliest, high risk stages of technology commercialization. Traditionally, government has only funded basic discovery research and, other than in defense technologies, provides relatively little in development funding. Although the funding required to demonstrate commercial proof of principle during the earliest stages of commercialization is relatively low, the risk is extremely high, so private sources of capital are reluctant to supply the funding until some demonstration of viability has taken place. This “Catch 22” situation is called the Valley of Death, a term first coined at least as early as 1985, though the underlying economic mechanisms were enunciated by the Nobel prize winning economist, Kenneth Arrow, in 1962.

Like beauty, the Valley of Death lies in the eye of the beholder, and there are many Valleys of Death. For biotechnology companies, going from Phase 1 or 2a clinical testing to Phase 2b or 3 clinical testing presents enormous financing challenges and is their Valley of Death.

In technology transfer, the Valleys of Death come much earlier. They are also shallower, at least in terms of the amount of funding needed, but that doesn’t make them any easier to navigate.

As discussed above, funding the technology transfer function itself is a major issue at most universities and is the first Valley of Death. Senators Bayh and Dole anticipated that the cost of technology transfer would be included in the indirect cost base of universities. When the administrative component of indirect costs was capped at 26 percent in the early 1990’s, this avenue was closed off, and, as was discussed above, for most universities, technology transfer represents a net cost.

Overall, universities only spend 0.59 percent of their research budgets on converting the results of that activity into intellectual property and licensing it and on a national policy level, this undoubtedly represents a serious under-investment. However, university presidents have a difficult time understanding why they should lose money so that the economy as a whole can benefit.

The next Valley of Death comes from the difficulty of finding sources of funding to demonstrate proof of concept for the commercial applications of academic inventions. The peer review system tends not to view such grant proposals favorably in comparison with new basic, discovery research. What federal funding is available—primarily through the SBIR and STTR programs—require that the technology already to have been transferred to a company. Even though these are admirable programs which play a critical role in the innovation ecosystem, they are of limited help in showing the viability of academic technologies. Fortunately, some states operate such proof of concept centers and there are some philanthropic initiatives, such as MIT’s Deshpande Center, the University of California San Diego’s von Liebig Center and the Wallace H. Coulter Foundations Translational Research Partnerships in Biomedical Engineering with 10 universities.

The next Valley of Death for technology transfer is the difficulty in finding start-up funding for university spin-out companies. As shown in Table 1, the most common place that professors turn to fund their start-ups isn’t venture capital but friends and family.

Moving beyond the Valleys of Death, another of the issues with technology transfer is that there have certainly been individual cases where there have been bitter lawsuits over ownership of technologies and infringement of university patents and companies seem to get particularly upset if they are sued by an academic institution for patent infringement. These disputes are probably inevitable if universities are to play an important part of the innovation ecosystem—if substantial value is created, there will inevitably be disputes over who should share in it.

Finally, there are issues of conflict of interest and

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35. Fawcett, S.L., 1985. “Macro-engineering projects in a free society.” Technology in Society, 7(4), 361-371. The term was popularized by Congressman Vernon Ehlers, himself a Ph.D. physicist when the term was used in a Report to Congress by the Science Committee, of which he was Vice-Chair in 1998.

36. Arrow, K. J. (1962). “Economic Welfare and the Allocation of Resources for Invention in the Rate and Direction of Inven-
tive Activity.” Science bought and sold : essays in the economics of science / edited by P. Mirowski and E.-M. Sent. Chicago, IL, University of Chicago.

37. Abrams, I., G. Leung, et al. “How U.S. Academic Licensing Offices are Tasked and Motivated—Is it all about the mon-
ey?” Research Management Review 17.1(Fall/Winter 2009).

38. The Kauffman Foundation has published an excellent review of these two programs, showing that projects funded through them have resulted in start-up companies at a rate 6 times higher than for normal and that these companies have attracted venture capital investment 80 times the amount of translational funding that went into the projects. Interestingly though, the overall rate licensing success remained at around 29 percent of all the projects. See http://www.kauffman.org/advancing-innovation/accelerating-commercialization-of-univer-
sity-innovation.aspx.


export controls that add layers of bureaucracy to scientists wanting to commercialize the results of their science that can be a deterrent to some who would otherwise move down the commercialization pathway.

The Future

Technology transfer has evolved enormously both as a process and as a profession over the 30 years since Bayh-Dole was passed. We’ve moved from a handful of technology transfer offices to over 200 in the U.S. alone. The average number of employees per office has grown by 85 percent. These professionals are growing in how they support the research enterprise at their institutions. They have moved from the narrow focus of filing patents and administering licenses to recommending paths for development, setting up mentorship and entrepreneur-in-residence programs, helping start-up companies find their initial management teams and helping them find their initial funding. The Annual Meeting of AUTM attracts close to 2,000 attendees from 35 countries, anxious both to learn from the U.S. experience and, increasingly, to share the learnings and best practices that work in their innovation ecosystems.

OTL’s and the professionals who staff them are moving from being labeled “technology transfer” or, even more archaically, “technology licensing” to “technology development,” working collaboratively with faculty to chart strategic pathways to develop technologies and to get the results of their research into the public’s hands. At the end of the day, this is the number one priority of the profession.

The Obama administration is taking a keen interest in university research commercialization. Over 120 responses were received in response to a “Request for Information” on ways of enhancing university research commercialization that was issued by the Office of Science and Technology Policy in March, 2010. Secretary of Commerce Gary Locke convened a day long meeting of academic leaders in February 2010 to identify how the process could be enhanced and has followed up with a series of four regional meetings to solicit new ideas from around the country.

The priorities for technology transfer in the future won’t change. It will always be to find someone willing to make the substantial investment needed to improve the viability of a technology and take it to market, because that was the purpose of the Act from the beginning, but how we get there will certainly change.

We need to broaden the base of technology transfer and find creative mechanism by which smaller institutions that do not have a sufficient idea flow to justify their own full time offices can form partnerships with bigger offices, so that when their faculty do have promising ideas they can get the support necessary to turn their ideas into reality.

We need to find creative new sources of funding translational research. The NSF has started moving in this direction, and has included a $12 million “NSF Innovation Ecosystem” component within its Partnerships for Innovation program in its 2010/11 budget. The NIH is also moving in this direction with its Clinical and Translational Science Awards. An equivalent to the SBIR and STTR program that could be spent entirely within a university, but which is evaluated on the same commercial criteria as SBIR’s and STTR’s would achieve this. It would not need to be as large as the SBIR and STTR programs—say a 0.15 percent set-aside would generate a meaningful level of funding. Entrepreneurial post doctoral fellowships. To allow graduate students to take the subject of their Ph.D. thesis towards commercialization, carrying out both the proof-of-principle studies and the first strategizing of the commercialization pathways would help in this regard. The Kauffman Foundation has successfully pioneered this concept.

Technology transfer will be recognized as a profes-

| Table 1. Source Of Initial Funding For University Spin-Out Companies |
|----------------|---------|---------|---------|---------|---------|
| Source          | 2004    | 2005    | 2006    | 2007    | 2008    |
| Individuals     |         |         |         |         |         |
| No External Funding | 57     | 55      | 54      | 86      | 76      |
| Friends and Family | 94     | 104     | 123     | 135     | 109     |
| Individual Angels | 49     | 48      | 82      | 82      | 62      |
| Angel Network   | 26      | 14      | 23      | 32      | 31      |
| Institutions    |         |         |         |         |         |
| State Funding   | 36      | 29      | 41      | 63      | 63      |
| Venture Capital | 85      | 84      | 81      | 88      | 92      |
| Corporate Partner | 25    | 28      | 45      | 33      | 38      |
| Own Institution | 26      | 28      | 42      | 51      | 53      |
| SBIR/STTR       | 32      | 43      | 45      | 42      | 43      |
| Other           | 28      | 40      | 52      | 47      | 42      |
sion, with its members having credentials such as the Certified Licensing Professional (“CLP”) being awarded by CLP, LLC or the Registered Technology Transfer Professional (“RTTP”) being awarded by the Alliance of Technology Transfer Professionals (“ATTP”), a global alliance of formed by AUTM and four regional professional technology transfer associations.\textsuperscript{41}

Thirty years from now it is imperative that technology development offices be fully funded by their institutions supported by federal funding. They will be viewed as service centers within their institutions, working to disseminate the results of the institutions’ research to the commercial sector, rather than being expected to be cash cows (and inevitably disappointing in this regard), and they will continue to work side-by-side with their industry counterparts to develop science into safe, life enhancing products. Most importantly, they will be advocates for the entire research enterprise.

\textbf{Conclusion}

We can sleep better at night knowing the U.S. has become an innovation powerhouse in part because of the Bayh-Dole Act; that we are getting a massive return on the nation’s investment in basic scientic research through the products we use every day; and that the Bayh-Dole Act will continue to create companies and jobs when we need them most. By moving the ownership of inventions back to the people and places who best understand their potential -- the same people and places that made the invention in the first place—and how to develop them, we have put a solid foundation under the U.S.’s innovation ecosystem and ensured that our academic institutions are full participants in that enterprise.

So perhaps Birch Bayh and Robert Dole are being remembered for truly changing American society forever after all.}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure4}
\caption{Academic Spin-Out Companies Formed}
\end{figure}

\textsuperscript{41. The Association of European Science and Technology Transfer Professionals (ASTP) in Europe, the Association of Technology Managers in Taiwan (“ATMT”), Knowledge Commercialization Australasia (“KCA”) in Australia and New Zealand and ParxisUnico in the UK.}