POLICY

The Bayh-Dole Act Turns 30

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On 12 December 1980, in the waning days of the lame duck session of the 96th Congress, the U.S. Senate passed the University and Small Business Patent Procedures Act, now known as the Bayh-Dole Act, a seemingly obscure act that allowed universities to claim title to inventions that had been made with federal funding. It is unlikely that many present that day realized what a dramatic impact that act would have. Data clearly show that it played a critical role in rejuvenating the entire U.S. economic system, transforming it from a manufacturing base to an innovation base. Yet ironically, the act has passionate critics.

In December 2002, the normally stiff-upper-lip English weekly *The Economist* gushed (*1*),

> *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.*
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> *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.*

The savior of America? Heady stuff indeed.

So, what is all the hoopla about? What on earth does this act—sponsored by Senators Birch Bayh of Indiana and Robert Dole of Kansas—accomplish? Why is Senator Bayh remembered not for authoring two amendments to the Constitution (the 25th and 26th) and the Title IX amendment to the Higher Education Act but for an obscure act that changed the way universities manage their patents?

The act's very name takes us back to what today feels like a distant, bygone era of bipartisanship, when a Republican and a Democrat would decide that something was important to do and would jointly author an act and bring their colleagues into a coalition to discuss, amend, and eventually pass it. Some of the United States's greatest pieces of legislation were born this way.

The act was born of desperation. To quote *The Economist* again,

Bayh-Dole was a competitiveness and economic development initiative. It was intended to reconnect academic innovation to the mainstream economy after three disastrously controversial cases in the mid 1960s (involving Gatorade, 5-fluorouracil, and the phenylketonuria test), in which the government asserted ownership of patents because it had funded the underlying research. Because the government would only grant nonexclusive licenses to patents it owned, a wall was erected between academic and corporate research. Research was literally described in this period as being "contaminated" by federal funding because of the government's licensing policies.

The Bayh-Dole 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 a request for title 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.

Yet the act is 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 leave of absence in 1875 so that he could apply his understanding of sound waves to electricity and create the telephone. It's not about whether professors at research universities should get 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. And it's not about whether their useful inventions should be developed; of 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% or more of the research funding at universities, were owned by the government, which believed that no single company should benefit from research that had been publicly funded and so would only grant nonexclusive licenses to the patents.

Although certainly high-minded and well-meaning, what this meant in practice was that the first company brave enough to take a license to an academic invention and take all the financial risk of proving that the technology worked could then expect to see other companies get a license on the same terms without having to bear 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% 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 commercial venture. 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.

Bayh-Dole gave ownership of inventions back to the universities that created them (*2*) and gave universities the freedom to negotiate whatever license terms would best encourage development of the technology. We should call it the "institutional

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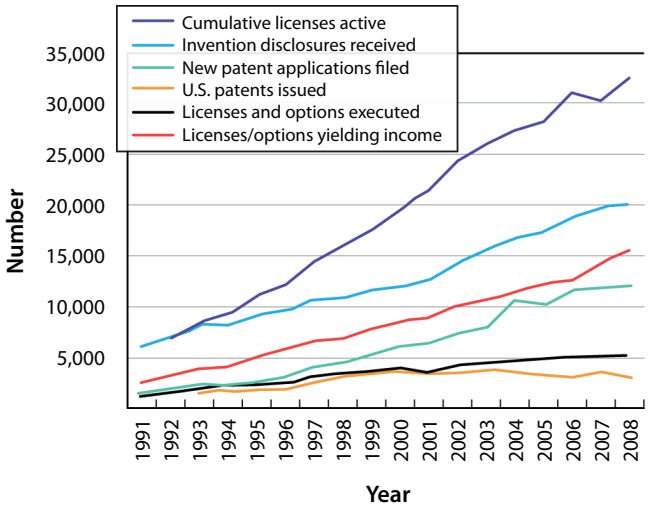

Fig. 1. Changes in core measures of technology transfer activity. Data are from (*14*).

model" of academic invention ownership.

So, what have been the effects of Bayh-Dole? First, after 1980, universities responded and started creating offices of technology licensing (OTLs). Only 23 universities had OTLs before Bayh-Dole; starting in 1983, the rate of creation increased dramatically. Today, all major research institutions have a technology transfer operation. The level of basic technology transfer activity—invention disclosures, patent applications, patent issuances, and licensing—has increased steadily, too. The Association of University Technology Managers (AUTM) has conducted an annual licensing activity survey since 1991. Fig. 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 (companies with 500 employees or fewer) account for 50% of licenses, whereas large companies account for 35% of licenses. Spin-out companies—newly created companies formed specifically to commercialize a particular academic technology—account for 15% of licenses. These proportions have held fairly constant for a number of years.

There has been an increasing trend toward nonexclusive licensing. In fiscal year 2008, nonexclusive licenses accounted for 56% of all licenses issued. Licenses to spin-out companies and to potential drugs, in which substantial investments will be required, are almost always exclusive.

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 shown by the examples in Table 1 and the trends shown in Fig. 2.

These examples show that Bayh-Dole has certainly delivered the desired benefits. But has the law of unintended consequences also come into play? Have bad things happened too? Just 3 years after its euphoric 2002 article, *The Economist* ran another article titled "Bayhing for Blood or Doling Out Cash?" in which the author started to identify some of the criticisms of the act by a coterie of academics (*3*). The most serious of these were that Bayh-Dole had (i) changed the nature of academia, (ii) shifted the focus of research away from groundbreaking, fundamental research to incremental applied research, (iii) instilled

Table 1. Benefits derived from publicly funded scientific research.

Public awareness	1992	Stories started to appear in the business press about how regions anchored by research universities were becoming centers of high-tech job growth (*16*).
New drugs	1980–present	154 FDA-approved drugs that were discovered in whole or in part at U.S. public sector research institutions have been brought to market (Fig. 2A) (*15*).
	1990–2008	9% of all drugs approved by the FDA, and 21% of the most innovative drugs approved by the FDA, were based on discoveries at public sector research institutions (*15*).
	1980	The rate at which public sector researchers started discovering new drugs that were eventually approved by the FDA increased substantially in the year Bayh-Dole was passed (Fig. 2B).
	2009	Worldwide sales of drugs discovered by public sector researchers was estimated to be $103 billion (*15*).
Startup companies	1980–2008	6652 startup companies were formed, and 3381 of these companies were still operating at the end of 2008 (Fig. 2C). In 2008 alone, 595 new startup companies were formed—11 every week. 72% of these companies have had their primary place of business in the institution's home state (*17*). Every state except Alaska has had a startup company formed as a result of licensing technology from university research (*18*).
	2008	In a study of just 100 university spin-outs, total employment at 81 of the companies was 167,000, and revenues at just 31 of these companies were $95 billion (*19*).
Job creation	1996–2007	University-licensed products created more than 279,000 jobs, and academic technology transfer contributed as much as $187 billion to the U.S. gross domestic product (*20*).
	1976–present	An entire industry, biotechnology, was created from university startup companies. The majority of university licenses are in the biotech sector. 76% of biotechnology companies have a license from a university, and at least 50% of current biotech companies got their start as a result of a university license. These biotech companies represented more than 1.42 million jobs in 2008. Continuing with this trickle-down view, the bioscience sector represents an employment effect of 8 million jobs, with 5.8 jobs created for every new bioscience job (*21*).
New products	Present	Well-known products such as the V-chip (which allows blocking of certain television programs), hollow optical fibers, the nicotine patch, the test for prostate-specific antigen (a screening test for prostate cancer), Google, Honeycrisp apples, Cochlear implants, lightning detection technology, *Haemophilus influenzae* type B vaccine, and cell phone technologies have their roots in university research (*22*).

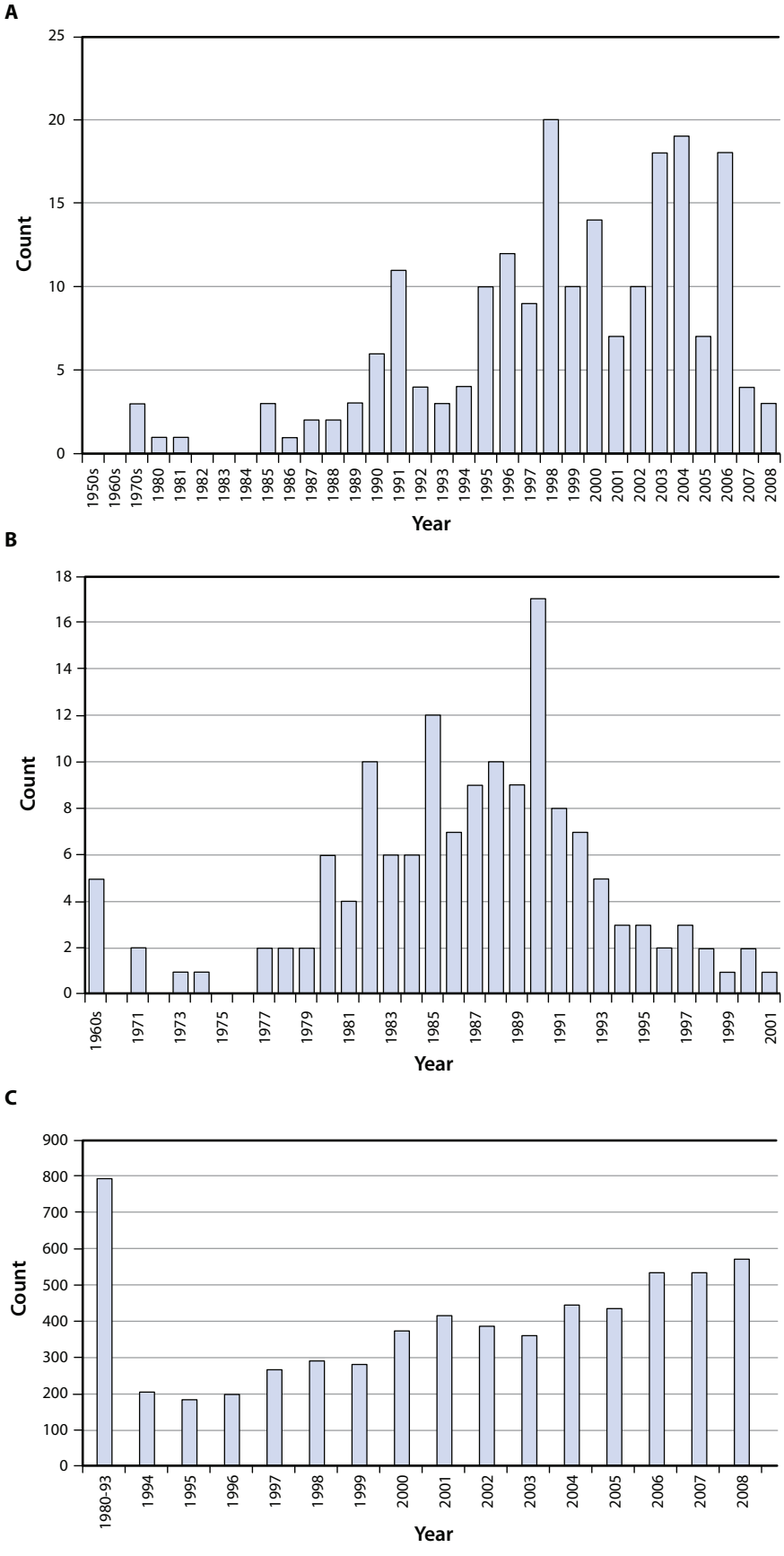

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Fig. 2. Trends in outcomes from publicly funded scientific research. (**A**) Number of approvals of New Drug Applications and Biologic License Applications to the U.S. Food and Drug Administration (FDA) of drugs discovered in the course of public sector research. Data are from (*15*). (**B**) Number of drugs discovered annually in the course of public sector research that eventually received FDA approval. The date of discovery is assumed to be the date of filing of the first patent claiming the product. Data are from (*15*). (**C**) Number of academic spin-out companies formed. Data are from (*14*).

a culture of secrecy on campus, and (iv) failed to protect the public good.

Fortunately, there is an equally vigorous industry of academic economists who have applied rigorous academic economic methodologies to study technology transfer. Their findings show that academic entrepreneurship benefits rather than harms the academic enterprise:

(i) In a long-term study covering a number of universities, Jerry and Marie Thursby found that only 6% of faculty are frequent invention disclosers, whereas two-thirds never disclose anything in their entire careers. These authors also found that despite a 10-fold increase in the level of disclosures over the course of their study, there hadn't been a shift from basic to applied research (*4*).

(ii) Blumenthal *et al.* found that faculty members receiving industrial funds had more peer-reviewed articles published in the previous 3 years, participated in more administrative activities in their institutions or disciplines, and were more commercially active than faculty members without such funding (*5*).

(iii) Shane and colleagues found that professors who had started companies raised twice as much grant funding to support their academic research as did professors who had not started a company (*6*).

(iv) Lowe and Gonzalez-Brambila found that the publication rate of professors who started companies went up 5 years before they started the company and that this elevated rate continued for 5 years after they started the company. They also found that professors who started companies were more than 10 times more likely to be "superstars" (as measured by citations to their papers) than their peers who had not started companies (*7*).

(v) Sauermann *et al.* found that life sciences and engineering professors who pat-

ented a lot did so because they wanted to change society (*8*).

Some critics have asserted that universities are only interested in the financial gain that can result from licensing technologies and, as such, 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 (*9*) showed that maximizing financial gain accounts for only around 10% of what drives technology transfer offices; helping faculty and translating the results of research are the primary drivers of technology transfer. AUTM has started establishing ethical practices for academic licensing through the publication of position papers such as "In the Public Interest: Nine Points to Consider in Licensing University Technology" (*10*) and the "Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies" (*11*) to ensure the availability of university-discovered drugs at affordable prices in the developing world. Currently, AUTM is developing guidelines for the licensing of genetic tests, an emotionally charged area of medical practice.

A legitimate concern has been funding the technology transfer activity itself. Senators Bayh and Dole anticipated that the cost of technology transfer would be included in the indirect cost base of universities, funds that are included in research grants. When the administrative component of indirect costs was capped at 26% in the early 1990s, this avenue was closed, and for most universities, technology transfer now represents a net cost.

Overall, universities spend only 0.59% of their research budgets, which exceed $50 billion annually, on converting the results of that activity into intellectual property and licensing it, which is an astonishingly low figure (*9*). The same study showed that in 2006, 52% of U.S. institutions spent more on technology transfer than the entire income they generated from the activity, whereas only 16% kept enough of the income they generated to cover their costs (*9*). This fact simply verifies the institutional mission of the research enterprise: getting science into the public's hands.

Technology transfer has evolved enormously both as a process and as a profession over the 30 years since Bayh-Dole was passed. Its infrastructure has grown from a handful of technology transfer offices to more than 200 in the United States alone. The average number of full-time employees per office has grown by 85%. And these professionals are expanding the ways in which they support the research enterprise at their institutions, moving from the narrow focus of filing patents and administering licenses to recommending paths for development and setting up mentors-in-residence programs to assist startup companies. These professionals are working collaboratively with faculty to chart strategic pathways to develop technologies and get the results of their research into the public's hands. This is the number one priority of the technology transfer profession.

Priorities for technology transfer won't change in the future because these priorities fulfill the purpose of the act, but how they are accomplished will certainly change. Creative new sources of funding for translational research must be developed to help bridge the multiple "valleys of death" (*12*, *13*) that technologies must traverse between the lab and the marketplace. The National Science Foundation (NSF) is moving in this direction and has included a $12 million NSF Innovation Ecosystem component in its Partnerships for Innovation program in its 2010–11 budget. The National Institutes of Health (NIH) is also moving in this direction with its Clinical and Translational Science Awards.

We need to broaden the base of technology development and find creative mechanisms by which smaller institutions that do not have a sufficient idea flow to justify the establishment of full-time technology development offices can form partnerships with bigger offices, so that when their faculty do have promising ideas, they can receive the necessary support to make them reality.

Within the next 30 years, it is imperative that technology development offices be fully financed by their institutions or by federal funding. Instead of being viewed as potential cash cows (and inevitably disappointing in this regard), these offices will be viewed as service centers within their institutions, working to disseminate the results of the institutions' research to the commercial sector. The offices will continue to work side by side with their industry counterparts to develop science into safe and life-enhancing products. Most importantly, they will be advocates for the research enterprise.

We need to bring market pull to academic technology push sooner and more efficiently. One possibility is to use coaches and mentors to help guide academic researchers to identify the products that will result from their discoveries and the markets for them. And we need to find new ways such as investment tax credits to encourage seed stage investment in university spin-out companies.

We should sleep better at night knowing that the United States has become an innovation powerhouse in part because of the Bayh-Dole Act, knowing that we are getting a substantial return on our nation's enormous investment in basic science through new products that we use every day, and knowing 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 and how to develop them, we have put a solid foundation under the United States's innovation ecosystem and ensured that our academic institutions are full participants in that enterprise. Birch Bayh and Robert Dole truly did fundamentally change American society.

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