The Bayh-Dole battle

It has been described as among the most important pieces of legislation passed in the US since the Second World War. But despite its clear successes, not everyone is convinced that the Bayh-Dole Act has been an unremitting force for good over the last 25 years

By **Victoria Slind-Flor**

It was a little like having the wicked fairy godmother show up at the princess's christening.

There everyone was, celebrating a milestone US law; one that has been credited with a vital role in helping to steer the US economy out of the doldrums of the 1970s and early 1980s and towards a promised land that has seen American companies assume leadership across a vast range of technological sectors. Then *Fortune* magazine carries an article stating that, far from being the success story its supporters claim, the Bayh-Dole Act is, in fact, a "nervous mother for a science that never needed one", which has caused US universities to evolve from "public trusts into something closer to venture capital firms".

Given the successes Bayh-Dole is deemed to have inspired over the last 25 years, it was an unpalatable message to say the least. According to the accounting firm Ernst & Young, for instance, the Act – or the Bayh-Dole Patent and Trademark Amendments Act of 1980, to give it its full name – has been directly behind the meteoric growth of the biotech industry. Since Jimmy Carter approved the legislation in the final weeks of his presidency, E&Y figures show, nearly 1,500 new biotech companies have been formed in the US, employing more than 180,000 people, generating upwards of US$40 billion in revenue and yielding myriad new products, with several hundred already out in the marketplace and more than 300 in late-stage clinical trials.

But *Fortune* was having none of it. It charged that Bayh-Dole had led to "a litigious scrum of data-hoarding and suspicion". In his article, published in the 19th September edition of the magazine, Clifton Leaf, *Fortune's* executive editor, states that Bayh-Dole has created "a legal frenzy that's diverting scientists from doing science". The operative mantra at universities today, he says, is "hey, we're in this for the money".

Leaf also tears into a 1980 US Supreme Court ruling that permitted the patenting of living organisms. That case, *Diamond v Chakrabarty*, he says, launched a gold rush with scientists "swooping into patent offices around the world with invention disclosures that... were simply knowledge – or research tools to further knowledge".

To say Leaf's article raised hackles would be a gross understatement. Ever since its publication, university tech transfer officials and the companies that are their licensees have talked of little else. Bayh-Dole supporters were quick to circle the wagons and fire off outraged responses. One of the first to weigh in was former Senator Bayh himself, now a partner in the Washington-based Venable firm. He wrote to *Fortune*, charging that Leaf's piece was filled with "egregious misconceptions". He said that far from being a mere licence to print money, Bayh-Dole is in fact responsible for unlocking "the untapped potential of [the US's] research universities".

Its supporters say that the central purpose of Bayh-Dole – co-sponsored by US Senator Birch Bayh, a Democrat from Indiana, and his Kansas Republican colleague Bob Dole – was to allow universities and other research institutes to keep the title to inventions stemming from government-funded research. In doing this, it

Senator Birch Bayh
Helped unlock the IP potential in US universities

created an environment within which it became much easier to move inventions from the lab bench out into commerce.

In this silver-anniversary year, university technology transfer offices, the Association of University Technology Managers (AUTM) and various state offices of industrial development have held many programmes celebrating the changes Bayh-Dole wrought. The statistics seem to tell a stunning success story, so much so that one technology-oriented publication has even called Bayh-Dole "the Viagra for campus innovation".

Dark days for America

One of the people present at the legislation's creation thinks that much of Leaf's grousing about Bayh-Dole is without foundation. Joseph Allen is now the vice president and general manager for the intellectual property management group of the West Virginia High Technology Consortium Foundation. But back in 1980, he was a young attorney on Senator Bayh's staff.

Those were hard years for the foundering American economy, he says. Hit hard by competition from the Japanese automobile industry, US automakers were on the skids, so much so that it took direct government intervention to save the Chrysler Corporation from going under. The Arab oil embargo and the sky-high cost of oil left Americans fuming in gas station lines and President Carter appearing on television in a sweater, urging Americans to turn down their home thermostats. Cheaper imported steel was savaging the domestic steel industry. All in all, industrial America was quickly turning into a technologically obsolete rust belt.

"It was pretty bleak," recalls Allen. "For the first time for my generation, it seemed as if America wasn't number one." At the time the federal government was funding 50% of all research in the country, but very little was being put to practical use. Almost everything the government funded went directly to the public domain, where it remained, overlooked and uncommercialised. "Because the private sector couldn't get IP rights, they would typically leave government-funded technology alone," Allen says.

There were some exceptions to this rule but largely the burden was on the inventor to retrieve the rights to an invention. Norman Latker, then patent counsel for the Department of Health, Education and Welfare, initiated a policy permitting the few universities with technology transfer offices to go through an administrative procedure to retrieve intellectual property rights to what had been invented on their campuses. But at that time, very few even had tech transfer offices – Stanford, Massachusetts Institute of Technology and the University of Wisconsin being among the pioneers that did.

Years later, Latker looked back to those times and wrote, in a letter to the NIH, that: "An enormous amount of government-sponsored research and innovation went to waste, as there were no clear mechanisms in existence to transfer the resultant inventions to the marketplace."

No licensing activity

Universities complained about this process but seldom found listeners who could make any changes, until they encountered Senator Bayh. He received a delegation from his home state's Purdue University outraged that it was taking them two years to get rights to a government-funded invention created on their campus. "We thought that wasn't a very good use of taxpayer funding," recalls Allen. So the senator's office asked the federal General Accounting Office to look at government-owned patents. The study found that only 5% of 28,000 patented technologies were licensed to anyone.

"People were frustrated and angry" with the study's conclusions, says Allen. "They were saying the government was putting US$80 billion into research and development, none of it was being commercialised, the Japanese were eating our lunch and people had to wait years for a bunch of bureaucrats to give the rights back."

So Bayh-Dole was drafted as a bi-partisan initiative. The co-sponsors, with Bayh and Dole, were liberal Democratic Senator Ted Kennedy from Massachusetts and arch-conservative Republican Strom Thurmond from South Carolina.

Opposition came mainly from two key figures, US Senator Russell Long, R-Louisiana, who said it was one of "the most far-reaching giveaways" he had seen in his years in Congress, and Admiral Hyman Rickover, who predicted Bayh-Dole would result in "greater concentration of economic power in the hands of large corporations". Rickover's connection to the heavily regulated nuclear energy may have fuelled his opposition, and Long had long been a supporter of the admiral.

After lengthy and bitter debate, the measure finally passed on the very last day of a lame duck session following the election that denied President Carter a second term. Carter gave Bayh-Dole the green light on the final day he could sign bills into law. Waiting

to see if the measure would ever pass "was like the Perils of Pauline", recalls Allen. "But the whole idea was to let a thousand flowers bloom, and they did."

A ticker tape parade

Allen says that Bayh-Dole deserves not criticism but "a ticker tape parade down 5th Avenue. It's not a bureaucracy. It moved the power out of Washington."

The Act has been "positively transformative" at the University of Wisconsin, says patent attorney Nicholas Seay. He's a partner at the Madison, Wisconsin, office of Milwaukee's Quarles & Brady, and prosecuted the university's human embryonic stem-cell patents. He represented the university's technology transfer office "for 10 years before I ever heard an inventor think about forming a company for his technology". Now, though, it is a regular event. "There are five to 15 new companies starting per year as university spin-offs. This has changed the local economy dramatically in my working life," Seay says.

Larry Gilbert, who is senior director of California Institute of Technology's Office of Technology Transfer, holds his present campus up as a model for what Bayh-Dole can achieve. The most recent AUTM survey, for fiscal year 2004, shows that in that year CalTech received US$9.8 million in licensing revenue, filed 416 new US patent applications and received 142 US patents. In addition, 14 new companies were started from CalTech's licensed technology, and 45 licences and options were executed. According to the survey, 549 invention disclosures came into the tech transfer office from faculty members that year.

CalTech has only 280 faculty members and every year Gilbert's office receives at least one invention disclosure from every faculty member involved in research that will yield inventions. One of his big success stories is Professor Robert H Grubbs, a Nobel chemistry laureate who now heads Materia Inc. His company uses technology for polymer creation that he invented. Grubbs wins praise as "a serial entrepreneur, our most prolific inventor," according to Gilbert.

The CalTech experience

When Gilbert came to CalTech in 1995, he found what he considered an anti-patent atmosphere. But by 1997, the number of invention disclosures had jumped from about 40 per year to 90. Education, Gilbert says, is the key. He spends a lot of time working with professors to explain how patenting and licensing operate, and his office is committed to filing a provisional patent application on every single invention disclosure. He does that internally, with his own staff, rather than calling in outside counsel. "It costs only US$100 a pop," he says.

Gilbert has no qualms about his office's focus on financial return. "Universities are based more on revenue than before," he says. But unlike many other tech transfer offices, Gilbert does not employ a sales staff. That approach is a big waste of money in his eyes. Those universities that do "fail to distinguish between selling an expertise in field X and targeting a particular technology company," he explains. He declines to identify the universities in question, but says that he knows of one school that spent US$40 million to bring in US$60 million in licensing revenues. He calls that approach just plain stupid.

Gilbert encourages CalTech scientists to do what academic researchers have always done: write papers in their fields of expertise

Bayh-Dole outside the US

David Mowery of the University of California's Haas School of Business and Bhaven Sampat of the Georgia Institute of Technology studied other countries' emulation of Bayh-Dole, and produced a report in 2004 for the National Bureau of Economic Research. They noted that around the world, governments are reducing funding for university research, and more and more countries are seeking to build technology transfer mechanisms comparable to Bayh-Dole.

However, Mowery and Sampat's study warns that Bayh-Dole is not a one-size-fits-all garment that can easily be donned by other countries. The structural differences in academic systems may provide barriers to successful commercialisation of university technology, they say, because of differing histories and paths to commercialisation. Negative results of this borrowing of Bayh-Dole's mechanisms may not reveal themselves for years.

That said, a number of countries have begun to reform their university sectors, with one eye at least on what has happened in the US. For example:

- In 1999, Japan enacted the Law on Special Measures for Industrial Revitalisation, which is commonly referred to as Japan's Bayh-Dole. This law reduced patent fees for university technology licensing offices by 50%.
- The professor's privilege, giving university researchers ownership of their inventions, is still the rule in Sweden. Nonetheless, the country has a research park affiliated with Lund University, financed largely by the Kamprad family, which founded and owns the IKEA furniture company.
- Germany got rid of the professor's privilege in 2002, changing the law so that the universities that employ the researchers retain ownership of the inventions.
- In Singapore, Nanyang Technological University has had its technology transfer office up and running since 2000.
- In 1999, France enacted its version of Bayh-Dole. The new law authorised universities to form tech transfer offices and permits university researchers to have equity in spin-off companies while they remain on their institutions' payrolls.
- Thailand's National Science and Technology Development Agency has established an initiative to launch a science park with the cooperation of the Asian Institute of Technology and Thammasat University.
- Hungary passed a law this year that permits universities to spin off start-ups without government permission.

***Larry Gilbert**, CalTech*
A model for what Bayh-Dole can achieve

***Michael Eisen**, Berkeley*
Rebelling against Bayh-Dole hassle factor

and make presentations to their learned societies. "Technology transfer is all about faculty, at the beginning, middle and end," he says. Companies with good competitive intelligence mechanisms look to see what's developing in technological areas of interest and will attend those meetings and read those papers.

Other universities, seeking to save money on patenting expense, will send an invention disclosure out to 30 or 40 companies to see if they will pay for patent filings. Gilbert calls that approach nonsense. "So many CEOs will say: why are they bothering me with this? I don't have time to review this." And forget sending an invention disclosure to a venture capital firm. "Universities don't take [technological discoveries] far enough for the VCs to be interested," Gilbert says.

Gilbert also does not seek big licensing fees for CalTech inventions. "We don't take up-front money. Universities that want big up-front money have the basic position that the licensee will fail, so they want to take their money and run," he says. Instead, CalTech takes equity in the nascent companies, an entrepreneurial act of faith.

Not ready for the leap

But some universities are not ready to make the commercial leap. And Professor Donald Hicks defends their right to stay out of the fray. Hicks, who teaches political economics at the University of Texas at Dallas, sees many universities having trouble letting go of a monastic mindset that places them in opposition to a capitalist model. "They like to be separated from the economy and don't want industry to come in and corrupt the culture of the university. They want curiosity-driven research, not market-driven," he says.

A young academic at the University of California at Berkeley falls precisely into this model. Professor Michael B Eisen has been conducting research in molecular and cell biology at the university for the last five years. He hates Bayh-Dole and what he considers the bureaucratic nightmare it has spawned.

Although Bayh-Dole has been the law for all of Eisen's professional life, he longs for the days when he could have called up a scientist at another university and ask for reagents, software or antibodies as easily as a housewife could borrow a cup of sugar across the backyard fence. Instead, though, he complains that he has to struggle with lengthy and complicated material-transfer agreements that he does not have the time to vet. "We're not talking about my trying to buy something from a company," he says. "It's getting stuff from another university. But now it's not an interaction between scientists, but between university business offices."

The hassle factor stops him from seeking something he needs in his research. Instead, he is likely to go without or to create the needed item himself, even though he knows it is protected by another university's patent. "It's such a pain in the ass, and it's an impediment to our research" to go through the proper bureaucratic channels, he complains.

Eisen has created a lot of software relevant to his research area but, because of his intense distaste for Bayh-Dole, he puts it in the public domain as open-source software. He has praise for the university's tech transfer office for letting him do this rather than forcing him to patent and license it. But others at the University of California are clearly on the Bayh-Dole bandwagon: the UC system ranks first in the 2003 AUTM survey, generating US$61 million in licensing income, applying for 490 US patents and receiving 323 new patents.

Bayh-Dole critics say they see the potential for grievous harm to researchers like Eisen. Professor Rebecca Eisenberg of University of Michigan Law School wrote a piece for *Science* magazine about an "anti-commons" in biomedical research in which scientists "underuse scarce resources because too many owners can block each other". Privatisation – through patent protection – of research tools could lead to "fewer useful products for improving human health," she charged.

And the patent battles between over-university-developed technology have sometimes been nasty and costly, such as the 2003 *Madey v Duke* case that effectively ended the so-called research exemption from patent infringement. Three years ago, Hewlett Packard's Dr Stanley Williams testified before the Senate Committee on Science, Technology and Transportation that Bayh-Dole has brought "significant polarisation" between attorneys representing universities and industry and said the level of acrimony "has risen to the point that I despair we can work together in the future".

His argument was that the continuing decline in federal funding for academic research has left universities cash-starved. To compensate for this lack of money, he says universities are now taking the "extreme position" that "the Bayh-Dole Act requires them to retain complete control of all intellectual property produced by a

university". An HP spokesperson confirms those remarks still reflect the views of Dr Williams today.

Quantifying the downside

Until recently, Bayh-Dole foes had only anecdotal evidence for what they claim to be the downside of university licensing. But in the last few years, several scholars have conducted empirical studies to gauge the impact of Bayh-Dole on federally funded research.

In 2004, Fiona Murray of MIT's Sloan School of Management and Scott Stern of the National Bureau of Economic Research looked at a series of papers published in the prestigious journal *Nature Biotechnology*. They found what they called "a modest anti-commons effect" with the citation rate for papers linked to patented subject matter declining between 9% and 17% after the patent issued.

Janet Bercovitz at the College of Business at the University of Illinois at Urbana-Champaign and Maryanne Feldman from the University of Toronto's Rotman School of Management studied organisational changes Bayh-Dole has brought to universities. They followed researchers from the medical schools of Duke and Johns Hopkins Universities and, in 2004, announced the unremarkable conclusion that entrepreneurial orientation can become infectious.

They found that researchers are much more likely to file invention disclosures if leading researchers at their institutions do so. Younger researchers are more likely to start filing disclosures than those who are advanced in their careers. And researchers are influenced by peers who have the same academic rank. "If an individual can observe others in their academic rank disclosing [inventions], then they are more likely to follow," the study concluded.

Negativity around Bayh-Dole comes as no surprise to James Pooley, a Palo Alto, California, based partner in New York's Milbank, Tweed, Hadley & McCloy. Pooley is a member of the Committee on Intellectual Property Rights of the California Counsel on Science and Technology. He says that as a member of that committee, he has heard a lot of Bayh-Dole bashing in recent months relating to discussions of California's stem-cell initiative. As a member of an advisory committee on patent law to the National Academies he has heard similar criticisms from people expressing concerns that Bayh-Dole-driven university patenting may limit others' access to research tools. "A number of people who are alarmed at the Bayh-Dole model say that patents are allowing people to hoard rather than spread knowledge around, that they're creating their own bottlenecks," Pooley says. "But we keep asking people to show us the evidence that anything has been shut down or held up over access to research tools." So far, he reports, the committee has seen nothing.

Pooley says that foes of Bayh-Dole do not seem to understand that without the mechanism to license university technology, extra burdens would be placed on innovative companies, which would have to become what he describes as Johanna Appleseeds and do absolutely everything themselves. "You would have to own the orchard and the food company and control the distribution

How Bayh-Dole makes a mark

One of the best metrics of Bayh-Dole's success is AUTM, the Association of University Technology, an organisation that now has well over 3,500 members, not only in the US and Canada, but across the world. AUTM research reveals that since Bayh-Dole came into force, nearly 5,000 companies have been spun out of American campuses, while well over 40,000 licence agreements have been concluded between academic institutions and outside parties. Companies with their roots in the US university system now contribute an estimated US$40 billion a year to the country's economy.

But it is not only about revenue and licensing agreements. The technology Bayh-Dole enables also makes a significant contribution to the wellbeing of people not just in the US but worldwide. Every year AUTM collects data and publishes the results of a survey of university and research institute patenting and licensing activities. The most recent available AUTM survey, from fiscal year 2004, touts a wide range of new products stemming from university-based research. They include:

- Scientists at Kansas State University developed nanomaterials that can neutralise a wide range of contaminants and chemical warfare agents. The technology is licensed to NanoScale Materials Inc of Manhattan, Kansas.
- A scientist at the University of North Carolina at Chapel Hill invented a software program that incorporates a 3D microscope, which allows students to experience microscopy in the classroom and from home. The technology is licensed to Science Learning Resources Inc, of Carboro, North Carolina.
- Semiconductor devices that are getting smaller and smaller intrigued researchers at Boston University, who developed an optical device known as the Numerical Aperture Increasing Lens (NAIL) to produce high-resolution images of wafer circuitry. Japan's Hamamatsu has taken a licence on the NAIL technology and will supply it to the semiconductor industry for failure analysis.
- EdgeTech of Marlborough, Massachusetts, has taken a licence to a sonar technology developed at Florida Atlantic Univeristy that can be used to locate buried underwater mines.
- Purdue University developed a miniature mass spectrometer now licensed to Griffin Analytical Technologies Inc, of West Lafayette, Indiana. This portable device can be used to identify chemical warfare agents, explosives and toxic industrial chemicals.
- University of Texas scientists developed wired enzyme technology, which allows diabetes patients to measure blood glucose with a much smaller sample than required by existing methods. TheraSense Inc, of Alameda, California, which was founded to commercialise the technology, was acquired in 2004 by Abbott Laboratories of Abbott Park, Illinois.
- Allergan Inc, of Irvine, California, is selling a new drug, Restasis, which is based on technology licensed from the University of Georgia. Restasis, an immunosuppressant, decreases tear duct inflammation and is used to treat dry eye.

***James Pooley**, Milbank Tweed*
Major Bayh-Dole lessons

and take the business risk and put in all the investment yourself."

New uses for university IP

Meanwhile, some university technology transfer offices have started to look at the social implications of university licensing. Usha Balakrishnan, who worked in the technology transfer office of the University of Iowa, decided in 2003 to try to form a special interest group within AUTM devoted to world health issues. The group, Technology Managers for Global Health, now has more than 180 member institutions, has picked up funding from the Ford Foundation and is developing a curriculum to train technology mangers to license inventions for the public good.

Professor Richard Mahoney of Arizona State University is a member of the board of the Center for the Management of Intellectual Property in Heath Research and Development, which works with Technology Managers for Global Health. He sees Bayh-Dole as flawed because it lacks "any incentive to do something good for developing countries".

Now that the Act has been in existence for 25 years, Mahoney says it is time to start asking how technology transfer can improve the health of the poor, through public private partnerships that can lead to the development of vaccines and drugs to aid developing countries. He wants universities not to abandon their IP rights but to use them in new ways.

Pressing world health issues now have university technology transfer offices and pharmaceutical companies' attention, he says. "The South African experience with AIDS and the shortage of Tamiflu against bird flu have changed the landscape. It used to be that when I talked to them, their response was 'Oh my God, don't bother me, the market [for a specialty drug] is so small and I can't be bothered.' But now, whether they want to or not, they have to be concerned about the rest of the world."

James Pooley says he is sympathetic to those who express concerns about the proper use of patents under Bayh-Dole. But at the same time, it is still necessary to work within the established system. "At the end of the day, what we've learned from Bayh-Dole is that by harnessing the capitalistic system, we get a lot more technologies out to market and, arguably, a lot more spread into other areas as well." There are thousands of companies, hundreds of thousands of employees and many whose lives have been enhanced – or even saved – by products commercialised as a result of Bayh-Dole that would say amen to that. ■

***Victoria Slind-Flor** is a San Francisco-based writer who specialises in covering issues around intellectual property and technlogy*