Carole Latker

From: Sullivan, Kristi [kristi@warf.org]
Sent: Monday, November 02, 2009 3:11 PM
To: Joe Allen; latkerc@bellatlantic.net
Cc: Bremer, Howard
Subject: FW: FROM HOWARD BREMER
Attachments: s2_Bremer.pdf

Joe and Norm:
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Kristi

From: JEdmondIP@aol.com [mailto:JEdmondIP@aol.com]
Sent: Monday, November 02, 2009 10:52 AM
To: Sullivan, Kristi
Subject: Re: FROM HOWARD BREMER

Dear Howard

Just to let you know that I am mailing to you copies of the October issue of Industry and Higher Education (one each for your co-authors and an extra one for yourself - your regular copy will arrive from our distributor in due course). I hope you will be pleased with the article looks. In the meantime, I attach a pdf of the published version of the article.

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With many thanks for your contribution and best regards,
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The US Bayh–Dole Act and revisionism redux

Howard Bremer, Joseph Allen and Norman J. Latker

Abstract: *In the past several years various published papers have questioned whether the Bayh–Dole Act of 1980 (The University and Small Business Patent Procedures Act) has in reality been a determining factor in promoting the transfer of technology from US universities, as has been credited to it. This paper responds to that criticism, presenting facts and analysis in support of the contributions universities have made under the auspices of the Act. The authors point out flawed interpretations and misreadings of pertinent data by critics and discuss the circumstances surrounding the inception, passage and implementation of Bayh–Dole.*

Keywords: *Bayh–Dole; Institutional Patent Agreements; university patenting; revisionist premise; US technology transfer*

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Summary

It is no secret that the US economy faces serious challenges. However, the USA has tremendous advantages for succeeding in technology markets to create wealth in the 21st century, if it chooses to exploit them.

That choice lies with policy makers and depends on their recognizing the inherent strengths of the US innovation system. This paper focuses on a key component of that innovation chain: the combination, functioning under the auspices of the Bayh–Dole Act of 1980,[1] of the USA's outstanding research universities and the entrepreneurial spirit that drives the private sector. That partnership has turned the results of publicly-funded science into products, jobs and companies, thus benefiting US taxpayers both economically and through an improved quality of life.

While this linkage between the academic and business sectors is generally believed to have been very successful, a persistent school of critics has charged that such is not the case. These advocates have become more vocal in recent years, urging policy makers to make changes in the Bayh–Dole Act to correct what they view as its shortcomings. Their arguments can be summarized as follows:

- The importance and influence of the Bayh–Dole Act is overrated, or at least unproven.
- Key data that Congress used to pass the Bayh–Dole Act – the small number of 28,000 government-owned patents that were licensed – were misleading.
- Bayh–Dole is not a model that should be adopted by developing countries because of its emphasis on patent ownership. Rather, what should be adopted is the pre-Bayh–Dole model of technology dissemination, stressing open access to scientific discoveries.

It is unfortunate that some policy makers appear to be accepting such arguments at face value. However, it is important to note that these critics lack the perspective of the pre-Bayh–Dole era, and the difficulties then encountered in turning government-funded research into tangible commercial and social benefits for the

taxpaying public. Reversing that trend, the Bayh–Dole Act encouraged the private sector to invest billions of dollars to develop inventions made in whole or in part with government-supplied (that is, taxpayers') dollars into market-ready products. This partnership between research universities and the private sector created millions of jobs for Americans, significant wealth for the USA and a higher standard of living, while helping to re-establish the USA as the technology innovation leader in a growing and increasingly competitive global economy.

Because the critics' recommended changes to Bayh–Dole would have a profound – and potentially very harmful – impact on the ability of the USA to respond to renewed international economic competition in the 21st century, any changes must be very carefully considered.

Therefore, it is our purpose to examine the charges levied against Bayh–Dole with the actual facts, and to set the record straight. Thus examined, the authors of this article firmly believe that the common revisionist arguments against Bayh–Dole are unfounded, finding a basis in anecdotal evidence or incorrect interpretations of data when logical conclusions should have pointed in another direction.

Reams of objective data exist to support the conclusion that the Bayh–Dole Act has greatly improved the commercialization of federally-funded research, that the system is working very well and that the public sector–private sector partnerships generated under the Act are essential both to the well-being and competitive position of the USA.

That these conclusions are correct is strongly reinforced by the fact that the USA's most serious economic rivals have adopted or are now adopting their own versions of Bayh–Dole to enable them to compete more effectively. Such imitation is the most sincere form of economic flattery. It would be ironic, indeed, if US policy makers chose this critical moment to weaken the well-established national innovation system which is respected throughout the world. This viable and functioning system is needed more than ever at this critical time to maintain a prosperous economy in an increasingly high-technology world.

Background

The USA, Europe and Asia are gearing up for a new round of competition to create wealth from the high-technology industries that are driving the international economy. In many ways, this is a replay of the 1970s and 1980s, when it appeared that Japan and Germany were riding the wave of the future – and many predicted that the USA's best days were behind it. At that time, the USA had lost its lead in traditional fields such as automotives, electronics, steel, and so on. Many experts confidently predicted that Japan and Germany would soon eclipse the USA in the few remaining markets where it led.

However, these predictions did not come true. Instead, the USA enjoyed a tremendous burst of entrepreneurial activity that restored its competitive advantage and laid the groundwork for decades of economic growth. This turnaround came through the adoption of many new policies that were hotly debated at the time. One of these was the passage of the Bayh–Dole Act of 1980. This is how the *Economist Technology Quarterly* (2002) summarized its impact:

> '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 the 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.
>
> 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 augmentations 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 helped to reverse America's precipitous slide into industrial irrelevance.'

Further on the article summarized the law:

> '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 to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.
>
> Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the US economy.

> America's trading partners have been quick to follow suit. Odd then, that the Bayh–Dole act [*sic*] should now be under such attack in America.'

Before examining the specific charges that have been used to attack the law, it is helpful to examine why Congress enacted the Bayh–Dole Act, and what it does. Before 1980, inventions that resulted from research supported by federal funding were rarely developed into commercial products. Because most government-funded inventions derive from the conduct of basic research, they are at a very early stage in their development. Consequently, it requires substantial time and investment by the private sector to turn them into commercially useful products and processes. It is frequently estimated that product development requires at least ten development dollars for every dollar spent in conducting the original research. Developing new drugs to market-ready condition can cost between $800 million to $1.3 billion and can take more than a decade. Even with such a resource commitment, commercial success is far from a sure thing. Many more products fail in the marketplace than succeed. Without an ability to protect such investments, commercial development is not possible.

Federal policies before 1980 mandated that any invention made with federal funding – whether made by employees, contractors or grantees – would be assigned to the government. They were then generally made available to all applicants through non-exclusive licences. Thus a company foolish enough to develop a federally-funded invention could not protect its investment in commercialization, since competitors could gain equal access to the technology from the federal government with the additional knowledge that the invention was feasible and there was a market for it.

It became clear that such policies rarely turned the results of government-funded research into commercially-available goods. A series of presidential policy memoranda, dating back to the Kennedy Administration, did allow contractors or grantees to petition funding agencies to acquire ownership of government-funded inventions they had made on a case-by-case basis. Decisions on such petitions by the various agencies could take eighteen months or more, and were generally negative. In the few situations when agencies did grant a petition, they usually also attached many restrictions on the use of the invention.

Not surprisingly, that general policy discouraged innovative small firms from accepting federal research contracts, because the inability to control the resulting inventions undercut their capacity to compete in commercial markets. Additionally, federal agencies and their employees could not receive royalties if their discoveries were commercialized.

President Lincoln, himself a patent owner, envisaged the patent system as 'adding the fuel of interest to the fires of genius'. With regard to federally-funded research, it was evident that those fires were extinguished. This was no small loss because at the time the federal government was funding the majority of basic research – precisely where breakthrough inventions were most likely to occur – and about 50% of all research and development in the country.

The National Institutes of Health (NIH) finally recognized that this general policy was not effective in promoting technology transfer. It was apparent that few, if any, NIH-funded discoveries were ever commercialized. Consequently, in the 1970s NIH adopted an administrative policy allowing universities which had a proven capability to manage inventions to own inventions made with NIH support. Termed the 'Institutional Patent Agreement' (IPA), this was the precursor to a revolution in federal patent policies. That programme proved so successful that it was later adopted by the National Science Foundation (NSF).

However, the IPA programme was undermined during the Carter Administration when the Secretary of Health and Human Welfare (now Health and Human Services) attempted to halt it, and the department later even sought to fire its creator. This reversal prompted several leading universities to approach Senators Birch Bayh (D-IN) and Robert Dole (R-KS) requesting that the IPA programme be made statutory and binding on all federal agencies, and that it be extended to small business contractors.

After examining the dismal record in commercializing federally-funded inventions and the pending loss of competitive markets to Japan and Germany, Congress adopted the NIH/NSF approach in 1980 in what became known as the Bayh–Dole Act.

One important statistic examined by the Senate Judiciary Committee as it considered the bill was that the government was licensing less than 5% of the 28,000 patents on inventions that it had amassed. Universities and small companies presented compelling evidence that potentially important discoveries would never be developed as long as the government took them away from their creators. Thus government policies destroyed the very incentives for development which the patent system was intended to foster. Senators Bayh and Dole stated that such inefficiencies denied US taxpayers the full benefits of their investment in publicly-funded research.

Congress agreed with the Senators' conclusion, and in 1980 it passed the Bayh–Dole Act overwhelmingly. The Act encourages the development of inventions

made by non-profit organizations and small business companies through the use of federal funds by:

- allowing ownership of such inventions to reside with those entities;
- providing universities with the discretion to license their inventions and discoveries under terms that encourage prompt commercialization through university–industry partnerships;
- stipulating that a percentage of royalties generated through successful commercialization efforts should be shared with inventors (royalties can also be used to pay for administrative costs associated with technology transfer, with the balance remaining designated to fund additional research or for educational purposes);
- providing that preferences should be given to licensing small businesses and requiring substantial US manufacturing where an exclusive license is granted for the USA;
- allowing the government to practise the invention royalty-free for governmental and treaty purposes; and
- allowing the government to 'march in' to require additional licensing if legitimate efforts are not being made by a licensee to develop the invention or in situations in which the licensee cannot produce sufficient quantities to meet a pressing national need (an action that has not been necessary in practice).

Congress, subsequent to the passage of the Bayh–Dole Act, created the Court of Appeals for the Federal Circuit. This destroyed many of the myths that afflicted the US patent system and thereby restored faith in the system and in the reliability of US patents. Congress also enacted the Small Business Innovation Research Act (SBIR)[2] to bring more technologically cutting-edge companies into government research. SBIR built on the assurances of the Bayh–Dole Act that small companies would own the inventions they made with federal funding.

The Bayh–Dole Act brought into play important factors and resources which other nations simply could not match:

(1) The US government funds far more R&D than other national governments – much of it in basic research, where breakthrough technologies are most likely to occur.
(2) This research is largely conducted at universities and other non-profit institutions that are world leaders in their respective technological fields.
(3) The Bayh–Dole Act permitted translation of this investment in science into practical applications which met important health, safety, environmental, food production and other critical needs.
(4) The USA is the acknowledged leader in entrepreneurship and the forming of small, high-technology companies which take the lead in driving new markets. Many of these companies are spun out of universities because of Bayh–Dole.
(5) The patents they own or license are a key asset of these small companies in attracting venture funding and competing in technology markets against larger companies. Those patents not only offer protection for their commercial position, but also the opportunity to recoup and reward the business risks that have been taken.
(6) The US patent system was thus a significant factor in spurring the revival of US competitiveness.

Even though the impact of the Bayh–Dole Act seemed evident as the USA enjoyed a reversal of fortune, as described in the *Economist Technology Quarterly* (2002) article cited above, a small group of academics began to question it. Their arguments can be summarized as follows:

- Bayh–Dole really was not that important. Universities were commercializing inventions anyway.
- Key data that Congress used to pass the Bayh–Dole Act – the small number of 28,000 government-owned patents that were licensed – were misleading.
- Bayh–Dole is not a model that should be adopted by developing countries because of its emphasis on patent ownership. Rather, what should be adopted is the pre-Bayh–Dole model of technology dissemination, stressing open access to scientific discoveries.

In the next section we review each of those charges in greater detail and in light of Ralph Waldo Emerson's admonition that, 'Numbers serve to discipline rhetoric. Without them it is too easy to follow flights of fancy, to ignore the world as it is and to remold it nearer the heart's desire.'

The Bayh–Dole Act and revisionist attacks

The Bayh–Dole Act of 1980 is now almost 30 years old. Few pieces of legislation have maintained their viability and significance in a rapidly changing environment for as long. However, it is being subjected to revisionist interpretations of its effects, benefits and the fundamental needs which caused its inception, passage and implementation.

Representative of these viewpoints is a paper by Bhaven N. Sampat (2002), later papers by critics such as Arti Rai and Robert Cook-Deegan (see, for example, So *et al*, 2008), and the writings of Rebecca Eisenberg (see Eisenberg, 1996). According to Sampat (2002, p 32),

'The political history of Bayh–Dole in Section 4 revealed that it was passed based on little solid evidence that the *status quo ante* resulted in low rates of commercialization of university inventions. More remarkably, the hearings completely ignored the possibility of potential negative effects of increased patenting and licensing on open science and on other channels of technology and knowledge transfer.

Nevertheless, the discussion in Section 5 suggests that the net effects of Bayh–Dole (and the rise of university patenting and licensing activity more generally) on innovation, technology transfer, and economic growth remains unclear, and much more research is necessary on that front. As such, while current efforts to emulate Bayh–Dole type policies in other OECD countries [. . .] are misguided (or at least premature), we also do not have enough evidence to suggest that major changes to the Bayh–Dole act [*sic*] are necessary in the United States.'

Thus, the fundamental premise is that the Bayh–Dole Act was not as influential in promoting the transfer of technology as has been credited to it, and it could be a serious mistake for other countries to emulate it . The first part of the argument is based on assertions by Eisenberg (1996) that experts at the time misunderstood why so few of the 28,000 government-managed patents were being utilized before Bayh–Dole. This failure to commercialize the inventions represented by those patents was a key piece of evidence presented at the hearings on the bill. According to supporters, it showed that the old patent policies (whereby government took inventions away from their creators – the government 'title policy') were ineffective and detrimental to achieving subsequent commercialization. Mowery *et al* (2001, p 117) further postulate that, 'The theory behind Bayh–Dole was that companies needed exclusive patent rights to develop and commercialize the results of university research.'

Actually, the driving force and theory behind Bayh–Dole was that the public was not reaping the full potential benefit from taxpayers' support of basic research, with expenditures for such support amounting to billions of dollars each year. Passage of the Act represented the ultimate step in a long-term effort towards reshaping government patent policy, and was Congress's response to the paramount question: *in whose hands – the federal government or the inventing organization – is the ownership and management of federally-funded inventions best placed to promote the prompt development of important discoveries for the benefit of the US taxpayer?*

It is not denied that, at about the same time as the Bayh–Dole Act was passed, there was a confluence of forces which had an effect on universities' technology transfer efforts. However, we find the proposition outlined by the critics to be a flawed conclusion. The Congressional intention in enacting the law is made abundantly clear in the provisions Senators Bayh and Dole wrote into the legislation as the Policy and Objectives of the Act in 1980 (35 U.S.C. 200):

> 'It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise, to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.'

That the effect of the Act was so profound, beneficial and far-reaching is attributable to several primary factors:

(1) It established a uniform patent policy for all agencies of the federal government.
(2) It changed the presumption of title to inventions made in whole or in part with federal monies from the government to universities, other non-profit institutions and small business.
(3) It established a certainty of title in such inventions which encouraged the private sector to engage in relationships with university and non-profit research organizations leading to the development and commercial use of many inventions for the public benefit.
(4) The protection offered by the chosen vehicle for technology transfer – the US patent system – provides needed incentives for the private sector to undertake the considerable risk and expense necessary to take early-stage university discoveries from laboratory to marketplace. Strong patent protection is also vital to small businesses, which have obtained the vast majority of licences from universities, so they can engage the venture capital community for needed funding – and for protection against the incursion of dominant companies in their markets.

Experience in the period before enactment of Bayh–Dole clearly established that ownership and management by universities of their inventions was clearly a superior policy than what had preceded it. For example, there had been an utter failure to commercialize university inventions when the National Institutes of Health had retained all rights to inventions made in whole or in part with federal money and adopted a non-exclusive licensing stance for those inventions. As the Comptroller General of the United States later testified: [3]

> '[. . .] we reported that HEW [Health, Education and Welfare] was taking title for the Government to inventions resulting from research in medicinal chemistry. This was blocking development of these inventions and impeding cooperative efforts between universities and the commercial sector.
>
> We found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry because manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of a promising product.'

Therefore, a revolutionary approach was announced. As mentioned earlier in this paper, NIH established and adopted an administrative policy entitled the Institutional Patent Agreement (IPA). The IPA programme allowed universities with established technology transfer offices to own and manage inventions made with NIH funding. The programme began at NIH in 1968 and was so successful that the National Science Foundation adopted it in 1973.

This is how the Senate Judiciary Committee summarized the impact of the IPA programme:

> 'Since instituting the IPA program a number of potentially important new drugs initially funded under HEW research have been delivered to the public through the involvement of private industry in developing, testing, and marketing these discoveries. Prior to the IPA program, however, *not one drug* had been developed and marketed from HEW research because of a lack of incentives to the private sector to commit the time and money needed to commercialize these discoveries.' (Committee on the Judiciary, 1979, p 21, emphasis added.)

The programme continued to achieve success, but during the Carter Administration efforts were made to end it because of the personal philosophy of the new Secretary of Health, Education and Welfare (the agency is now Health and Human Services). That philosophy, much like the philosophies of many of the current critics of the Bayh–Dole Act, called for a return to case-by-case determination by NIH of whether university inventions made with its funding should be retained by NIH, or whether the ownership should be transferred to the universities for management. The Comptroller General testified that such determinations were taking 'from 8 to 15 months to complete' (Committee on the Judiciary, 1979, p 37). It was this movement to end the most successful patent policy in any federal agency that led universities to approach Senators Bayh and Dole, arguing that effective patent policies must have a legislative mandate so they could not be changed at the whim of a political appointee.

The potential to make changes in patent policies arbitrarily at the agency level, and the adherence to a non-exclusive licensing mandate, established a lack of predictability that was unnerving and unacceptable to potential industrial partners. Companies simply would not expend the sizeable amounts of private-sector time and money needed to turn patented university-based early-stage technologies into marketable products if the government could change the rules at a whim.

Shortly after introducing their bill, Senators Bayh and Dole held a press conference and gave examples of potentially important medical discoveries that were being strangled with red tape because of NIH's weakening of the IPA programme. Senator Dole compiled a list of '29 important medical discoveries that had been delayed from 9 months to well over a year before HEW were able to reach a determination whether or not the agency would retain patent rights. Follow-up review has shown no improvement in HEW's performance.' [4]

As a result, a rapid succession of Senators from across the political spectrum began to sign on as co-sponsors of the proposed Bayh–Dole bill.

While the current critics acknowledge the connection between the IPA programme and the Bayh–Dole Act, their dramatic impact on the commercialization of university inventions tends to be downplayed. For example, Sampat *et al* state:

> 'Bayh–Dole was passed in the throes of the ''competitiveness crisis'' of the 1970s and 1980s in the belief that the requirement to obtain IPAs or waivers and the frequently inconsistent policies of federal funding agencies regarding these agreements (especially regarding exclusive licensing) impeded technology transfer and commercialization of federally funded research results. In particular, the framers of the legislation argued that if universities could not be granted clear title to patents that

Table 1. IPA participants and filing applications, HEW, 1968–1976.

	1968	1969	1970	1971	1972	1973	1974	1975	1976
IPA participants[a]	17	24	34	39	41	50	57	61	66
Patent applications by HEW contractors[b]			35	51	50	44	76	79	118

Sources: [a] Government Patent Policy: Institutional Patent Agreements, Hearings Before the Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business, US Senate, 95th Congress, 2nd Session, Part 1, May 22–23, June 20, 21, 26 1978, pp 147–150. [b] Federal Council for Science and Technology Report on Government Policy, Combined Dec. 31, 1973 through Dec. 31, 1976, p 424.

> allowed them to license rights to patented inventions exclusively, firms would lack the incentive to develop and commercialize university inventions.'

And they add a footnote: 'this argument was based on "evidence" that government-owned patents had lower utilization rates than those held by contractors, evidence that Eisenberg (1996) has shown to be faulty [. . .]' (the Eisenberg evidence will be addressed later in this paper).

Sampat *et al* (2003) do recognize the existence of the IPA programme and some of the same authors in an earlier paper (Mowery and Sampat, 2001) acknowledge their awareness of that programme more extensively. However, they tend to minimize the connection between the advent of the IPAs and increasing university-sector patenting and licensing when most of the predominant research universities were operating under such agreements.

Interestingly, looking at the actual data, the increase in the filing of patent applications on the results of extramural research sponsored by HEW and NSF directly correlates with the increased participation in their IPA programmes .[5] Table 1 shows the numbers for HEW (then the parent agency of NIH). As can be seen, patent applications increased by over 300% between 1970 and 1976 at HEW as the IPA programme expanded. The numbers are even more striking for the NSF after it implemented the IPA programme in 1973 (see Table 2). NSF had an 800% increase in patent applications between 1973 and 1976 as its IPA programme kicked in.

These data substantiate a strong correlation between the incentives of patent ownership and management under the IPA programme with the subsequent rise in patent applications on university inventions made with federal support. Since the IPA programme was essentially later codified by the Bayh–Dole Act, it is only fair to credit these new approaches to federal patent policies with the increases in university patenting. It is illogical to conclude otherwise.

Yet the critics seem reluctant to acknowledge this connection clearly. Mowery and Sampat (2001) describe the phenomenon as follows:

> '[. . .] Figure 9 [reproduced here as Figure 1] shows that institutions with IPAs dominated the growth of university patenting during the 1970s.
>
> Nonetheless, although IPAs may have encouraged entry by lowering the costs of patenting and licensing, fewer than half of entrant institutions had IPAs. Moreover, Figure 10 [reproduced here as Figure 2] shows that patenting during the 1970s grew for entrants with IPAs and entrants without IPAs. The diffusion of IPAs alone does not explain entry by universities into patenting.
>
> Analysis of the contributions to entry of these various factors – increased inter-institutional dispersion of federal research funding, the growth of IPAs, the rising costs and inefficiencies in Research Corporation's "central broker" model, and reduced aversion to university patenting generally and in biomedical technologies in particular – remains an important task for future research. All of these

Table 2. IPA participants and filing applications, NSF, 1970–76.

	1970	1971	1972	1973	1974	1975	1976
IPA participants[a]	na	na	na	na	11	11	13
Patent applications by contractors[b]	6	2	4	8	17	40	67

na=not applicable

Sources: [a] Government Patent Policy: Institutional Patent Agreements, Hearings Before the Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business, US Senate, 95th Congress, 2nd Session, Part 1, May 22–23, June 20, 21, 26 1978, pp 258–260; [b] Federal Council for Science and Technology Report on Government Policy, Combined Dec. 31, 1973 through Dec. 31, 1976, p 424.

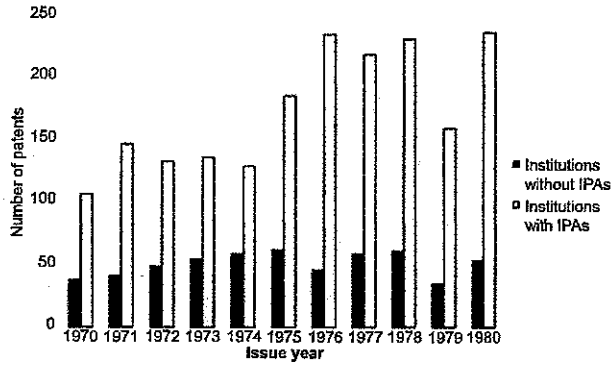

Figure 1. Mowery and Sampat's (2001) Figure 9 – 'Patenting by Carnegie research universities, by IPA status'.

> factors appear to have influenced growth in university patenting in the 1970s. Interestingly, only one of these factors (the IPAs) represented a change in federal policy toward the patenting of publicly funded research. It is likely that a similar diverse range of factors, and not the Bayh–Dole Act alone, underpinned the continued growth of US university patenting after 1980.' (Mowery and Sampat, 2001.)

What is striking about this conclusion is that Mowery and Sampat's Figure 9 (see Figure 1) clearly illustrates the impact of IPAs on university patenting. The chart shows that while the IPA programme was the only one of the factors cited as 'a change in federal policy toward patenting publicly funded research', it clearly made a dramatic and sustained impact that was not occurring without it.

Even their Figure 10 (see Figure 2) underscores the importance of the IPA programme on university patenting. IPA participants double the number of reported patents between 1973 and 1975. The increase of reported inventions by IPA participants increases by almost 400% between 1974 and 1976 according to the

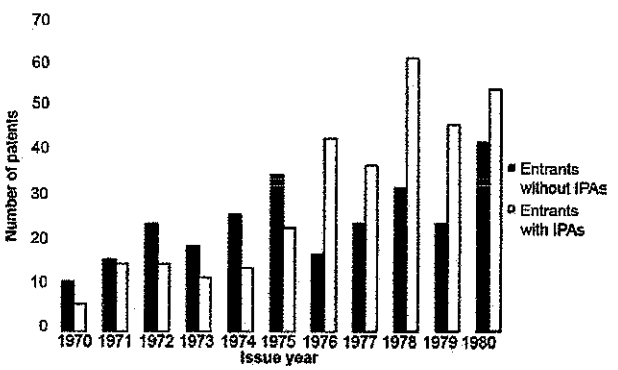

Figure 2. Mowery and Sampat's (2001) Figure 10 – 'Patenting by Carnegie research universities, by IPA status – entrants only'.

figure. Even more striking, as the IPA programme starts to grow at the NSF, and participants increase at NIH, as shown in Tables 1 and 2, IPA schools permanently pass those not in the programme in 1976 – and never look back.

The impact of Bayh–Dole on individual universities like MIT which had already been active in technology transfer is also illustrative. It could be argued that Bayh–Dole did not really impact on the legal structure of patent ownership at MIT, because MIT had an existing agreement with the government that generally gave it ownership of its inventions. However, Bayh–Dole did have a major impact because it pushed MIT as well as other universities to recognize that using inventions for the benefit of society could often be best accomplished through commercialization – which required the cooperation and risk-taking of the private sector. For example, a novel and patented chemical entity projected for use as a new pharmaceutical product would not benefit patients unless it were available commercially. Likewise, a newly-discovered material or alloy would not make aircraft lighter and stronger unless it could be made commercially.

Within one year of MIT's rethinking its licensing activities as a result of Bayh–Dole, the number of licences it issued increased by nearly 1,000%. During the next twenty years, the MIT Technology Licensing Office helped in the formation of nearly 800 new companies. A recent study of MIT spin-off companies showed that, if the active companies founded by MIT graduates formed an independent nation, their revenues would make that nation at least the 17th largest economy in the world.[6] While MIT clearly was spinning out companies before the passage of Bayh–Dole, the rate of new company formation based on MIT inventions and discoveries increased almost exponentially after its enactment.

Another point advanced by the critics as a basis for the increase of university patenting, apparently undercutting the influence of Bayh–Dole, was the large subsequent infusion of federal money, primarily through NIH, in support of life science research. However, the IPA programme and later the Bayh–Dole Act were critical incentives for recipient universities to file patent applications to protect important discoveries emanating from research supported by such funding. This would not have happened if NIH had retained its policy of taking title to inventions made in whole or in part with NIH funds.

Clearly, it was the incentive of patent ownership and the certainty of title accompanying ownership on which the private sector could rely in a licensing arrangement that spurred the increase of university patenting under the IPA programme. The patenting activity accelerated

even more after Bayh–Dole was enacted because it applied uniformly to all federal funding agencies, and all universities in receipt of federal funds for research activities could then engage in technology transfer.

There is therefore little doubt that the negotiation, establishment and existence of the IPAs were of predominant importance in the rapid growth of the university technology transfer function. Moreover, those agreements and the provisions in them were the template for the Bayh–Dole Act. Fundamentally, Bayh–Dole is a codification of terms and provisions of the IPAs. Indeed, when Senators Bayh and Dole first introduced the bill in 1978, they used several inventions whose development was threatened by the Carter Administration's undermining of the IPA programme as examples of the need for legislation.

Additional data support the proposition that the Bayh–Dole Act, drawing on the preceding IPA programme, was a decisive factor in the promotion and growth of the technology transfer profession in the university, non-profit and small business sectors of the economy. Simple statistical evidence, such as the rapid growth in the membership of the Association of University Technology Managers (AUTM) and the number of technology transfer offices established in the university community (from about 30 in 1972 to about 300 in 2007–08) bear that out.

Moreover, data presented in the annual AUTM Licensing Survey that show increasing year-to-year activities in invention disclosures, patenting and licensing are also evidence of the positive effects of the Bayh–Dole Act. The ultimate measure of the wisdom in passing the Bayh–Dole Act and its success in transferring technology for the public benefit – the Act's primary objective – can be found in an annual compilation by AUTM entitled the *Better World Report*, which lists and describes some of the university technology-based inventions which have been developed for the marketplace contributing to public health, safety and welfare – a virtual panoply of inventions in many and diverse scientific disciplines.

Additionally, consider the following evidence of the impact of the law (AUTM, 2007):

- *University technologies helped create 5,724 new companies in the USA since the enactment of the Bayh–Dole Act in 1980.* In FY 2006 alone, 553 new companies were spun off based on campus discoveries and inventions. Astoundingly, that is more than two new companies formed each working day of the year. The formation of new, technology-based companies drives state economic development.
- *University research created 4,350 new products from FY 1998–FY 2006, with 697 introduced in FY 2006 alone.* This means that 1.32 new products were introduced every day for that period.
- *Federally-funded research at universities and federal laboratories resulted in the development for public use of 130 new drugs, vaccines or in vivo* diagnostic devices. Many of these discoveries were treatments for infectious diseases and new cancer therapies. The majority of licences initially went to small companies licensed under the provisions of the Bayh–Dole Act (Jensen *et al*, 2008).
- *There were almost 5,000 existing active university licences in FY 2006 – each representing a university–industry partnership.* The majority of these licences were with small businesses and start-up companies. Although the bulk of licensing arrangements were non-exclusive, most of the exclusive licences issued were to small businesses and start-up companies, which require strong patent protection to succeed in highly competitive markets against larger, established and well-financed competitors.

Important health-related and life-saving discoveries commercialized under Bayh–Dole include: Cisplatin and carboplatin cancer therapeutics (Michigan State University); Hepatitis B vaccine (University of California, University of Washington); Vitamin D metabolites and derivatives (University of Wisconsin-Madison); Human growth hormones (City of Hope Medical Center); Taxol (Florida State University); and Citracal® calcium supplement (University of Texas SW Medical Center).

There was nothing even remotely approximating these successes outside of the IPA program and its subsequent uniform application across all federal agencies caused by the enactment of the Bayh–Dole Act.

The 'evidence' (Sampat *et al*, 2003) disproving the commonly-held theory that government-owned inventions had lower utilization rates than those held by 'contractors' (read 'universities') is based on an article by Rebecca Eisenberg (1996). The same argument is repeated by So *et al* (2008) in their article 'Is Bayh–Dole good for developing countries? Lessons from the US experience'. That paper, intended to warn other countries of the 'dangers' of adopting a Bayh–Dole type law, includes the following passage:

> 'Nevertheless, many advocates of adopting similar initiatives in other countries overstate the impact of BD in the US [. . .] They also cite data (originally used by US proponents of the Act) on the low

licensing rates for the 28,000 patents owned by the US government before BD to imply that the pre-BD legal regime was not conductive to commercialization. But as Eisenberg has argued, that figure is misleading because the sample largely comprised patents (funded by the Department of Defense) to which firms had already declined the option of acquiring exclusive title. Moreover, these figures are of questionable relevance to debates about public sector research institutions, because most of the patents in question were based on government-funded research conducted by firms, not universities or government labs.'

In our view, this assertion is wrong on both counts. In her referenced paper, Eisenberg (1996) maintains that 'the primary argument against government ownership was a statistical one' based on the 'testimony of numerous witnesses' that 'only a small percentage of its estimated 28,000–30,000 patents had been successfully licensed and exploited commercially'. She further submits that '. . .the statistical evidence presented was inadequate to document this claim' because it 'reflected a huge selection bias; as it consisted largely of inventions made by contractors whose research was sponsored by DOD . . . that could have retained title to the patents if they had wanted to do so'.

On the basis of her analysis, Eisenberg (1996) concludes that,

> 'It is hardly surprising that few firms were interested in taking licenses from the Government to patents that had already been rejected by contractors that could have been owned by them outright if they had found them at all commercially interesting.'

Eisenberg alleged that 17,632 of the 28,021 inventions in the government patent portfolio were made by Department of Defense (DOD) contractors, waived to the government because they lacked commercial importance. However, a review of the actual data indicates that this in fact was not the case. The evidence that fewer than 5% of government-owned inventions were being successfully licensed came from the 1976 Federal Council for Science and Technology (FCST) combined report (see Figure 3).[7] But in her paper, Eisenberg (1996) fails to note that the 1976 report clearly established that the 17,632 DOD patents included:

(1) 7,046 US patents granted during the 1970–76 reporting period to DOD employees obligated to assign their rights to DOD.

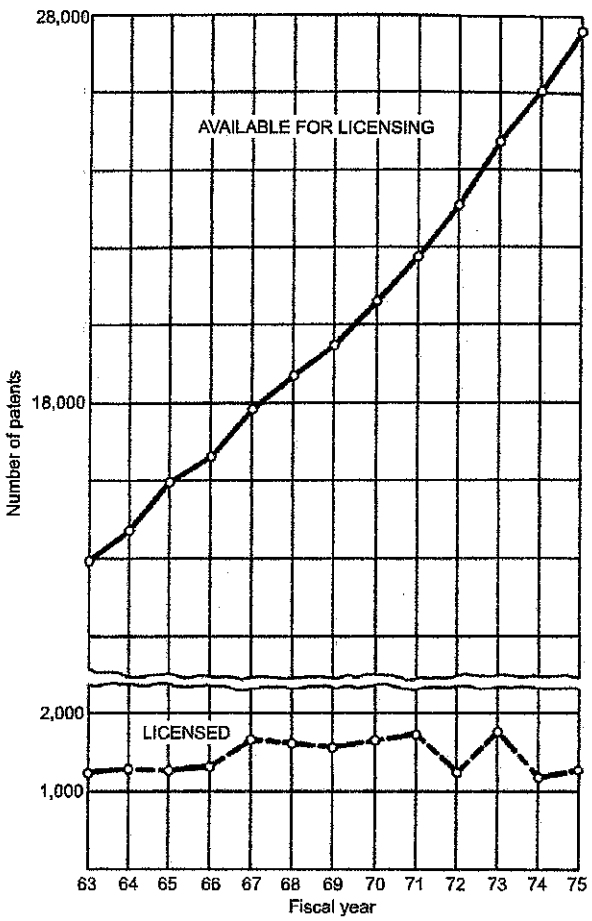

Figure 3. Licensing of government-owned interventions, 1963–75.

Source: Federal Council for Science and Technology Report on Government Patent Policy, Combined Dec. 31, 1973 through Dec. 31, 1976.

(2) 2,594 US patents based on reported inventions during the 1970–76 reporting period from contractors.

(3) In addition, a portion of these 2,594 contractor-generated inventions were taken from universities and other non-profits which, because of the DOD title policy then in place (prior to the passage of the Bayh–Dole Act), had no choice but to assign their inventions to the government.

Combining the two categories in (1) and (2) above gives a total of 9,640 patents accrued to the DOD patent portfolio during the 1970–76 reporting period, or about one-half of the 17,632 DOD patents identified in the report.

The remaining 7,992 patents (17,632 – 9,640) are unexpired patents granted and assigned to DOD prior to 1970 that remained open for licensing within the 1970–76 reporting period. Since there are no data in the

1976 report indicating the source of patents granted before 1970, it is not unreasonable to assume that the ratio of these patents is approximately equal to that of the 1970–76 reporting period. That is, about 70% were generated by government employees and about 30% were contractor-generated (including universities and non-profit organizations). Accordingly, of the 7,992 patents granted before 1970, 5,594 would have been generated by government employees, and 2,398 would be contractor-generated. Thus the total DOD employee-generated patents would be 12,640 (7,046 + 5,594) and the total DOD contractor-generated patents would be 4,992 (2,594 + 2,398).

Since DOD employee-generated patents came from cutting-edge federal laboratories like the Naval Medical Center at Bethesda, MD, or the Walter Reed Hospitals in Washington, DC, they do not fit Eisenberg's characterization as 'rejected' inventions without commercial interest. Nor do they fall within her definition of 'contractor' inventions.

The remaining 4,992 patents generated by actual DOD contractors do not support Eisenberg's (1996) allegation that the patents available for licensing 'reflected a huge selection bias; [consisting] largely of inventions made by contractors whose research was sponsored by DOD'. The DOD contractor-generated portion of the government patent portfolio amounts to no more than 18% (4,992/28,021) rather than the 63% (17,632/28,021) suggested by Eisenberg.

There is also no empirical or documentary evidence advanced that even the 18% of the government patent portfolio as identified above were based on inventions 'rejected by contractors' as not 'at all commercially interesting', as Eisenberg argues. This is because an unidentified number of these patents were generated by university and other non-profit contractors and were simply taken by DOD under its existing patent policies, whether they had commercial potential or not.

It is not even possible to support Eisenberg's (1996) contention that there was little commercial value in the unknown subset of patents from for-profit contractors. Most large-company contractors of the time kept their government and commercial research operations segregated because of fears that federal agencies would try to assert ownership to important discoveries. In addition, a proportion of this category of inventions was generated by *small business contractors* who, like universities, had no choice but to assign any inventions made to DOD. Thus Eisenberg's assertion is not proven even for the limited subset of industry contractors.

In summary, the revisionists' theory that the supporters of the Bayh–Dole Act misinterpreted the lack of commercialization of 28,000 government-owned inventions does not hold up. The data present their own case and contradict that theory.

The revisionists are also turning their sights abroad. So *et al* (2008) warn of the dangers of following the US model in a series of recitations of virtually every objection critics have advanced over the past 30 years. Building their case, So *et al* say:

> 'Finally, and most importantly, the narrow focus on licensing of patented inventions ignores the fact that most of the economic contributions of public sector research institutions have historically occurred without patents through dissemination of knowledge, discoveries, and technologies by means of journal publications, presentations at conferences and training of students.'

Such arguments present a false dichotomy. Bayh–Dole has not harmed the dissemination of knowledge in the USA; nor has it prevented journal publications, presentations for the training of students, etc. Indeed, it complements the historical mission of university research by making its contribution to social good much more tangible and immediate through the creation of new products directly benefiting the taxpaying public.

More fundamentally, So *et al* (2008) do not address how developing countries in a competitive global economy can hope to prosper by putting their university research freely into the public domain (as the authors advise). The US experience, as previously discussed, certainly does not support this contention. Unless innovative companies have the incentive of strong intellectual property laws, they cannot undertake the considerable risk and expense of product development. Consequently, public-sector research lies fallow. Rather than following the same course that failed in the USA before Bayh–Dole, developing countries would be well-advised to listen to other arguments.

South American economist Hernando De Soto's groundbreaking book, *The Mystery of Capital* (De Soto, 2000) forcefully demonstrates that the fundamental weakness of perennially underdeveloped countries is the inability of their citizens to establish clear ownership of their property, both physical and intellectual. Without the incentive of ownership, wealth creation is not possible.

At its founding, the United States of America was also a 'developing country'. One of the primary reasons behind the American Revolution was an imperial system that doomed its colonies to remain only the providers of raw materials devoid of manufacturing capabilities. It was to reverse this unjust and subservient role and to develop a society based on internal innovation that the Founding Fathers placed the

intellectual property protection provision in Article I, Section 8 of the Constitution. Their faith in creating such incentives through a strong and viable patent system was well placed. As President Abraham Lincoln aptly stated, without a patent system 'any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.' Strangely, the modern critics think that the way to innovation is to turn Lincoln's dictum on its head.

Inventor Frederick Cottrell, when founding Research Corporation, noted that '[. . .] a number of meritorious patents given to the public absolutely free have never come upon the market chiefly because what is everybody's business is nobody's business'. It was precisely because inventors could secure protection for their discoveries and inventions that the 20th century became an era of huge innovation in the USA. It can hardly be disputed that, because of such protection, the benefits to humanity have been enormous. While the critics bemoan the ability of the patent system to grant such ownership of intellectual property, the only alternatives are open-source technology or trade secrets, neither of which provides similar motivation and incentives for innovation. It is truly the protection that the patent system creates that makes the commercial development of groundbreaking discoveries possible.

Developing countries would do well to consider these hard-won lessons when urged by external 'experts' to give away the results of their research. Interestingly, South Africa recently enacted a Bayh–Dole type law to help integrate its research universities fully into its economy. That a country which has changed so dramatically in recent years can look past the speculative fears of the critics and lay the groundwork for a confident future should give hope to us all.

Critics have also raised concerns that Bayh–Dole harms the advancement of science. Contrary to the anecdotes that are offered as the basis for that allegation, the data show that the law has substantially contributed to the US economy, and that US science is actually better because of university–industry research collaborations. Additionally, university researchers are successfully balancing patenting and publishing, and not shifting their focus away from fundamental research. In 2005, according to the President's Council of Advisors on Science and Technology (PCAST, 2008, p 22), fully 29% of articles authored worldwide by scientists and engineers were from the USA:

> 'Publication and citation of scientific results in peer-reviewed journals is one common metric for evaluating research outputs [. . .] The United States remains the world leader in citations of S&E [science and engineering] research articles. The number of US articles with co-authors by sector is a metric that can be used as an indicator of public–private research partnerships. Between 1995 and 2005, co-authorship with academic institutions increased by 10.3 percent, the largest percentage point increase of all cross-sector co-authorships.'

This co-mingling of the best and brightest minds in the public and private sectors in authoring joint scientific publications was fostered by the Bayh–Dole Act. Before the Act was passed, industry segregated its most creative researchers from university collaborations because the federal government could assert ownership rights in resulting inventions when federal support of university research was also present.

The health of US scientific publications is also reflected in the findings of the National Science Board's 2008 *Science and Engineering Indicators* report (NSB, 2008, Vol 1, p 5–7). Traditionally, about three-quarters of all US scientific and engineering publications come from academia. In its 2008 report, the NSB found:

> 'Although the US share of world article output and article citations has declined, the influence of US research articles has increased, as indicated by the percentage of US articles that are among the most highly cited world-wide. In 1995, authors from US institutions had 73% more articles in the top 1% of cited articles in all S&E fields than would be expected based on US total article output; in 2005, the percentage had grown to 83%.'

That the share of US scientific papers has fallen is because of the huge explosion of international publications, particularly from Asia. However, while the percentage of US publications has decreased, their scientific impact has increased. Scientific papers by US researchers are the most cited across every field of science (NSB, 2008, Vol 1, p 5–41). The number of citations by other authors is the standard criteria for determining the significance of a scientific publication in its field. The report explains (NSB, Vol 1, 2008, pp 5–49–5–50):

> 'In other words, a country whose research has high influence would have higher shares of its articles in higher citation percentiles.
>
> This is the case in every field for US articles – only US publications display the ideal relationship of

consistently higher proportions of articles in the higher percentiles of article citations across the period.

However, when citation rates are normalized by the share of articles during the citation period to produce an index of highly cited articles, the influence of US articles is shown to increase [. . .] In other words, the United States had 83% more articles than expected in the 99th percentile of cited articles in 2005, while the European Union had 16% fewer than expected and the Asia-10 had 59% fewer than expected.'

The USA ranked number 1 in every broad science and engineering field surveyed in the study for 2005. It also held this ranking in 1995.

Another classic argument espoused by the critics is that Bayh–Dole lures academic researchers away from basic research towards applied research in order to attract industry sponsors. Of course, it is precisely because university researchers are doing fundamental research which industry either cannot do or chooses not to do that academic alliances are so attractive. Asking 'Has academic R&D shifted toward more applied work?', the NSF examined this allegation and found as follows (NSB, 2006, Vol 1, p 5–36):

'Emphasis on exploiting the intellectual property that results from the conduct of academic research is growing [. . .] Some observers believe that emphasis has been accompanied by a shift away from basic research and toward the pursuit of more utilitarian, problem-oriented questions.

We lack definitive data to address this issue. As indicated earlier in the chapter, it is often difficult to make clear distinctions among basic research, applied research, and development. Sometimes basic and applied research can be complementary to each other and embodied in the same research. Some academic researchers may obtain ideas for basic research from their applied research activities.

Two indicators, however, bear on this issue. One indicator is the share of all academic R&D expenditures directed to basic research. Appendix table 5–1 does not show any decline in the basic research share since the late 1980s. The second indicator is the response to a question S&E (science and engineering) doctorate holders in academia were asked about their primary or secondary work activities, including four R&D functions: basic research, applied research, design and development.

As figure 5–33 [reproduced here as Figure 4] shows, for those employed in academia who reported research as their primary activity, involvement in basic research declined slightly between 1993 and 2003, from 62% to 61% probably not statistically significant. The available data, although limited, provide little evidence to date of a shift toward more applied work.'

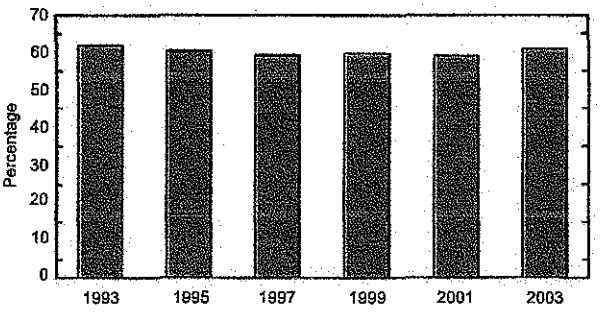

Figure 4. S&E doctorate holders with primary activity research whose primary activity is basic research, 1993–2003.

Note: S&E doctorate holders involved in research include those primary work activity is basic or applied research, development or design.

Source: National Science Foundation, Division of Science Resources Statistics, Survey of Doctorate Recipients, Special Tabulations, from NSB (2006), Science and Engineering Indicators, National Science Board, Arlington, VA.

Once again, an examination of the data contradicts the critics' charges.

To reinforce what the Bayh–Dole Act has contributed to the US economy and to the benefit of mankind, one need only look at the inventions listed below, in addition to those listed previously. Of course, these represent only a small sample of commercialized inventions derived from basic research in academia and generated in diverse disciplines by different university research institutions: rDNA technology, central to the biotechnology industry (Stanford and University of California); TRUSOPT® (dorzolamide) ophthalmic drop for glaucoma (University of Florida); Hotbot Internet search engine (University of California at Berkeley); Ultrasonic removal of dental plaque (University of Washington); Lycos® Internet search engine (Carnegie Mellon University); Mosaic Web browser (University of Illinois at Urbana-Champaign); Yahoo Internet search engine (Stanford); and Cardiovascular and magnetic resonance imaging techniques (University of Wisconsin-Madison).

Conclusion

The Bayh–Dole Act has exceeded the expectations of its authors and of Congress, and is as viable and needed in today's economic crisis as it was in 1980. Its

contributions to the benefit of the USA and its citizens were recognized by a resolution of the US House of Representatives on 6 December 2006:

> 'The Bayh–Dole Act (Public Law 96–517) has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefited the economic and trade policies of the United States.'

Moreover, an important factor that is often overlooked is that the success of the Bayh–Dole Act in motivating technology transfer has been accomplished without cost to the taxpayer. In other words, no separate appropriation of government (read taxpayers') funds was needed to establish or manage the effort. Yet its contributions to the US economy and to its citizens, as well as to the citizens of the world, has been exemplary. For example, in FY 1999 US economic impact models showed that $40.9 billion could be attributed to academic licensing, and that 270,900 jobs were created.[8]

Why was the Bayh–Dole Act a determinatiing factor in the evolution of university technology transfer? There are a number of reasons that critics conveniently overlook:

(1) It produced order out of chaos because it established a uniform government patent policy. Prior to Bayh–Dole, when federal monies were used in whole or in part in the making of an invention, there were some 20 agency policies depending on where the research was funded. Indeed, frequently an agency covering different programmes had more than one patent policy. Because universities received federal funds from a wide range of sources, this made it extremely difficult, if not impossible, to sort out the applicable policies and restrictions on patenting and licensing by the university. The most restrictive of the policies generally controlled, but all applicable funding agency policies had to be considered, as did the bureaucratic climate and restrictions within a given agency. Consequently, with the exception of the IPA programme, a federally-supported university invention seldom found its way to the marketplace.

(2) Bayh–Dole was the first statutory authority for government agencies to obtain, hold and license patents generated within government laboratories. This greatly increased the effective management of important inventions made by federal employees, previously languishing without development.

(3) It was the template for the subsequently passed Federal Technology Transfer Act, which promoted technology transfer from federal laboratories and recognized the contributions of federally-employed inventors. Indeed, the first version of this legislation by Senator Dole was written as an amendment to Bayh–Dole.

(4) It called for the sharing of royalties collected by the contractor with inventors, thus recognizing their imaginative scientific contributions and supplying them with the incentive to consider the practical applications of the results of their research. It also promoted contractors' use of the expertise of inventors in the technology transfer function.

(5) It promoted collaboration among scientists with diverse funding from different federal sources to explore and embrace interdisciplinary approaches to solving scientific challenges.

(6) It promoted the science–innovation interface through the establishment of a new university–industry relationship because of the certainty of title to inventions retained by universities under the provisions of the Act. This was, and still is, the critical element in private-sector development of inventions for the marketplace.

(7) It promoted private-sector as well as government investment in university research.

(8) It promoted innovation and the attendant creation of jobs through, in part, its mandate to give preference to US industry and small business in technology transfer practices.

(9) It protected confidential information in the possession of the contractor and its licences from undue and untimely disclosure – a prime consideration for the private sector in a globally competitive economy.

(10) It preserves certain rights in the government to protect the public against non-use or unreasonable use of inventions supported in whole or in part with taxpayers' money.

(11) It provides universities and non-profit sectors with the possibility of generating income to support research and educational activities through the technology transfer function.

The suggestion that the Bayh–Dole Act has not been a critical factor in the development of university technology transfer, and that this evolution would have occurred anyway, seems to us simply unsupportable.

Prior to the passage of the Bayh–Dole Act, and the preceding Institutional Patent Agreements, the environment in which technology transfer existed was, at best, inhospitable and, at worst, hostile. That environment slowly progressed, through the creation of the IPA program and a succession of unpassed legislation to the enactment of the Bayh–Dole Act, into one that actually encouraged technology transfer. The result has been of great benefit to the US taxpayer in terms of the availability of important new products – particularly in biomedicine – and improved international competitiveness. Indeed, the USA is internationally recognized for its efficiency in the integration of its research universities into its national economy. The proof is in the number of competing nations seeking to adopt the Bayh–Dole model abroad – a movement that persists despite the warnings of its critics.

Unfortunately, the Bayh–Dole Act of 1980 has come under relentless scrutiny and attack by revisionist historians, whose pronouncements have little basis in empirical data. If their criticisms were heeded, the same policies would be resurrected that clearly failed before the enactment of the Institutional Patent Agreements and the Bayh–Dole Act.

It seems strange that a piece of legislation which arose out of failed policies almost 30 years ago and which has proven its worth, is now again being decried on many of the same bases that were raised against its initial passage. Outspoken claims, with little basis in empirical evidence, under the guise of guardianship of the public interest provide a rich field for the cultivation of political power and special interests. Such initiatives are dangerous in an evolving technologically-focused, increasingly fragile, global economy. Intellectual property and its ownership have become the preferred currency for economic growth, with invention and innovation the hallmarks not only of technological leadership, but of survival.

The authors of this article fully acknowledge that improvement can always be made in the technology transfer system. It is always possible to find licensing decisions that could be open to criticism or universities that are more difficult to deal with than others. However, it is important not to blame Bayh–Dole for sub-optimal practices on the basis of examples of its poor implementation.

The bottom line is that the Bayh–Dole Act, over its 30 years of implementation, continues to provide a superb framework for government-funded research to benefit Americans through job and wealth creation, and to improve the lives of people worldwide. This is a lesson it would be well to remember, and perhaps one that the critics could take to heart. As Nietzsche said, 'Convictions are more dangerous foes of the truth than lies.'

Notes

[1]University and Small Business Patent Procedure Act, P.L. 96–517, 1980 (commonly referred to as the 'Bayh–Dole Act' or, simply, 'Bayh–Dole').
[2]Small Business Innovation Development Act of 1982, P.L. 97–219, July 22, 1982, 96 Stat. 217.
[3]Testimony of Elmer B. Staats, Comptroller General of the United States, before the Senate Judiciary Committee on S. 414, the University and Small Business Patent Procedures Act, May 16, 1979, Report No 96–11, p 37.
[4]The GAO patent policy study presented to the Senate Judiciary Committee on 16 May 1979 also found that the Department of Energy frequently took up to 15 months to process these patent ownership requests from its contractors.
[5]Government Patent Policy: Institutional Patent Agreements, Hearings before the Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business, US Senate, 95th Congress, 2nd Session, Part I, May 22–23, June 20, 21, 26 1978, pp 147–150; and Federal Council for Science and Technology Report on Government Patent Policy, Combined Dec. 31, 1973 through Dec. 31, 1976, p 424.
[6]See: http://web.mit.edu/newsoffice/2009/kauffman-study-0217.html?tr=y&auid=4551551.
[7]Federal Council for Science and Technology Report on Government Patent Policy, Combined Dec. 31, 1973 through Dec. 31, 1976.
[8]*AUTM Licensing Survey, FY 1999* (Pressman, 2000) – see pp 1,3,7,8 and 22. Economic numbers derived from approaches by Stevens, 1994, and Pressman, 1995.

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