The Bayh-Dole Act and Revisionism Redux

~~Why the Revisionist Attacks on the Bayh-Dole Act Are Wrong—and Dangerous to Our Future~~

Summary

It is~~'s~~ no secret that the U.S. economy faces serious challenges. However, the U.S. has tremendous advantages for succeeding in the technology markets creating wealth in the 21st Century, if we choose to utilize them.

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

While that~~is~~ linkage is generally believed to have been very successful, a persistent school of critics has~~ve~~ charged that that~~is~~ is not the case. These advocates have become more ~~v~~vocal in recent years, urging policy makers to make changes in the Bayh-Dole Act to correct~~ing~~ 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. ~~unproven;~~
- Key data ~~and influence~~ Congress used to pass the Bayh-Dole Act-- the small number of 28,000 government owned patents that were licensed-- was 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.

~~And many~~It is unfortunate that some policy makers appear to be accepting their arguments at face value. However, it is important to note that these critics lack the perspective of the pre- Bayh-Dole era, and the~~its associated difficulties~~ difficulties encountered in ~~associated with turning~~ turning government funded research into tangible commercial and social benefits for the taxpaying public. Reversing that~~is~~ trend, the Bayh-Dole Act ~~enabled billions of private sector~~encouraged the private sector to invest billions of dollars to develop inventions made in whole or in part with government-supplied (i.e. taxpayer'ss) dollars to market-ready ((condition)) products. ~~,~~ ((thereby creating t)~~thereby creating) t~~

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T ~~This~~ partnership between research universities and the private sector created millions ~~of dollars to be invested in developing federallydeveloping federally funded inventions, creating millions of~~ jobs for Americans, ~~—~~significant wealth for the U.S., and a higher standard of living, ~~while helping to reestablish the U.S. as a competitive~~the (innovative) technology innovation leader in a growing and increasingly competitive global economy.

Because the critic's recommended changes to Bayh-Dole would have a profound -- and potentially very harmful-- impacts on the ability of the U.S. to respond to renewed international economic competition in the 21st Century, any ~~(such~~ changes~~) such revisions~~ must be very carefully considered.

Therefore, it is our purpose to examine the levied charges against Bayh-Dole ~~with against~~ 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 ~~shown to be~~ unfounded, ~~based on~~finding a basis in anecdotal evidencees or incorrect interpretations of data, where ~~the~~ logical conclusions should have pointed in another (the opposite) direction~~n~~.

Reams of objective data exist supporting~~s~~ the conclusion that the Bayh-Dole Act greatly improved the commercialization of federally-funded research, that the system is working very well, and that the public sector-private sector partnerships which were generated under the Act are essential both to the~~our~~ well being and the competitive position of the U.S.

That these conclusions are correct is ~~amply apparent~~strongly reinforced by ~~from~~ the fact that our most serious economic rivals have or are now adopting their own versions of Bayh-Dole to enable them to better compete with the United States~~.S. in the global market economy.~~ Such imitation is the most sincere form of economic flattery. It would be ironic, indeed, if U.S. policy makers chose this critical moment to weaken the well-established U.S. innovation system~~. That system,~~ which is the envy of the world~~,~~. ~~is~~That viable and functioning system is needed more than ever at this critical time to maintain a prosperous U.S. economy in an increasingly high technology world. The choice is ours to make.

BACKGROUND

The U.S., Europe and Asia are gearing up for a new round of competition to create wealth from high technology industries driving the international economy. In many ways, this is a replay of the 1970's and 80's when it appeared that Japan and Germany were riding the wave of the future—and many predicted that America's best days were behind it.

At that time, the U.S. had lost its lead in traditional fields like automotives, electronics, steel, etc. Many experts confidently predicted that Japan and Germany would soon eclipse the U.S. in the few remaining markets where it~~we~~ led.

However, these predictions did not come true. Instead, the U.S. enjoyed a tremendous burst of entrepreneurial activity that restored its~~our~~ competitive advantage and laid~~,~~ ~~laying~~ the groundwork for decades of economic growth. This turnaround came through ~~adopting~~the adoption of ~~-~~many ~~-~~new policies that were hotly debated at the time. One of those was the passage of the Bayh-Dole Act of 1980. Here's how the Economist Technology Quarterly[2] summarized its impact:

> *Remember the technological malaise that befell America in the late 1970's? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning 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 U.S. economy. America's trading partners have been quick to follow suit. Odd then, -that the Bayh-Dole (A) ~~a~~act (sic) should now be under such attack in America.*

~~The Economist Technology Quarterly, Dec. 14, 2002~~

Before examining the specific charges being used to attack the law, it is helpful to examine why Congress enacted the Bayh-Dole Act, and what it does.

Prior to 1980, inventions ~~made with~~which resulted from research supported by federal funding were rarely developed into commercial products. ~~.~~ Because most government funded inventions derive~~resulted~~ from the conduct of basic research, they are at a very early stage in their development. ~~Therefore~~Consequently, it requires ~~considerable~~substantial time and investment by the private sector to turn them into commercially useful products and processes. ~~These investments of time and money are not insubstantial.~~ It is frequently estimated that product development requires at least ten~~10~~ 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 ~~over~~and consume more than a decade of time. Even with such ~~expenditures~~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 ~~at the time~~ 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 licenses. Thus, a company foolish enough to develop a federally-funded invention could not protect its investment in commercialization ~~expenses~~ 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 ~~practices~~government policies rarely turned the results of ~~publicly government funded~~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 ~~g~~ agencies to acquire ownership of government-funded inventions they had made on a ~~case by case~~case-by-case basis. Decisions on such petitions by the various agencies could take 18 months or more~~, and subsequent decisions~~ and were ~~were~~ ~~ge~~generally negative. In the few situations ~~W~~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 business firms~~es~~ from accepting federal research contracts because the inability to control 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, envisioned 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 -the federal government was funding the majority of basic research – precisely where breakthrough inventions were most likely to occur- and approximately 50% of all the research and~~R&D~~ development in the country at the time.

~~That this general policy was not effective in promoting technology transfer was recognized in by the National Institutes of Health (NIH)~~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 1970's NIH adopted an administrative policy allowing universities with the proven capability to manage inventions, to own inventions ~~they~~ made with NIH support. Termed the "Institutional Patent Agreement" (IPA), this was the precursor to a revolution in federal patent policies. That program proved so successful that it~~s~~ was later adopted by the National Science Foundation.

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

After examining the dismal record at 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 ~~would~~ become known as the Bayh-Dole Act.

One important piece of data examined by the Senate Judiciary Committee as it considered the bill was that the government was ~~successfully~~ 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~~Thus, government policies destroyed~~ing~~ the very incentives for development which the patent system was intended to foster. ~~.~~ Senators Bayh and Dole stated that such inefficiencies denied U.S. taxpayers the full benefits of their investment in publicly funded research.

Congress agreed with the Senators' conclusion and in 1980 overwhelmingly passed ~~the University and Small Business Patent Procedures Act commonly known at~~ the Bayh-

Dole Act. The Bayh-Dole 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 ~~by~~to reside those entities;
- Providing universities 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 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 be given to licensing small businesses and ~~a requirement for~~requiring substantial U.S. manufacturing where an exclusive license is granted for the United States;
- Allowing the government to practice the invention royalty free for governmental and treaty purposes; and
- Allowing the government to "march in" to require additional licensing if legitimate efforts were~~are~~ not being made by a licensee to develop the invention, or in situations where 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, which destroyed many of the myths that afflicted the U.S. patent system, and, thereby restored~~ing~~ faith in that system and in the reliability of U.S. patents. Congress also enacted the Small Business Innovation Research Act (SBIR)[3] to bring more technologically cutting edge companies into government research. SBIR built upon the assurances of the Bayh-Dole Act that small companies would own~~ed~~ inventions they made with~~under~~ federal funding.

-The Bayh-Dole A~~a~~ct brought into play important factors and resources- -which other nations simply could not match:

1. ~~1.~~ The U.S. government funds far more R&D than ~~our competitors,~~other national governments, much of (it) ~~(~~which lies~~)~~ 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 remain world leaders ~~in their fields~~in their respective technological fields.
3. The Bayh-Dole Act permitted translation of~~ed~~ this investment in science into practical applications which met important health, safety, environmental, food production, and other -critical ~~important~~ needs.

4. The U.S. 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. A key asset of these small companies(,) in attracting venture funding and competing in technology markets against larger companies -are the patents they own or license.~~d which~~ ~~These protect their~~Those patents not only offer protection for (any) their commercial position, (generated) but offer the opportunity to recoup and reward ~~position and~~ the business risks that~~they~~ have been assumed.
6. Thus, the U.S. patent system ~~greatly helped create~~ was a significant factor in spurring the ~~this~~ revival of American competitiveness.~~.~~

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Even though the impact of the Bayh-Dole Act seemed evident as the U.S. enjoyed a reversal of fortune as described earlier in the Economist Technology Quarterly, a small group of academics ~~grounded in the social sciences~~ began questioning it. Their arguments can be summarized as follows:

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

In the next section the authors review each of those charges in greater detail and in the light of the admonition of Ralph Waldo Emerson: "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 next section reviews each charge in greater detail.~~

The Bayh-Dole Act and Revisionist Attacks

The Bayh Dole Act of 1980 is now almost 30 years old. There are not many pieces of legislation that 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 ~~(delete: David C. Mowerey et al entitled "The Growth of Patent and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980." Res. Pal 30, 99-119 (2001) al [4]& [5])~~ Bhaven N. Sampat[4], and later papers ~~by~~ critics such as ~~Arti Rai and Robert Cook-Deegan (eg. So et al "Is Bayh-Dole Good for Developing Countries? Lessons from the Experience," PLOS Biology, October 2008 Vol. 6 Issue 10)~~ Arti Rai and Robert Cook-Deegan[5], and the writings of Rebecca Eisenberg[6].[7]

Sampat states:

> 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 (see OECD 2002) 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.
>
> ~~Private Parts: Patents and Academic Research in the Twentieth Century by Bhaven N. Sampat, p.32)~~

Thus, t~~T~~he fundamental ~~(delete: Mowerey et al)~~ premise is that the Bayh-Dole Act was not as influential in promoting the transfer of technology as ~~has~~ has been ~~credited~~credited to it, and ~~it ,I~~could be a serious mistake for other countries to emulate~~copy it; (delete: that the university technology transfer. (effort would have occurred anyway). Both~~Both papers ~~also cite~~That premise finds basis in) The first part of the argument is based on (the) assertions by Rebecca Eisenberg 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 these inventions ~~was~~ represented by those patents was a key piece of evidence presented at the hearings on the bill. Supporters said that it showed that the old patent policies (whereby government took inventions away from their creators ~~the government "title policy"~~) were~~as~~ ineffective and detrimental to~~in~~ achieving subsequent commercialization.

~~Professor~~ David Mowrey et al further postulate that ~~that~~: "The theory behind Bayh-Dole was that companies needed exclusive patent rights to develop and commercialize the results of university research." [7] ~~(We need to cite the paper this came from in the endnotes)~~

Actually, the driving force and theory behind Bayh-Dole was that the public was not reaping the full potential benefit from the taxpayer's support of basic research, with expenditures for such support amounting to billions of dollars each year. Passage of the Bayh-Dole Act represented the ultimate step in a long term effort toward reshaping government patent policy, and was Congress' response to the paramount question:

> "In whose hands - the federal government or the inventing organization s - is the ownership and management of federally- funded inventions best placed ~~so important discoveries~~to promote the ~~are~~ promptly development of~~ed to~~ important discoveries for the benefit of the U.S. taxpayer?"

It is not denied that about the same time the Bayh-Dole Act was passed, there was a confluence of forces which had an effect upon universities' technology transfer efforts. However, ~~we find~~ we find the proposition advanced as outlined by the critics ~~(Delete: in Mowrey et al)~~ to be a flawed conclusion. The Congressional intent for enacting the law is made abundantly clear in the provisions Senators Bayh and Dole wrote in the legislation as the Policy and Objectives of the Act in 1980 (325 U.SC. 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 because of 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 U.S. patent system-- provides needed incentives for -the private sector to undertake the considerable risk and expense necessary to take early stage university discoveries from the laboratory to the marketplace. Strong patent protection is also vital to small businesses, whichwho have obtained the vast majority of licenses 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.

Delete: Mowrey et al (supra) focus on the increased patenting and licensing efforts by the university sector in the 1970's, prior to the Bayh-Dole Act, as proof of their premise that the Act was not a determinative factor in the increase in university technology transfer, as they allegingе that such activity it was already occuringoccurring.

Rather than minimizing why Bayh-Dole was necessary, Experience in the period before its enactment of the Bayh-Dole Act clearly established that ownership and management by universities of their inventions was clearly a superior policy than what had preceded it. For example, Tthere 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:d:[8]

"... we reported that HEW 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."

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 Serial No. 96-11, p. 37.

~~Indeed, NIH found that not a single drug had ever been developed when the government had retained patent ownership—clearly not a record that was benefiting the U.S. public.~~ Therefore, a revolutionary approach was announced. NIH established and adopted an administrative policy titled the Institutional Patent Agreement (IPA).

The IPA program allowed universities with established technology transfer offices to own and manage inventions made with NIH funding. The program began at NIH in 1968 and was so successful that the National Science Foundation adopted it in 1973.

Here's how the Senate Judiciary Committee summarized the impact of the IPA program:

"Since instituting the I.P.A. 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 I.P.A. 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. [9]

~~University and Small Business Patent Procedures Act, Report of the Committee on the Judiciary, United States Senate on S. 414, Report No. 96-480, December 12, 1979, p. 21.~~

The program continued in achieving~~ts~~ success, but during the Carter Administration efforts were made to end it because of the personal philosophy of ~~ical reasons by~~ of the new Secretary of Health, Education and Welfare (the agency is now Health and Human Services). That philosophy, much like those 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 ~~by NIH-funded universities~~ should be retained by NIH, or the ownership transferred to the ~~inventing~~ universities for management. The Comptroller General testified that such ~~reviews~~determinations were taking "from 8 to 15 months to complete." [10]

~~Op. cit., p. 37~~

It was this movement to end the most successful patent policy in any federal agency which 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 arbitrarily make changes in patent policies at the agency level, and the adherence to a non-exclusive licensing mandate established a lack of predictability unnerving and unacceptable to potential industrial partners. ~~They~~Companies simply would not expend the sizeable amounts of private sector time and money needed to

turn ~~(delete "a")~~ patented university based early stage technologies into ~~a~~ marketable products if the government could change the rules at a whim~~.~~.

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Shortly after introducing their bill~~,~~ Senators Bayh and Dole held a press conference using examples of potentially important medical discoveries that were being strangled in red tape because of NIH's weakening of the IPA program. Senator Dole compiled a list of:

"29 important medical discoveries that had been delayed from 9 months to well over a year before HEW wereas able to reach a determination ~~e~~whether or not the agency would retain patent rights. Follow-up review has shown no improvement in HEW's performance." [11]. ~~(delete ")"]The GAO patent policy study presented to the [Senate Judiciary] Committee on May 16, 1979,~~ [11] ~~also found that the Department of Energy frequently takes up to 15 months to process these patent ownership requests from its contractors). "."~~

~~(move endnote to the end of the quote)~~

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~~(new paragraph) University and Small Business Patent Procedures Act, Report of the Committee on the Judiciary, United States Senate on S. 414, Dec. 12, 1979, Report No. 96-480, p. 21~~

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

While t~~T~~he current critics acknowledge ~~(delete: previous language here either misunderstand, misinterpret or ignore)~~ the connection between the IPA programs and the Bayh-Dole Act, the dramatic impact ~~they~~that they collectively(,) ~~had~~ on the commercialization of university inventions tends to be downplayed. For example, Sampat et al [12] state:

"Bayh-Dole was passed in the throes of the 'competitiveness crisis' of the 1970's and 1980's 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 allowed them to license rights to patented inventions exclusively, firms would lack the incentive to develop and commercialize university inventions."

And then in 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....." [note: the Eisenberg evidence will be addressed later in this paper.]

(Although in the above referenced paper those) The cited authors do recognize the existence of the IPA program (and that) (and some of those same authors in an earlier paper [13] more extensively acknowledge their awareness of that program). However,, they tend to minimize the connection between the advent ~~(Delete: seem to make no connection between the advent)~~ of the IPAs, and increasing university sector patenting and licensing ~~(delete: in the time period)~~ when most of the predominant research universities were operating under such agreements.

Interestingly, in looking at the actual data, (~~The current critics either misunderstand or misinterpret the connection between the IPA program and the Bayh-Dole Act. It would seem that misunderstanding and/or misinterpretation finds it basis in the recitation. For example, in "Changes in University Patent Quality After the Bayh-Dole Act: A Re-Examination by Bhaven N. Sampat, David C. Mowrey and Arvids A. Ziedonis state that:~~

> ~~*The Bayh-Dole Act was passed in the throes of the "competitiveness crisis" of the 1970s and 1980s, in response to the belief that IPAs and other arrangements for university patenting of publicly funded research results impeded technology transfer and commercialization of these results, thereby weakenngweakening U.S. competitiveness.* (emphasis added) *(emphasis added) (p.3)*~~

~~Although the authors recognize the existence of the IPA program, pointing out that by 1978, 72 institutions were participating in that program, they make no connection between the advent of the IPAs and increasing university sector patenting and licensing in the time period when most of the predominant research universities were operating under such agreements.~~

T) the increase in the filing of patent applications on ~~federally sponsored~~the results of extramural research ~~a~~sponsored by HEW and NSF directly correlates with the increased participation in their IPA programs. [14, 15]

Here are the numbers for HEW (~~(~~then the parent agency for NIH):

	1968	1969	1970	1971	1972	1973	1974	1975	1976
[16]IPA participants	17	24	34	39	41	50	57	61	66

~~(1)~~

[17]Patent applications ~~(2)~~	———	35	51	50	44	76	79	118

by ~~-~~HEW contractors

Thus, patent applications increased over 300% between 1970 and 1976 at HEW as the IPA program expanded.

The numbers are even more striking ~~after~~for the National Science Foundation after it implemented the IPA program in 19734.

	1970	1971	1972	1973	1974	1975	1976	
[18]IPA participants	N/A	N/A	N/A	N/A	11	11	13	~~(3)~~
[19]Patent applications by contractors	6	2	4	8	17	40	67	~~(4)~~

NSF had an 800% increase in patent applications ~~-~~between 1973--1976 as ~~the~~its IPA program ~~went~~ kicked in.

This~~is~~ data ~~implies~~substantiates a strong correlation between the incentives of patent ownership and management under the IPA program with the subsequent rise in ~~university~~ patent applications on university inventions ~~(generated)~~s made with federal support. ~~As~~Since the IPA program was essentially later codified by~~under~~ 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.

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~~*Source: Government Patent Policy: Institutional Patent Agreements, Hearings before the Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business, U.S. Senate, 95th Congress, 2nd Session, Part I, May 22, 23, June 20, 21, 26 1978, pp. 147-50.*~~

Yet the critics seem reluctant to clearly acknowledge this connection. Here's how they describe this phenomena: [20]

> "... Figure 9 shows that institutions with IPAs dominated the growth of university patenting during the 1970's.
>
> 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 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 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 U.S. university patenting after 1980." ~~(Mowery *et al.*, 2001).~~

~~(Show Figures 9 and 10 here)~~

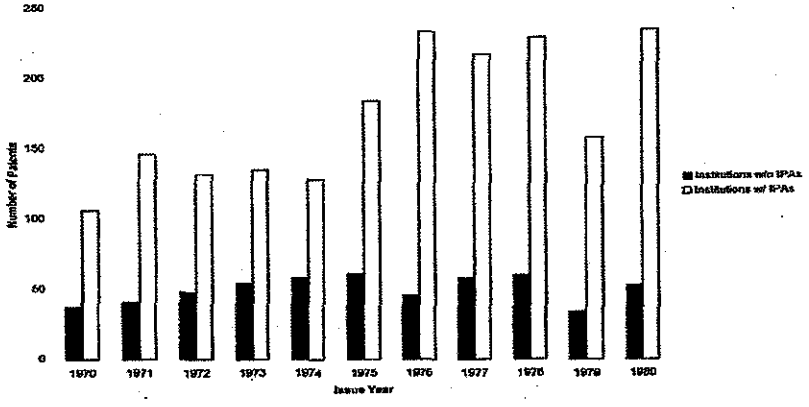

FIGURE 9. Patenting by Carnegie research universities, by IPA status.

What is striking about this conclusion is that their Figure 9 clearly illustrates the impact of IPAs on university patenting. The chart shows that while the IPA program 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.

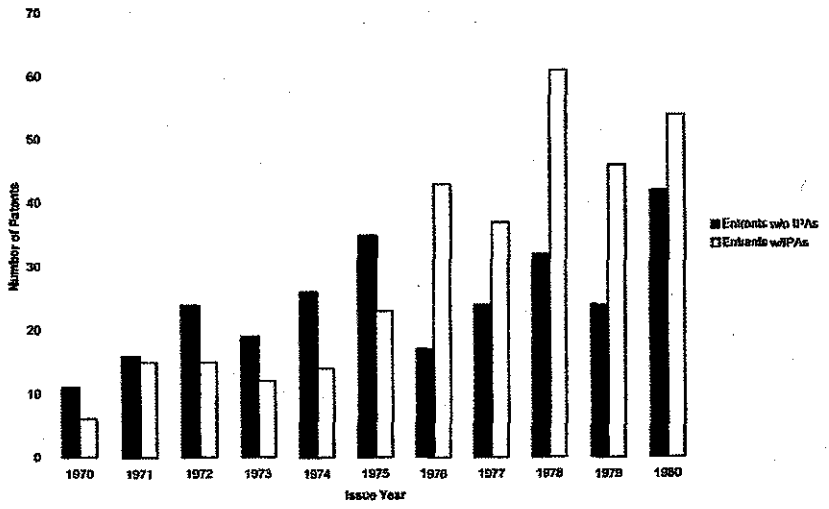

FIGURE 10. Patenting by Carnegie research universities, by IPA status—entrants only.

Even their Figure 10 underscores the importance of the IPA program on university patenting. IPA participants double the number of reported patents between 1973 and 1975. The increase of reported inventions by IPA participants increases almost 400% between 1974 and 1976 according to the Figure. Even more striking, as the IPA program starts to grow at the National Science Foundation, and participants increase at NIH as shown in our own chart above, IPA schools permanently pass those not in the program in 1976-- and never look back.

~~(Howard: I suggest deleting this paragraph :~~

~~*Federal Council for Science and Technology Report on Government Patent Policy, Combined Dec. 31, 1973 through Dec. 31, 1976, p. 424*~~

- ~~*Op. cit, p. 258-260*~~
- ~~*Op. cit., p. 424*~~

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~~In fact, both the University of California and Stanford University, which occupy much of the "empirical" evidence in Mowerey et al (supra), operated under IPAs prior to the passage of the Bayh-Dole Act.~~

The impact of Bayh-Dole on individual universities like MIT ~~that~~which had already been active in technology transfer, is also illustrative. It could be argued that Bayh-Dole did not really impact 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 utilizing inventions for the benefit of society could often be best accomplished through commercialization – which required the ~~help~~cooperation and risk taking of the private sector.

For example, a novel ~~idea~~and patented chemical entity projected for use as ~~for~~ a new pharmaceutical product did not benefit patients unless it was available commercially. Likewise, a newly discovered material or alloy would not make ~~planes~~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 ~~licenses which it issued~~licenses that it issued increased nearly 1000%. During the next twenty years, the MIT Technology Licensing Office ~~formed~~helped in the formation of nearly 800 new companies. A recent study of MIT spin-off companies shows that ~~these companies alone would be the 17th largest economy of the world~~ 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 ~~See http://web.mit.edu/newsoffice/2009/kauffman-study-0217.html?tr=y&auid=4551551.~~[210]

While MIT clearly was spinning out companies before the passage of Bayh-Dole ~~passed~~, the rate of new company formation based upon MIT inventions and discoveries increased~~went up~~ almost exponentially after its enactment.

Another ~~point which~~point that the critics ~~raise~~advance as a basis for the increase of university patenting, making it appear to undercut the influence of Bayh-Dole, was the large subsequent infusion of federal money, primarily through NIH, in the support of life science research. However, the IPA program 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 ~~these fund~~such monies. This would not have happened if NIH had retained its policy to take title to inventions made in whole or in part with NIH funds.

Clearly, it was the incentive of patent ownership and, ~~therefore,~~the certainty of title accompanying ownership upon which the private sector could rely in a licensing arrangement that spurred the increase of university patenting under the IPA program. ~~This increased~~ 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 in support of research activities could then engage in technology transfer activities.

Thus, there is 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 ~~(that matured into the Bayh-Dole Act)~~ in 1978, they used several inventions whose development was threatened by the Carter Administration's undermining of the IPA program as examples ~~of for~~ the need for legislation. ~~(of a legislative mandate, several inventions the development and commercialization of which were threatened by the Carter Administration's undermining of the IPA program).~~

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~~The Mowery et al paper, "Changes in University Patent Quality a~~After ~~the Bayh-Dole Act" contains another misunderstanding about the history of the Bayh-Dole Act. That assertion is highlighted below in the context it appears:~~

> ~~*The Bayh-Dole Act was passed in the throes of the "competitiveness crisis" of the 1970's and 1980's in response to the belief that IPA's and other arrangements for university patenting of publicly funded research results impeded technology transfer and commercialization of these results, thereby weakening U.S.* competitiveness. *In particular, the framers of Bayh-Dole argued that if universities could not be granted clear title to patents and allowed to license them exclusively, firms would lack that incentive to develop and commercialize university inventions.* **This argument was based on the "evidence" that government owned patents had lower utilization rates than those held by contractors, evidence that Eisenberg (1996) has shown to be faulty.** (emphasis added)~~
>
> ~~*Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. Patenting and Licensing, by Bhaven N. Sampat, David C. Mowery and Arvids A. Ziedonis, pg*~~ ~~*p. 3*~~

~~A~~There is additional ~~ample and adequate empirical data~~evidence ~~to~~ supports the proposition that the Bayh-Dole Act, drawing on the preceding IPA program, 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 of membership in the Association of University Technology Managers (AUTM) as well as the number of technology transfer offices established within the university community – from about 30 in 1972 to approximately 300 in 2007-08 – bear that out.

Moreover, data presented in the annual AUTM Licensing Survey which show~~ing~~ increasing year-to-year activities in invention disclosures, patenting and licensing ~~which~~ are also evidence of the positive effects of the Bayh-Dole Act. The ultimate measure of the wisdom in passage of the Bayh-Dole Act and its success in transferring technology for the public benefit – the Act's primary objective – can be found in a compilation by AUTM entitled "The Better World Report." Thosee reports~~"~~ list~~s~~ ~~(ing, with appropriate)~~ and describes ~~(iptions,)~~ some of the ~~(many)~~ university technology-based inventions that have been developed for the market place ~~(and which have contributed to the lives,)~~ contributing to the health, safety and welfare of the public– a virtual panoply of inventions in many and diverse scientific disciplines.

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Additionally, consider the following evidence of the impact of the law~~Consider the following~~:[21]

- University technologies helped create 5,724 new companies in the U.S. since the enactment of the Bayh-Dole Act in 1980. In FY 2006 alone, 553 new companies were spun off based upon campus discoveries and inventions. Astoundingly, that is more than two new companies formed each working day of the year. Formation of new, technology based companies drive state economic development.
- University research created 4,350 new products from FY1998–2006, with 697 introduced in FY 2006 alone. This means that 1.32 new products were introduced every day for that period. Such success is unique to the U.S.
- Federally funded research at universities and federal laboratories resulted in 130 new drugs, vaccines, or in vivo diagnostic devices being developed for public use. Many of these discoveries were treatments for infectious diseases and new cancer therapies. The majority of licenses initially went to small companies licensed under the provisions of the Bayh-Dole Act.[23] ~~(Source: The Contribution of Public Sector Research to the Discovery of New Drugs, Jonathan J. Jensen, Kathrine Wyller, Eric R. London, Sabami K. Chatterjee, Fiona E. Murray, Mark L. Rohrbaugh, and Ashley J. Stevens, poster presented at 2008 AUTM annual meeting, with updated information.~~
- There were almost 5,000 existing active university licenses in FY 2006-- each representing a university-industry partnership. The majority of such licenses were with small businesses and start-up companies. Although the bulk (of) of licensing arrangements were non-exclusive (in nature), the majority of exclusive licenses issued were to small businesses and start-up companies, which require strong patent protection to succeed in highly competitive markets (with) against larger, (well-)established and well-financed competitors.

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Important health related and life-saving discoveries commercialized under Bayh-Dole include:

Synthetic penicillin — Massachusetts Institute for Technology
~~Human growth hormones~~
~~Treatments for Crohn's disease — Avian Flu vaccine~~
—Cisplatin and carboplatin cancer therapeutics - Michigan State University~~Taxol~~
Hepatitis B vaccine – Univ. of California, Univ. of Washington
~~Citracal calcium supplement~~
Vitamin D m~~M~~etabolites and derivatives – University of Wisconsin-Madison
Human growth hormones – City of Hope Med Center
Taxol – Florida State University
Citracal® calcium supplement – Univ. of Texas SW Med 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 Mowery et al paper, "Changes in University Patent Quality after the Bayh-Dole Act" contains another misunderstanding about the history of the Bayh-Dole Act. That assertion is highlighted below in the context it appears:~~

~~*The Bayh-Dole Act was passed in the throes of the "competitiveness crisis" of the 1970's and 1980's in response to the belief that IPA's and other arrangements for university patenting of publicly funded research results impeded technology transfer and commercialization of these results, thereby weakening U.S.* competitiveness. *In particular, the framers of Bayh-Dole argued that if universities could not be granted clear title to patents and allowed to license them exclusively, firms would lack that incentive to develop and commercialize university inventions.* **This argument was based on the "evidence" that government owned patents had lower utilization rates than those held by contractors, evidence that Eisenberg (1996) has shown to be faulty.**~~

> ~~*Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. Patenting and Licensing, by Bhaven N. Sampat, David C. Mowery and Arvids A. Ziedonis, pg. 3*~~

~~The Mowery et al premise that~~

~~t~~The "evidence"[24] -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.[25] ~~titled "Public Research and Private Developments: Patents and Technology Transfer in Government-Sponsored Research", Vol. 82:1663 Virginia Law Review.~~

This same argument is repeated by critics such as Arti Rai and Robert Cook-Deegan in their article *"Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience."*[24][26] That paper, intended to warn other countries of the "dangers" in adopting a Bayh-Dole type law, includes the following:

> 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. (PloS Biology, October 2008, Volume 6, Issue 10, e262, page 2078.

As will be shown, this assertion is wrong on both counts.

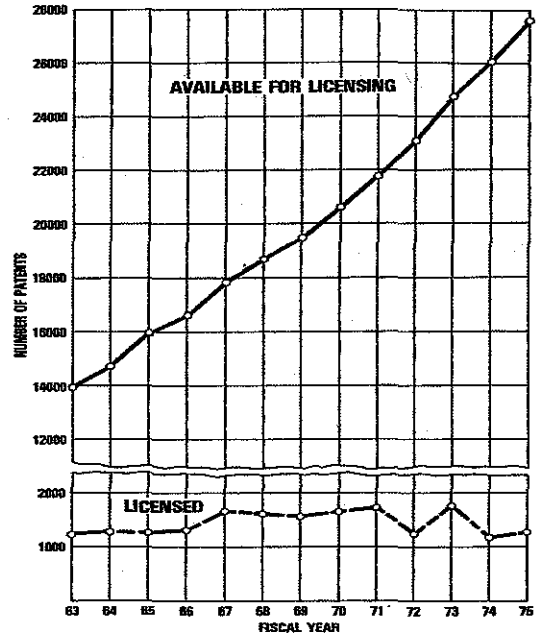
In her referenced paper, Ms. Eisenberg maintains that "the primary argument against government ownership was a statistical one -"", based on the "testimony of numerous witnesses" that "only a small percentage of its estimated 28,000 - 30,000 patents had been successfully licensed and exploited commercially". 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, Ms. Eisenberg 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."

Ms. 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, review of the actual data indicates that, in fact, Ms. Eisenberg's conclusion is simply wrong.

The (following is) 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.[1][2]



(Source: Report- Government Patent Policy, Combined Dec. 31, 1973, Dec. 31, 1974, Dec. 31, 1975, Dec. 31, 1976, Federal Council for Science and Technology)

In her paper, Ms. Eisenberg fails to note that the 1976 report clearly establishes that the 17,632 DOD patents includes:

(1) 7,0466,026 U.S. patents granted during the 1970-1976 reporting period to DOD employees obligated to assign their rights to DOD; and

(INSERT SPACE HERE)

(2) 2,594 U.S. patents based on reported inventions during the 1970-76 reporting period from contractors.

(3) (2) In addition, some portion of these 2,594 contractor generated inventions were taken from universities and other non-profits that,

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[1] See footnote 57 of 1 above.

[2] Norman J. Latker - served as DHEW representative when Patent Counsel, DHEW.

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 above -totals 9,6408,620 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 7,9929,012 patents -(17,632 - 9,6408,620) are unexpired patents granted and assigned to DOD prior to 1970 that remained open -for licensing within the 1970-76 reporting period. Since there is no data in the '76 report indicating the source of the 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, they were about 70% government employee generated, and about 30% contractor generated (including universities and non-profit organizations).

Accordingly, of the 7,9929,012 patents granted before 1970, 5,5946,310 would be government employee generated patents, and 2,702 would be contractor generated patents. Thus, the total DOD employee generated patents would beis 12,336 (6026+6310)12,640 (7046 +5594) and the total DOD contractor generated patents would beis 49925,296 (2594+2398702).

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

The remaining 4,9925,296 patents generated by actual DOD contractors most certainly do not support Ms. Eisenberg's 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 189% (5,2964,992/28,021) rather than the 63% (17,632/28,021) erroneously alleged by Ms. Eisenberg.

There is also no empirical or documentary evidence advanced that even the 18 (9)% of the government patent portfolio as identified as above are based on inventions "rejected by contractors" as not "at all commercially interesting", as alleged by Ms. Eisenberg.

~~Moreover,~~ ~~This is because title to~~ an unidentified number of these 5,296 patents ~~that~~ were generated by university and other non-profit contractors ~~and were was~~ simply taken by DOD under its existing patent policies, whether they had commercial potential or not.

It's not even possible to support Ms. Eisenberg's 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, some percentage 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, Ms. Eisenberg's assertion is not even proven in 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 actual data speaks for itself and strongly belies that theory.

The revisionists are also turning their sights abroad. An article by several critics "Is Bayh Dole Good for Developing Countries? Lessons from the U.S. experience" ~~(cited above)~~ [58] warns of the dangers of following the U.S. model in a series of recitations of virtually every objection the critics have ~~come up with over~~advanced the past 30 years. Building their case, the critics 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. ~~(pg. 2078)~~

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

More fundamentally, how developing countries in a competitive global econom~~m~~y can hope to prosper by putting their university research freely into the public domain (as the authors advise) is not addressed. ~~As~~The experience in the U.S., as previously discussed, ~~(shown above),~~ certainly ~~this was certainly not the case in the U.S.~~ 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. Thus, public sector research lies fallow, despite the claims of the critics. ~~. If their theory actually worked in the hard, cold light of day, surely the late, unlamented Soviet Union would have led the world in innovation.~~ Rather than following the same course that failed in the U.S. before Bayh-Dole, developing countries would be well advised to heed other advisors.

South American economist Hernando De Soto's groundbreaking book, *The Mystery of Capital*,[29] [8] forcefully demonstrates that the fundamental weakness of perennially under-developed 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 causing the American Revolution was an imperial ~~system which~~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 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 ~~ere~~ 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." ~~(do we need an endnote here? This came from Lincoln's second lecture on patents)~~

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Strangely, the modern critics think the way to innovation is by turning Lincoln's dictum on its head. They could not be more wrong.

As inventor Frederick Cottrell said while founding Research Corporation: *".....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 protections for their discoveries and inventions that in the 20th century ~~(in the U.S.)~~ a huge era of U.S. innovation resulted. It can be hardly disputed that because of that protection the benefits to humanity have been unprecedented. While the critics bemoan the ability of the patent system to grant such ownership of intellectual property, ~~with~~ the only alternatives ~~are being~~ open source technology or trade secrets, neither of which provides similar motivation and

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incentives for innovation. It is truly the protection that the patent system creates that makes the commercial development of ground breaking discoveries possible.

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

Critics have also raised concerns that ~~The referenced Mowery et al article~~ [28] ~~(are we talking about Mowery or the Rai/Cook-Deegan article "Is B-D good for developing countries? If we're talking Mowery, it would be good to insert an actual quote supporting our contention)~~(supra) ~~also alleges that~~ Bayh-Dole harms the advancement of science. Interestingly, unlike the~~ir anecdotes~~ anecdotes ~~(anecdotal basis)~~ which are ~~(is)~~ the presumed basis for that allegation, ~~actual~~ data shows that the law has substantially contributed to the U.S. economy, and that~~that~~ U.S. 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)[30][29], fully 29% of articles authored worldwide by scientists and engineers were from the U.S.

> "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 U.S. 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."

~~(University-Private Sector Research Partnerships in the Innovation Ecosystem, President's Council of Advisors on Science and Technology, November 2008, p. 22.)~~

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 passage, industry segregated its most creative researchers from university collaborations because the federal government could ~~(take away resulting)~~assert ownership rights in resulting inventions when federal support of university research was also present.

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The health of U.S. scientific publications is also reflected in the findings of the National Science Board's *Science and Engineering Indicators* reports.[31] Traditionally, about three ~~fourth's~~fourths of all U.S. scientific and engineering ~~scientific~~ publications come from academia. In its 2008 report, it found:

> Although the U.S. share of world article output and article citations has declined, the influence of U.S. research articles has increased, as indicated by the percentage of U.S. articles that are among the most highly cited world-wide. In 1995, authors from U.S. institutions had 73% more articles in the top 1% of cited articles in all S&E fields than would be expected based on U.S. total article output; in 2005, the percentage had grown to 83%.
> ~~(National Science Board Science and Engineering Indicators 2008, Volume I, p. 5-7, NSB 08-01)~~

That the share of U.S. ~~world - wide~~ scientific papers ~~output~~ has fallen is ~~not because U.S. scientists and engineers are publishing less, but~~ because of the huge explosion of international publications, particularly from Asia. However, while the percentage of U.S. publications has decreased, their scientific impact has increased.

Scientific papers by U.S. researchers are the most cited across every field of science.[32] ~~I(looks like this should be moved to the endnotes (p. 5-49).]~~ 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: [33]

> "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 U.S. articles." - "....only U.S. 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 U.S. 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." ~~. (another endnote: op cit: (p 5-49 to 5-50))~~

The U.S. ranked number 1 in every ~~(one of the)~~ broad science and engineering field ~~(s)~~ surveyed in the study for 2005. It also held this ranking in 1995. ~~(5-41)~~

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Another classic argument espoused by the critics is that Bayh Dole lures academic researchers away from basic research toward applied research in order to attract

industry sponsors. Of course, it is precisely because university researchers are doing fundamental research that industry either cannot do, or chooses not to do, that makes academic alliances so attractive. ~~Nevertheless, t~~The National Science Foundation looked at ~~the~~ that allegation and here is ~~in its 2006 Science and Engineering Indicators report.~~[32] ~~Here's~~ what it found:[34]

Has Academic R&D Shifted Toward More Applied Work?

Emphasis on exploiting the intellectual property that results from the conduct of academic research is growing... ~~....Among the criticisms raised about this development is that it can distort the nature of academic research by focusing it away from basic research and toward the pursuit of more utilitarian, problem-oriented questions.~~ 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.
~~Did such a shift toward applied research, design and development occur during the 1990's, a period when academic patenting and licensing activities grew considerably?....~~

Two indicators, however, bear on this issue. ~~can be examined to determine whether any large-scale changes occurred.~~ 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 1980's. ~~shows that basic research share increased slightly between 1990 and a996 and that there was hardly any change in this measure between 1998 and 2002.~~ 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.

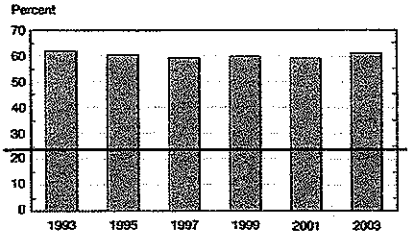
As figure 5-33 (reproduced below) ~~2933~~ shows, ~~for~~ those employed in academia who reported research as their primary activity, involvement in basic research declined slightly between 1993 and 2003, ~~3,~~ from 62 ~~%1.92 %~~ to ~~61%~~ probably not statistically significant. ~~59.1 61 a shift that barely reaches statistical significance. probably not statistically significant. A similar shift occurred for all academic doctoral researchers~~

~~(from 58.7% in 1993 to 56.5% in 2001).~~ The available data, although limited, provide little evidence to date of a shift toward more applied work. [353] ~~that pressures on academic institutions and faculty to change research agendas led to a shift toward more applied work.~~

~~National Science Board. 2006. National Science Board. 2006. *Science and Engineering Indicators 2006 6.*~~
~~Arlington, VA: National Science Foundation (volume I, NSB 06-01), p. 5-36The 2006 Science and Engineering Indicators report repeated the same finding illustrated by a bar chart.~~

Figure 5-33

S&E doctorate holders with primary activity research whose primary activity is basic research: Selected years, 1993–2003



NOTE: S&E doctorate holders involved in research include those whose 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.

Science and Engineering Indicators 2006

S&E doctorate holders with primary activity research whose primary activity is basic research: Selected years, 1993–2003

Percent

70
60
50
40
30
20
10
0
1993
1995
1997
1999
2001
2003

NOTE: S&E doctorate holders involved in research include those whose 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.

Science and Engineering Indicators 2006

~~The **2006 Science and Engineering Indicators** in a section entitled "Has Academic R&D Shifted Toward Applied Work?", said again evidence "does not show any decline in the basic research share since the last 1980's" and concludes: "the available data, although limited, provide little evidence to date of a shift toward more applied work."~~

Once again, by examining the data, the critic's charges ~~fall flat~~are unsubstantiated and incorrect.

To reinforce what the Bayh-Dole Act has contributed to the U.S. economy and the world wide -benefit of mankind one need only to look at ~~some of~~ the inventions listed below, in addition to those listed ~~(on)~~ previously. Of course, these, represent ~~(ing)~~ only a small sample of commercialized inventions derived ~~(which arose)~~ from basic research in academia ~~(and which have reached the marketplace~~ and which were ~~)~~ generated in diverse disciplines ~~at~~ by different university research ~~diverse~~ institutions.~~.~~ Among such inventions and discoveries ~~arising in academia that have reached the marketplace and have contributed to the health, safety, convenience and welfare of the public~~ are the following: ~~(INDENTED THE LIST BELOW)~~

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rDNA technology, central to the biotechnology industry – Stanford and Univ. of CA
TRUSOPT® (dorzolamide) ophthalmic drop for glaucoma – Univ. of FL
Hotbot internet search engine – Univ. of CA, Berkeley
Ultrasonic removal of dental plaque – Univ. of WA
Lycos® internet search engine – Carnegie Mellon Univ.
Mosaic web browser – Univ. of IL – Urbana-Champaign
Yahoo internet search engine – Stanford

~~*List inventions*~~

Conclusion

The Bayh-Dole Act has clearly 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 United States and its citizens were ~~as~~ recognized ~~-~~ by a resolution of the U. S. House of Representatives on December 6, 2006 as follows:

The Bayh-Dole Act (Public Law 96-517) has made substantial contributions ~~s~~ 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 which 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 taxpayer's ~~(s)~~) funds were needed to establish or manage the effort. (–)~~an (effort) exercise~~ that has been estimated to add about $41 billion ~~annually~~ to the U.S. economy. ~~(do we need a source here?)~~Yet, its contributions to the U.S. economy and to its citizens, as well as citizens of the world (other countries), has been exemplary. For example, (it was estimated that) in Fiscal Year 1999 U.S. economic impact models showed that (in that fiscal year) $40.9 billion could be attributed to academic licensing, and that 270,900 jobs were created. [36]

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Why was the Bayh-Dole Act a determinative factor in the evolution of university technology transfer~~r and technology transfer in general~~? There are a number of reasons that the critics conveniently overlook:

~~1.~~ It produced order out of chaos because it established a uniform government patent policy.

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~~1.~~ Prior to the Bayh-Dole Act, when federal monies were utilized 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, t~~T~~here was ~~ere~~ frequently more than one ~~-~~patent policy in an agency covering different programs. Because universities receive federal funds from a wide number 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 funding agency policies applicable had to be considered as did the bureaucratic climate and restrictions within a given agency. Consequently, ~~—~~with the exception of the IPA program~~–~~, it was seldom that a federally supported university invention found its way into the marketplace.

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~~2. 2.It~~ 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.

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~~2.~~

2.

~~3.~~ 3. ~~3.~~ It was the template for the subsequently passed Federal Technology Transfer ~~Act which~~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.

3.

~~4.~~ 4. ~~.~~

~~5.~~ 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 the contractor's use of the expertise of inventors in ~~(the)~~ technology transfer ~~(function)~~.

4.

~~6.~~ 5.

~~5.~~ It promoted collaboration among scientists having diverse funding from different federal sources to explore and embrace interdisciplinary -approaches to solving scientific challenges.

5.

~~7.~~6. ~~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 ~~(the university sector)~~ under the provisions of the Act. ~~(- an element, if not THE element,)~~ This was, and still is, ~~is~~ the critical element for ~~(to)~~ private sector development of inventions for the marketplace.

~~8.~~ 7. It promoted private sector as well as government investment in university research.

7.

~~9.~~ 8. It promoted innovation and the attendant creation of jobs through, in part, its mandate to give preference to U.S. industry and small business in technology transfer practices.

8.

9. ~~9.~~ It protected confidential information in the possession of the contractor and its licenses from undue and untimely disclosure - a prime consideration to the private sector in a globally competitive economy.

~~10.~~

~~11.~~ 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 taxpayer's ~~(federal (taxpayers))~~ money.

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~~12.~~11. ~~11.~~ It provides the university and non-profit sectors the possibility for generating income to support research and educational activities through the technology transfer function.

To now suggest that the Bayh-Dole Act was not a critical factor in the development of university technology transfer~~,r,~~ and that this evolution would have occurred anyway is simply not a supportable premise.

Prior to the passage of the Bayh-Dole Act, and the predecessor Institutional Patent Agreements, the environment in which technology transfer existed was, at best, inhospitable, and at worst, hostile. That environment slowly progressed, through creation of the IPA program, and ~~(and later through)~~ a succession of unpassed legislation to ~~(, ultimately,)~~ the enactment of the Bayh-Dole Act – into an environment that ~~(to one)~~ that to one THAT actually encouraged ~~(the)~~ technology transfer. ~~(function).~~

The result has been of tremendous benefit to the U.S. taxpayer in terms of the availability of important new products—particularly in biomedicine—and improved international competitiveness. Indeed, the U.S. is widely recognized as the most efficient nation on the world in the integration of its research universities into the national economy. The proof is in the number of competing nations seeking to adopt the Bayh-Dole model abroad. This movement is occurring despite the writings and efforts of many ~~domestic~~ critics.

Unfortunately~~,(, in recent years and with increasing regularity,)~~, the Bayh-Dole Act of 1980 has come under relentless scrutiny and attack through the efforts of revisionist historians and their rhetorical pronouncements, with little basis in empirical data. These activities would resurrect ~~(seem to be an apparent effort to resurrect)~~ the same policies ~~(government agency "policies")~~ that clearly failed ~~so clearly~~ prior to ~~(the advent of)~~ the enactment of the Institutional Patent Agreements and the Bayh-Dole Act. ~~(and, even, the)~~ Institutional Patent Agreements.

It seems strange ~~(an anomaly)~~ that a piece of legislation which arose out of clearly failed preceding policies ~~(conflict)~~ almost 30 years ago and which ~~(, from all indications,)~~ has proven its worth, ~~(and the prescience of its authors and supporter),~~ is now again being decried on many of the same baseies as were raised ~~(advanced in arguments)~~ against its initial passage.

Outspoken claims, ~~(which find)~~ with little basis in empirical evidence, under the guise of guardianship of the public interest ~~(or welfare)~~ provide a rich field for the cultivation of political power and special interests.

One must recognize that such initiatives are extremely dangerous in an ~~(evolved and)~~ evolving technologically-focused, ~~(and)~~ increasingly fragile, global economy. Intellectual

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property and its ownership have become the preferred currency for economic growth, where invention and innovation are the hallmarks of not only technological leadership but of survival.

The authors of this article fully ~~do~~ acknowledge that improvement can always be made in the technology transfer system. ~~(While)~~ It is always possible to find licensing decisions that could be open to criticism or universities that~~who~~ are more difficult to deal with than others. But, it is important to note the difference between poor implementation of Bayh-Dole as opposed to blaming Bayh-Dole for sub optimal practices.
~~While it is always possible to find licensing decisions that could be open to criticism or universities who are more difficult to deal with than others, it is important to note the difference between poor implementation of Bayh-Dole as opposed to blaming Bayh-Dole for suboptimal practices.~~

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 ~~new the lines~~improve the lives of citizens of the world wide-community. 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 referenced as the Bayh-Dole Act or simply, Bayh-Dole).

2. The Economist Technology Quarterly, Dec. 14, 2002.
3. Small Business Innovation Development Act of 1982, Pub. L. 97-219, July 22, 1982, 96 Stat. 217.
4. Private Parts: Pfatents and Academic Research in the Twentieth Centurye, Bhaven Nn. Sampat (page 32).
~~David C. Mowery et al *"The Growth of Patent and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980."* Res. Pal 30, 99-119 (2001).~~
~~*Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. Patenting and Licensing*, David C. Mowery and Arvids A. Ziedonis, in Innovation Policy and The Economy, National bureau of Economic Research, MIT Press (2001)~~
5. Arti Rai and Robert Cook-Deegan eg. So et al *"Is Bayh-Dole Good for Developing Countries? Lessons from the Experience"* PLOS Biology, October 2008 Vol. 6 Issue 10
6. Rebecca Eisenberg "Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research" Virginia Law Review. Vol. 82, No. 8 Symposium on Regulating Medical Innovation (1996) pp 163-172
7. David C. Mowery, et al "The Growth of Patent and Licensing by U.S. Universities: An assessment of the Effects of the Bayh-Dole Act of 1980" Res. Pol 30, 99-119 at 117.
8. 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.
9. University and Small Business Patent Procedures Act, Report of the Committee on the Judiciary, United States Senate on S. 414, Report No. 96-480, December 12, 1979, p. 21.
10. Note 9, supra, p. 37
11. The GAO patent policy study presented to the Senate Judiciary Committee on May 16, 1979 also found that the Department of Energy frequently takes up to 15 month to process these patent ownership requests from its contractors.
12. Note 9, supra, pg.21
13. *Changes in University Patent Quality for the Bayh-Dole Act: a Re-examination.* Bhaven N. Sampat, Arvids A. Ziendonis, International Journal of Industrial Organization 21 (2003) 1371-1390.
14. Note 7, supra (also see Note 9)
15. Government Patent Policy: Institutional Patent Agreements, Hearings before the Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business, U.S. Senate, 95th Congress, 2nd Session, Part I, May 22- 23, June 20, 21, 26 1978, pp. 147-50.
16. Federal Council for Science and Technology Report on Government Patent Policy, Combined Dec. 31, 1973 through Dec. 31, 1976, p. 424.
17. Note 14, supra, pg 258-260
18. Note 15, supra
19. Note 14, supra

20. University patents and Patent Policy Debates in the USA, 1925-1980, Industrial and Corporate Change. Vol. 10, Number 3, 2001.
21. See: http://web.mit.edu/newsoffice/2009/kauffman-study-0217.html?tr=y&auid=4551551]
22. Association of University Technology Managers (AUTM): U.S. Licensing Activity Survey, 2006
23. The Contribution of Public Sector Research to the Discovery of New Drugs. Jonathan J. Jensen, Kathrine Wyller, Eric R. London, Sabami K. Chatterjee, Fiona E. Murray, Mark L. Rohrbaugh and Ashley J. Stevens; poster presented at 2008 AUTM Annual Meeting with updated information.
24. Note 12, supra
25. Note 7, supra
26. Note 5, supra
27. Note 15, supra
28. Note 5, supra
29. The Mystery of Capital, Why Capitalism Triumphs in the West and Fails Everywhere Else. Published by Basic Books, 2006.
30. University-Private Sector Research Partnerships in the Innovation Ecosystem, President's Council of Advisors on Science and Technology, November 2008, p.22
31. Science and Engineering Indicators, National Science Board. 2008, Volume I, p.5-7, NSB 08-01
32. Id supra pg. 5-41
33. Id page 5-49 to 5-50
34. Science and Engineering Indicators, National Science Board. 2006 (two volumes)
35. Science and Engineering Indicators, National Science Board. 2006 Arlington, VA National Science Foundation (volume 1, NSB 06-01), p.5-36.
36. AUTM Licensing Survey, FY 1999 pp.1,3,7 and 8. Economic numbers derived from Ashley J. Steven's approach entitled "Measuring Economic Impact," AUTM Advanced Licensing Course, Phoenix, AZ Dec. 1994.