THE FIRST TWO DECADES OF THE BAYH-DOLE ACT AS PUBLIC POLICY

by Howard W. Bremer,
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At the outset it is interesting to note that the length of time the Bayh-Dole Act has been in effect is now the approximate time that it took to achieve its passage.

This presentation is given in the context of a plaque affixed near the entrance to the National Archives in Washington, D.C. The plaque reads:

"the heritage of the past is the seed that brings forth the harvest of all the future"

Today, we are witnessing 20 years of living with the Bayh-Dole Act and, I believe, can truly celebrate the technology transfer harvest that sprang from the seeds of efforts to revise government patent policies.

Whereas, technology transfer, as we know it today was little understood or practiced 20 years ago, it is now a recognized profession both within and outside of the university community. Of all the controversial subjects which have been addressed by members of Congress and discussed by newspaper editors and columnists over the years none appears to be less understood than the allocation and disposition of rights to inventions arising from government-funded research and development. In addition, the U.S. patent system has always seemed to be mysterious to the lay public as well as its duly elected representatives. In the words of Howard Markey, Chief Judge of the Court of Appeals for the Federal Circuit ...."no institution has done so much for so many with so little public and judicial understanding as has the American patent system." That dichotomy on disposition of rights to inventions and the lack of understanding of the operation and contribution of the patent system to the benefit of the public persists today.

What were the origins of technology transfer and the Bayh-Dole Act?

PRESENTATION TO NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND GRANT COLLEGES
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I. Concept

Technology Transfer—the transfer of research results from universities to the commercial sector—is closely linked to fundamental research activities in United States universities, and, now, globally.

The concept is said to have its origin in a report entitled "Science—The Endless Frontier" which was written by Vannevar Bush for the President of the United States in 1945. At that time the success of various projects had demonstrated the importance of university-conducted research to the national defense effort. Vannevar Bush, however, recognized the value of university research as a means for enhancing the economy by increasing the flow of knowledge to be used by industry through support of basic science.

Dr. Bush's report became instrumental in providing a substantial and continuing increase in funding of basic research by the federal government. It stimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Because of the success of these and other governmental agencies in utilizing universities to conduct research, the funding of basic research is now considered to be a vital role of the federal government.

II. Technology Transfer Defined

Long before the Vannevar Bush concept, but without federal support for their research efforts, United States universities had been engaged in the transfer of technology, although that specific term may not have been applied to their activities.

Their greatest technology transfer efforts have probably been expended in preparing papers on research results for publication in scientific journals. Another area involves the activities of the Extension Services, particularly the Agricultural Extension Services, which communicates a great variety of useful information, largely technical, but also in social and economic fields, to many users, both rural and urban.

Another area of communication of information lies in the continuing education programs, e.g. in law, medicine, pharmacy, engineering, to keep professionals in those fields abreast of the latest developments.

Technical consultantships provide technology transfer in both directions—the consultant imparts information to whomever is engaging him while the consultant, in turn, can expect some professional enrichment from that activity.

Still another means for transferring technology is by making a tangible product of research available to others with or without a view toward commercialization. For example, seedling plants for propagation by others, appropriate fragments of tissue for tissue culture, cell lines, hybridomas, and seeds as well as mechanical or electronic prototypes and computer programs.

Thus, technology transfer occurs in many ways—through writings, the simple spoken word, the physical transfer of a tangible product of research or through the relative complexity of an intellectual property licensing program.

Although all of these forms of technology transfer have been and are being practiced today in the university sector in the United States and now many other countries the focus of this presentation is upon the transfer of technology as represented by the transfer of a property right as the result of ownership of the intellectual property generated during the conduct of research. Such ownership may be manifested by patents, copyrights, trademarks, trade secrets or a proprietary right in the tangible products of research.

III. Intellectual Property

A. Constitutional Basis

The fundamental basis for the university technology transfer programs in the United States lies in the Constitution of the United States in the language of Article 1, Section 8 of that document:

> "The Congress shall have Power—To promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respecting Writings and Discoveries."

Under this specific power the present patent statute, Title 35 of the United States Code (35 U.S.C.) was enacted. It is significant that the face of a U.S. patent document contains the following statement:

> "—these Letters Patent are to grant unto the said claimant(s)—the right to exclude others from making, using, or selling the said invention throughout the United States."

and that 35 U.S.C. 261 characterizes this right to exclude as a property right. The technology transfer function is in great part based upon the recognition of and the specific provision for that very special property right.

B. Nature of University Research

The universities were, of course, organized as teaching institutions with any research conducted being directed to that end. Little thought or impetus was given to the transfer of the results of that research to the public other than through the academically acceptable route of publication in scientific journals. In fact, a researcher who accepted corporate support was thought by his academic colleagues to have been diverted from his basic research to serve corporate interests. The perception then was because the researcher had accepted corporate money his research would no longer be directed to the seeking of new knowledge but by the money-driven need to solve current problems in the real world, even to the development of products and processes to a market-ready condition.
That was the prevailing attitude at the University of Wisconsin when, in 1924, it was suggested that a plan be developed to make use of patentable inventions generated by faculty members which would:

(1) protect the intellectual property of the individual taking out the patent;

(2) insure proper use of the patent; and at the same time

(3) bring financial help to the University to aid in its further research efforts.

The fears that the implementation of such a plan would divert the university researcher from his basic research did not materialize. There was no great rush toward patenting; there was no mass movement toward applied research tied directly to product development; nor was there any pronounced change in the researchers' attitudes. University research then, as now, remained essentially basic in character and directed primarily to the seeking of new knowledge.

The generation of inventions is almost never the main objective of basic research. If inventions do flow from that research activity, it is a largely fortuitous happening that takes place because the researcher, or perhaps, an associate, has the ability to see some special relationship between his scholarly work product and the public need. It is from the recognition of this connection, which can convert a discovery or invention into a patentable invention, that innovation arises.

It was not too many years ago that there was little appreciation of the value of intellectual property generated during the course of research being conducted on the university campus or of the value of that intellectual property to the university if properly transferred to the private sector for development and marketing through appropriate arrangements. In fact, on numbers of campuses those activities would have even been unwelcome as an incursion into academic pursuits as was the early experience at Wisconsin. Nevertheless, prior to the legislative initiatives under which, today, most universities engage in the protection and licensing of intellectual property, several universities and organizations carried out such practices with the attendant opportunity to generate funds to aid in supporting research efforts. Prominent among such institutions were the University of California, Iowa Sate University, Battelle Development Corporation, Research Corporation, which represented a number of universities and the University of Wisconsin through its patent management organization the Wisconsin Alumni Research Foundation established in 1925.

C. The Government Vector

During the early history of the United States very little technical development work was done by the Government and therefore, as a practical matter, the question of the Government owning a patent never arose. Gradually, federal agencies begun to undertake the practical kind of development work which led to inventions. Since prior to World War II almost all Government-financed research and development work was conducted in federal laboratories by full-time Government employees, there was a small but recurring problem of what to do with inventions resulting from such work—inventions which, if made by private parties, would have become the subject of patent applications.

This situation changed rapidly during and after World War II when the technological demands imposed by more and more sophisticated military requirements, as well as the increasing complexity of support services, made it quickly evident that there were not sufficient resources within the Government to undertake all the scientific projects necessary to a winning war effort. The absolute necessity to utilize the best technical ability available, regardless of its locus, spawned a rapid proliferation of Government-sponsored and -funded research and development contracts.

The proper disposition of rights to patents resulting from this work was theoretically as important then

as now but was never seriously addressed as a major problem because of the exigencies of wartime needs.

The basic issue was whether the Government should always take the commercial rights to patentable inventions generated under a Government-sponsored contract or from Government-funded research or whether such rights would be better left with the contractor or grant recipient to permit utilizing the patent system for transferring the technology developed to the public sector for its use and benefit.

Post World War II the rapid technological strides made under the impetus of a wartime footing and the obvious necessity for continuing technological superiority, at least in defense-oriented efforts, made it imperative to continue to provide public support for science. Nor was this support limited to the military. For example, in 1950 Congress finally provided an annual budget of $15 million for the National Science Foundation to conduct basic scientific research at universities.

During this same period, hundreds of millions of dollars were appropriated by the Government in the area of medical research in the beginnings of an all-out attack on disease.

With the rapid expansion of scientific projects being undertaken and supported by the Government, the same shortage of technical ability and facilities continued to prevail as had been experienced under the pressures of World War II. Since the Government could not do all the necessary work in its own facilities, qualified private companies, universities and nonprofit organizations were sought out to perform many of the programs through contractual arrangements. In each arrangement, the same old problem of ownership of patent rights existed but was seldom, if ever, directly addressed. In the case of universities and other non-profit organizations, few were engaged at the time in patenting the results of research and in technology transfer activities. Since one of the prime objectives of such an institution was to support its respective research efforts and since the government was a ready source of funds for supporting such efforts, the prevailing attitude was simply to accept the readily available government support with little thought being given to the underlying property rights and the value of those rights in the long term.

The Government itself had not developed a uniform patent policy for all of its agencies regarding the disposition of rights in intellectual property generated during the course of research supported by those agencies. In fact, there was no existing statutory authority which gave the agencies the right to hold patents or license technology. Such acts were viewed as objectives of the agency mission. Consequently, each governmental agency which supported a research and/or development effort, through either or both of contractual or grant arrangements, developed its own policy. The ultimate result was that many and varied policies evolved to the point that there were some 26 different agency policies. Also, since to support a given research project, funds from different agencies were often co-mingled within universities, the most restrictive agency policy became the controlling policy.

Operating under the various agency policies, the Government had accumulated in its patent portfolio about 30,000 patents of which only about 5% had been licensed to industry with an even smaller percentage reflected in products or processes in commercial use. Thus, with the Government, as represented by its agencies, adopting, in general, a non-exclusive licensing policy the experience of licensing Government-owned patent had without question been one of non-use of the technology. For example, in 1978 the National Aeronautics and Space Administration (NASA) reported that through 1978 it had had 31,357 contractor inventions reported to it. Of those, title had been waived to the contractor in 1,254 cases, or less than 4%. The results of NASA's own licensing program were said to have been disappointing representing a commercialization rate of less than 1%. In contrast, the rate of commercialization of the waived inventions was consistently in the 18-20% range. Therefore, the intended benefits which were to flow to the public in the form of new products and processes as a result of federal support of research both within the government itself and in the university sector were left unrealized.

Moreover, under the agency policies then in place, Government ownership of a patent was in a sense an anomaly. The patent system was created as an incentive to invent, develop, and exploit new technology to promote science and useful arts for the benefit of the public. When the government held title to those many inventions under the policy that the inventions should be freely available to all, much the same as if the invention had been disclosed in a publication, the patent system could not operate in the manner in which it was intended. The incentive inherent in the right to exclude conferred upon the private owner of the patent, and which is the inducement to development efforts

necessary to the marketing of new products or the use of new processes, was simply not available. What is available to everyone is of interest to no one.

The ineffectiveness and inadvisability of such agency policies and their adverse effect on the public benefit should have been apparent.

D. Government Policy—Move Towards Uniformity

In 1963, Jerome Weisner, President Kennedy's Science Advisor, recognized a need for some guidelines to effect a more uniform Government policy toward inventions and patents on a Government-wide basis. The results of Dr. Weisner's study culminated in the Policy Statement issued on October 10, 1963 by President Kennedy to establish Government-wide objectives and criteria, subject to existing statutory requirements, for the allocation of rights to inventions as between the Government and its contractors, which would best serve the overall public interest while encouraging development and utilization of the inventions.

The ensuing studies and experience culminated in the issuance of a revised Statement of Government Patent Policy by President Nixon on August 23, 1971. The thrust of that statement was:

> A single presumption of ownership of patent rights to government-sponsored inventions either in the government or its contractors is not a satisfactory basis for government patent policy and, that a flexible, government-wide policy best serves the public interest.

The considerations basic to the Statement of Government Patent Policy were the following:

> (1) The Government expends large sums for the conduct of research and development which results in a considerable number of inventions and discoveries.
>
> (2) The inventions in scientific and technological fields resulting from work performed under Government contracts constitute a valuable national resource.
>
> (3) The use and practice of these inventions and discoveries should stimulate inventors, meet the needs of the government, recognize the equities of the contractor, and serve the public interest.
>
> (4) The public interest in a dynamic and efficient economy requires that efforts be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiatives to this end, and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under government contracts. Where the contractor acquires exclusive rights, he remains subject to the provisions of the antitrust laws.
>
> (5) The public interest is also served by sharing of benefits of Government-financed research and development with foreign countries to a degree consistent with our international programs and with the objectives of U.S. foreign policy.
>
> (6) There is growing importance attaching to the acquisition of foreign patent rights in furtherance of the interest of U.S. industry and the Government.
>
> (7) The prudent administration of Government research and development calls for a Government-wide policy on the disposition of inventions made under Government contracts. The policy must recognize the need for flexibility to accommodate special situations.

Although there is evidence that the guidelines did bring the patent practices of the Agencies into greater harmony, divergent policies still existed and there was a strong presumption, if not evidence, in terms of the transfer of technology to the public sector, that the more restrictive the policy of the Agency, i.e. the more an Agency was inclined to take title to inventions and patents generated under its funding, the less was the likelihood that the technology would be transferred for the public benefit.

E. Institutional Patent Agreements

During the period from 1963 to 1971, while experience with the Weisner-Kennedy effort was being gained, further efforts were being made to persuade several federal agencies, specifically the Department of Health, Education and Welfare (now Health and Human Services [HHS]) and the National Science Foundation, to enter into Institutional Patent Agreements, (IPAs) with universities. The policies of both of these agencies permitted a waiver of rights to the inventions made with their funds (referred to as an 8.2(b) grant of greater rights). However, on the very few occasions where such a waiver was granted, it was under such restrictive provisions that it presented an unworkable basis for transferring technology to the private sector. No commercial firm was willing, under the conditions imposed under many of the waivers, to risk the expenditure of the necessary development funds.

Subsequently, after five years of negotiation, the then Department of Health, Education and Welfare, in 1968, issued its first new IPA to the University of Wisconsin. This was followed in 1973, after another five years of effort, by an Institutional Patent Agreement between the National Science Foundation and the University of Wisconsin. The first ever of such agreements with that agency.

That evidence of not only the availability of an IPA, but that those two agencies would actually grant them, appeared to provide some impetus to universities to engage in the technology transfer business. Nevertheless, some of the provisions of the IPAs available from those two agencies were unacceptable under some universities' policies, while many other governmental agencies still clung tenaciously to the policy of taking title to all inventions made with funds they had supplied.

Fundamental to the success of technology transfer under the IPAs was the certainty that the universities would be the owner of the inventions made under those agreements. That factor and, in addition, the ability of universities to grant exclusive licenses were instrumental to the subsequent willingness of private sector industry to engage in licensing arrangements with universities that had IPAs.

Although limited to two agencies, the NIH and NSF, the IPAs were not only important as manifesting a change in the attitude of those agencies and potential licensees but, more importantly, as establishing, through negotiation, terms and provisions which were carried into and set the tone for the legislative effort which resulted in the passage of Public Law 96-517, the Patent and Trademark Law Amendments Act, in 1980 (the Bayh-Dole Act). In fact, that law is often looked upon as a codification of the terms and provisions of the IPAs.

F. The Bayh-Dole Act

The passage of the Bayh-Dole Act was the reward for almost 20 years of effort by the non-profit sector to stimulate the transfer of technology through the vehicle of the patent system. It was the culmination of the many pieces of legislation introduced over many years that had sought to establish a uniform patent policy within the government. It should be considered a landmark piece of legislation in that, after many false starts and unsuccessful efforts it was, finally, a recognition by Congress:

> (1) that imagination and creativity are truly a national resource;
>
> (2) that the patent system is the vehicle which permits the delivery of that resource to the public;
>
> (3) that placing the stewardship of the results of basic research in the hands of universities and small business is in the public interest; and, significantly,
>
> (4) that the existing federal patent policy was placing the nation in peril during a time when intellectual property rights and innovation were becoming the preferred currency in foreign affairs.

The most significant feature of the Bayh-Dole Act was that it changed the presumption of title in and to any invention made in whole or in part with the use of government-supplied funds from the government to the universities.

This was the final step in establishing the strong university-industry connection which today exists in the United States.

It is also not universally recognized that the Bayh-Dole Act provided, for the very first time, statutory authority for the Government to apply for, obtain and maintain patents on inventions in both the United States and foreign countries and to license those inventions on a non-exclusive, partially exclusive or exclusive basis. Even where the government contractor (a university or other non-profit entity or a small business) chooses to retain title to an invention under the Bayh-Dole Act the government always receives an irrevocable royalty-free license to practice such invention for governmental purposes. The government also reserved march-in rights for non-performance. In the face of such circumstances there is, in reality, a university-industry-government relationship.

IV. The Economic Climate

To more fully appreciate what has evolved through the sequence of events which has been enumerated, it must be kept in mind that through this period, the economy of the country as a whole, as well as the economy of each state, was and still is in transition. Today, universities operate in an economic climate which:

(1) is knowledge based—not capital based (although, without question, availability of capital is a necessity);

(2) is entrepreneurially based—witness the large numbers of new companies created in recent years;

(3) involves world markets—the international aspect of protection for intellectual property generated through the research function must be a consideration;

(4) reflects continuous and often radical technology changes;

(5) is becoming more decentralized—making state and local options and initiatives more significant;

(6) is an economy of appropriateness not one of scale—i.e., merely increasing the size of a production plant will not necessarily reduce the cost of product or increase its quality;

(7) is increasingly competitive on a global scale—witness the advent of the European economic community and other geographic economic blocks.

In view of this continually evolving economic climate, and since new products arise from new fundamental ideas as well as from new applications of existing technology, the necessity for supporting research is evident. However, support of research is not enough. That support must be coupled with a creative technology transfer capability because inventions are of little value to society unless and until they are utilized by society. To quote Thomas Edison:

"The value of an idea lies in the using of it."

With the passage of the Bayh-Dole Act and, in the same year, the decision of the United States Supreme Court in the Chakrabarty Case, which stood for the proposition that merely because something was alive (in that case a bacterium) it was not precluded from being patentable, along with the evolution of genetic engineering concepts, the universities were literally propelled into an awareness of the potential economic value of the technology that was being generated in their research programs.

Because the government has been and still is the primary source of the funds supporting the research effort at universities, the passage of the Bayh-Dole Act permitted the universities to position themselves, through the establishment or expansion of technology transfer capabilities, to transfer the technology generated during the course of government-funded research to the public, generally through the licensing of an industrial partner, for the public's use and benefit—the transfer of a property right.

The patent system is the most viable means for accomplishing the transfer of technology since it offers protection to the intellectual property base while at the same time providing an incentive to the industrial partner because of the right it conveys to exclude other than the licensee from practicing the invention patented. Consequently, full and careful consideration must be given to the making of any policy which will affect the transfer of technology that has been generated by government-funded research. In addition, careful consideration must also be given to any proposed changes in patent laws including treaty accommodations, which could adversely affect technology transfer capabilities. The most pertinent question to ask is:

> In whose hands will the vestiture of primary rights to inventions serve to transfer the inventive technology most quickly to the public for its use and benefit?

In the U.S. the answer has been the university-private sector partnership.

In the United States five events, led by the passage of the Bayh-Dole Act, reshaped government patent policies which, in turn, shaped university technology transfer as we practice it today.

(1) The passage of the Bayh-Dole Act itself.

(2) The issuance in 1982 by the Office of Management and Budget (OMB) policy guidance to federal agencies for implementing that Act.

(3) The issuance of a Presidential Memorandum on Government Policy under which federal agencies were directed to extend the terms and provisions of the Bayh-Dole Act to all government contractors.

(4) The amendment of the Bayh-Dole Act by Public Law 98-620 to remove some politically-motivated restrictions on exclusive licensing placed in the original Act (PL96-517).

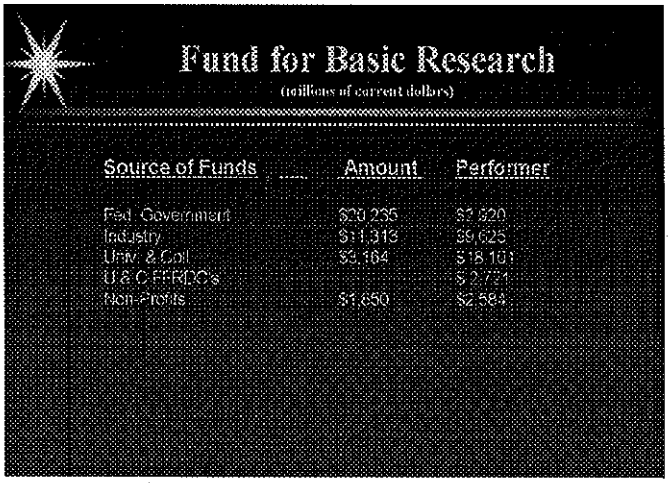
(5) Publication of rulemaking by the Department of Commerce. This did not occur until 1987.

Also in this same period, one should not overlook the establishment in 1982 of the Court of Appeals for the Federal Circuit which, under the able leadership of Chief Judge Howard Markey, gave further impetus to the value of patents and a uniformity to their interpretation which put to rest the disparities which existed among the Judicial Circuits and had led to forum shopping in patent litigation.

These events, led by the passage of the Bayh-Dole Act created the revolution in university technology transfer.

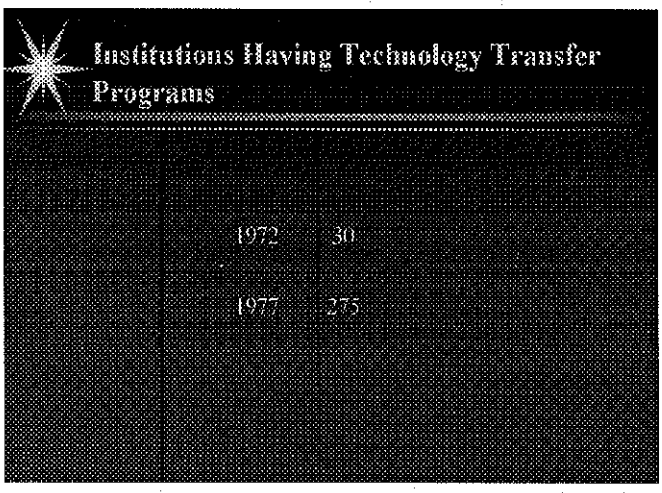
That reshaping of government patent policies has had a highly significant effect upon the academic sector because of the extensive federal support for research carried out in that sector and particularly for basic research. The relative amounts of research dollars in the university sector by source of those funds and by the performers of that basic research presents an interesting contrast.

(double-click on graphs to view enlarged versions)



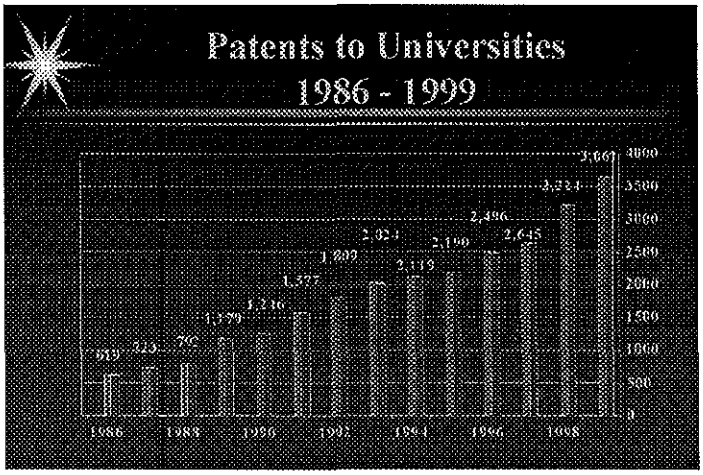
V. The Impact of the Bayh-Dole Act

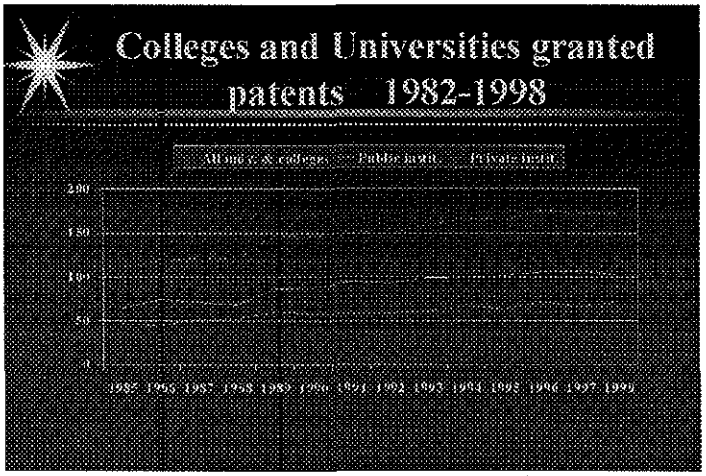
How can the practical impact of the Bayh-Dole Act on university technology transfer be measured?



The number of institutions engaged in technology transfer efforts has increased dramatically.

Since we are dealing for the most part with the transfer of technology from a protected base, i.e., patents and other forms of intellectual property protection, an obvious answer is to look at the change in the number of patents issued to universities and other non-profit entities, e.g. teaching hospitals, since the effective date of the Bayh-Dole Act in 1981.

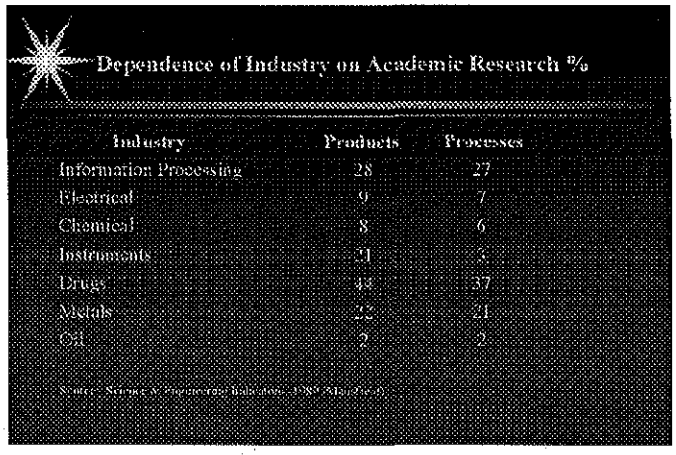




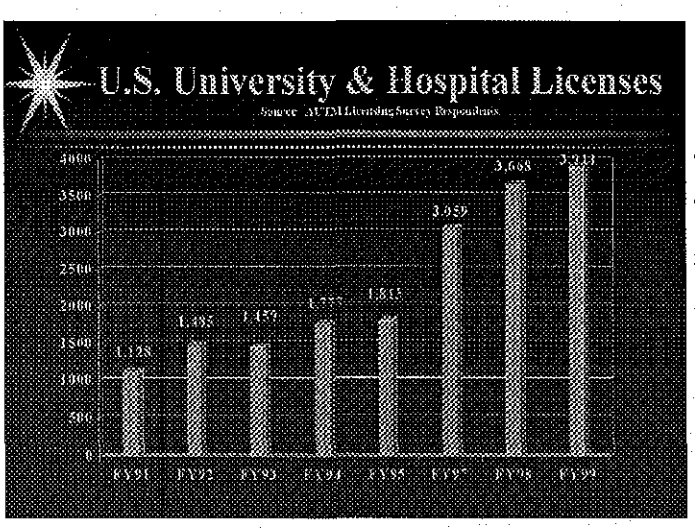
In addition, because more institutions have the technology transfer programs, a greater number of institutions are receiving patents. The growth and trend lines are evident. The university sector now receives about 3% of all United States origin patents issued.

The real measure of technology transfer is not, of course, the number of patents which the university sector holds, but the amount of technology represented in and by those patents which has been transferred to the private sector for further development into products and processes useful to mankind. In a study conducted in 1989 among executives in various industries, it was shown that a number of industries relied heavily on research conducted at universities for new products or for shortening the time necessary to bring a product or process into commercial use.

Although this was a study published in 1989 there are no indicators that this reliance has changed. In fact, with the down-sizing in corporate America it would not be at all surprising that there is greater reliance on the university sector.

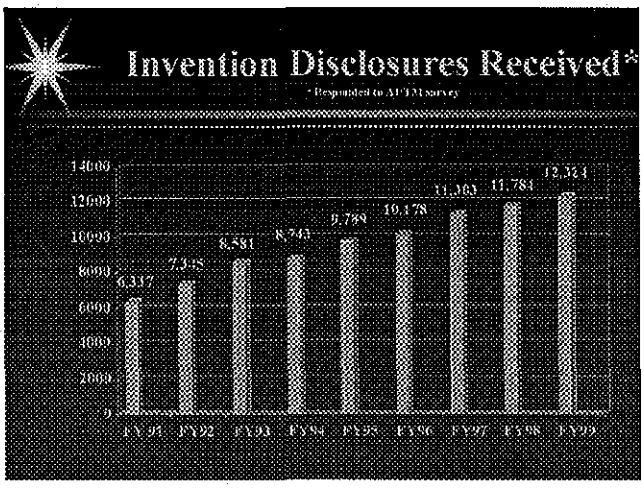


What has been the licensing experience?

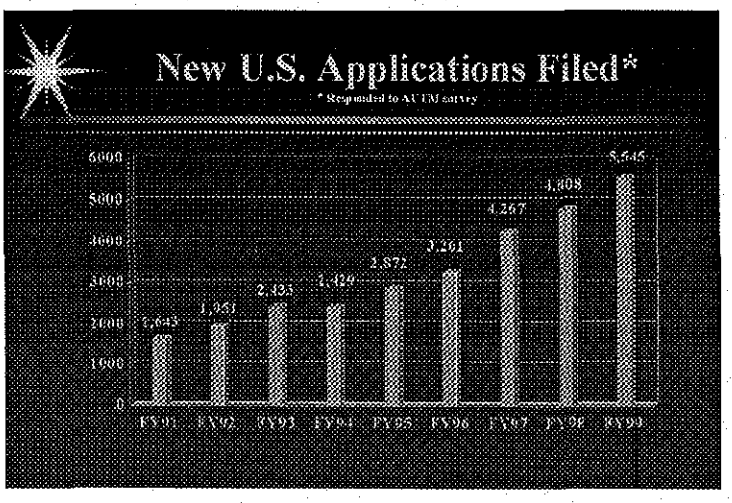


The most recent licensing survey by the Association of University Technology Managers (AUTM) shows a continuing growth in patenting and licensing activities by the university sector. At the end of fiscal year 1999, the university sector reported almost 18,617 active licenses or options.

The patenting and licensing activities are, of course, based upon the number of invention disclosures received and the patent applications filed. The invention disclosures received have been increasing every year and in 1999 reached 12,324.

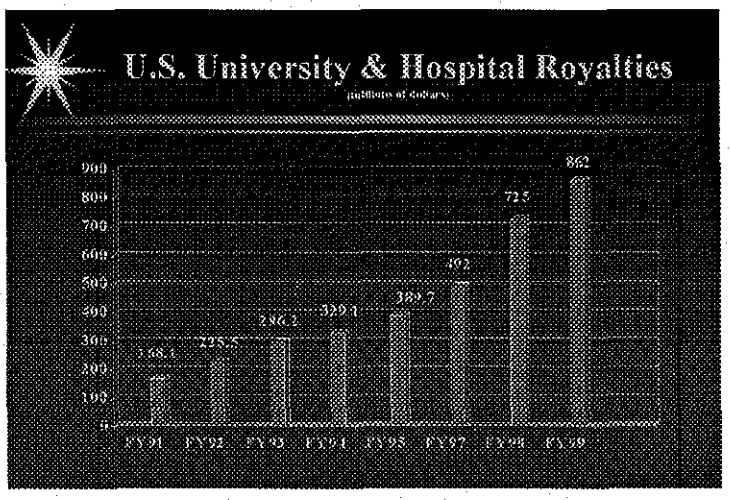


The number of new applications filed, as might be expected, have also increased year-to year to a total of 5,545 new applications in 1999.

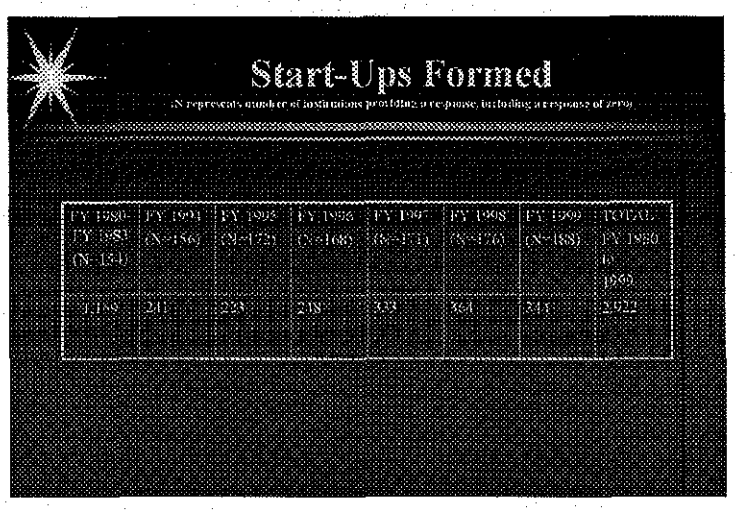


As a result of these patenting and licensing activities, university and hospital (teaching hospitals

usually connected with universities) have experienced growing royalty income that reached 862 million dollars in 1999. For the most part these monies, after sharing with the inventor or inventor group, are utilized to support further research within the university or hospital.

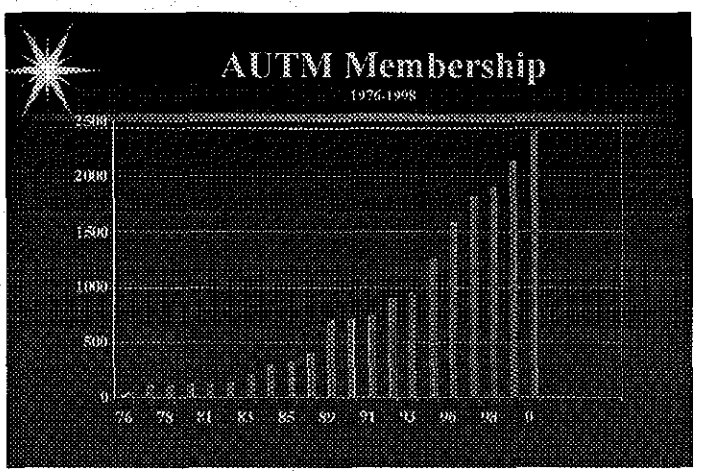


Another significant outgrowth of the university technology transfer programs are the number of new start-up companies which have been formed that find their basis in the technology generated during the course of basic research. The most visible example of this phenomenon has been in the field of biotechnology. In fact, the biotech industry evolved from basic university research. Since 1980 at least 2,922 new companies have been formed based on license from an academic institution, including 344 reported formed in 1999. With universities taking an equity position in such companies the potential for financial return over and above a royalty stream is increased. Moreover, the start-up companies offer the opportunity to enhance local or regional employment.



The impact of the Bayh-Dole Act is also seen in other indicators. For example, I believe that an excellent indicator which parallels the growth of the technology transfer function in the university sector is the growth of the membership in the Association of University Technology Managers (AUTM).

After the passage of the Bayh-Dole Act, and particularly after the effective date of that Act in 1981, there has been a dramatic increase in the number of members to the current approximately 2700.



Growth in membership from overseas has also dramatically increased as countries recognize the contributions that their universities can make modeled on the United States experience.

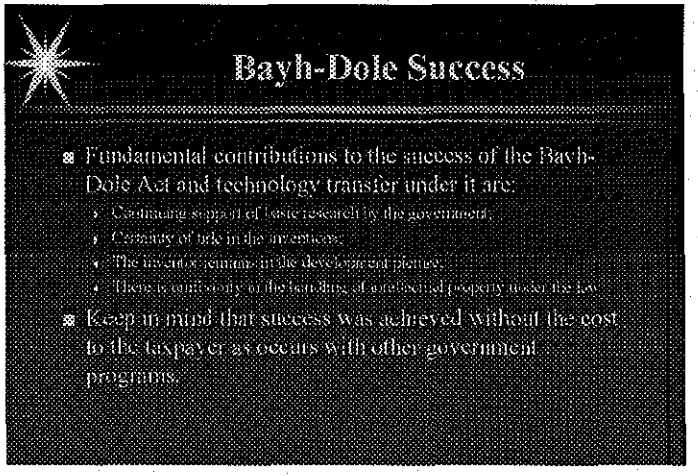
Several things contributed to the success of the Bayh-Dole Act and the transfer of technology under it.

(1) The continuing support for basic research by the federal government,

(2) the ownership of the inventions by the universities as opposed to the government,

(3) the inventor remains in the development picture, and

(4) the uniformity to handling of intellectual property generated with federal support regardless of the federal agency from which the support funds were obtained.



One important factor, which is often overlooked, is that the success was achieved without cost to the taxpayer. In other words, no separate appropriation of government funds was needed to establish or manage the effort. In fact, it has been estimated that the economic benefits flowing from the universities' licensing activities adds about $41 billion to the United States economy.

Significant as that dollar amount is, it should not be overlooked that university inventions, arising, as most of them do, from basic research, have led to many products which have or exhibit the capability of saving lives or of improving the lives, safety and health of the citizens of the United States and around the world. In that context their contribution to society is immeasurable.

VI. The Heritage of the Bayh-Dole Act

The Bayh-Dole Act can be given credit for focusing congressional interest on intellectual

property-oriented legislation. With that focus established, the years since have seen many pieces of such legislation introduced. Some have become law, most have not. Of these, the Federal Technology Transfer Act (FTTA) of 1986 can be considered to have been a direct result of the Bayh-Dole Act and experience by universities under it. The FTTA was intended to promote the utilization of technology generated in government owned and operated laboratories. The FTTA was built on certain fundamental principles.

(1) The federal government will continue to underwrite the cost of much important basic research in scientifically promising areas that takes place in the United States.

(2) Transferring this research from the laboratory to the marketplace is primarily the job of the private sector, with which the federal government should not compete.

(3) The federal government can encourage the private sector to undertake this effort by judicious reliance on market-oriented incentives and protection of proprietary interests.

That the university sector has made a tangible contribution to the competitiveness of the United States in a global market through the technology transfer function cannot be denied. The seminal piece of legislation which made that contribution possible was the Bayh-Dole Act. Without doubt, the objectives of the Act has been realized. Through operation under that Act:

(1) Small business, which is frequently the test bed for embryonic university technologies, has benefited to a very large extent;

(2) the government is comforted in knowing that taxpayer dollars, which support the bulk of basic research in the university sector, have lead to the development of products and the use of processes that have advanced the quality of life for its citizens.

(3) industry can rely on a source of technology, data and information and a pipeline of manpower which fulfills its needs and feeds the production processes.

In sum, all sections of society enjoy both the protection and benefits afforded under the Bayh-Dole Act and its progeny. Moreover, academic institutions, after the government, provide the second largest share of academic R & D support. Because of the commingling of funds for the support of research the university sector's stake in the Bayh-Dole Act and operation under it is very direct.

We must understand that no matter how much money we spend on research and development the findings are not going to benefit the public unless there are suitable incentives to invest in commercialization. And because no one knows which venture will succeed, we must strive for a society and an environment ruled by the faith that the guarantee of reasonable profits from risk-taking will call forth the endless stream of inventions, enterprise and art necessary to resolve society's problems.

In the Bayh-Dole Act, Congress made a determination that private (not government) ownership of inventions, motivated by the prospect of financial gain would lead to more efficient commercialization and distribution of federally funded technology.

We must not fail to recognize and to remember that the Bayh-Dole Act and the opportunities as well as the obligations which it presents to the university sector represents a blend of science and law – the two most important forces that have shaped our society as it exists today. These are and will continue to be the fundamental building blocks for the betterment of the human condition.

Endnotes

Vannevar Bush held the following positions in government: Chairman, National Defense Research Committee 1940; Director-Office of Scientific Research and Development 1941; Chairman-Joint Research and Development Board 1946-47; Member-Research and Development Board of National Military Establishment 1944-48

See Resume of U.S. Technology Policies—Dr. Betsy Ancker-Johnson-Les Nouvelles (Journal of the Licensing Executives society) Dec. 1976, Vol. XI No. 4, P. 186; Statement before the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Dec. 11, 1976. (This latter document also contrasts the experience of universities in licensing patents owned by them some or most of which may have resulted from research supported in whole or part by Federal

monies.)

Presidential Memorandum and Statement of Government Patent Policy (F.R. Vol. 28, No. 200, October 12, 1963).

Presidential Memorandum and Statement of Government Patent Policy (F.R. Vol. 66, No. 166, August 26, 1971).

For historical interest re Institutional Patent Agreements and early DHEW practice see Report to the Congress on "Problem Areas Affecting usefulness of Results of Government-Sponsored Research in Medicinal Chemistry" by the Comptroller General of the United States, August 12, 1968.

P.L. 96-517, Patent and Trademark Amendments Act of 1980. This law amended Title 35 United States Code by adding Chapter 18, Sections 200-212.

Diamond, Commissioner of Patents v. Chakrabarty, 206 USPO 193, U.S. Supreme Court. (A companion case to Chakrabarty was In re Bergy [1950USPQ 344 (1977)] which held that "the fact that microorganisms. . . are alive. . . is without legal significance for purposes of the patent law." Certiorari was granted for both Bergy and Chakrabarty but Bergy was then dismissed as moot.)

§ 200. Policy and objective. "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 commercialization and public availability of inventions made in the Unites States by United States industry and labor; to ensure that 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."

OMB Circular A-124 was subsequently codified as 37CFR Part 401.

The Presidential Memorandum was incorporated into the text of OMB Circular A-124 on March 24, 1984.

PL-98-620, The Trademark Clarification Act amended Chapter 18 of Title 25 U.S.C.

Final rules were published on March 18, 1987 (52FR8552) and subsequently codified at 37CFR Part 401.1-401.16.

Court of Appeals for the Federal Circuit established effective October 1, 1982.

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