

**University Technology Transfer
Evolution and Revolution**

by

Howard W. Bremer

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I. **University Technology Transfer: Evolution and Revolution**

“Upon this gifted age, In its dark hour
Rains from the sky a meteoric shower

Of Facts-; They lie unquestioned, uncombined—
Wisdom enough to leech us of our ill
Is daily spun, but there exists no loom
To weave it into fabric.

--from a poem by
Edna St. Vincent Millay

Prologue

Apropos to the basic research function at universities, it is suggested that the loom for weaving into a substantive fabric the wisdom derived from the conduct of research lies in the enlightened cooperation between the universities, industry and the government which, through voluntary acts and legislative initiatives, has permitted and continues to permit the transfer of that wisdom to the public for its use and benefit.

Technology Transfer Defined

The concept of technology transfer—the transfer of the results of research from universities to the commercial sector—is said to have had its origins in a report made, to the President in 1945 by Vannevar Bush^[1] entitled “Science—The Endless Frontier.” Having witnessed the importance of university research to the national defense for its role in the successful Manhattan Project, he projected that experience to a recognition of the value of university research as a vehicle for enhancing the economy by increasing the pool of knowledge for use by industry through the support of basic science by the federal government. The report stimulated substantial and increasing funding of research by the federal government leading to the establishment of several research-oriented governmental agencies, e.g. the National Institutes of Health, the National Science Foundation, the office of Naval Research, and, ultimately, to the acceptance of the funding of basic research as a vital activity of the federal government.

Long before the Vannevar Bush concept, but absent federal support in their research endeavors, the universities have been engaged in the transfer of the 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, and 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 the simple spoken word, through 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 the focus of this paper 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.

Intellectual Property

Constitutional Basis

As we all know, the Constitution was drafted in the context of a struggle with a government which had abused its obligations to defend the rights of its citizens. It was no accident, therefore, that the salient portion of the Constitution drafted for the purpose of protecting your liberties, the fifth amendment, made the Government the servant and protector and not the master of your individual rights. The Fifth Amendment of the Bill of Rights provides that:

“No person shall—be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation.”

Thus, the Fifth Amendment provides generic protection for individual property. Since there is little doubt that the term “property” as used in the fifth amendment includes intellectual property, it would seem that the protection afforded the individual by that amendment would be adequate. Yet, the framers of the Constitution felt compelled to be even more explicit about intellectual property and provided the following language in Article 1, Section 8:

“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 respective Writings and Discoveries.”

Why this special handling of intellectual property?

There was no recorded debate in the Constitutional Convention on September 5, 1787, when Article I, Section 8, was presented and it was approved unanimously. That intellectual property, the products of the mind, should prospectively receive legal protection, even from a centralized Government to be formed, was a principle upon which no one disagreed.

The power given under this clause is not general. Hence, it expressly appears that congress is not empowered by the Constitution to pass laws for the benefit of protection of authors and inventors except as a means to “promote the Progress of Science and useful arts.”

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 the 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.

Nature of University Research

During the prevalence of the “ivory tower” concept of universities and the research that was carried out in them, little thought or impetus was given to the transfer of the results of that research to the public other than through the accepted and acceptable route of scientific publication. In fact, under that “ivory tower” concept, a researcher who accepted a corporate subsidy aroused the suspicion among his colleagues that he had been diverted from his basic research and had become a tool of vested interests. He had accepted “tainted money.”

When, in 1924, it was suggested at the University of Wisconsin that a plan be developed to make use of patentable inventions generated by faculty members which would:

1. protect 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 further its research effort,

the purists quickly applied the “tainted money” theory to the plan. It was feared that any such arrangement would divert the scientist from basic research to work only on those ideas which appeared to have commercial potential. In other words, the research function would no longer be driven by the seeking of new knowledge but by the dollar-driven need to solve current problems in the real world, even to the development of products and processes to market-ready condition.

The fears propounded by the purists then, and which are still embraced in academia by some, did not materialize. There was no great rush toward patenting. There was no evident movement among university researchers toward applied research tied directly to actual product development. Nor was there any observable change in the research scientists’ attitude. In fact, University research then, even as now, remained essentially basic in character.

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 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 State University, Battelle Development Corporation, Research Corporation, which represented an number of universities and the University of Wisconsin through its patent management organization the Wisconsin Alumni Research Foundation.

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 began 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 “take the money and run” 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 the university sector was faced with the prospect of having to deal with some 26 different agency policies. Also, since to support a given research pursuit, funds from different agencies were often co-mingled, more than a single agency policy had to be considered with the most restrictive policy becoming 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 and the inventions of which had found their way into commercial use in an even smaller percentage. Thus, with the Government, as represented by its agencies, espousing, in the main, a non-exclusive licensing policy the experience of licensing Government-owned patent had been irrefutably one of non-use. For example, in 1978 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 disappointment 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 that were to flow to the public in the form of new products and processes as a result of federal support of research both intramurally and in the university sector and stimulated through use of the patent system were left unrealized.

An interesting comparison along these lines was made by Harbridge House^[2] in its 1968 study of Government funded patents put into use in 1957 and 1962. It was found that contractor-held inventions were 10.7 times as likely as Government-held inventions to be utilized in products or processes employed in the private sector for the benefit of the public.

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 aegis 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.^[3]

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^[4] 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.

Since the policy, as promulgated, would most likely have to be revised after experience had been gained in operating under it, a Patent Advisory Panel was established under the Federal Council for Science and Technology to assist the Agencies in implementing the Policy, acquiring data on the Agencies' operations under the policy, and making recommendations regarding the utilization of Government-owned patents. In December 1965, the Federal Council established the Committee on Government Patent Policy to assess how the Policy was working.

The studies and experience of the Committee and the Panel culminated in the issuance of a revised Statement of Government Patent Policy by President Nixon on August 23, 1971.^[5] The changes effected in the Nixon Policy Statement were made as a result of analysis of the effects of the Policy on the public interest over the seven years from the Kennedy Policy Statement. The fundamental 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:

- (a) The Government expends large sums for the conduct of research and development which results in a considerable number of inventions and discoveries.
- (b) The inventions in scientific and technological fields resulting from work performed under Government contracts constitute a valuable national resource.
- (c) 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.
- (d) 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.
- (e) 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.
- (f) There is growing importance attaching to the acquisition of foreign patent rights in furtherance of the interest of U.S. industry and the Government.
- (g) The prudent administration of Government research and development calls for a Government-wide policy on the disposition of inventions made under Government contracts reflecting common principles and objectives, to the extent consistent with the missions of the respective agencies. 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 “title” oriented the Agency was toward inventions and patents generated under its funding i.e. the Agency generally took title to most if not all inventions made with the use of the funds, the less was the likelihood that the technology would be transferred for the public benefit.

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 [HSS]) 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 so fraught with 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^[6] 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 vestment of certainty of title to inventions held by the universities under those agreements. That factor and, in addition, the ability of universities to grant exclusive licenses were instrumental in the subsequent willingness of private sector industry to engage in licensing arrangements with universities that had IPAs.

Although limited to two agencies, 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 culminated 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.

The Bayh-Dole Act^[7]

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 us to deliver 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 on peril during a time when intellectual property rights and innovation were becoming the preferred currency in foreign affairs.

The most significant feature of the Act was that it changed the presumption of title to any invention made by small business, universities and other non-profit entities through the use, in whole or in part, of government funds from the government to the contractor-grantee. Another factor, often overlooked, is that the Act did away with the distinction between grants and contracts, which agencies had often made when dealing with universities, a distinction which a number of agencies rigorously applied in their zeal to retain rights to intellectual property as a contractual obligation.

It is also not universally recognized that the 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. The passage of the law was not, however, the end of the battle. It took over a year to settle the controversy which arose over the drafting of the regulations under the law. During the course of the legislative effort, an almost adversarial relationship had developed as between the University sector on the one hand and the Departments of Energy, Defense, and NASA on the other hand. The nature of that relationship became very clear when those agencies combined to voluntarily draft regulations which actually controverted the law and its intention. As a consequence, much greater attention was given to the regulations by the Council on Governmental Relations which promoted and influenced subsequent regulations that afforded protection against both arbitrary exemptions to the law at agency discretion and to the exercise of march-in rights by the Government.

The Bayh-Dole Act represented the first cautious step into a new relationship between the Government, as represented by its agencies, and the universities. It also presaged a new and closer relationship with industry. The certainty of title in the universities to inventions made with government funds afforded by the Bayh-Dole Act, which was the stimulus to successful technology transfer under the Institutional Patent Agreements, provided the major impetus to new and expanding university-industry relationships. Inasmuch as the Government always receives an irrevocable royalty-free license under any of such inventions and because of other provisions of the Bayh-Dole Act and the ensuing regulations under that Act, the relationship is, in reality, a university-industry-government relationship.

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. Invention without innovation has little economic value.

With the passage of the Bayh-Dole Act and, in the same year, the decision of the Supreme Court in the Chakrabarty Case,^[8] 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. That fact made it self-evident that steps had to be taken to make innovation follow invention since invention alone holds little hope for generating needed revenues to support an expanding research effort. 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 better insure that innovation would follow invention.

Government Patent Policy Reshaped

At the outset it must be presumed that Government research dollars are made available in the expectation of not only developing basic knowledge, but also in the expectation that the funded research will lead to products, processes and techniques which will be useful and acceptable in all or part of our society to improve the well-being of society in general.

In the face of this presumption it is apparent that inventions, whether made through the expenditure of private or governmental funds, are of little value to society unless and until they are utilized by society. In order to achieve such utilization it is essential that the invention be placed in a form or condition which will be acceptable and beneficial to the public. In other words, the technology must somehow be transferred to the public sector. To quote Thomas Edison: “The value of an idea lies in the using of it.”

In a free enterprise system such transfer is normally accomplished as the result of pertinent and appropriate activities of private enterprise. Since such activities obviously entail the commitment and expenditure of substantial monies—many times the amount needed to make the invention—adequate and appropriate incentives to such commitment and expenditures must be afforded. Consequently, and since the patent system provides such incentives and is the most viable vehicle for accomplishing the transfer of technology, full and careful consideration must be given to the making of any policy which will affect the transfer of technology that has been generated in whole or in part by Government-funded research. In addition, careful consideration must also be given to proposed changes in the patent laws, including proposed treaty accommodations, which could adversely affect the technology transfer capabilities.

One would not disagree that the primary objectives of a Government patent policy should be to:

- (1) promote further development and utilization of inventions made in whole or in part with government funds;

- (2) ensure that the Government's interest in practicing inventions resulting from its support is protected;
- (3) ensure that the intellectual property rights in Government sponsored inventions are not used for unfair, anti-competitive or suppressive purposes;
- (4) minimize the cost of administering patent policies through uniform principles; and
- (5) attract the best qualified contractors.

However, of all of the considerations attendant upon the establishment of a governmental patent policy only one consideration should be paramount:

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?

The passage of the Bayh-Dole Act was the beginning of the reshaping of Federal Patent Policy. Subsequent events between 1981 and 1985 further shaped that policy. The Bayh-Dole Act, the first event, became effective on July 1, 1981. The Congressional intent in its passage is abundantly clear from the recitation of the Policy and Objectives portion of the Act 35 U.S.C. 200.^[9]

The second event was the issuance in 1982 by the Office of Management and Budget policy guidance to federal agencies for implementing the Bayh-Dole Act in the form of OMB Circular A-124.^[10] This Circular clarified provisions in the Bayh-Dole Act regarding:

- (1) standard patent rights clauses for use in federal funding agreements;
- (2) reporting requirements for universities electing title; and
- (3) special federal rights in inventions.

A third event was the issuance of a Presidential Memorandum on Government Policy^[11] under which federal agencies were directed to extend the terms and provisions of the Bayh-Dole Act to all government contractors with a follow on amendment to the Federal Acquisition Regulations (FAR) to assure that all federal R&D agencies would implement the Bayh-Dole Act and the Presidential Memorandum.

The fourth event was the amendment of the Bayh-Dole Act by Public Law 98-620^[12] to remove some politically-motivated restrictions on exclusive licensing placed in the original Bayh-Dole Act. That law, in essence, made the Department of Commerce the lead Agency in administration of the Bayh-Dole Act as amended.

The fifth event, which did not occur until 1987, comprised publication of rulemaking^[13] by the Department of Commerce which finalized the provisions of the Bayh-Dole Act, P.L. 98-620, the OMB Circular A-124 and the Presidential Memorandum.

Also, in this same period the establishment of the Court of Appeals for the Federal Circuit, 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. To paraphrase Chief Judge Markey—no

institution has done so much for so many with so little understanding as the United States Patent System.

The government patent policy, as reshaped by the events noted, presented a charge and a challenge—a charge to show, through performance, that the confidence which was placed in the hands of the universities by Congress to transfer technology for the public benefit was not misplaced—a challenge to maximize the benefits which can be derived from the opportunity offered through that patent policy to aid in maintaining the United States as the world leader in innovation.

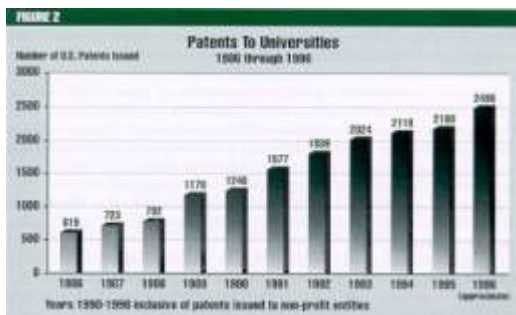
These events, led by the passage of the Bayh-Dole Act created the revolution in university technology transfer.

The Impact of the Bayh-Dole Act

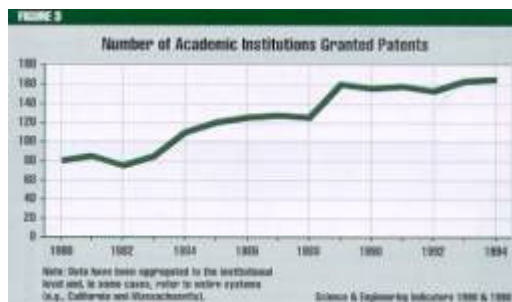


How can we measure the practical impact on universities of the Bayh-Dole Act and the reshaped Government patent policy? Since we are dealing for the most part with the transfer of technology from a protected base, i.e., patents and other forms of intellectual property protection, an obvious answer is 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. The increase in numbers of patents issued can be readily seen from Figure 1. The growth and trend lines are evident. The Figure is also significant in that it evidences that in the period from 1981-1985 the university sector was gearing up to either engage in or expand technology transfer efforts and that the fruits of those efforts became abundantly clear in the large increase in patents in the post-1986 period. That trend continues today. Universities now receive approximately 3% of all U.S. origin patents issued. That figure was up from about 1% in 1980.

It is tempting to view patents issued on a year-to-year basis as evidence of current activity, particularly for those who are not familiar with the patenting process. Because of the varying periods of time patent applications are in prosecution in the United State Patent and Trademark Office, over the short-term that kind of assessment can be very misleading. Over the longer term, however, for example, since the passage of the Bayh-Dole Act in 1980, the number of patents issued to the university sector is a more meaningful measure.



If the total count of patents issued is inclusive of non-profit entities in addition to the universities, as has been done in Figure 2 for the years 1990-1996, the observable impact of the Bayh-Dole Act is even greater.



Perhaps even more significant is the increase in the number of U.S. universities receiving patents. This is strongly indicative of

more universities engaging in technology transfer activities. It can be seen from Figure 3 that the number of universities receiving patents doubled from 1980 to 1994. It is reasonable to assume that this was in great measure due to the Bayh-Dole Act.

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. What has been the licensing experience? The most recent licensing survey by the Association of University Technology Managers (AUTM)^[14] shows a continuing growth in patenting and licensing activities by the university sector. The data presented in the Survey Summary was utilized by the General Accounting Office in part in formulating its required periodic review of the administration of the Bayh-Dole Act.^[15]

Licenses and options executed have increased steadily since the passage of the Bayh-Dole Act, representing both an increase in the number of universities engaging in patenting and technology transfer activities and in the increasing activities of those universities already engaged in those functions. In accordance with the GAO report for fiscal 1996, the percent increase from the previous year was 8.4 percent for recurring correspondents in the AUTM survey. About 10.9 percent of the licenses or options granted were to start-up companies. 54.7 percent were to small businesses. Moreover, at the end of fiscal 1996, the university sector reported 10,487 active licenses or options, the latter being up by 12.9 percent over the previous year. The number of such licensees and options producing income increased by 16.1 percent over the previous year while the income of \$365.2 million generated by those activities in 1996 represented an increase of 22.1 percent over 1995.

Although, the foregoing figures represent the effect of all licensing activities and not only those attributable directly to operation under the Bayh-Dole Act, it is submitted that because of the overwhelming support of research and development in the university sector by government funding, being 60.2% of all funding in 1995, and the traditional co-mingling of funding by the universities it is legitimate to conclude that the bulk of patenting and licensing activity in the university sector is government-fund driven and falls within the ambit of the Bayh-Dole Act.

Without question, the economic impact of the universities' licensing activities is substantial—estimated, on the basis of the AUTM survey, to add \$24.8 billion to the U.S economy.

Significant as these figures are, 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.

WHAT IS TRULY REMARKABLE TOO IS THAT THESE BENEFITS HAVE BEEN REALIZED AND THE BAYH-DOLE ACT HAS BEEN ADMINISTERED WITHOUT THE NECESSITY FOR CONGRESS TO APPROPRIATE ANY OF THE TAXPAYERS' MONEY FOR ITS OPERATION.

Another measure of the effect of the Bayh-Dole Act is the growth of membership in the Association of Technology Managers and its predecessor the Society of University Patent Administrators. That growth, which is graphically shown in Figure 4 is, perhaps, the most direct measure of the interest in and growth of the technology transfer functions in the university sector. It also evidences the creation and growth of technology transfer as a professional calling.

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. One piece of legislation which could be considered to have been almost directly spawned because of or as the result of the Bayh-Dole Act is the Federal Technology Transfer Act of 1986 (FTTA). That act was introduced as an amendment to the Stevenson-Wydler Act of 1980 which had been intended to promote the utilization of technology generated in government laboratories, but was singularly unsuccessful in accomplishing that goal.

The FTFA was largely a response to the increasingly tough international competition facing the United States and the prevalent complaint that "the US wins Nobel Prizes while other countries walk off with

the market.” The designers of the FTTA built the act under 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 by judicious reliance on market-oriented incentives and protection of proprietary interests.

The principles enumerated were first tested through experience with the Bayh-Dole Act and the FTTA responded to the lessons learned from that law, perhaps the most important of which was its success in promoting university-industry cooperation.

The FTTA is, clearly, a direct highly beneficial legacy of the Bayh-Dole Act, as has been additional legislation designed to expand the use of the results of research carried out within government-owned government operated laboratories by expanding the licensing opportunities for those laboratories.

Commentary

The growth of technology transfer has taken place over the last 30 years in an environment that slowly progressed from hostile to favorable. That progression was given major impetus by the passage of the Bayh-Dole Act. During that period we have seen a dramatic change in the attitude of the Justice Department and the interpretation of the anti-trust laws where patents and anti-trust are no longer viewed as antithetical. We have seen a move toward a favorable statutory basis under which we have much greater freedom to operate. We have had an active effort by various administrations to obtain equitable treatment for U.S. citizens in foreign venues, both in trade and intellectual property pursuits. We have had numerous and far-reaching changes in the patent laws of those foreign venues for example the Patent Cooperation Treaty which provided greater opportunities for technology transfer to these venues. We have also experienced extensive changes in our own patent laws and practices which have further expanded the opportunities to engage in technology transfer. We have had the benefit of a knowledgeable court in the Court of Appeals for the Federal Circuit which has slain many of the mythical dragons attached to intellectual property law to provide uniformity of interpretation of those laws and before which we can expect equitable treatment. We have obtained the attention of Congress and, particularly, the attention in that body to the university sector’s perspective on intellectual property law issues. We have seen the introduction and passage of legislation favorable to the universities and their technology transfer efforts. We have also seen developed, not only in the university sector, but in university-industry relationships and university-industry-government relationship, a greater awareness of technology transfer and a growing recognition of the possibilities which can be made available through creative technology transfer efforts and a much greater sophistication in handling those possibilities. Today we operate in a climate that recognizes the value of intellectual property and the technology transfer function. We would like to think that much of this has come about because the universities, as a source of fundamental discoveries and inventions, have been the source of enlightenment for a recognition of the value of innovation.

A word of caution, however! We work in a very uncertain business where, on the average, it takes in excess of 10 years and hundreds of thousands, even millions, of dollars to bring an invention to the marketplace. We must also remember that, as a licensor, we have very little actual control over the process by which an invention is brought to the market or how, ultimately, it is marketed. We are always vulnerable to the attacks of special interest groups, whether inside or outside of government, which are based not on fact but on emotion or which may be waged for psychological reasons. As long as envy and jealousy are part of the human condition such attacks are inevitable, only the intensity will

rise and fall.

The emphasis today, as well as the “buzzword” in Washington is “competitiveness.” 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^[16] of the Act have 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.

In recent years we have been experiencing an increasing incidence of efforts to restrict or curtail the technology transfer capabilities of the University sector under the Bayh-Dole Act through government agency actions, agency programs and legislative activities and through agency-industry consortiums. For example, pending legislation would disenfranchise the universities, as well as other non-manufacturing entities utilizing the patent system, from exercising the constitutional-based right vested in the patentee to exclude others from practicing the invention patented.

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. The words of the poet Edna St. Vincent Millay seem most apropos to this situation.

We have already passed through an era where science was being made subservient to politics. In today’s technologically intense atmosphere, where the maximum protection for intellectual property is more than ever necessary to provide protection for the heavy investment necessary to technology development, we must remain alert.

Even in the current favorable climate for university technology transfer as the heritage of the Bayh-Dole Act, views on the issues in the control of intellectual property, whether by government or special interests, can lend themselves to emotional molding. Outspoken claims to the guardianship of the public interest or welfare is a rich field for cultivating political power. We must never forget that freedom demands a constant price and that vigilance is essential. To quote Pogo, “We have met the enemy and he is us.”

In the struggle to obtain the passage of the Bayh-Dole Act as well as on other pieces of proposed legislation which impinged on the university sector, the universities, collectively, spoke with a loud and single voice. We must continue to do so in all circumstances which threaten the rights and opportunities which we have earned over many years by dint of perseverance, patience and hard work. This will require a unified, active and continuing participation by all members of the university sector.

“THE HERITAGE OF THE PAST IS THE SEED THAT
BRINGS FORTH THE HARVEST OF THE
FUTURE.”^[17]

Endnotes

- [1] 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.
- [2] Harbridge House, Inc., Government Patent Policy Study for the FCST Committee on Government Patent Policy, May 15, 1968 Vol. II, Parts II and III.
- [3] 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.)
- [4] Presidential Memorandum and Statement of Government Patent Policy (F.R. Vol. 28, No. 200, October 12, 1963).
- [5] Presidential Memorandum and Statement of Government Patent Policy (F.R. Vol. 66, No. 166, August 26, 1971).
- [6] 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.
- [7] 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.
- [8] *Diamond, Commissioner of Patents v. Chakrabarty*, 206 USPO 193, U.S. Supreme Court.
- [9] § 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 United 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.”
- [10] OMB Circular A-124 was subsequently codified as 37CFR Part 401.
- [11] The Presidential Memorandum was incorporated into the text of OMB Circular A-124 on March 24, 1984.
- [12] PL-98-620, The Trademark Clarification Act amended Chapter 18 of Title 25 U.S.C.
- [13] Final rules were published on March 18, 1987 (52 FR 8552) and subsequently codified at 37CFR Part 401.1-401.16.
- [14] AUTM Licensing Survey 1996, Survey Summary, 1997.
- [15] Technology Transfer—Administration of the Bayh-Dole act by Research Universities, GAO, Report to Congressional Committees May 7, 1998.
- [16] See note 9.
- [17] From a tablet affixed to the front of the National Archives in Washington D.C.