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THE EVOLUTION OF MODERN TECHNOLOGY TRANSFER

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Louis Pasteur once observed that:

"There is no greater charm for the investigator than to make new discoveries; but his pleasure is heightened when he sees that they have a direct application to practical life".

During Pasteur's lifetime, a significant number of new discoveries reached application to practical life through the investigator's own resources and effort or those of an organization directed by the investigator.

Samuel B. Morse virtually camped out on the steps of the Congress until he was given a grant to build a 40-mile demonstration telegraph line between Baltimore and Washington. Alexander Graham Bell demonstrated the application of his telephone in his own makeshift laboratory and then pursued its marketing through the incentive of his patent position. Edison's hundreds of patents helped fund the reduction to

practice and the licensing of a flood of now every day products from his Menlo Park laboratory.

But as the early and fundamental discoveries in the life sciences evolved, it became clear that the resources necessary to bring them to practical life exceeded what their investigator could provide through their own effort.

In 1885, Pasteur saved a young boy with rabies in his laboratory. Patients flocked from all parts of the world but his office was too small to receive them all. The next year, before the Academy of Sciences, Pasteur declared that "There is a need for prophylactic measures against rabies. An anti-rabies vaccine should be created." The request from "the father of microbiology" resulted in an extensive, international public subscription generating a fantastic burst of generosity that built the Pasteur Institute as a clinic for rabies treatment, a research center for infectious disease and a teaching center, with Pasteur as director.

Today's Pasteur Institute continues its research, funded in part through royalty returns from discoveries made in their laboratories.

Among the examples of investigator driven application of their discoveries, the practices leading to the discovery and application of the cure for syphilis discovered by the "father of chemotherapy", Paul Ehrlich, comes closest to present day practice.

In 1906, at Ehrlich's urging, the Georg-Speyer-Haus Research Institute for chemotherapy was established with its own staff under Ehrlich's direction. The Institute was an interdisciplinary institute formed to define problems to be attacked through exchange of ideas among biochemists, pharmacologists, clinicians and other scientists working inhouse. A percentage of the profits from patents was designated to be reinvested in the institute to cover its operating costs, including the costs of undertaking new research. The German firms of Hoechst and Casella contributed substantially to the initial endowment and also supplied the raw materials used in the department of chemistry's research. In exchange, the two firms received first refusal on any marketable patents. But the choice of research problems was left to be determined solely by Ehrlich and his staff.

It can be agreed that Pasteur and his peers did not view their efforts as technology transfer nor did they need the assistance of a technology manager.

Notwithstanding these few examples, Professor Frederick Cottrell, the inventor of the electrostatic precipitator, recognized,

> "…the ever growing number of men in academic positions who evolve useful and patentable inventions from time to time in connection with their regular work … (who) would gladly see these further developed for the public good, but are disinclined … to undertake such developments themselves" …

He also noted that there was,

> "…a certain amount of intellectual by-products … going to waste … in our colleges and technical laboratories all over the country,"

and that

> "…a number of meritorious patents given to the public absolutely freely have never come upon the market chiefly because what is everybody's business is nobody's business."

He finally concluded that:

> "A certain minimum amount of protection is usually necessary by any

> manufacturing concern before it will invest … to put a new invention on the market."

These observations led Professor Cottrell to donate his patents and their royalty return from the electrostatic precipitator to fund the creation of the Research Corporation in 1913 to serve as the technology transfer agent for investigators isolated from the commercial marketplace.

In 1925, Professor Steenbock made a similar donation of his vitamin D patents to fund the creation of the Wisconsin Alumni Research Foundation (WARF) limited to serve as the technology transfer agent only for investigators at the University of Wisconsin at Madison. These targeted services were intended to provide greater attention to reported inventions than previously provided by universities.

During these early years of the century, the services of Research Corporation and WARF were clearly limited by their resources. The majority of investigators were left to determine on their own whether to pursue moving their discoveries into practical life. Some of these determinations did not produce an opportune result.

For example, in 1929, Fleming discovered the utility of penicillin, but unlike Pasteur or Ehrlich, made no identifiable effort to bring it into practice beyond its publication. Patent protection was not pursued.

Absent a champion, the benefits of penicillin languished until Florey and Chain devised a method to produce it economically in volume and, prompted by World War II, the Department of Agriculture began manufacture and distribution in 1941.

The huge increase in funding of research and development by the Federal agencies proposed by presidential science advisor Vannevar Bush following World War II brought with it the establishment of a patchwork of different policies covering the ownership of inventions resulting from this funding. Outside the Department of Defense, the policies were heavily weighted in favor of government ownership, resulting in either dedication to the public or non-exclusive licensing of the government's patent rights.

By the 1960's, it was clear to the science management at the National Institutes of Health that their Department's title policy was an impediment to

industry development of the life science inventions resulting from N.I.H. funding.

In 1963, Dr. Endicott, the Director of the National Cancer Institute vigorously pursued the Department (DHEW) until it amended its regulations to provide for industry ownership of new uses of industry compounds submitted to the Institute's cancer chemotherapy screen.

Dr. Shannon, the N.I.H. Director, emphasized before Congress that NIH's research effort was complementary to that of other elements of society and that it was in the best interests of the American people to assure that the various interests of the medical research community can interact and suggested that the Department's patent policy impeded this interaction.

The problem was dramatized by increasing numbers of invention ownership disputes involving inventions assigned without notice to NIH to industrial developers by NIH grantee investigators motivated, as was Pasteur, to see their direct application to practical life.

In the case of Gatorade, Mr. Cade of the University of Florida, frustrated by the Department's

failure to timely respond to his good faith request for patent rights to Gatorade, assigned the invention to Stokely-VanCamp, who thereafter sued the Department for clear title. Under this threat, the Department negotiated leaving the invention to the University of Florida under conditions which were later adopted in the Department's Institutional Patent Agreements (IPA's) and then later in the Bayh-Dole Act.

Earlier, in another notorious situation, Dr. Heidelburger and the University of Wisconsin, after being publicly accused by Sen. Long's staff of confiscating ownership of 5FU, a breakthrough cancer chemotherapy drug and licensing it to an industry developer, successfully convinced the Department that minimal government funds were involved in its conception.

Further, Dr. Guthrie, a Department grantee and the inventor of the then preferred test for PKU being marketed by an industrial developer under license, after being publicly pilloried by Sen. Long's staff for confiscating the invention, assigned ownership to the Department.

These cases had a further chilling effect on industry involvement as they suggested that any amount

of government funding touching an industry invention could result in a similar claim of right by the Government.

Thereafter, in 1968, the G.A.O. added additional urgency to resolving the problem, by reporting that due to Department Patent Policy, inventions resulting from all of NIH's medicinal chemistry grants could not find the necessary industry support to continue development.

Finally, in 1969, responding increasing internal pressure, the Department changed its patent policy and established a uniform institutional patent agreement policy that left ownership to grantee institutions who agreed when they requested an agreement to staff a technology transfer office to manage and license these rights. The conditions attached to these agreements reflected the accepted practices of Research Corporation and WARF. NSF followed with similar changes in 1972. Thereafter, the HEW and NSF staff responsible for IPA policy joined together in a long series of interagency discussions aimed to establish the IPA policy throughout the government agencies.

In 1974, the newly established IPA holders formed the Society of Patent Administrators to enhance outreach to industry so as to overcome industry's continuing resistance to development of government funded inventions because they were not made in the company's laboratories. (Ironically, this impediment was called the NIH or not-invented-here syndrome).

In that same year, members of the Society found their political legs by assisting in preventing the inclusion in legislation creating the Energy Research and Development Agency of a requirement for government ownership of inventions resulting from its funding.

By 1976, 75 IPA's had been negotiated and executed with institutions who received well over 50% of the annual DHEW extramural funding, and GSA regulations expanding the IPA policy to the rest of the government agencies, otherwise covered by statute, were accepted by the interagency Federal Council for Science and Technology (FCST) and published.

Also in 1976, Dr. Frederickson, the Director of NIH, agreed with the consent of the FCST to permit the University of California and Stanford to administer the Cohen-Boyer gene splicing patent under their IPA's. Stanford's non-exclusive licensing of Cohen-Boyer to

dozens of commercial concerns sparked the start of the biotech industry.

Notwithstanding the clear record of increasing licensing by IPA holders, Joe Califuno, the Secretary of the DHEW, instituted a 1977 "reassessment" of the Department IPA policy which stopped further invention processing on the ground that the introduction of new technology into the marketplace was escalating the price of healthcare which required Department oversight. Legislation was introduced in the Senate to provide the Department with this oversight authority at the same time.

Simultaneously, Sen. Nelson of Wisconsin initiated hearings to discuss the legality of IPA's and the GSA regulations expanding their use to all government agencies.

The Califuno and Nelson actions served as the flashpoint for organizations having IPA's to pursue legislation to assure continuance of the 1969 Department policies and their further expansion by the GSA regulations to other federal agencies having conflicting policies. Led by the University of Wisconsin, Stanford University, the University of California, and Purdue, the IPA community, over a

period of two years, were so successful in making their views know to the Congress that Bayh-Dole passed the Senate by a vote of 91-4.

Some suggest that the primary purpose for Bayh-Dole is the production of income for those that participate in the conception and delivery of inventions to the marketplace. I do not believe that was the primary motivation of the Act's architects. Income, which was a distant possibility at the time of enactment, was viewed only as a collateral benefit of success. The Act is structured so as to assist investigators in their pursuit of direct application of their discoveries to practical life up to the point of either success or definitive failure. As such, investigators intuitively understand that the Act provides to them the possibility of their advancing mankind, as Pasteur presumed was their wish, which explains their growing enthusiasm to participate.

The Bayh-Dole Act Redux

Introduction

The Bayh-Dole Act was borne out of conflict. It was the culmination of an almost twenty year effort by, primarily, the United States university sector through educational advocacy to convince agencies of the Federal government and legislators that government patent policies as practiced by its agencies were placing the vaunted technological leadership of the United States in peril at a time when invention and innovation were fast becoming the preferred currency in foreign affairs.

The Act embraced the Congressional answer to the fundamental question posed by the university sector as the basis for its advocacy:

> "In whose hands will the vestiture of primary rights to inventions made with the support of Federal monies, serve to transfer the inventive technology most quickly to the public for its use and benefit?"

The Act's passage was thus 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 the universities and small business was in the public interest; and
4. that the existing federal patent policy, or the lack thereof, was placing the nation in peril.

That the Bayh-Dole Act and its progeny unlocked the door to the technological leadership of the United States in the current global economy cannot be disputed. In 1980 U.S. universities were being issued about 1% of all U.S. origin patents. Today, that figure is 3% or higher. For the most part the inventions represented by those patents arise from basic research and

therefore form the basis for new products, new processes and even new industries – witness the biotech industry. Since 1980 American universities have spun off more than 2,200 new companies (start-ups) based upon the results of the basic research conducted, have, by estimate, created some 260,000 high tech jobs in the process and contribute $40 billion to the U.S. economy on an annual basis.[1] Most notably those goals have been achieved and the benefits derived from them have been realized without the necessity for Congress to appropriate any of the taxpayer's money for the Act's administration.

On January 6, 2003 the *Economist Technology Quarterly* called the Bayh-Dole Act "Innovation's Golden Goose" and gave the Act a ringing endorsement and accolade in the following words:

> " Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayer's money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

Acknowledging that "copying is the sincerest form of flattery", many other countries, through legislative or other acts, are actively trying to emulate the Bayh-Dole Act and its objectives in an effort to utilize their internal resources and thereby maintain a competitive stance. With that international recognition of the value of what has been accomplished in the U.S. because of Bayh-Dole and its progeny, as well as its unprecedented success domestically, it seems paradoxical that the Bayh-Dole Act should be under attack in the U.S. To again quote from the Economist article:

> "....suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of

competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot."

BIOMEDICINE and BAYH-DOLE

With the advent of increasingly rapid discoveries in biotechnology and biomedicine and the emphasis placed on that technology because of the promise it contains for the prevention and treatment of disease, the patenting of discoveries which appear to be pertinent to the chain of drug development has been called into question as being a deterrent to innovation. This premise has been addressed in the light of the increase in the number of patents on various facets of the drug discovery chain and which are collectively called "research tools." The concept of research tools broadly is to include within that definition any tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing disease, e.g. any cell receptor, enzyme or other protein that is implicated in a disease and, consequently, represents a promising focus for drug intervention as well as vehicles and instrumentalities to determine and/or evaluate such intervention.[2]

The focus on research tools under patent stifling innovation is the concept that patent holders will make such tools available to others only at a price or because of a relationship with another which would preclude their broad application in exploratory research.

To carry the definition to an extreme, one can take the position that, since science builds on science, every invention is in reality a research tool. One should, however, not overlook the fact that many patented items which fall within the broad definition of research tools are in fact marketable and marketed products in the hands of many companies. Then too, products sold in kit form for example, to utilize newly discovered processes, can also be classified as research tools. The line is not as bright as might appear only from rhetorical definition.

Also, fundamental to the patent system as first perceived under the constitutional provision for it and as it exists today

through evolution and judicial interpretation, is the intention to encourage imagination and creativity in finding another way to accomplish a particular end if one way was not available because of the existence of patents unavailable for licensing or for access only via perceived onerous and unacceptable conditions i.e. to "invent around" existing patents. These factors have often been the driving force in providing alternative solutions to a given problem and serve to expand the knowledge base available to the scientific community.

There have been two papers recently which have addressed the perception that the patent system today, expanded in its subject matter scope as promulgated under the Chakrabarty case,[3] may be creating difficulties for those engaged in research in the biomedical field and particularly in the drug development chain. These are:

"Research Tool Patenting and Licensing and Biomedical Innovation" by Walsh, Arora and Cohen in W. Cohen & S. Merrill eds Patents in the Knowledge – Based Economy. Washington, D.C.: National Academies Press. (forthcoming)[4]

and

"Bayh-Dole Reform and the Progress of Biomedicine" by Rai and Eisenberg cited as 66-SPG Law and Contemp. Probs. 289.

Inasmuch as the Walsh et al article's conclusion are based upon 70 interviews with intellectual property attorneys, business managers and scientists from 10 pharmaceutical and 15 biotech firms, university researchers and technology transfer offices from 6 universities, patent lawyers and government and trade association personnel and the Rai el at conclusions find their basis in rhetorical reasoning supported in part by a few examples, of which one prime example recites an incorrect fact foundation, we are strongly inclined to accept the Walsh et al conclusions as being the more pragmatic and reflective of actual practices in addressing the problem of relatively broad upstream patents unduly limiting subsequent research. The interviews among diverse participants in biomedical research and development elicited and supported a conclusion that there are no cases in which valuable research projects were stopped because of IP

problems relating to research inputs and that where potential problems were encountered "working solutions" allowed research to proceed. Our own experiences would support that conclusion.

Rai et al, to the contrary, posit on the one hand that ".....patents on biomedical research discoveries plainly offer important social benefits in the form of motivating further private investment in product development" and on the other hand: that "the presumption that patent incentives are necessary to promote research and development has less force for inventions arising from government-sponsored research than for inventions arising from private funding." The experience which the university sector has had under the Bayh-Dole Act would tend to belie the latter statement. What Rai et al seem to have overlooked is that there was recognition by the Congress that incentives to private investment in developing the results of federally sponsored research were necessary since the attendant government patent policy at the time, with title in the government and a non-exclusive licensing policy, was ineffective in transferring the results of federally-supported research to the public for its benefit. And further, that Congress recognized that the vehicle to supply those incentives was the U.S. patent system.

Rai et al in their conclusion, following the above-quoted statements further state: "It is therefore important that decisions about patenting the results of government-sponsored research be made on the basis of a careful balancing of the costs and benefits that they entail for future R&D. Current law entrusts these decisions to the unbridled discretion of institutions, such as universities, that receive federal funds, but these institutions are inadequately motivated to take the social costs of their proprietary claims into account in deciding what to patent. A more sensible approach would give research sponsors, such as NIH more authority to restrict patenting of publicly-funded research when such patenting is more likely to retard than promote subsequent R&D."

The authors here strongly disagree with the conclusions expressed by Rai et al and submit that the reasoning applied to reach such conclusion is faulty for a number of reasons which have been either overlooked, dismissed or ignored by Rai el al.

1. The "decisions about patenting the results of government-sponsored research be made on the basis of careful balancing of the costs and benefits that such patenting will entail for future R&D" presumes that that is possible. In the university sector research that is to be supported by Federal funding is based upon the peer review system and, unlike the private sector, is not product-driven. As a consequence there is already a mechanism of control in place at the funding end which must be presumed to reflect a social consciousness of the projected value of such research. Moreover, as with most if not all basic research one cannot predict the outcome and therefore, the cost to benefit ratio at such an early stage. To then make a forecast as to what effect it will have on future R&D tends to defy logic.
2. "Current law entrusts these decisions to the unbridled discretion of institutions, such as universities, that receive federal funds. But universities may be inadequately motivated to take the social cost of their proprietary claims into account in deciding what to patent."

The use of the word "unbridled" connotes that there are no restraints on the universities' discretion with regard to the patenting of research results whereas in reality there are many restrains imposed upon that discretion. Given that the results of federally-supported basic research tend to be embryonic in nature the patent laws and the regulations under them are not the least of the restraints e.g. there may be no specific, substantial and credible utility that can be expressed for the research results which is a requirement for patentability. Perhaps the greatest restraint upon the university sector in patenting is the lack of discretionary money to do so. Then too, given the generally embryonic nature of most university inventions, the so-called social costs defy assessment.

In this consideration it is of great consequence that the bulk of research results are published through scientific journals without patenting. The generation of inventions is almost never the main objective of basic research. If an

invention is generated it is a largely fortuitous happening where a connection is made between the scholarly work product and the potential for public need. Then too, it is interesting to note that in accordance with the latest AUTM survey[5] of the 13,569 invention disclosures received by the reporting universities (196) only about one-half of the disclosures resulted in a patent application being filed. Of those disclosures where no patent application was filed, presuming some federal support, ownership of the technology effectively was transferred to the government via the particular funding agency with the inventor only assuming title with agency permission.

The patent system does afford a way for universities to position themselves to enable them to take advantage of an opportunity to license an invention when the private sector contemplates a commercial use of the invention. Moreover, when a licensing situation does present itself the bulk of any income generated under and as a result of the license is utilized to support research or education under the dictates of the Bayh-Dole Act. It would appear that Rai et al have overlooked in their assessment and in reaching their suggested conclusion that decisions on patenting and licensing should reside in a government agency, is that the universities have had over 20 years of experience under the Bayh-Dole Act and at least 12 years under the Institutional Patent Agreements with NIH prior to the Bayh-Dole Act to hone their skills in evaluating the results of basic research called to their attention in deciding what technology rises to a level justifying seeking a patent. As pointed out, there are many constraining considerations which affect that decision making it not a willy-nilly approach but one that reflects thoughtful consideration. In addition, universities are fully aware of the social aspects of patenting and licensing in that with licensed technology, whether the license is exclusive or non-exclusive, the right is reserved in the university to continue to use the technology for research purposes. Then too, in accord with the AUTM survey[6] the respondents indicated that about 52% of the licenses

granted were non-exclusive. There is also adequate sophistication in university technology licensing offices to recognize that the value of inventions, in terms of both potential monetary return as well as public interest use, that might truly be classified as research tools might well lie with non-exclusive as opposed to exclusive licensing. The experience with the Boyer-Cohen inventions from Stanford and the University of California is clear in that teaching – a teaching that has not been ignored by the university community. In this regard Rai et al point to the licensing of embryonic stem cell technology by the Wisconsin Alumni Research Foundation as an "example of exclusive licensing of a broadly enabling research tool..." and implying that such license "threatens to throttle scientific progress by limiting the number of players in a developing field. It is at best a disingenuous example in support of the premise advanced by those authors when the applicable fact situation they recite is incorrect. In the embryonic stem cell situation. WARF always reserved the right to license for research purposes and today has some 196 outstanding non-exclusive licenses for that purpose.

Also, it is not offered by Rai et al that often field of use licenses are utilized to increase the number of players in a field while still supplying the incentive, through licensing, for the private sector to engage in product development under the auspices of patent protection.

Rai et al make a further argument, with reference to embryonic stem cells as an example, pointing out that unconstrained by prior art, patents on early-stage discoveries may be quite broad permitting their owners to control subsequent research across a significant range of problems. They then state that the standard response to this argument is that profit seeking owners of pioneer patents will find it in their own best interests to disseminate path-breaking discoveries to as many follow on improvers as possible and utilize as examples, where the latter did not occur, the electric lighting, radio, automobile and aircraft industries. In the examples given, the patents were

generally held by individuals and/or companies bent on having their own products in the marketplace. Why then should they license them to actual or potential competition since they i.e., the private sector companies, are driven by a profit motive and profitability or product sales is more important and most often generates a higher return than licensing. This analysis by example would appear to be flawed when the authors themselves point out that the necessity for patents to motivate investment is more plausible for discoveries that depend on private investments than discoveries made with public funds. Further, the argument ignores the purpose of the Bayh-Dole Act to provide incentives for the private sector to engage in product and process development so that the public can benefit from government-supported research conducted in the university sector.

3. "A more sensible approach would give research sponsors such as NIH, more authority to restrict proprietary claims on publicly-funded research when such claims are more likely to retard than promote subsequent R&D.

At the outset, the tortuous history of the evolution of The Bayh-Dole Act belies the proposal that a government agency should be the residence of decisions to be made regarding the mode of licensing an invention made with federal funds or whether or not a patent on such invention should be sought at all. Every government agency by its very nature is highly bureaucratic in its structure as well as in its decision making. Based upon past experience any such decision will lean heavily toward a fail-safe mode which would be more likely to stifle innovation.

Rai et al state that the Bayh-Dole Act "seriously limits the extent to which it can oversee the deployment of intellectual property rights by its grantees" and then decry what they term the "elaborate administrative procedure" which accompany the "declaration of exceptional circumstances" or the exercise of "march-in rights" under the Bayh-Dole Act. They then conclude that the NIH has never exercised its "march-in rights" because the

"administrative obstacles are sufficiently cumbersome...." It does not seem to occur to those authors that perhaps there have been no abuses of the rights retained by the university sector (or small business) under the auspices of the Bayh-Dole Act which dictate the exercise of march-in.

In the drafting of the Bayh-Dole Act due account was given to the observed predeliction of a government agency to be driven bureaucratically to a "fail-safe" decision and of the admitted failure of the government's "title" and non-exclusive licensing policy in transferring the technology of government-held patents to the public for its use and benefit. For those reasons, as well as the strong reluctance of the private sector to license government-owned inventions because of the government's licensing policy and the vulnerability of those licenses and policies to political pressure, it was concluded that the exercise of "exceptional circumstances" and "march-in rights" should be, in fact, must be, subject to rigorous scrutiny and high-level decision making with appropriate appeal procedures. To now adopt the solution proposed by Rai et al would be a regression to a set of conditions which the Bayh-Dole Act was intended to correct. Such action would amount to contravention of the goals and purposes of Bayh-Dole. Moreover, an accommodation as proposed by Rai et al to one agency of the government, the NIH, would politically and bureaucratically be an invitation to all other government agencies to alter their requirements and procedures too and we could again find ourselves back in the case-by-case determination situation which preceded the Institutional patent Agreements and Bayh-Dole and which was recognized by Congress as being unworkable and a major deterrent to transferring the results of federally-supported research to the public.

Many of the fundamental premises and regulatory controls under the Bayh-Dole Act also govern the licensing of technology today by the government agencies themselves and particularly the NIH. In fact, the Bayh-Dole Act supplied the first statutory authority for the government itself to

patent and license inventions. The amendments that permitted government agencies to license on a partially exclusive or exclusive basis gave strong impetus to the federal laboratories' associations with the private sector.

Rai et al further state: "Although we have no illusions that public sector research can be completely insulated from political controversy, we expect that judicial review of agency determination provide a check on an agency's use of its discretion under the Bayh-Dole Act to advance agendas unrelated to research and development." If one is concerned with transaction costs where multiple patent holders are involved the challenging of an agency disposition decision would be a major concern and deterrent in terms of transaction costs. What that rhetorical comment completely overlooks is that the time delays involved may serve to destroy the viability of an invention for commercialization purposes. To the private sector certainty of title in a given invention was the key element in establishing the university-industry interface. That was afforded the universities under the Bayh-Dole Act. In addition, the opportunity to exclude others from practicing an invention as a reward for the investment of risk monies in development of the invention for the marketplace responded to the risk-reward assessment of the private sector. The latter point was finally recognized by the government laboratories as being an essential element in their invention licensing efforts.

FINANCIAL CONSIDERATION

In addition to the transaction costs as mentioned above Rai et al postulate that the self-interest of universities is an imperfect proxy for the overall public interest "particularly given the large role played in university decision making by technology transfer professionals who are not themselves academics." The implication is, of course, that if the technology transfer professionals were academics (meaning, we must presume, that they themselves were directly engaged in the research function) they would be less driven by a profit motive since, according the Rai et al, the costs are those of the scientists while the benefits

are to the technology transfer offices as a university constituency.

First of all, the technology transfer professionals are in the end governed by academics – university administration is derived from academics – and operate under established university rules as well as statutes and the regulations under them. Under the Bayh-Dole Act any monies in excess of the costs involved in the technology transfer operations and the share allocated to the inventors must be used for further research or education. The academics therefore benefit directly from that technology transfer function if it is successful. Thus, for Rai et al to say that the "gains from licensing revenues are much more salient to the technology transfer offices" is fundamentally misleading.

One of the primary considerations in universities engaging successfully in the technology transfer function is the availability of discretionary monies to enable them to obtain the necessary patent coverage. Absent that critical support the failure of that function is practically assured. Funds for support of that function are not available from federal sources and most often not from university and/or state or other sources except, perhaps, at the inception of a new program. Consequently, for a sustainable operation the technology transfer offices must in the long term generate their own funds to permit them to engage in a patenting effort. To that extent licensing revenues are salient to those offices and their use for the administration of subject inventions, including payments to inventors, as permitted under the Bayh-Dole Act (35 U.S.C. 202 (c)(7).

Technology transfer offices in their functions and through experience are fully aware of the many limitations which are imposed upon them monetarily, academically and ethically. They are also attuned to the requirements of the private sector which are both small and large entity driven, the controlling laws and regulations which impact upon their operation and the lengthy time frames which are encountered in ultimately seeing the results of basic research transformed into commercial applications which accrue to the public benefit. They are and must be therefore selective in the inventions on which patent protection are to be sought in order to position their institutions should a

commercial technology transfer opportunity present itself. This selection process manifests itself in the statistics of the recent AUTM survey with regard to the ratios of patent applications filed to disclosures received and exclusive versus non-exclusive licenses granted.

University technology transfer offices have been engaged in that enterprise extensively since the completion of the first new Institutional Patent Agreement with the NIH beginning in 1968, the Institutional Patent Agreements with National Science Foundation beginning in 1973 and under the Bayh-Dole Act since its effective date of July 1981. This cumulative experience which has to a great extent been memorialized through interchange and interaction in the university sector and complementarily with the private sector under the auspices of AUTM, as well as other university-oriented organizations imparts to the technology transfer professional an understanding of the many facets of the interface between the university and private sectors as well as an appreciation and application of academic principles which is without peer.

Several further reasons why the decisions on patenting of university inventions in general and biomedical inventions in particular should be left with the technology transfer professional as opposed to some government agency are:

1. There is direct access to the inventor(s) – a strong attribute of the Bayh-Dole Act;
2. decisions can be timely made on site as opposed to submitting invention disclosures into a bureaucratic line up--any delay may be costly to the licensing and development process which is highly time-sensitive;
3. there is generally a greater familiarity with the technology package being evaluated, with university personnel involved and with the chronology attaching to the invention;
4. there is greater access to the university community and the collegiality of the residents of that community including technology transfer professionals;

5. there has been no call from NIH to exercise the control suggested by Rai et al – the readily foreseeable staffing necessity and attendant costs would be counter-productive.

CONCLUSION

We have gone through an era in the 1960's and 1970's where science was being made subservient to politics and which generated the expression that the United States walks away with the Nobels but foreign countries walk away with the markets. There is good cause to accept that government patent policy during that period and particularly the absence of a uniform government patent policy was a significant contributor to that malaise.

A sustained effort over many years by the university community to enlighten Congress of the need for action, culminated in the passage of the Bayh-Dole Act in 1980. That Act reversed the presumption of title in and to inventions made by and at universities and small businesses with federal support from the government to the universities and small businesses. According to the Economist Technology Quarterly: ".....More than anything this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

Despite this recognition the Bayh-Dole Act now appears to be under attack, most often not in direct confrontation, but by diluting the premise of ownership of inventions made in whole or in part with federal funds which it embraces. Not the least of these is the recent suggestion that in the field of biomedicine the decision to patent or dedicate to the public domain inventions which are perceived to be "research tools" should reside in the National Institute of Health and not the universities operating under the Bayh-Dole Act. The presumption is that that agency is in a better position to determine what should or should not be patented. That suggestion made by Rai et al, is based upon the presumption that the patent system may be creating difficulties for those trying to do research in biomedical fields. That presumption has been refuted by Walsh et al who conducted a

series of interviews directed to determine the viability of that presumption among those who had exposure to and experience in dealing with that issue.

The Rai et al suggestion is viewed as a regression in policy to the pre-Bayh-Dole Act time where decisions left to government agencies resulted in delays, procrastination and political influence, all of which contributed to the stifling of innovation. To now suggest a reversion to such circumstances would be to again encounter those impediments particularly when the cadre of technology transfer professionals within or on behalf of universities are better trained and experienced in addressing the university-private sector interface attendant upon the transfer of technology under the Bayh-Dole Act. Despite the potential problems which may be encountered, the universities are in a unique position to objectively seek the best qualified commercial partner(s) for developing an invention for the marketplace, to make an assessment of the mode of licensing which will benefit the public most quickly and to monitor the diligence of its licensees in the licensees' development efforts through appropriate arrangements.

The fundamental premise of the Bayh-Dole Act is still the order of the day, namely, that intellectual property derived from the federal support of research within and at universities (and in small businesses as well) in hands other than the government's will transfer the technology to the public more quickly. The university sector has satisfied its role under the Bayh-Dole Act and the obligations which attach to that role. The universities, as a whole, are fully cognizant that they cannot afford to commit to private relationships which would inhibit their flexibility and ability to respond to changing times and the challenges and opportunities which accompany those changes.

The suggestion that a government agency should be delegated the right to determine what should or should not be patented is tantamount to an attack on the U.S. patent system. To single out the biomedical field is disenfranchising inventors is that field of their constitutional rights under the patent system to secure to them, for limited times, the exclusive right to their

respective discoveries. If this exception is made for the biomedical/biotechnology field what is the next exception that someone perceives and advances should also be made. It was evident from the Economist article's conclusion, that the Bayh-Dole Act was a major contributor in bringing the United States back from the brink of industrial irrelevance and that the patent system was the linchpin in achieving its goals and successes.

ENDNOTES

1. Economist science Technology Quarterly, January 6, 2003
2. Walsh, J.P., W.M. Cohen and A. Arora forthcoming (2003) "Patenting and licensing of research tools and biomedical innovation" In S. Merrill, R. Levin and M. Meyers, eds Innovation in a Knowledge-Based Economy. Washington: National Academies Press
3. Diamond, Commissioner of Patents v. Chakrabarty 206 USPQ 193, U.S. Supreme Court
4. Id.
5. AUTM Licensing Survey: FY 2001. Available from the Association of University Technology Managers, 60 Revere Drive, Suite 500, Northbrook, IL 60062
6. Id.