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.

5/737

Pgs. 416-17

II Employee Invention Disclosures
B. Patent Protection
2(a) Government has title
Total for '70-'76 8,566
Pgs. ~~420-421~~ 422-423

III. Contractor Invention Disclosures
B Patent Protection
~~1~~ 1(a) Government has title
Total for '70-'76 5,737

	CMC
~~33~~ 341	1,222
12 347	1259
14 310	1267
17 274	1089
6 261	1124
13 316	1144
102 377	1411

of the Act"

In an article by one of the early critics, Rebecca Eisenberg, the author maintained that "the primary argument against government ownership was a statistical one," based on the "testimony of numerous witnesses," that "only a small percentage of its estimated 28,000 - 30,000 patents had been successfully licensed and exploited commercially." The author ~~further challenged this argument~~ argues that "... the statistical evidence ~~presented~~ was inadequate to document this claim" because it "reflected a huge selection bias as it consisted largely of inventions

1. Pages 1702-3, Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research, Vol. 82: 1663 Virginia Law Review

inventions made by contractors whose research was sponsored by DOD. . . That . . could have obtained title to the patents if they had wanted to do so. On the basis of this ~~any~~ analysis, Ms. Eisenberg concluded that, "It is hardly surprising that few firms were interested in taking licenses from the ~~few firms~~ were interested in government the patents that had already been rejected by contractors that could have owned by them outright if they had found them at all commercially interesting."

It is clear to those involved in assembling the data that Ms. Eisenberg's comments, ~~are~~ having both mere speculation ~~unsupported by any analysis~~ and unfounded for the following reasons:

NO foundation in fact for the patents in question

~~1) The 1000 - 3,000~~

28,021 patents

First, the 28,521 patents placed in contravention by Ms. Eisenberg, 17,000

of which are owned by DOD.
are Not a) the sci. art are
not Contractor INVENTIONS --
All of the 18,021 and
17 000 Fig Univ. found on
page 446 are the ~~result~~
~~of~~ a total of the
Employee generated patents
found on page 416.477 and
the contractor generated of
on ~~page 426~~. Accordingly,
~~The Contractor Connect Number~~
~~must~~ The DOD employee
patents were generated at
laboratories ~~that~~ such as
those ~~of~~ the Naval medical
Center in Bethesda, on
Walter Reed ~~Hospital~~ Hospital in
Wash. D.C. most of which
are ~~of~~ pursuing general
technologies ~~that~~ such as
electronics materials medical
~~that may have~~ the findings of
which may have public utility.
More important is the
fact that the remaining
~~of~~ contractor patents are

generated by military
contractors whose business
is directed to producing
products for military use
rather than commercial
use. Accordingly Ms Eisenberg
conclusion that ~~these~~
~~patents were~~ the "contractor innovation"
~~from these patents had no~~
~~commercial~~ resulting
in patents filed by DOD
~~but~~ were neglected by
the contractor because

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PLoS BIOLOGY

Perspective

Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience

Anthony D. So*, Bhaven N. Sampat, Arti K. Rai, Robert Cook-Deegan, Jerome H. Reichman, Robert Weissman, Amy Kapczynski

Recently, countries from China and Brazil to Malaysia and South Africa have passed laws promoting the patenting of publicly funded research [1,2], and a similar proposal is under legislative consideration in India [3]. These initiatives are modeled in part on the United States Bayh-Dole Act of 1980 [4]. Bayh-Dole (BD) encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licenses to private firms [5,6], on the assumption that exclusive licensing creates incentives to commercialize these inventions. A broader hope of BD, and the initiatives emulating it, was that patenting and licensing of public sector research would spur science-based economic growth as well as national competitiveness [6,7]. And while it was not an explicit goal of BD, some of the emulation initiatives also aim to generate revenues for public sector research institutions [8].

We believe government-supported research should be managed in the public interest. We also believe that some of the claims favoring BD-type initiatives overstate the Act's contributions to growth in US innovation. Important concerns and safeguards—learned from nearly 30 years of experience in the US—have been largely overlooked. Furthermore, both patent law and science have changed considerably since BD was adopted in 1980 [9,10]. Other countries seeking to emulate that legislation need to consider this new context.

Overstating Claims

On a positive note, the BD Act required different agencies that funded US research and development to adopt more consistent policies about ownership of patents arising from federal funding [5]. One of BD's intended virtues involved transferring default patent ownership from government to parties with stronger incentives to license inventions. BD assigned ownership to institutions, such as universities, nonprofits, and small businesses, although it could just as easily have opted for individual grant and contract recipients.

Nevertheless, many advocates of adopting similar initiatives in other countries overstate the impact of BD in the US. Proponents note *The Economist's* 2002 claim that the Act was "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century" [11]. They also cite data (originally used by US proponents of the Act) on the low licensing rates for the 28,000 patents owned by the US government before BD to imply that the pre-BD legal regime was not conducive to commercialization [12]. But as Eisenberg [5] has argued, that figure is misleading because the sample largely comprised patents (funded by the Department of Defense) to which firms had already declined the option of acquiring exclusive title. Moreover, these figures are of questionable relevance to debates about public sector research institutions, because almost of the patents in question were based on government-funded research conducted by firms, not universities or government labs [13]. Finally, and most importantly, the narrow focus on licensing of patented inventions ignores the fact that most of the economic contributions of public sector research institutions have historically occurred without patents—through dissemination of knowledge, discoveries, and technologies by means of journal publications, presentations at conferences, and training of students [6,14,15].

Throughout the 20th century, American universities were the nation's most powerful vehicles for the diffusion of basic and applied research results [16], which were generally made available in the public domain, where industry and other public sector researchers could use them. These activities were central to the rise of American technological success broadly and to the growth of knowledge-based industries, such as biotechnology and information technology, in particular.

Public sector research institutions also relied on generous public funding for academic research—from a highly diverse group of federal funding agencies—which grew dramatically after the Second World War, and on the availability of venture capital to

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Abbreviations: BD, Bayh-Dole; NIH, National Institutes of Health; R&D, research and development

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foster the development of early-stage ideas [6]. These and other unique features of the US research and development system explain much more about innovation in the US after BD than the rules about patenting that BD addressed.

In the pre-BD era, discoveries emanating from public research were often commercialized without patents, although academic institutions occasionally patented and licensed some of their publicly funded inventions well before BD, and these practices became increasingly common in the 1970s [17]. Since the passage of the Act in 1980, US academic patenting, licensing, and associated revenues have steadily increased. BD accelerated this growth by clarifying ownership rules, by making these activities bureaucratically easier to administer, and by changing norms toward patenting and licensing at universities [6]. As a result, researchers vested with key patents sometimes took advantage of exclusive licenses to start spin-off biotechnology companies. These trends, together with anecdotal accounts of "successful" commercialization, constitute the primary evidence used to support emulating BD in other countries. However, it is a mistake to interpret evidence that patents and licenses have increased as evidence that technology transfer or commercialization of university technology has increased because of BD.

Although universities can and do patent much more in the post-BD era than they did previously, neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively [6,18].

Another motivation for BD-type legislation is to generate licensing revenues for public sector research institutions. In the US, patents are indeed a source of revenues for some universities, but aggregate revenues are small. In 2006, US universities, hospitals, and research institutions derived US$1.85 billion from technology licensing compared to US$43.58 billion from federal, state, and industry funders that same year [19], which accounts for less than 5% of total academic research dollars. Moreover, revenues were highly concentrated at a few successful universities that patented "blockbuster" inventions [20].

A recent econometric analysis using data on academic licensing revenues from 1998 to 2002 suggests that, after subtracting the costs of patent management, net revenues earned by US universities from patent licensing were "on average, quite modest" nearly three decades after BD took effect. This study concludes that "universities should form a more realistic perspective of the possible economic returns from patenting and licensing activities" [21]. Similarly, the head of the technology licensing office at MIT (and former president of the Association of University Technology Managers) notes that "the direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research)... [M]ost university licensing offices barely break even" [22].

It is thus misleading to use data about the growth of academic patents, licenses, and licensing revenues as evidence that BD facilitated commercialization in the US. And it is little more than a leap of faith to conclude that similar legislation would automatically promote commercialization and technology transfer in other, very different, socioeconomic contexts.

Sources of Concern

What have we learned from the US experience with BD? Because the Act gives recipients of government research funds almost complete discretion to choose what research to patent, universities can patent not only those inventions that firms would fail to commercialize or use without exclusive rights, but also upstream research tools and platforms that do not need patent protection and exclusive licensing to be adopted by industry [6,9,10].

For example, while the patented technologies underlying recombinant DNA were fundamentally important for biotechnology and generated ample revenues for Stanford, the University of California, Columbia University, and City of Hope Medical Center [6], the patenting and licensing of these research platforms and technologies were not necessary for commercialization. Both the Cohen-Boyer patents for recombinant DNA and the Axel patents on cotransformation were rapidly adopted by industry even though neither invention came with the BD "carrot" of an exclusive right. The Cohen-Boyer patents reportedly contributed to 2,442 new products and US$35 billion in sales. Its licensing revenues to Stanford University and the University of California San Francisco were US$255 million [23]. With 34 firms licensing the technology, the Axel patents earned US$790 million in royalties for Columbia University over the patent period (Colaianni and Cook-Deegan, unpublished data). While the patenting and licensing of these inventions clearly enriched the universities involved, there is no reason to believe that nonexclusive licensing (as opposed to simple dedication to the public domain) deterred commercialization of the invention(s). In fact, Columbia University justified efforts to extend the life of its Axel patents not because such extension would improve commercialization, but rather because it protected royalty income that would be channeled back into its educational and research mission.

While BD gave those conducting publicly funded research the discretion to patent fundamental technologies, changes in US patent law since 1980 provided the means, by expanding eligibility standards to include basic research and research tools. These trends have been notable in the biotechnology and information technology sectors [24,25]. A widely watched, recent consequence of this shift involves the suite of University of Wisconsin patents on embryonic stem cell lines [26–28]. Biotechnology firms eager to do research on stem cells have complained about the excessive licensing fees that Wisconsin charges (as well as about "reach through" provisions that call for royalties on any product developed from research on embryonic stem cells, and impose restrictions on use) [29]. Rather than promote

commercialization, these patents on basic research platforms constitute a veritable tax on commercialization [30]. Nor were these efforts to tax future innovation unprecedented, as the example of recombinant DNA shows. The Wisconsin Alumni Research Foundation's extension of licensing terms to academic research institutions [31] and its imposition of restrictions on use became especially controversial because these measures went beyond the Cohen-Boyer precedent. The manager of recombinant DNA licensing at Stanford quipped, "[W]hether we licensed it or not, commercialization of recombinant DNA was going forward…a nonexclusive licensing program, at its heart, is really a tax…But it's always nice to say 'technology transfer'" [32].

The broad discretion given to publicly funded research institutions to patent upstream research raises concern about patent thickets, where numerous patents on a product lead to bargaining breakdowns and can blunt incentives for downstream research and development (R&D) [33,34]. Barriers to bundling intellectual property necessary for R&D become higher in frontier interdisciplinary research areas, such as synthetic biology, microarrays, and nanobiotechnology, because they draw upon multiple fields, some of which may be likelier than others to form thickets over time [9,10,32,35]. Although there is some evidence that biotechnology and pharmaceutical firms may be able to avoid thickets through secret infringement or by "off-shoring" research to countries with fewer patent restrictions [36], secret infringement and the transfer of R&D to other countries are hardly tactics that government policy should encourage.

The problems that BD has raised for the biopharmaceutical industry are dwarfed by the problems it has raised for information technology. Universities may too often take a "one size fits all" approach to patenting research results, notwithstanding the evidence that patents and exclusive licensing play a much more limited role in the development of information technology than they do in the pharmaceutical sector [37]. In testimony to the US Congress, a prominent information technology firm complained that aggressive university patenting impeded both product development and university–industry collaboration, which encouraged companies to find other university partners, often outside the US [38]. Expressing similar concerns in a proposal to explore alternatives to the BD model, officials from the Ewing Marion Kauffman Foundation (the leading US foundation supporting entrepreneurship research) recently argued that "Technology Transfer Offices (TTOs) were envisioned as gateways to facilitate the flow of innovation but have instead become gatekeepers that in many cases constrain the flow of inventions and frustrate faculty, entrepreneurs, and industry" [39].

These problems have not escaped the attention of funding agencies, most notably the US National Institutes of Health (NIH), which has issued guidelines stating that patents should be sought, and exclusive licenses should be restricted, only when they are necessary for purposes of commercialization [40,41]. Beyond such hortatory guidelines, however, US funding agencies retain very limited authority to guide the patenting and licensing practices of publicly funded research institutions. Under BD, agencies can declare particular areas off-limits to patenting only when they find "exceptional circumstances." Moreover, they must present this decision to the Department of Commerce, the primary administrator of BD. The "exceptional circumstances" authority has only rarely been used [30]. However, when exclusive licensing demonstrably impeded commercialization, the funding agencies did not intervene by exercising their authority to mandate additional licensing. Their reluctance to take such action stems in part from the realization that, under the BD regime as enacted, any mandate could immediately be challenged (and its effect stayed) pending the outcome of protracted litigation [30].

Some of the top US universities have themselves begun to recognize the difficulties that overly aggressive proprietary behavior can engender, as demonstrated by their March 2007 declaration highlighting "Nine Points to Consider in Licensing University Technology" [42]. How this declaration will affect university behavior is difficult to predict. Moreover, the "Nine Points" declaration focuses almost entirely on licensing and fails to address how universities should determine whether patents are necessary for commercialization in the first instance.

BD has also led to downstream concerns. The BD framework makes minimal reciprocal demands from licensees of government-funded technologies, and neither universities nor government agencies have sought to include requirements that products derived from these inventions be sold to consumers on reasonable terms [43]. Nor do funders require either disclosure of follow-on investments, so that prices might reflect the private contribution to development or the avoidance of abusive or anticompetitive marketing practices [43–47].

Some have raised concerns that the Act contributed to a change in academic norms regarding open, swift, and disinterested scientific exchange [48,49]. For example, in a survey to which 210 life science companies responded, a third of the companies reported disputes with their academic collaborators over intellectual property, and 30% noted that conflicts of interest had emerged when university researchers became involved with another company [50]. Nearly 60% of agreements between academic institutions and life science companies required that university investigators keep information confidential for more than six months—considerably longer than the 30 to 60 days that NIH considered reasonable—for the purpose of filing a patent [50]. Similarly, in a survey of life science faculties at universities receiving the most NIH funding, nearly a third of the respondents receiving a research-related gift (e.g., biomaterials, discretionary funds, research equipment, trips to meetings, or support for students) reported that the corporate donor wanted pre-publication review of any research articles generated from the gift; and 19% reported that the companies expected ownership of all patentable results from the funded research [51].

Although the surveys discussed above were conducted in the mid to early 1990s, their findings appear robust over time. In a more recent

survey of university geneticists and life scientists, one in four reported the need to honor the requirements of an industrial sponsor as one of the reasons for denying requests for post-publication information, data, or materials [52]. This finding is also corroborated by a survey of US medical school faculty. In these settings, researchers most likely to report being denied research results or biomaterials by others were "those who have withheld research results from others" or who had patented or licensed their own inventions [53]. So the practices of patenting and licensing clearly encumber the openness of scientific exchange in universities.

Instituting Safeguards

Countries seeking to enhance the contributions of universities and public sector laboratories to social and economic development have numerous policy options. Many of these policies do not involve intellectual property rights at all, but rather look to provide funds for basic and applied research, subsidize scientific and engineering education, strengthen firms' ability to assimilate university research, and invest in extension, experimentation, and diffusion activities [39,54,55]. But even policies focused on intellectual property management need not presume that patenting and exclusive licensing are the best options. For example, they may instead focus on placing by default or by strategy government-funded inventions into the public domain, creating a scientific commons, enabling collective management of intellectual property, or fostering open-source innovation [56–60]. Where greater commercial incentives seem necessary, the benefits of nonexclusive licensing should always be weighed against the social cost of exclusive licenses.

The appropriate array of policies will vary from country to country: there is no "one size fits all" solution. Based on our review above, we believe it is doubtful that the benefits of legislation closely modeled on BD would outweigh their costs in developing counties. For those countries that nonetheless decide to implement similar laws, the US experience suggests the crucial importance, at a minimum, of considering a variety of safeguards (see Box 1).

Conclusion

While policies supporting technological innovation and diffusion contribute to economic growth and development, the appropriate sets of policies to harness public sector R&D are highly context-specific. Much depends on factors such as the level of publicly funded research, the focus of such research on basic versus applied science, the capabilities of industry partners, and the nature of university–industry linkages [54,55].

Recognizing these difficulties, reasonable minds may disagree about the likely impact of BD-type legislation elsewhere. Nevertheless, the present impetus for BD-type legislation in developing countries is fueled by overstated and misleading claims about the economic impact of the Act in the US, which may lead developing countries to expect far more than they are likely to receive. Moreover, political capital expended on rules of patent ownership may detract from more important policies to support science and technology, especially the need for public funding of research. Given the low level of public funding for research in many developing countries, for example, the focus on royalty returns at the expense of public goods may be misplaced [61]. Furthermore, it is unclear whether any of the positive impacts of BD in the US would arise in developing countries following similar legislation, absent the multiagency federal pluralism, the practically oriented universities, and other features of the US research system discussed above.

In any event, both the patent laws and patterns of scientific collaboration have changed substantially since BD was passed in 1980. To the extent that legislation governing the patenting and licensing of public sector research is needed in developing countries at all, it should reflect this new context rather than blindly importing a US model that is 30 years old. ■

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Competing interests. The authors report the following nonfinancial conflicts of interest:

ADS is a Member of the Advisory Board for Universities Allied for Essential Medicines and has conducted commissioned research for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

BNS is a Member of the Advisory Board for the Initiative for Medicines, Access & Knowledge and has testified before the Secretary's Advisory Committee on Genetics, Health, and Society, Task Force on Impact of Patents and Licensing Practices on Clinical Access to Genetic Testing (July 10, 2007).

AKR is a Member of the Scientific Advisory Board for Science Commons and the Advisory Board for the Peer-to-Patent Project. She has testified before the Senate Committee on the Judiciary hearing on "The Role of Federally-Funded University Research in the Patent System" (October 24, 2007) and has conducted commissioned research for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

RC-D is a Member of the National Research Council Committee on Management of University Intellectual Property and the Task Force on Patent Reform of the Association of American Universities, Council on Government Relations, Council on Education, National Association of State Universities and Land Grant Colleges, and Association of American Medical Colleges (joint committee). He has also conducted commissioned research for the Secretary's Advisory Committee on Genetics, Health, and Society, Task Force on Impact of Patents and Licensing Practices on Clinical Access to Genetic Testing (ongoing) and for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

JHR is a Member of the Editorial Board for the *Journal of International Economic Law*. He has testified before the NIH Public Hearing on March-In Rights under the Bayh-Dole Act, National Institutes of Health (May 25, 2004).

Box 1: Safeguards Serving the Public Interest

Governments adopting laws styled after the US BD Act should be vigilant to ensure that the public's interests are served. In commercializing publicly funded research, a number of safeguards on patenting and licensing practices should be built into any law or its regulatory implementation.

No Exclusive Licensing Unless Necessary for Commercialization

Any BD-style legislation should be founded on the principle that publicly funded research should not be exclusively licensed unless it is clear that doing so is necessary to promote the commercialization of that research. Public sector institutions should not, for example, exclusively license research tools that were developed with public funding if those tools can instead be used off the shelf by others. Where exclusive licenses are not required for commercialization, one may ask whether universities and public sector labs should be patenting research at all. Will encouragement of patenting and nonexclusive licensing, as in the Cohen-Boyer model discussed above, help or hurt researchers, firms, and the public in developing countries? Even nonexclusive licenses will tax downstream users, although presumably with lower rents and transaction costs and more procompetitive effects. As suggested above, revenues from licensing academic inventions are likely to be minuscule for most institutions, and aggressive university patenting can have other deleterious effects. A robust research exemption can ward off some of the problems potentially associated with restrictive licensing of upstream inventions [62].

Transparency

The legislation should ensure transparency in the patenting and licensing of publicly funded research. Public accountability should follow public funding. Institutions that engage in patenting and licensing should be required to report or make public all information that is necessary to determine whether they are reasonably serving the public interest. Such information may include the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, and the key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights) of licenses. The lack of a transparency mandate is a key flaw of the BD Act that should not be replicated.

Government Authority To Issue Additional Licenses

Where licensing arrangements for publicly funded research do not achieve public interest objectives, governmental authorities must have power to override such licenses and to grant licenses to additional or alternative parties [9,10,43]. In the US, this authority is formally embodied in the government's "march-in" rights under BD, but this power has never been exercised. Petitions to invoke it have been made a few times [46,47,63,64], but they have never been granted, and because of the administrative disincentives built into BD, this power is unlikely ever to be used [30]. To avoid this result, legislatures must develop standards to ensure that march-in rights or comparable authority will be exercised when public interest objectives are not otherwise attained.

In evaluating licensing options, those receiving government research funding could also be required to consider the option of licensing patented inventions to a "technology trust," that is, a commons that would ensure designated inventions remained available to all interested parties on predetermined terms. Such a commons could enable the pooling of socially useful bundles of technology, particularly research tools and health technologies for neglected or rare diseases. Governments might also consider reducing or waiving patent application and maintenance fees for such inventions when they are made broadly available for research and humanitarian application, without royalty, for a specific geographical area or field of use.

Government Use Rights

The government should retain an automatic right to use any invention arising from its funding. Under BD, the US government has an automatic "nonexclusive, nontransferable, irrevocable, paid-up license" [65] to use any invention developed with government funds. Typically, however, it does not invoke such a license and often pays monopoly prices for products that it funded. The US experience shows the importance both of establishing that the government should be provided with an automatic license in products resulting from its funding and of elaborating standards to ensure such licenses are actually exercised in appropriate circumstances.

From a broader perspective, governments retain the right to use any invention, whether or not it arises from public funding, under international law [66]. Governments may choose to use patented inventions to promote public health [67], national security [66], or comparable objectives, while public-interest compulsory licenses may sometimes be granted to avoid abusive licensing practices or to ensure access to patented research products on reasonable terms and conditions [43,66]. Where publicly funded grantees fail to commercialize a technology appropriately or to foster its availability, the trigger for government use—under any enabling provision adopted in domestic law—must work better than the march-in right has under BD.

Access to End Products

Besides promoting commercialization, the government must ensure consumer access to end products. The public is entitled to expect that the inventions it paid for will be priced fairly. The US experience shows that a BD system that lacks mandatory rules concerning the affordability of end products will not deliver on this reasonable expectation [43–47]. As a condition of receiving a license to a government-funded invention, parties should be required to ensure that end products are made available to the public on reasonable terms and conditions. What constitutes "reasonable" will vary by national context, but it is important to ensure that the term is defined with enough precision to be enforceable.

Licenses to government-funded inventions should presumptively include access-oriented licensing provisions that address humanitarian needs in other countries [68]. One such provision is an open license for production and sale of end products in (or to) developing countries in exchange for a fair royalty [69]. At the very least, when inventions have foreseeable applications in resource-poor regions, a plan for access in those regions should be explicitly incorporated into technology licensing.

RW is the Director of Essential Action. He is also Counsel to, and Member of the Board of Directors of, Essential Inventions, which has petitioned for the issuance of march-in licenses for two government-funded pharmaceutical products, ritonavir and latanoprost. He is also a Member of the Board of Directors for Health GAP (Global Access Project) and the Board of Directors for Union for the Public Domain. He has testified before the Senate Committee on the Judiciary hearing on "The Role of Federally-Funded University Research in the Patent System" (October 24, 2007).

AK is a Member of the Board of Directors for Universities Allied for Essential Medicines.

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