November 11, 1971

Mr. Roman C. Braun
Chairman, Study Group No. 6
Commission on Government Procurement
1717 H Street, N. W.
Washington, D. C. 20006

Re: Report by Task Force #1 of Study Group #6
Commission on Government Procurement
Allocation of Rights to Inventions Made
in the Performance of Government Research
and Development Contracts and Grants

Dear Mr. Braun:

Attached is the Final Report of Task Force #1 of Study Group #6 which we respectfully submit will provide some new and practical solutions for the allocation of government contract patent rights.

May I take this opportunity to thank each of the members of Task Force #1 for their conscientious, diligent and objective efforts in arriving at the conclusions set forth therein. It has been a great pleasure to me to serve with all of them and I have learned a great deal from the various viewpoints and expertise of the members of this widely-based group. We are especially grateful to Mr. Norman J. Latker of HEW who labored over numerous drafts of the report. While it has not been possible to resolve some of the details of the problems which we discussed, I believe the report reflects the general concensus on the more important items. It also enumerates a few of the other features which still require specific resolution.

The primary mission of the Commission and the Task Force is to provide recommendations to Congress for possible legislation, which may involve extensive hearings with resultant long-time delay. The majority of the Task Force believes that the question of allocation of patent rights under government contracts is a long-standing one which has not been satisfactorily resolved by the two Presidential Memoranda on Government Patent Policy or by the piecemeal patent legislation previously provided by the Congress. We also have been very aware of the vast differences between such statements or legislation and the specific implementations thereof by the many government agencies which have

been given wide discretion or only very broad policy criteria. Even different departments in the same agency have had quite different policies and procedures.

We have attempted to provide a much more simplified and equitable procedure and policy for resolving such questions at the more appropriate times when maximum relevant information is available to both the Government and its contractors. We have been cognizant of the attempts by Congress and the Executive to reduce government red tape and have attempted to provide means which we believe will save a great deal of presently-wasted effort in negotiation and administration. Contractor participation in R&D contracting is encouraged.

We respectfully submit that the essential features of the recommended policies and procedures could just as well be implemented by Executive Order under existing powers and legislation. Much earlier and more efficient and uniform administration could be provided with considerable manpower and tax savings. We recommend that a copy of this report be forwarded to the Committee on Government Patent Policy under the Federal Council for Science and Technology for consideration. We also submit that any such solutions cannot be reached solely by consultation between the various executive agencies, but must include resolution of the practical considerations encountered by industry in its attempts to serve the Government and public interests.

We recommend a general policy which would utilize a single government-wide Patent Rights R&D contract clause. It would provide "exclusive commercial rights" in contract inventions for a period of three years after issuance of a patent thereon to the R&D contractor, while providing the Government a non-exclusive, irrevocable, royalty-free, worldwide license for all federal government purposes. Such action would provide ease of administration of patent matters at the time of contracting. It should also provide for more widespread and effective contractor participation in government R&D contracts, especially by the portions of industry having large commercial investment, patent interests, and expertise in the related field, who could best provide the Government's needs. The contractor would be granted the initial period of exclusivity, since he would generally be the entity most likely to utilize, or license, the invention to provide new products for public use. In order to maximize competition in the commercial markets and the broadest possible utilization of the inventions, the Government would have the right, after the initial exclusive period, to acquire, or require, such additional rights for itself or for others as would be necessary and equitable.

We believe that the vast negotiation effort now wasted both in the

Government and in industry in deciding the disposition of patent rights at the time of contracting could be eliminated. Much more realistic effort could be expended on a greatly reduced scale by consideration of patent rights when the real interests of the Government, the Contractor, and the public are better defined with respect to a relatively few specific inventions of real public interest. Such a solution would be much superior to resolution of patent rights on an uninformed basis of supposedly relevant broad technical fields or agency missions prior to the time of contracting. It also always offers an acceptable degree of patent protection to the Contractor at the time of contracting.

Instead of resolution of patent rights according to the discretion of the individual agencies, we believe that issues arising under the general policies should be settled by an unbiased Board of Review comprising a permanent chairman and secretary, and expert members selected from a panel representing government, the public and industry. In unusual circumstances, preliminary appeal could be made to the Board by an agency believing that a special situation is involved in a particular contract. It is contemplated that no blanket deviations should be authorized by the Board. Prospective licensees under government contract inventions also would have the right of appeal to the Board in the event they were unable to negotiate suitable licenses with the contractor under government contract inventions. Prospective contractors could appeal unreasonable Agency actions or demands.

The Task Force has differing views on whether "exclusive commercial rights" to the contractor should involve "title" in contract inventions or "exclusive license and sublicense rights" to the contractor, all subject to the Government's license for governmental purposes. We recommend the solution of such details by the Congress, or the Executive, depending upon the specific means in which our recommendations might be implemented.

We also submit herewith a Minority Report submitted by James E. Denny, Esq., a member of the Task Force, who believes the present government patent policy should be adequate. Mr. Denny's report comments favorably on some of the features, including the Review Board, of the Majority Report, while questioning the desirability of other features. He concludes by stating that he considers the Majority policy to be an alternative he could support.

We are not forwarding herewith the numerous background items listed in Appendix A since Study Group #6 already has this

material. However, we are forwarding Appendix B which includes some additional background items of current importance which may assist in evaluating our report.

If Task Force #1 can be of further assistance, please do not hesitate to call upon us.

Very truly yours,

J. L. Whittaker

J. L. Whittaker
Chairman

cc: Members of Task Force #1
G. D. O'Brien, Esq.
O. A. Neumann, Esq.
Leonard Rawicz, Esq.

REPORT BY TASK FORCE NO. 1 OF STUDY GROUP NO. 6 OF THE COMMISSION ON GOVERNMENT PROCUREMENT ON THE ALLOCATION OF RIGHTS TO INVENTIONS MADE IN THE PERFORMANCE OF GOVERNMENT RESEARCH AND DEVELOPMENT CONTRACTS AND GRANTS

THE TASK FORCE AND ITS ASSIGNMENT

The Task Force was assigned to consider the problems involving allocation of rights to inventions made in the performance of government research and development contracts and grants. (The terms "rights to inventions" or "invention rights" should be understood to include "patent rights" when patent applications or patents are involved. Further, the terms "contract(s)" or "contractor(s)" should be understood to hereinafter include, respectively, "grant(s)" and "grantee(s)".

The membership of the Task Force consists of individuals chosen for their patent expertise from government, industry, universities and the private bar. In an effort to obtain an objective view, each representative was requested to present his own views and not those of his employer.

BACKGROUND MATERIALS

During the deliberation of issues presented to the Task Force it took into consideration a number of factors, including the experience of its membership, President Kennedy's and Nixon's Statement of Patent Policy and the experiences thereunder, existing legislation, Executive and Congressional hearings and reports, regulations of the Executive, and hearings and investigations of this Commission and other private groups. A bibliography listing an extensive amount of literature generated by the debate over allocation of invention rights is attached as APPENDIX A.

INTRODUCTION AND HISTORY

The rapid increase of government-funded research and development since the end of World War II to the level of 15 billion dollars in fiscal year 1971 has focused attention upon the adequacy of government policies governing the disposition of inventions made by contractors in performance of government contracts.

During the early stages of the expansion of government-sponsored research and development those departments and agencies of the Executive most affected issued regulations making disposition of inventions between themselves and their contractors. In the main, such policies provided for either (a) a first option to title in the contractor with a royalty-free license to the government for governmental purposes or (b) title in the department or agency with a nonexclusive license to the contractor for commercial use. The former policy was best exemplified in the Department of Defense patent regulations. The Department of Defense has stated that this policy satisfied their needs since it gave the government as a minimum the world-wide right to utilize all Department-funded inventions for governmental purposes. The latter policy was best exemplified in the patent regulations of departments and agencies whose research and development mission is directed toward generating results that might be useful in the civilian economy.

As the issue surrounding the allocation of invention rights became more pronounced, the Congress acted to provide statutory guidance. This guidance took the form of individual statutes which covered inventions evolving from a portion of or an entire department or agency's research and development program.

The language of the statutes reveals no consistent intent on the part of Congress to provide a uniform government patent policy. To the contrary, the statutes provide in some instances for title in the government and in other instances direct the department or agency to take into consideration the equities of the contractor.

An attempt to moderate the controversy revolving around the different statutory and regulatory patent policies eventually resulted in President Kennedy's October 10, 1963 Memorandum and Statement of Government Patent Policy. This Statement was the first effort by the Executive Branch to resolve the allocation of invention rights issue on a government-wide basis. President Kennedy's Statement is based on the assumption that no single disposition of ownership could accommodate the different missions of the various government agencies. Thus, the Statement indicated as one of its objectives, ". . . . a government-wide policy (subject to statute) on the disposition of inventions made under government contracts reflecting common principles and objectives, to the extent consistent with the missions of the respective agencies." (Underlining and parenthetical clause added.) Accordingly, the Statement left to the various departments and agencies the determination as to whether their prior existing policies were consistent with the intent of the Statement.

On August 23, 1971, President Nixon issued a revised Memorandum and Statement of Government Patent Policy. The revised Statement left unaltered the basic principles on the allocation of invention rights set forth in President Kennedy's 1963 Statement. However, the revised Statement does provide for additional authority in the departments and agencies (not otherwise restrained by statute) to grant exclusive rights to contractors in identified inventions to which the government has either retained a first option to title or has already taken title. This authority has been previously exercised by some of the departments and agencies upon a contractor's petition for title at the time of identification of the invention or through the granting of exclusive licenses to interested developers under government-owned patents.

As of this date, the departments and agencies have the authority under the revised Presidential Statement or under statute to take title or license in the government; delay determination of ownership until identification of the invention; or grant exclusive licenses under government-owned patents. Since issuance of President Kennedy's Statement, most of the departments and agencies have been increasingly utilizing various combinations of these mechanisms of disposition. A contract clause reserving title to the government is generally utilized when the contract relates to certain technical fields or missions and less often under other specified conditions. Only in the absence of such fields or conditions and providing the contractor can establish special expertise, facilities, patent position, etc. does the government utilize a contract clause permitting the contractor a first option to title to inventions which may arise in performance of the contract. Clauses which defer determination until identification of the invention are generally used when neither the criteria for a title or license clause are clearly met.

Notwithstanding the issuance of the 1963 Kennedy Statement of Government Patent Policy, Congress continued to provide guidelines in the form of individual statutes as new research programs were initiated. The Task Force is of the opinion that President Nixon's revised Statement will probably not deter similar statutory enactments.

(For further detail concerning the historical development of government patent policy prior to President Nixon's revised Statement see "Remarks of James E. Denny Before the Intellectual Property Rights Seminar, Smithsonian Institution, April 7, 1971," APPENDIX B)

ANALYSIS OF CURRENT GOVERNMENT PATENT POLICY

The Task Force, after reviewing the different statutory and regulatory patent policies under which the departments and agencies now operate, was critical of a number of aspects of the policies'

overall impact. The Task Force believes that some of these criticisms would be inherent to any government-wide policy which permits Congress or an individual department or agency to establish and/or implement policies for such department or agency different from other department or agency policies. The following were considered to be the most important areas of concern:

1. The existing patchwork of statutory and regulatory policies under which the departments and agencies now operate does not afford government contractors, who deal with multiple departments and agencies, the degree of predictability of ownership of resulting inventions and the ease of administration one could reasonably expect when dealing with a single entity such as the Federal Government. In addition to the difficulties encountered in mastering the multiplicity of different department and agency policies, the administrative burden now imposed on the contractor to establish his equities in inventions that have resulted or will result from his government-sponsored research is out of proportion to the total number of economically significant inventions generated. It is further noted that the burden on the contractor to establish these equities also creates an administrative burden on the government to review the contractor's position. The Task Force believes that a government patent policy should provide for predictability and ease of administration on the part of both the contractor and the government wherever possible.

2. The Harbridge House Study on Government Patent Policy indicated that in certain situations the retention of exclusive commercial rights in the contractor "will, on balance, promote utilization better than acquisition of title by Government". It is axiomatic that those departments and agencies that retain title to all inventions generated by their programs for dedication or non-exclusive licensing, by policy decision or through statutory direction, are precluded from identifying those inventions best retained by the contractor. The Task Force believes that a government patent policy should encourage commercial utilization of government-funded inventions. It was also noted, however, that any policy should contain provisions which would preclude anticompetitive consequences which may result from an excessive period of exclusivity in a contractor.

3. Under present policies, the Task Force believes there are instances in which the contractor, knowing he will be unable to retain exclusive commercial rights to inventions generated under a proposed contract, will refuse to participate in a government program because of jeopardy to his privately financed commercial position.

Hence, a new advance in the art generated in performance of a government-funded contract which will not be owned by the inventing contractor could severely undermine that contractor's background position. The Task Force believes that it is in the national interest that government patent policy encourage maximum participation of all industry in government programs.

4. The Task Force has found no persuasive reason why the technical field or mission of a department or agency program should be an overriding factor, as exists under present policies, in dictating the disposition of inventions, whether that disposition be by title or license in the government. The disposition of ownership based only on technical field or mission necessarily eliminates consideration of significant equities of either the public or the contractor. Further, inventions resulting from research in a particular field or mission do not necessarily have any relation to such technical field or mission, or may have much broader application, as has been the case in many instances.

5. The different existing statutory and regulatory policies result in different disposition of inventions within a single field of technology. In practice, President Kennedy's Statement has not brought about a uniform disposition of such inventions, due to differing department or agency interpretation of its language. The Task Force believes that this situation will continue under President Nixon's Statement, since the revised Statement is not specifically aimed at overcoming this problem.

6. Many of the factors identified in the Presidential Statements as influencing utilization, participation and competition have little relevance prior to invention identification, and are of questionable benefit in making determination at the time of making a contract. Furthermore, a number of these factors do not become relevant until some attempt has been made to undertake the exploitation of the invention commercially.

TASK FORCE CHOICE OF DIRECTION

Rather than concur in separate department or agency policies or a uniform government patent policy providing for different disposition of inventions, depending on technical field, mission, or case circumstances, as exemplified by the President's revised Statement on Government Patent Policy, the Task Force determined to explore the possibility of formulating a uniform government patent policy which would make a single disposition of invention rights in all instances. As discussed above, the Task Force believes that any uniform government patent policy providing for a single disposition of invention rights should maximize to the extent possible:

"Utilization" of the inventions resulting from government-funded research;

Contractor "participation" in government programs;

"Ease of Administration" on the part of both the government and the contractor; and

"Competition in the marketplace".

With these goals in mind, and with the expectation that the policy would resolve a number of separately posed and related issues, the Task Force considered and agreed on the following in making its proposal:

1. The Task Force agrees, as did the President's Commission on the patent system in its November 17, 1966, report, that a patent system stimulates the investment of additional capital for the further development and marketing of products using an invention by giving the patent owner the right, for a limited period, to exclude others from --- or license others for --- making, using, or selling the invented product or process.

2. A uniform government patent policy resulting in government ownership of inventions made in performance of its contracts for dedication to the public, or the granting of only non-exclusive licenses, whether such ownership is based on a technical field or mission or otherwise, would necessarily eliminate the stimulus envisioned by the patent system.

3. Under such a policy, there is a prospect in some cases that the market potential of an invention and other means of property protection will not adequately serve to encourage the investment of risk capital for development when not financed by the government. The research investment in such inventions will to a large extent be lost to the public.

4. It was therefore agreed that any uniform policy recommended must provide for exclusive commercial rights in the inventing organization or another developer in those inventions which would not otherwise be utilized. (It should be understood that the term "exclusive commercial rights" includes either title to the invention or an exclusive license thereunder.) The Task Force agrees that exclusivity could be provided in the following two ways:

   a. Granting commercial exclusivity at the time of contracting to all inventions to be generated in performance of such contracts; or

   b. Granting commercial exclusivity selectively after identification of the inventions on the basis of evidence that development may not proceed without such exclusivity. (For the purposes of this discussion, this mechanism shall be referred to as a deferred determination policy, and should be understood to include a government exclusive license policy now possible under President Nixon's revised Statement where not otherwise negated by statute or agency policy.)

5. The Task Force recognizes that under a deferred determination policy the possibility of maximizing "competition" exists, since exclusive commercial rights will only be granted when it is shown that exclusivity is the determining factor in bringing the invention to the marketplace. However, even assuming that the government could correctly identify all inventions requiring exclusivity, albeit a remote possibility, it is the opinion of the Task Force that a deferred policy has and will negatively affect contractor "participation" in government programs, "utilization" of the results of such programs, and "ease of administration" on the part of both the government and the contractor as amplified by the following:

a. The uncertainty of ownership involved in a deferred determination policy would discourage at least some contractors from participating in government programs. Most certainly a contractor whose privately financed background position would be jeopardized by newly generated inventions which he might not necessarily own must think seriously before taking a contract which intends to capitalize on his background position. Refusal to participate in this situation will probably necessitate the government contract with a less qualified contractor or not contract at all.

b. The long processing periods inherent in a deferred determination policy would in some cases delay prompt utilization of government inventions, since a participating contractor would wish to establish his rights prior to investing his risk capital. Utilization would also be adversely affected by the administrative burden of petitioning the government for exclusive commercial rights and the probable requirement that the contractor file patent applications to protect the property rights during the petition period. Faced with these tasks, the participating contractor will have little interest in inventions that appear economically marginal on first review.

c. Finally, the Task Force agreed that the increased administrative costs to both the contractor and the government for the drafting, submission, and review of petitions on a case-by-case basis would be out of proportion to the result to be achieved through implementation of a deferred determination policy.

6. In light of the deficiencies inherent in a deferred determination policy, the Task Force agreed that a policy of granting exclusive commercial rights to the contractor at the time of contracting to all inventions generated in performance of government contracts was the single means of maximizing "utilization" without generating adverse conditions for "participation." In addition to these advantages, a policy which makes disposition at the time of contracting offers the opportunity for maximum "ease of administration". The Task Force did note, however, that "ease of administration", under such a policy would be proportional to the degree of follow-up or "march-in" rights reserved to the government, but under no circumstances would such a policy create the level of administrative difficulties now encountered by departments and agencies in the deferred determination portions of their policies.

7. Notwithstanding the advantages to be gained through a uniform policy of granting exclusive commercial rights at the time of contracting to all inventions generated, the Task Force was of the opinion that such a policy could adversely affect "competition" in the marketplace if such exclusivity were to remain in the contractor for the full period of the patent grant in all cases. In order to avoid this consequence, the Task Force agreed that rights must be reserved to the government under such a policy which would enable it to assure against individual abuse of the privileges retained by the contractor. These "march-in" rights would insure that a contractor's exclusivity would extend only over a period justified by the contractor's equities and the public's need for competition in the marketplace.

8. The Task Force agreed that the benefits to be derived through a policy of disposition at the time of contracting outweigh the need for ideal conditions to generate "competition", which may not be maximized since some exclusive commercial rights would remain with the contractor to a greater extent than under a deferred determination policy. Thus, the Task Force believes that a policy of disposition at the time of contracting will positively effect utilization of government-funded inventions and participation of contractors thereby increasing the nation's potential to employ labor and raising the level of its exports. Further, maximization of participation will increase the government's ability to focus public funds on the kinds of research and development which have high, long-run social value, but is risky and not sharply reflected in profit opportunities for a sponsoring private business firm. Since it cannot be predicted with any

accuracy how competitors will meet the introduction of a new product made under exclusively held patent rights, it cannot be determined whether implementation of such a policy will result in any decrease in competition. Of much greater significance are the rights reserved to the government under such a policy to assure against individual abuse of the privileges retained by the contractor, and the knowledge that the contractor remains subject to the provisions of the antitrust laws.

SYNOPSIS OF TASK FORCE PROPOSAL

Based on the above analysis the Task Force drafted a proposal, set forth below, which provides for a uniform patent policy making a single disposition of invention rights in most instances. Implementation of this proposal envisions repeal of all inconsistent statutory provisions.

The proposal provides contractors a guarantee at the time of contracting of a first option to the exclusive commercial rights to all inventions generated in performance of government-funded research. Upon exercising the option, such rights in the contractor are subject to a royalty-free, nonexclusive license to the government for Federal Governmental purposes throughout the world. Failure to exercise the option results in such rights enuring to the government.

The guarantee of an option will be extended to universities and other nonprofit organizations only after government review of the adequacy of their organizational patent management capability. While it can be expected that most commercial concerns will have an established procedure for identifying, reporting, and administering inventions, the same capabilities cannot be presumed to exist at all universities and nonprofit organizations. Therefore, it was concluded that the public interest is better served by retention of such rights in the government in situations where the university or nonprofit organization has no patent administration capability.

Where the option has been exercised, and a U. S. patent application filed, the proposal contemplates that contractors retain the exclusive commercial rights during the period from patent filing to three years after issuance of a patent. If a contractor has not brought the invention to the marketplace within the time from patent filing to three years after patent issuance, such rights may be revoked and vested in the government. If the contractor should succeed in commercialization of the invention during this guaranteed period, the exclusive commercial rights vest in the contractor for the full period of the patent grant, subject to the possibility that the government may require nonexclusive licensing of the U. S.

patents after the guaranteed period has passed. The requirement for such licensing will be determined by a Government Patent Review Board on petition of any interested party after a contractor holding title to any invention made in performance of a government contract has refused to grant entirely or on acceptable terms a nonexclusive license under such invention. The board, in making its determination and setting the terms of the license, if any, will take into consideration the equities of the individual case.

The proposal envisions that the period of guaranteed exclusivity, coupled with the possibility of continued exclusivity for the life of the patent, will create an incentive for participation in government programs and the earliest possible utilization of inventions generated by such programs. The guaranteed period further recognizes the contractors' background equities which are presumed to be present in all cases. In addition, the proposal places commercial development of the invention in the hands of the party most likely to accomplish that task and provides the incentive for the investment of risk capital required to bring it to the marketplace which has been estimated on the order of 10 to 1 when compared to the cost of making the invention. The reversion of rights to the government in the event the contractor fails to commercialize the invention provides greater assurance of utilization of government-funded inventions.

The creation of the Government Patent Review Board assures the public that the guaranteed period of exclusivity will not be extended unjustifiably. The existence of the Board will encourage both the contractor and a prospective licensee of a government-funded invention to negotiate acceptable terms and thereby avoid going to the Board to settle differences. In general, it is presumed that if the contractor had made significant private investment in the development and utilization of the invention and the invention was available to the public in reasonable quantities and prices it could expect to prevail in a dispute brought to the Board. On the other hand, the larger the government investment in bringing the invention to the point of utilization, the less likely the contractor could justify continued commercial exclusivity.

The Board, by the nature of the policy, would need to consider only economically significant inventions in which there was a serious interest and controversy. Further, the invention will have been identified rather than hypothetical and the economic and investment data available to the Board would be realistic and current.

The government agencies would provide the Board with relevant information regarding their role in the development of the invention in question. They would also provide the Board with the appropriate public interest and mission considerations which they believe should affect the Board's decision. However, the Board will make its decisions on the record and will be guided by statutory or administrative criteria and be subject to judicial review.

In drafting the proposal, the Task Force took particular note of the small number of inventions which are known to have been developed for the commercial marketplace substantially at government expense. The number of such inventions becomes even smaller if the additional cost of promotional activities in bringing the invention to the marketplace is undertaken by the government. It was agreed that under the circumstances the equities in favor of leaving exclusivity for any period in the contractor to this small number of inventions are less than the usual situation in which the contractor contributes his risk capital to bring the invention to the marketplace. A close analysis of such inventions indicates that their continued development at government expense would generally require additional funds from follow-on contracts. However, where follow-on contracts are deemed appropriate the period of time over which such an invention is conceived and brought to the marketplace would generally exhaust the guaranteed period of exclusivity, thus precluding a windfall to the contractor.

Notwithstanding the view that a contractor will ordinarily exhaust his guaranteed period of exclusivity if development for the commercial marketplace is undertaken substantially at government expense, the proposal provides to the Board the right to substitute a patent clause at the time of contracting which leaves to the government the first option to exclusive commercial rights in inventions which are the primary object of the contract. The Board would exercise this right upon a department or agency request made prior to contract which is accompanied by a showing that such department or agency intended to develop substantially at its expense an identified product or process for use by the general public.

It should be noted that the proposal contemplates that exclusive title to all foreign patents will vest in the contractor for the full term of the patent grant if the contractor complies with the conditions of the proposal.

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PROPOSED POLICY FOR THE ALLOCATION OF RIGHTS TO INVENTIONS

MADE UNDER GOVERNMENT R & D CONTRACTS

1. POLICY

A. With the exception set forth in 5(A)(3) below, contractors shall be guaranteed at the time of contracting a first option to the exclusive commercial rights in all inventions made in performance of government-funded contracts. (The term "exclusive commercial rights" should be understood to include either title to the invention or an exclusive license thereto with the exception that as the term relates to foreign patents or patent applications it means title).

B. Any statutory provisions which are inconsistent with such guarantee or the principles of this policy shall be repealed.

C. The guarantee of exclusive commercial rights will be extended to universities and other nonprofit organizations only after government review of the adequacy of those organizations' patent management capabilities.

D. The government may later revoke such rights in a contractor after failure of the contractor to meet conditions as hereinafter provided.

E. Exclusive commercial rights in a contractor will be subject to a world-wide, royalty-free, nonexclusive license in the government for Federal Government purposes.

F. After a specified period of time, contractors who have retained exclusive commercial rights may, on petition of any interested party, be required by a Government Patent Review Board to grant licenses under U.S. patents with terms that are reasonable under the circumstances.

2. DISCLOSURE, ELECTION AND REPORTS

Each invention made in performance of a government-funded contract will be disclosed to the government with an indication of contractor's election to acquire exclusive commercial rights.

A. Election to Acquire Exclusive Commercial Rights

Election by the Contractor would include agreement to file a patent application covering the invention in the United States Patent Office within a specified period of time. Patent Office procedures will be established to assure proper affixation of the letter "G" or other appropriate designation on all such patent applications and patents issued thereon. Election and filing would guarantee exclusive commercial rights in the contractor for a period starting from filing until three years after issuance of a patent. Under special circumstances disclosed by the contractor, the agency head may extend the period as deemed appropriate.

B. Election Not to Acquire Exclusive Commercial Rights

Election not to acquire the exclusive commercial rights will result in such rights vesting in the government for disposition as it sees fit, as set forth in Paragraph 4.D hereafter.

C. Reports

The contractor shall promptly advise the agency upon issuance of any U. S. patent covering an invention to which he acquired exclusive commercial rights. During the three year period after issuance of a patent the contractor will submit, upon the agency's request reports setting forth progress made toward commercial utilization. If after three years from patent issuance utilization has not been achieved, the agency may take steps to revoke the exclusive commercial rights unless satisfactory evidence is presented that the time for utilization shall be extended.

3. CONTINUING RIGHTS

Whenever utilization has been achieved by the contractor within the time agreed upon by the agency, the exclusive commercial rights will continue in the contractor for the life of any patent(s) claiming the invention, subject to the provisions set forth in paragraphs 4 and 5 below.

4. CONTRACTOR LICENSING

A. Three years after issuance of a patent claiming an invention in which a contractor has elected to acquire exclusive commercial rights, the contractor may be required to grant non-exclusive licenses under such patent by the Government Patent Review Board under conditions set forth in paragraph 5 below.

B. Contractor shall have the right to sublicense others on an exclusive or non-exclusive basis under any terms he deems appropriate, subject only to existing laws and the requirements of the Government Patent Review Board.

C. If the contractor permits utilization to cease, the agency may require the contractor to grant an exclusive or non-exclusive license to responsible applicants on terms that are reasonable under the circumstances.

D. Upon a contractor's election not to retain the exclusive commercial rights, or after an election to retain such rights and subsequent revocation by the agency for failure to meet the conditions of this proposal, the contractor shall be granted a revocable, non-exclusive, royalty-free license under the invention. Such license shall be revoked upon notice to the contractor of the intent of an agency to grant an exclusive license, subject to the right of the contractor to make application to the Government Patent Review Board for a license under terms and conditions that are reasonable under the circumstances.

5. GOVERNMENT PATENT REVIEW BOARD

A. General

(1) The Board will consist of a full-time Chairman and Executive Secretary and a panel of 20 members, any four of which may be chosen by the Chairman to sit on specified cases. The Board will meet upon the call of the Chairman to consider and rule upon the issues arising under the operation of this policy. The Chairman and two members will constitute a quorum.

(2) Its decisions shall be subject to judicial review by United States District Court for the District of Columbia.

(3) The Board shall have the power to review requests by agencies to substitute a patent clause which leaves to the agency the first option to exclusive commercial rights in inventions which are the primary object of the contract. The Board shall exercise this right only upon agency requests made prior to contract which are accompanied by a showing that such agency intends to develop substantially at government expense an identified product or process for use by the general public.

(4) The Board shall have the power to review on petition of any interested party the refusal of a contractor holding exclusive commercial rights to any invention made in performance of a government contract to grant entirely or on acceptable terms a license under such invention.

(5) Such petition may be filed at any time after the contractor has elected to acquire such rights and has filed a patent application on such invention.

(6) At any time after the period set for utilization by an agency has expired, the Board may require the granting of non-exclusive licenses under U. S. patents or patent applications with terms it deems appropriate on the basis of:

(a) The failure of the contractor to show cause why such license should not be granted; or,

(b) The factors contained in paragraph 5.B below.

B. Board Review of Refusal to Grant Licenses

The Board shall take into consideration, in addition to the arguments of the parties, at least the following factors in making its determination to require licensing of an invention made in performance of a government contract.

(1) Achieving the earliest practicable utilization of government-assisted inventions in commercial practice;

(2) Encouraging, through the normal incentives of the patent system, private investment in the commercial realization of government-assisted inventions;

(3) Fostering effective competition in the commercial development and exploitation of government-assisted inventions;

(4) Assuring against non-utilization of government-assisted inventions and excessive charges for use of such inventions stemming from private ownership of patents on such inventions;

(5) Balancing the relative equities of the public, the inventor and the patent owner or developer in the specific government-assisted invention, measured by the investment necessary to bring the invention to the point of commercial application. This would include the following:

(a) The relative contribution of the government and the contractor in bringing the invention to the marketplace;

(b) The mission of the program funding the contract from which the invention arose;

(c) The type of invention and the magnitude of the problem it solves;

(d) The scope of the patent claims;

(e) The contractor's background position;

(f) The government's funding of background technology;

(g) The scope of the market and the success of the contractor in meeting it;

(h) The profit margin in relation to other similar inventions; and

(i) The feasibility and likely benefits of competition in the market served.

C. Foreign Rights

The Board's jurisdiction in requiring the granting of a non-exclusive license shall extend only to licenses under U.S. patents. Nothing herein shall be construed to extend that jurisdiction to foreign patents.

D. Background Rights

The Board's jurisdiction in requiring the grant of a non-exclusive license shall extend to only those inventions made in performance of government-funded contracts. Nothing herein shall be construed to extend that jurisdiction to data or other inventions made at private expense.

E. Agency Cooperation

The departments and agencies of the Executive shall provide to the Board whatever aid and information it deems necessary to accomplish its assigned duties.

F. Board Review of Agency Determinations

The Board, on petition of contractor, shall have the power to review an agency decision in implementing this proposal under which such contractor is aggrieved.

G. Intervention

All interested parties, including any agency of the U. S. Government, shall have the right to intervene in any proceeding before the Board.

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RAMIFICATIONS OF IMPLEMENTATION OF PROPOSAL

Implementation of the proposal will serve to mitigate or resolve a number of related issues generated by present allocation-of-rights policies. Some of the more important areas that would be affected by the proposal are as follows:

A. The Employed Inventor

Permitting contractors a guarantee at the time of contracting to a first option to the exclusive commercial rights in all inventions generated in performance of their government-funded research places the contractor in a better position to accomodate the equities of his employed inventors through award programs if the contractor deems such programs advantageous to his needs.

B. Scope of the License Retained by the Government

Present policies provide that the non-exclusive license retained by the Federal Government include state and domestic municipal governments unless the agency head determines that this would not be in the public interest. The scope of the license retained by the government under the proposal specifically excludes state and domestic municipal governments. It was the opinion of the Task Force that to expand the scope of the license to state and domestic municipal governments would be tantamount to retaining exclusive commercial rights in the government in situations where the market for the invention would be substantially federal, state and municipal programs. Inventions directed to solution of saline water and educational problems would fall within this category. To extend the scope of the license retained by the government to include state and domestic municipal governments would therefore defeat the purpose of the proposal as it relates to such inventions. To permit the agency head to determine the scope of the license retained by the government at the time of contracting was not deemed practical, since the

type of invention that will evolve from a research and development contract cannot be accurately predetermined. Further, the Review Board assures that competition will ultimately exist for such inventions if economically significant and demanded by the equities of the public.

C. University and Non-Profit Organizations

As noted previously, the proposal extends the guarantee of an option to exclusive commercial rights to universities and non-profit organizations after government review of the adequacy of their patent management capability. With such option, universities and non-profit organizations are in a better position to license industrial concerns as an incentive to use their risk capital in bringing the results of university and non-profit organization research to the marketplace. Without the ability to transfer exclusive commercial rights to industry, universities and non-profit organizations have found it difficult to overcome the "not-invented-here" syndrome. (See Harbridge House Report and the August 12, 1960, GAO Report, "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry".) The Task Force considers this an important matter since approximately 25% of the government's research and development budget is expended through contracts with universities and non-profit organizations.

D. Definition of "Conceived" and "First Actually Reduced to Practice

Present policies stipulate that any invention "conceived" or "first actually reduced to practice" in performance of a government-funded research and development contract be disposed of in accordance with the contract provisions under which it arose. Any invention so conceived or first actually reduced to practice affords to the government at least a royalty-free nonexclusive license. The precise definitions of "conceived" or "first actually reduced to practice", therefore, are important as they are determinative of the rights in the government or the contractor. The proposal contemplates that it will similarly speak only to those inventions conceived or first actually reduced to practice in performance of government-funded research and development contracts. In order to resolve any present problems with the terms "conceived" or "first actually reduced to practice", it is suggested that any patent rights clause utilized in implementing the proposal include the following definitions:

(1) "Conceived" means a disclosure in a form which would enable someone skilled in the art to which the invention pertains to make and use the invention without the use of further inventive effort.

(2) "First actually reduced to practice" means a successful test of the invention in a simulated environment, or in an environment similar, to the one in which it will be used for a purpose for which it was intended.

E. Rights Obtained by the Government Through Its Research and Development Contracts in Inventions Conceived and First Actually Reduced to Practice at Private Expense

A great deal of uncertainty has been generated by AMP, Inc. v. U. S. 156-USPQ 647, as this case appears to extend the rights the government obtains through its research and development contracts to inventions conceived and first actually reduced to practice at private expense. In order to eliminate this uncertainty, the Task Force recommends that the following language be added to any patent clause utilized to implement its proposal:

(1) Nothing contained in this patent rights clause or construed therefrom shall be deemed to grant to the government any rights in any invention which is neither conceived nor first actually reduced to practice in the course of or under this contract. However, this shall not deprive the government of any rights to which the government may be entitled under other clauses in this contract, under other contracts, or by statute; and

(2) That in those situations in which the government wishes to acquire rights in an invention which is neither conceived nor first actually reduced to practice under a government contract, this be done through a separate expressed provision of the contract.

It is the opinion of the Task Force that any background patent rights clause negotiated as provided by (2) above speak only to inventions in existence and identified at the time of contracting and that any rights acquired by the government to such inventions reflect the contributions to be made by the government toward its enhancement, testing, or development. It should be noted that the proposal limits the Patent Review Board's jurisdiction in requiring the grant of licenses to only those inventions conceived or first actually reduced to practice in performance of government contracts.

F. Inventions Conceived and Patented at Private Expense But Reduced to Practice in Performance of a Government-Funded Contract

It has been suggested to the Task Force that inventions having been conceived at private expense and which are identified by patents or patent applications but first actually reduced to practice in performance of a government-funded contract remain the property of the contractor, subject to a royalty-free, non-exclusive license to the government. The Task Force rejects this suggestion, as it does not properly take into consideration the contribution of the government in first reducing the invention to practice in all cases. It is recommended by the Task Force that this type of invention be brought to the attention of the agency funding the proposed contract under which such invention may be reduced to practice at the time of contracting so that the equities of both parties may be considered in making a disposition. The Task Force feels that this problem has been further mitigated by the proposal in that the contractor will at very least retain his option to exclusive commercial rights unless otherwise negotiated at the time of contracting.

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* Mr. James E. Denny has filed a Minority Report attached hereto.

** Messrs. Ryan and Davidow participated in the deliberations of the Task Force, and many of their suggestions are reflected in the majority report, but they did not vote for or against the total report.

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O. A. Neumann, Esq.
Executive Secretary
FCST Committee on Government Patent Policy

APPENDIX A

GOVERNMENT PATENT POLICY

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HIGHLIGHTS Of FEDERAL TECHNOLOGY TRANSFER

- 1964 - DHEW inventions not reaching the marketplace.
- 1968 -Disputes over Federally funded inventions
- 1968 - G.A.O. Report.
- 1969 - DHEW patent policy changed.
- 1973 - First technology transfer Association formed
- 1976 - First gene splicing patent licensed

TECHNOLOGY TRANSFER LEGISLATION

- 1977 - DHEW reassesses 1969 patent policy changes.
- 1977 - Universities press for legislation.
- 1980 - Bayh-Dole enacted.
- 1983 - Executive order extends Bayh-Dole.
- 1986 - Federal Technology Transfer Act enacted.

RESULTS OF BAYH-DOLE

- Royalty returns
- Industrial Research Support

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RESULTS OF BAYH-DOLE

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Brief History of Federal Technology Transfer

Norman J. Latker

September 24, 2000

Before the Advisory Committee of the

National Institute for General Medical Sciences

First Slide

As early as 1964, the failure to attract industry development of Government funded life science inventions was well known.

Dr. Shannon, then NIH director, characterized the source of the problem before Congress by emphasizing that NIH grantees do not engage in the direct development and manufacture of inventions and it is industry that must bring grantee inventions to the marketplace. But in doing so, an industry developer must decide that the patent rights offered are sufficient to protect the risk investment involved not only for the invention offered, but for the huge number that fail in development compared to few successes. He concluded by saying 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. The Department's policy to own all such inventions for non-exclusive licensing at most clearly precluded the cooperation Dr. Shannon suggested.

By 1968, while factions in the Department continued to argue policy, the problem had been dramatized by increasing numbers of invention ownership disputes involving inventions assigned to industrial developers by NIH grantee investigators without notice to NIH.

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 the 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 Department 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 surmised that any amount of government funding touching an industry invention could result in similar a claim of rights by the Government.

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

Finally, in 1969, in direct response to these situations, the Department relented and changed its patent policy by establishing a uniform IPA policy that left ownership to grantee institutions who agreed to staff a technology transfer office to manage and license these rights. The changes also included administrative authority that permitted the Department to grant exclusive licenses to industry in inventions made by DHEW employees. NSF followed with similar changes in 1972.

In 1973, 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).

By 1976, 75 IPA's had been negotiated and executed with institutions who received well over 50% of the annual DHEW extramural funding.

Also in 1976, Dr. Frederickson, then Director of NIH, agreed with the consent of other Federal research agencies 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 biotech industry.

Second Slide

Notwithstanding the clear record of increasing licensing by IPA holders, the secretary of the Department, instituted in 1977 a "reassessment" of the 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 conducted hearings as to the legality of IPA's.

Frustrated, organizations having IPA's (led by the University of Wisconsin, Stanford University, the University of California, and Purdue) responded by pressing for legislation to assure continuance of the 1969 Department policies and its further expansion to other federal agencies having conflicting

policies. This resulted in Senators Bayh and Dole introducing what became the Bayh-Dole Act.

In December 1980, in a lame duck session of Congress, Bayh-Dole was enacted with no executive support, establishing for the first time a uniform government patent policy guaranteeing ownership of all federally funded inventions to non-profit organizations and small business but with a limitation on the life of exclusive licenses granted to industry. In addition it created for the first time, statutory authority for exclusive licensing of all other Government owned inventions, the bulk of which were generated by intramural Federal Employees. The Act repealed 22 conflicting agency statutes, many of which were a result of amendments by Sen. Long to Agency Appropriation Acts. Enactment was achieved against formidable opponents including the Attorney General, Sens. Long and Nelson, Ralph Nader, Ad. Rickover of Atomic submarine fame, the Agency administrators of the Acts to be repealed and others.

In 1983, the ownership principles of Bayh-Dole were extended to all other recipients of Federal funding not otherwise precluded by statute by Executive order, which received little notice other than from its opponents. This

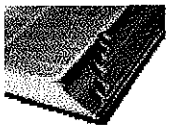
established for the first time a uniform government patent policy covering all federal agencies conducting research and ended 40 years of the Government requirement for ownership of grantee and contractor inventions as a condition for funding.

In 1984, Bayh-Dole was amended to permit exclusive licenses for the life of the patent.

Finally, in 1986 with strong White House support, the Federal Technology Transfer Act of 1986 was enacted, which required decentralizing the statutory licensing authority for government owned inventions created in Bayh-Dole to the Federal laboratories at which the were made. This was intended to put the Federal laboratories on an equal basis with the laboratories covered by Bayh-Dole. The Act also extended the Bayh-Dole principles of an option to future invention rights to industrial concerns in return for their funding a cooperative research and development agreement (CRADA) at a federal laboratory.

Third Slide

The success of Bayh-Dole can be easily measured by the royalty return to grantees and the increase in research funding



Dictionary

Game Theory: Dictionary: Terms: Nash Equilibrium

Nash Equilibrium

A Nash equilibrium, named after **John Nash**, is a set of **strategies**, one for each player, such that no player has incentive to unilaterally change her action. Players are in equilibrium if a change in strategies by any one of them would lead that player to earn less than if she remained with her current strategy. For games in which players randomize (**mixed strategies**), the *expected* or average payoff must be at least as large as that obtainable by any other strategy.

To learn more:

- Try the normal-form game solver to automatically calculate equilibria on the applets page.
- Take an online quiz on finding equilibria in games.

A resource for educators and students of game theory.

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- Dictionary - News - Games - Updates -

Technology Transfer in U.S. Research Universities: Dispelling Common Myths

Preamble

During the past two decades, universities have surprised everyone, including themselves, with the tremendous success in licensing their research results for commercial application. Through "technology transfer" they provide commercial sector companies with access to new discoveries and innovation resulting from research. Industrial partners develop these inventions and manufacture products that help to improve the lives of Americans. However, with success tends to come notoriety, often based on misunderstanding or distortion of facts. News stories of university millionaires tend to catch the eye more effectively than scientific articles about the drugs and devices that would not have become available had university inventions not been successfully commercialized.

This pamphlet addresses commonly held myths about university technology transfer. Some of them are explained by the provisions of the underlying legislation, which not only provides incentives, but also imposes controls to guard the public taxpayer's interests. Some of them are explained by statistics, which deflate the perception that universities derive a steady income stream from technology transfer.

The biggest myth to dispel is that universities engage in technology transfer "for the money". Three factors explain why universities are currently so active in partnering with industry. First, under the Bayh-Dole Act, universities have a mandate to ensure, to the extent possible, that inventions arising from federally funded research are commercialized. It is an obligation they have increasingly embraced since 1980 when the law was enacted. Secondly, universities need to make sure they have adequate resources to enable faculty to continue to do research and to provide learning opportunities for students. And finally, universities must consider their obligation to respond to the needs of local and state economies and the nation as a whole.

This brochure was prepared by the Technology Transfer and Research Ethics Committee of the Council on Governmental Relations (COGR). COGR is an organization which includes in its membership 145 research-intensive universities.

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1200 New York Avenue NW, Suite 320
Washington, DC 20005
(202) 289-6655

May 2000

Technology Transfer in U.S. Research Universities: Dispelling Common Myths

Myth: ***The new emphasis on technology transfer is diverting universities from their main mission of education and research.***

Reality: Technology transfer is not a new phenomenon for universities. Dating from the early 1800's in Europe, companies are known to have been developed around the expertise of faculty at universities. Research universities have historically transferred technology through the traditional methods of publication, the training of students, and through their extension programs. Formal technology transfer through the licensing of university-owned intellectual property adds new educational dimensions and research opportunities for students and faculty.

Myth: ***The government is better at commercialization through technology transfer than universities are. Therefore, the government should regain control of university patents that have come from federally-funded research projects***

Reality: The university sector has been highly successful in its technology transfer efforts since it was given the right to own and license university inventions under the Bayh-Dole Act in 1980. Prior to 1980 when university patents were generally owned by the federal government, no more than 10% of those patents were licensed to industry for commercialization. Data for FY98 on university licensing activities show that universities are filing in excess of 4,000 patent applications a year and issuing more than 3,500 licenses or options to license annually.[1] Trend data show a cumulative total of licenses and options issued since 1991 standing at over 20,000 and that the percentage of licensing activity has doubled between 1991 and 1998.[2] Anecdotal reporting from universities shows a licensing to patenting ratio of better than 1:3. There is a general consensus that licensing is most effective if it directly involves the inventor and the inventor's institution.

Myth: ***University technology transfer is an unnecessary barrier to effective commercialization. More rapid commercialization would be achieved if universities gave their inventions to industry.***

Reality: As owners of their inventions, universities have established procedures for the earliest possible identification of inventions. The patenting and commercialization process benefits from day-to-day communication with inventors, access to complementary technology that may be under development within the university and awareness of continuing efforts on the part of the inventor to enhance a technology. Through licensing, universities ensure diligent efforts toward commercialization by the licensee, or require the license to be returned to the university to be issued to a more serious commercial partner. Universities have both

the incentive and the ability to build internal relationships and structure to make certain that rapid and effective commercialization occurs.

Myth: ***Most university patents come from federally-funded research paid for by U.S. taxpayers. Neither the U.S. government nor the taxpayer is benefiting.***

Reality: Recent data and the application of impact models[3] show a return to the U.S. government and the national economy from university licensing of $33.7 billion, and - supported 280,000 jobs during the university fiscal year ending June 30, 1999. The return to the federal government in taxes paid on university technology transfer induced corporate and individual earnings, alone, equals a 15% return on sales of licensed products.[4] The public is currently benefiting from the products, processes and services available in the marketplace as a result of more than 17,000 active university licenses.

Myth: ***Technology Transfer is a major source of revenue for universities.***

Reality: While successful technology transfer activities may be an important source of discretionary revenues for universities, comparison data[5] show that annual gross revenues generated from a university's technology transfer activities generally total less than three percent of research dollars spent by that university and a far lesser percent of total university revenues.

Myth: ***University inventors are receiving substantial personal financial benefit from University licensing.***

Reality: No more than one-third of all university patent applications and patents are licensed and producing revenues at any given time. Because the majority of university inventions are very early stage, a large number go unlicensed and produce no revenues. Among those that are successfully licensed, there is wide disparity as to the amount of licensing revenue generated. Relatively few are large earners. While university revenue-sharing policies vary, the most commonly reported percentage of royalties paid to university inventors is a total of 30% of revenues earned, after deducting patent and marketing expenses. This percentage is shared among all inventors named on the licensed patent.

Myth: ***Universities over-inflate the value of their inventions, setting rates too high.***

Reality: Royalty rates are dependent upon market factors and determined through negotiation. While defining an "average" royalty rate will not reflect the true value of an invention, one study[6] cites an average royalty at approximately 2% of the revenues generated by a licensee-company from its sales of products or services under the license. A small study conducted by the Association of University Technology Mangers finds the rate at 2.3%.

Myth: ***Universities are more likely to license big companies because they can afford to pay more. Small companies cannot afford to license university inventions.***

Reality: Data for FY '98 reported by 179 U.S. and Canadian institutions show that 63% of the licenses granted were to small businesses (those with fewer than 500 employees). This figure is consistent with activity reported by the universities from prior years.[7]

Myth: ***University technology transfer offices are prospering through charging high royalties.***

Reality: The vast majority of university-licensed inventions result from research funded by the federal government. Under Bayh-Dole (35 USC 202 et.seq.), universities have an obligation to commercialize these inventions and distribute a portion of licensing revenues to inventors. This obligation is carried out by the technology transfer office, usually an administrative unit within each university. Universities are permitted to recoup only those expenses incurred in the patenting and licensing process. Any excess revenues must be used by the institution for purposes of education and research and may not be accumulated for the benefit of the technology transfer office.

Myth: ***Universities are more interested in patenting inventions than publishing research findings for the public to use.***

Reality: All universities must adhere to the academic tradition of publication. Publication remains a primary factor in tenure decisions. Publication is also the main vehicle for academic professional recognition and is important to establish credibility in grant applications. Most importantly, publication in peer-reviewed journals is validation of the findings of the academic scientist. Patenting does not mean there is no publication. All university research findings are available for publication whether or not patenting occurs. Publication, on the other hand, does not necessarily result in public use. Most often new products would not be developed without the exclusivity afforded by patent protection. Further evidence of the preference for publishing over patenting is provided by figures cited in an NSF study[8], showing that -73% of patent applications citing publications as published disclosures of the art which the new patent application has advanced and seeks to protect-cited academic, government or non-profit publications.

Myth: ***Universities are doing too much patenting. It would be better for economic growth and U.S. competitiveness to put more inventions into the public domain.***

Reality: As the United States enters a period where articles attributing economic growth to a pro-patenting environment are commonplace, it is difficult to quantify how much patenting is "too" much. Universities are filing at an annual rate of less than one new U.S. application for every three inventions disclosed to the technology transfer office.[9] The real measure of useful patenting for universities is whether patenting encourages commercial licensing. FY '98 data show that the universities issued 3,668 licenses/options during the same year in which they were filing 4,808 new patent applications.[10] Whether companies would have

picked up the 3,668 new university technologies to commercialize from the public domain is highly questionable.

A further reality is that patenting is expensive. Since no university has the resources for indiscriminate patent filing, we know that budgetary limitations, alone, require technology transfer professionals to carefully select for filing only those inventions most likely to be licensable.

Myth: ***University patenting of biological materials and research tools is harmful to the advancement of science and is hampering the efforts of researchers.***

Reality: The patenting of research tools is currently a high-profile debate among universities, industry and the government. To aid universities, NIH has recently issued principles and guidelines to underscore the importance of striking a balance between preserving access for research use and the broader public interest in the acquiring the intellectual property protection required for commercialization. The university community, itself a community of academic researchers, has always been acutely aware of the importance of preserving rights to use patents for research purposes.

Myth: ***The recent focus on industrial relationships and entrepreneurial activities in U.S. universities is detrimental to the university's fundamental mission of educating students.***

Reality: In fulfilling their educational mission in today's changing world, universities must seek to provide students with experience that is more closely aligned with contemporary industry. Enabling students to participate in industry research gives students a window to the industrial world and provides them with the opportunity to assist in solving real world problems. It also provides them with experience in teaming with industrial scientists as well as giving them an opportunity to become comfortable with the industrial workplace environment. Often companies are funding university research in anticipation of finding future talented future employees. As universities involve students in relationships with industry or provide them with opportunities to start new companies, universities recognize an obligation to do so in a manner that preserves the students' sense of balance and perspective as to the long-term value of the university experience.

Myth: ***Partnering with industry will skew the academic research agenda from basic to applied research.***

Reality: The research agenda at many of the major U.S. universities is not exclusively restricted to basic research. There is general agreement in many universities that both faculty and students find benefit from participating in more applied research funded by industry. Industry-funded programs permit faculty to keep abreast of the current trends and practices important to American industry and give students an opportunity to learn the teaming and other knowledge skills that will be important to their success as they join the workforce. The growing number of research programs jointly supported by industry and government agencies clearly shows a convergence of interest in supporting both basic and more applied research.

Carefully managed, university-industrial partnerships provide universities with new educational opportunities, expand infrastructure, provide alternative sources of research revenue and contribute new and useful science to the commercial marketplace.

Myth: ***By taking industry sponsorship, universities are inviting industry to determine the direction of university research.***

Reality: Industrial funded research programs are collaborative from inception. They match the commercially-oriented objectives of companies with the scientific interest of the university principal investigator and students. If there is not commonality of interest in the science to be pursued, there is no prospect for success. Universities insist on directing the conduct of the research program; require the research to be supervised by the university investigator; and require final control of research work product and publication.

Myth: ***Collaboration with industry invariably creates financial conflicts of interest for academics.***

Reality: University faculty interact with industry as educators, principal investigators under research programs, consultants, creators of intellectual property used by industry and as entrepreneurs. It is the responsibility of universities to continually explore the implications of these relationships and to establish effective policies to manage them. Accordingly, universities' conflict of interest policies seek to ensure that the personal financial interests of faculty do not improperly affect the content, quality or timely release of research. These conflict of interest policies have become fairly uniform among universities since they must meet standards that have been established by the federal granting agencies.

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[1] AUTM Licensing Survey: FY1998. The Association of University Technology Managers, Survey Summary, page 2

[2] Ibid. Survey Table S-12

[3] Stevens, Ashley: "Measuring Economic Impact" and Pressman, Lori, et.al.: "Pre-Production Investment and Jobs Induced by MIT Exclusive Patent Licenses"

[4] Campbell, Kenneth D.: "R&D yields public rewards," Mass High Tech, May 11-17, 1998.

[5] Op. cit., AUTM Licensing Survey: FY1998, page 14, Adjusted gross licensing income of $725M compares with $24.4B in total university FY98 sponsored research expenditures

[6] AUTM Economic Impact Survey, October 24, 1966

[7] Ibid, page 6

[8] Narin, Francis; Hamilton, Kimberly and Olivastro, Dominic: "The Increasing Linkage between U.S. Technology and Public Science" Research Policy: 26, No.3, 1997

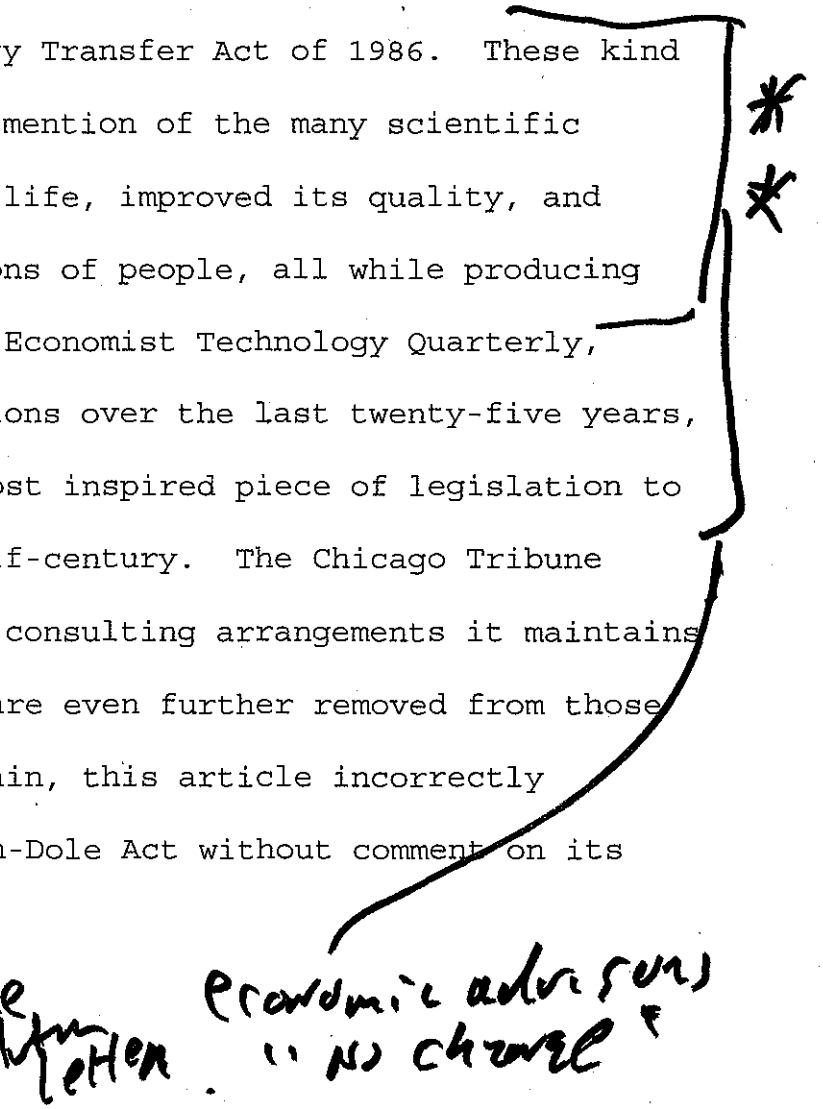
[9] Op. cit, AUTM Licensing Survey, Survey Tables, S-6 and S-8

[10] Ibid, S-12 and S-8

DRAFT
February 7, 2005

I would like to thank you for your February 2 article defending the public purpose of the government's technology transfer policies. It is the most sensible comment on the subject in quite a while.

In contrast, at lest the Los Angeles Times and The Boston Globe have both run a series of columns focusing on consulting arrangements tat involve "conflicts of interest" that they incorrectly maintain are the direct result of the Bayh-Dole Act of 1980 or the Technology Transfer Act of 1986. These kind of articles usually make no mention of the many scientific advances that have extended life, improved its quality, and reduced suffering for millions of people, all while producing thousands of new jobs. The Economist Technology Quarterly, recognizing these contributions over the last twenty-five years, concluded the Act is "the most inspired piece of legislation to be enacted over the past half-century. The Chicago Tribune article below pursues other consulting arrangements it maintains involves "conflicts" which are even further removed from those in the Times and Globe. Again, this article incorrectly attributes these to the Bayh-Dole Act without comment on its contributions.



I am disappointed that the NIH Director has reacted to the Congressional pressure engendered by the public press in such a draconian manner without first pursuing a public comment period. I view his discussion as a major step backward for technology transfer which is damaging for at least the reasons you indicated and will not silence its critics, as their real target is the emasculation of the Bayh-Dole Act and the Technology Transfer Act of 1986.

I hope you will continue to pursue this problem. If I can be of any assistance please call.

Norman J. Latker
Former Patent Counsel
DHEW and NIH 1963-1978
and
Director
Federal Technology Policy
DOC 1980-1989

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Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

We are writing on behalf of the Association of University Technology Managers (AUTM®), to comment on the petition to use the authority under the Bayh-Dole act to promote access to: (a) Ritonavir, supported by National Institute of Allergy and Infectious Diseases Contract no. AI27220; and (b) Latanoprost, supported by U.S. Public Health Service Research Grant Numbers EY 00333 and EY 00402 from the National Eye Institute, filed by Essential Inventions, Inc. with Secretary Thompson on January 29, 2004. AUTM® is a nonprofit association with membership of more than 3,200 technology managers and business executives who manage intellectual property at over 300 universities, research institutions, teaching hospitals and a similar number of companies and government organizations.

While the subject of delivering affordable health care is certainly a serious issue for the United States, we believe it must be addressed through other means. There are no expressed authorities in the Act or implementing regulations that would support the petitioner's position for Governmental actions such as those requested. As noted in 35 U.S.C. 200, the general description of the authorities reserved to the government are limited, "...to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of the invention..." (underlining added).

The general reservation of rights in the Government is specifically implemented in the march-in provision of 35 U.S.C. §203, which should not be read to be any broader than intended in the general reservation of 35 U.S.C. §200, which would be necessary to grant the requested march-in request. Indeed, such actions as proposed by the petitioner were never contemplated by the Congress and are not reflected in a proper understanding of the legislative history of the law. On the contrary, it is clear that such authorities would actually frustrate the stated policy and objectives of the Act to create incentives for commercial development by assuring, when necessary, an exclusive patent position (see 35 U.S.C. 200).

We believe that an NIH interpretation of the Bayh-Dole Act as advocated by Essential Inventions would disable the Act. The primary basis for the Act lies in the belief of individual action as opposed to government action and the power of the market. Most inventions resulting from government research are conceptual in nature and require significant investment by the private sector to bring them into practical application. This is particularly true of life science inventions requiring licensure by the Food and Drug

Administration. Commercial concerns are unlikely to invest substantial financial resources in the commercial development of any invention, funded in part by the government, knowing that the government could challenge their competitive position after the product was introduced onto the market. As was the experience in the years before the passage of the Bayh-Dole Act, when government policy was to grant only non-exclusive licenses, no drugs for which the government held title were developed and made available to the public.

Currently, exclusive licenses of federally funded inventions are believed to be dependable. This dependability can be maintained only if all those involved in the process retain full confidence that the march-in remedy will be exercised only in those extraordinary circumstances clearly anticipated by the Act. In 1997, Harold Varmus, then Director of the NIH, recognized this potential when he rejected the march-in petition of CellPro after it lost a patent infringement suit brought by Johns-Hopkins University, Becton Dickinson and Baxter. In issuing his determination, he stated:

> *"The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the dissemination and development for new and useful technologies. It has proven an effective means for the development of healthcare technologies."*

On May 13, 2003, after a detailed study of technology transfer mechanisms, the President's Council of Advisors on Science and Technology concluded:

> *"Existing technology transfer legislation works and should not be altered."*

Interpreting agency authority to exercise march-in rights as advocated by the petitioner would be a major alteration to the existing technology transfer legislation. Granting a march-in in this instance would, we believe, serve only a narrow interest and be contrary to the broader public interest the Act is intended to serve. While we do not wish to diminish the seriousness of the issue of delivering affordable health care we believe it must be addressed through other means and urge the NIH to reject Essential Inventions's petition.

Sincerely,

AUTM

the Bayh-Dole Act

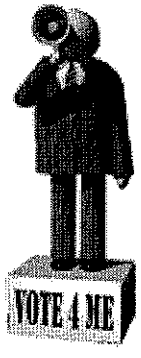
Features Index

Are you ready for the second academic revolution? Or don't you remember the first one?

From the ivory tower to the marketplace:

the Bayh-Dole Law and the myth of better mousetraps

Michael Odza



In order to understand why the aloof ivory tower of academia is bending toward the unruly marketplace--that is, why universities have added technology transfer and economic development to the better established missions of education and research- -it's necessary to look back 18 years to a law known as the Bayh-Dole Act. But to put the Act in proper perspective, we must look back a bit further--to the birth myths of the university.

One account says two universities were founded simultaneously, on contrasting principles. One group of medieval monks, isolated from the plague-ridden rest of society in their high stone tower, possibly in Salamanca, Spain, decided they could support their

scholarly works by imparting what they knew to healthy (and, need we say, wealthy) students. However, another account suggests that universities also have a parallel tradition of serving the society in which they are embedded more directly. This story holds that a group of ambitious merchants, possibly in Cambridge, England, believing that education would help them in their worldly pursuits, set out to hire some expert tutors. These two models--one based on research, with teaching as a way to pay for it, and the other based on learning, apparently for its utility--persisted almost unchanged and usually separate until midway through the 20th century. In this light, technology transfer is part of a long tradition of response to changes in society's needs.


Birch Bayh

Even the industrial revolution had little immediate effect on the university's divided identity. Formal academic technology transfer really began with the spread of scientific agricultural practices through the land-grant university system. With the notable exception of the Massachusetts Institute of Technology, guided by industrialist Vannevar Bush, most of academia resisted the messy charms of real-world problems. However, when World War II arrived, the governments of Germany, England, Canada, and the United States turned to their universities for the technologies to win the war. Famously, MIT's Radiation Laboratory contributed to anti-aircraft gun control, radar, and electronics, while Columbia physicists such as I.I. Rabi, George Pegram, Enrico Fermi, and John Dunning served the war effort through the Manhattan Project. So when Bush prepared his famous plan for the future of research in the United States, *Science: The Endless Frontier* (Washington: U.S. Government Printing Office, 1945), it was only after academicians had descended patriotically from the

ivory tower to dirty their hands in designing the new weapons of war--and had succeeded, spectacularly.

What followed, of course, were 30-plus glorious years of steadily rising, indeed seemingly endlessly expanding federal funding for research back in the ivory tower, in an isolation welcomed by both society and the academy. (Of course, the purity was partial, at best. Military funding of university research soared. However, contemporary fears that federal funding would lead to federal control have an interesting parallel today in fears that industrial funding leads to industrial control.)


Bob Dole

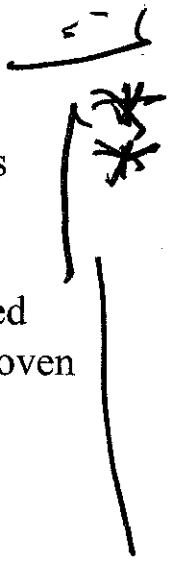
This decision to add research to the traditional academic mission of education was the first academic revolution, so designated by Christopher Jencks and David Riesman in *The Academic Revolution* (Garden City, N.Y.: Doubleday, 1968). The second academic revolution (the title of a forthcoming book by Henry Etzkowitz, SUNY Purchase), codified by Bayh-Dole and still in progress, was initiated as part of the controversial attempt to forge a national industrial policy in response to the innovations and manufacturing competition from Germany and Japan.

Could society do anything to save U.S. industry, after the cutbacks by the great central corporate research labs? Internal funding of corporate research fluctuates not in accordance with the need for new products 10 or more years out, but with sales, or worse, in accordance with the value Wall Street places on cost-saving vs. investment at any given moment. Partly as a result of the cutbacks and the short- term focus, and partly as a result of the increasing technology intensity of all industries, even in the very best cases -- IBM, Merck, Du Pont, Bell Labs, GE, 3M--companies discovered that they could not invent everything

they needed themselves.

According to Jim Turner, long-time staffer at the House Science Committee, such large companies were the main focus of attention in 1979 and 1980. They complained that federal bureaucracy made it difficult to develop civilian or commercial applications of inventions made under federal (usually military) contracts. But Howard Bremer of the Wisconsin Alumni Research Foundation, the late Roger Ditzel of the University of California, and several others saw an opportunity to extend the law to universities and other non-profits and small businesses also conducting research with federal funding. The Commerce Department's Norman Latker helped mightily by publishing a study revealing that of 30,000 federally owned patents, almost none had been commercialized.

President Carter signed the Bayh-Dole Act (Public Law 96-517) in December 1980. Its main function was to standardize previously disjointed federal policy. It reaffirmed that ownership and control of patents derived from federally funded research belonged to the performing institution, not to the sponsoring federal agency. Bayh-Dole took the decision about commercialization out of federal hands, insulating the process from political interference, and incidentally helped start the shrinking of federal government. With later amendments, it allowed non-profits to offer exclusive licenses, which provided the incentive for the venture capital industry to invest in unproven university technology, and it required the institutions to share proceeds with the inventors. Clarification of title helped give companies the confidence to make investments in unproven technologies.



The results have been dramatic. A trickle of university patents, 200 in 1980, has turned into a flood -- now more than 3,000 applications a year. Universities' share of the total U.S. patents issued rose from a fraction of a percent to 3 percent, and much

more in certain classes of advanced technology. In 1980 only a handful of major universities had the resources to fight the bureaucracy for months or years to get each invention waiver. Now more than 250 belong to the professional society, the Association of University Technology Managers (AUTM), and according to AUTM's most recent survey, more than 100 have at least 10 active licenses of inventions, meaning that companies are vigorously pursuing commercialization. Overall, 166 institutions reported nearly 13,000 active licenses, a number rising by 1,000 or more every year. More than 1,900 new companies have been formed since 1980 -- nearly 250 in 1996 alone, the most recent year surveyed.

While most licenses are for relatively modest improvements or components of products, some of them have helped transform our society in ways the sponsors, Sens. Birch Bayh and Bob Dole, probably never imagined. Within the technology transfer community, the most famous invention to date is the technique for recombinant DNA, or gene splicing, patented in 1980 by Stanley Cohen and Herbert Boyer of Stanford University and the University of California-San Francisco, respectively. Although it is difficult to separate history's contingencies from causes, it is striking that the biotechnology industry really got going after Niels Reimers, the founder of Stanford's licensing office, designed the non-exclusive licensing program for what turned out to be one of the essential tools of the industry. The Cohen-Boyer patent went on to garner more than 300 licensees and to return hundreds of millions of dollars to the institutions and the inventors.

Only three years later, Columbia obtained a patent on the co-transformation process, which extended recombination to enable the delivery of specific genes into mammalian cells. It has been used to develop numerous

pharmaceuticals, including tissue plasminogen activator (t-PA), which can prevent damage from heart attacks; erythropoietin (EPO), which stimulates red blood cell production for AIDS and kidney dialysis patients; colony stimulating factor, which stimulates white blood cells; and factor VIII, for other blood deficiencies. Co-transformation's nearly 30 licenses and more than 200 other active licenses have now propelled Columbia to the top of the tech transfer charts. Indeed, Columbia, which ranked 23rd in total sponsored research in 1996, ranked first among private universities and second only to the University of California multi-campus system in net licensing revenue, with $62.1 million.

It's important to remember how universities use such income. First, it helps defray the multi-million-dollar cost of obtaining patent protection for all promising inventions (often years before royalties, if any, begin to flow). Office expenses for managing the process take another (smaller) chunk. The bulk is divided among the inventors and the institution, which may choose to invest in risky but promising research by younger investigators, pay for early-stage validation of technology, or contribute to the general fund of the department and/or school.

For all the success of technology transfer, or perhaps because of it, problems loom. Probably no more than 5 percent to 10 percent of faculty are inventors, even at leading research universities. While their numbers are likely to increase as multimedia and software spread through the humanities faculties, many faculty may still object to the financial success, industry ties, or even utilitarian bent of their entrepreneurial colleagues.

Ironically, large companies, which once ignored university inventions (and never did do much with their own federally funded inventions), are now pushing proposals in Washington to require universities to license research tools non-exclusively, or to return the licensing of life-saving drugs to the government.

Etzkowitz observes that companies, having learned the lessons both of continuous innovation and brutal cost control, now say they "want to encourage the free flow of knowledge from academia to industry, intending 'free flow' to mean both 'without impediment' and 'without cost.'"

Yet these are problems of success. The fundamental truth confirmed by the success of the Bayh-Dole Act is that early-stage technology needs the security of law, the potential for reward, and the active promotional and negotiating skills of the technology-transfer professional to attract investment from the private sector. Remember that old saw, "if you invent a better mousetrap, the world will beat a path to your door?" It's still not true.

Related links...

- National Technology Transfer Center
- Council on Governmental Relations, an association of leading research universities
- Technology Transfer Legislative History
- *R&D Magazine*

MICHAEL ODZA is a consultant and publisher of *Technology Access Report*, a newsletter for technology transfer professionals, and of *Intellectual Property Advice*, for researchers.

the Bayh-Dole Act

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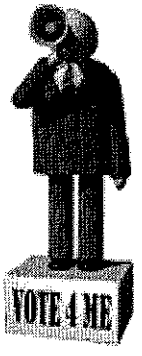

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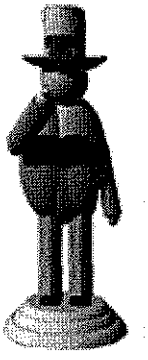

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President Carter signed the Bayh-Dole Act (Public Law 96-517) in December 1980. Its main function was to standardize previously disjointed federal policy. It reaffirmed that ownership and control of patents derived from federally funded research belonged to the performing institution, not to the sponsoring federal agency. Bayh-Dole took the decision about commercialization out of federal hands, insulating the process from political interference, and incidentally helped start the shrinking of federal government. With later amendments, it allowed non-profits to offer exclusive licenses, which provided the incentive for the venture capital industry to invest in unproven university technology, and it required the institutions to share proceeds with the inventors. Clarification of title helped give companies the confidence to make investments in unproven technologies.

The results have been dramatic. A trickle of university patents, 200 in 1980, has turned into a flood -- now more than 3,000 applications a year. Universities' share of the total U.S. patents issued rose from a fraction of a percent to 3 percent, and much

more in certain classes of advanced technology. In 1980 only a handful of major universities had the resources to fight the bureaucracy for months or years to get each invention waiver. Now more than 250 belong to the professional society, the Association of University Technology Managers (AUTM), and according to AUTM's most recent survey, more than 100 have at least 10 active licenses of inventions, meaning that companies are vigorously pursuing commercialization. Overall, 166 institutions reported nearly 13,000 active licenses, a number rising by 1,000 or more every year. More than 1,900 new companies have been formed since 1980 -- nearly 250 in 1996 alone, the most recent year surveyed.

While most licenses are for relatively modest improvements or components of products, some of them have helped transform our society in ways the sponsors, Sens. Birch Bayh and Bob Dole, probably never imagined. Within the technology transfer community, the most famous invention to date is the technique for recombinant DNA, or gene splicing, patented in 1980 by Stanley Cohen and Herbert Boyer of Stanford University and the University of California-San Francisco, respectively. Although it is difficult to separate history's contingencies from causes, it is striking that the biotechnology industry really got going after Niels Reimers, the founder of Stanford's licensing office, designed the non-exclusive licensing program for what turned out to be one of the essential tools of the industry. The Cohen-Boyer patent went on to garner more than 300 licensees and to return hundreds of millions of dollars to the institutions and the inventors.

Only three years later, Columbia obtained a patent on the co-transformation process, which extended recombination to enable the delivery of specific genes into mammalian cells. It has been used to develop numerous

pharmaceuticals, including tissue plasminogen activator (t-PA), which can prevent damage from heart attacks; erythropoietin (EPO), which stimulates red blood cell production for AIDS and kidney dialysis patients; colony stimulating factor, which stimulates white blood cells; and factor VIII, for other blood deficiencies. Co-transformation's nearly 30 licenses and more than 200 other active licenses have now propelled Columbia to the top of the tech transfer charts. Indeed, Columbia, which ranked 23rd in total sponsored research in 1996, ranked first among private universities and second only to the University of California multi-campus system in net licensing revenue, with $62.1 million.

It's important to remember how universities use such income: First, it helps defray the multi-million-dollar cost of obtaining patent protection for all promising inventions (often years before royalties, if any, begin to flow). Office expenses for managing the process take another (smaller) chunk. The bulk is divided among the inventors and the institution, which may choose to invest in risky but promising research by younger investigators, pay for early-stage validation of technology, or contribute to the general fund of the department and/or school.

For all the success of technology transfer, or perhaps because of it, problems loom. Probably no more than 5 percent to 10 percent of faculty are inventors, even at leading research universities. While their numbers are likely to increase as multimedia and software spread through the humanities faculties, many faculty may still object to the financial success, industry ties, or even utilitarian bent of their entrepreneurial colleagues.

Ironically, large companies, which once ignored university inventions (and never did do much with their own federally funded inventions), are now pushing proposals in Washington to require universities to license research tools non-exclusively, or to return the licensing of life-saving drugs to the government.

Etzkowitz observes that companies, having learned the lessons both of continuous innovation and brutal cost control, now say they "want to encourage the free flow of knowledge from academia to industry, intending 'free flow' to mean both 'without impediment' and 'without cost.'"

Yet these are problems of success. The fundamental truth confirmed by the success of the Bayh-Dole Act is that early-stage technology needs the security of law, the potential for reward, and the active promotional and negotiating skills of the technology-transfer professional to attract investment from the private sector. Remember that old saw, "if you invent a better mousetrap, the world will beat a path to your door?" It's still not true.

Related links...

- National Technology Transfer Center
- Council on Governmental Relations, an association of leading research universities
- Technology Transfer Legislative History
- *R&D Magazine*

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To: Mike Remington
From: Norm Latker
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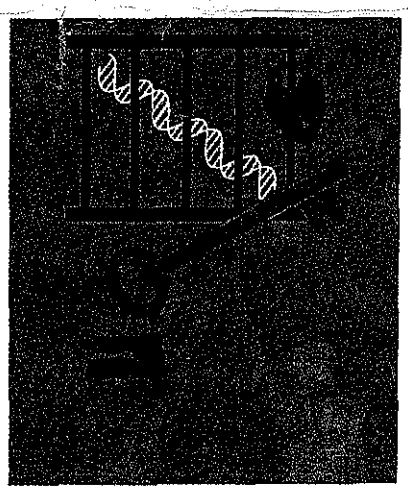
Razing the Tollbooths

A call for restricting patents on basic biomedical research By GARY STIX

The Bayh-Dole Act, a 1980 law intended to prod the commercialization of government-supported research, gave universities a major role in ushering in the new era of biotechnology. The law fulfilled legislators' most ambitious expectations by encouraging the patenting of academic research—and the exclusive licensing of those patents to industry. In 1979 universities received a mere 264 patents—a number that in 2000 rose to 3,764, about half of which went to biomedical discoveries. The 14-fold increase far outpaced the overall growth in patents during that period. A few voices in the intellectual-property community have now charged that Bayh-Dole has gone too far. Patents, they claim, have been granted on the fruits of biomedical research that should remain in the public domain. In recent co-authored articles, Arti K. Rai of the University of Pennsylvania and Rebecca S. Eisenberg of the University of Michigan at Ann Arbor have proposed reform of the law, contending that development of new biopharmaceuticals and related technologies has been hindered by extending patent coverage beyond actual products to basic research findings. DNA sequences, protein structures and disease pathways should, in many cases, serve as a general knowledge base that can be used freely by everyone.



JENNIFER HAINE

Rai and Eisenberg cite the case of a patent obtained by teams at Harvard University, the Massachusetts Institute of Technology and the Whitehead Institute for Biomedical Research in Cambridge, Mass. It covers methods of treating disease by regulating cell-signaling activity involving nuclear factor kappa B (NF-κB), which controls genes for processes ranging from cell proliferation to inflammation in various maladies. Those institutions and Ariad Pharmaceuticals (also in Cambridge), the exclusive licensee of the patent, are now suing Eli Lilly, claiming that two of its drugs—one for osteoporosis, one for sepsis—infringe the patent. Ariad has contacted more than 50 other companies that are researching or commercializing drugs that work through this pathway, asking them for licensing fees and royalties. The broad-based patent does not protect specific drugs. Instead it has become a tollbooth for commercial drug research and development on the NF-κB pathway. "In this case, as in many others, upstream [precommercial] patents issued to academic institutions serve as a tax on innovation, diluting rather than fortifying incentives for product development," the authors wrote in the winter-spring issue of *Law and Contemporary Problems.* (Their other article on the Bayh-Dole Act appeared in the January-February issue of *American Scientist.*)

Rai and Eisenberg suggest that the law should be altered to make it easier for the government—in particular, the National Institutes of Health—to specify that such upstream research remain public and not be subject to patents. They also recommend facilitating the government's ability to mandate the nonexclusive licensing of a patent at reasonable rates. Both actions are permitted under the current law but have almost never been exercised; the law makes it cumbersome to do so.

Fiddling with Bayh-Dole does bear risks. For instance, an executive-branch agency such as the NIH could be subject to political pressure in barring patents: an administration opposed to using embryos in scientific investigations might order an agency to withhold patents on such research. But university technology-transfer offices, Rai and Eisenberg contend, cannot be entrusted to make decisions about when to forgo patenting, given that a big part of their mission is to bring in licensing revenues. So more leverage is needed to ensure that basic biomedical research remains open to all. SA

Who Pays for U.S. Prescription Drug R&D?

Prescription drug prices for the American taxpayer increased from over $50 billion dollars in 1993 to over $93 billion dollars in 1998.

Almost all of the health care research and development dollars in the United States, both public and private, is spent on the development of prescription drugs. In 1970, 70 percent of the money came from the American taxpayer. Beginning in 1985, spending on the treatment of AIDS began, with most of these R&D dollars going towards the development of anti-AIDS prescription drugs. As of 1995, the last year for which data is available, taxpayer-paid R&D and AIDS dollars amounted to 55 percent of $41 billion dollars spent on heath care R&D in the United States, with 45 percent of this coming from the pharmaceutical industry.

Health Care R&D & AIDS Funding - minus Private Non-Profit Organizations -- Data from Tables 126 and 127 , HHS Handbook, Health, 2000 (funds in $ millions)

	1995	*1994*	*1993*	*1990*	*1985*	*1980*	*1970*
TOTAL R&D +AIDS	**$41,312**	**$38,452**	**$35,201**	**$25,199**	**$13,234**	**$7,662**	**$2,632**
Industry	$18,645	$17,106	$15,711	$10,719	$5,360	$2,459	$795
	45%	**44%**	**45%**	**43%**	**41%**	**32%**	**30%**
Federal Taxpayer R&D	$13,423	$12,821	$12,108	$9,791	$6,791	$4,723	$1,667
Federal Taxpayer AIDS	$6,821	$6,329	$5,328	$3,064	$205		
State /Local Taxpayer	$2,423	$2,196	$2,054	$1,625	$878	$480	$170

TOTAL Taxpayer	**$22,667**	**$21,346**	**$19,490**	**$14,480**	**$7,874**	**$5,203**	**$1,837**
	55%	**56%**	**55%**	**57%**	**59%**	**68%**	**70%**
Federal Taxpayer dollars for AIDS Funding: 1996-$7,522; 1997-$8,363, 1998-$8,931, and 1999-$9,988							

As can be seen, the American taxpayer continues to pay most of the money spent on health care R&D and AIDS spending in the United States, almost all of it for the development of prescription drugs. One would think that the American taxpayer would somehow benefit from this investment, perhaps in the reduction of the prices for those prescription drugs their taxpayer dollars paid to develop. But this is not happening. As **Congressman** Bernie **Sanders** of Vermont said in 1995, "When 42 percent of all U.S. health care research and development expenditures is paid for by the taxpayer, and 92 percent of the cancer drugs developed since 1955 were developed with Federal funding, we owe it to the taxpayer to give them a fair return on their investment with a reasonable price on the drugs they paid to develop." **Congressman Sanders** figures excluded the money spent on the development of drugs for AIDS since 1985.

And the Pharmaceutical Industry Keeps on Winning

On August 3rd, 1995, **Congressman Sanders** (I-VT) introduced an amendment to HR.2127, the FY1996 appropriations bill for the HHS, requiring the National Institute of Health to require that all such drugs developed with taxpayer dollars be marketed at a "reasonable price."

In House Roll Call Vote 624 on August 4th, 1995, the **Sanders** amendment LOST on a vote of 141 AYES to 284 NAYS. Of the 141 AYES, there were (4R, 136D, 1I). Of the 284 NAYS, there were (225R, 59D,) with 9 Representatives not voting (2R, 7D).

Of the 229 Republicans voting, 225 (98%) voted AGAINST the Sanders amendment, and 4 (2%) voted FOR it. Of the 195 Democrats voting, 136 (70%) voted FOR the Sanders amendment, and 59 (30%) voted AGAINST it.

In 1996, **Congressman Sanders** proposed a similar amendment to HR.3755, the FY1997 appropriations bill for HHS. This was defeated in House Roll Call Vote 306 on September 27, 1996 on a vote of 180 AYES (23R, 156D, 1 I) to 242 NAYS (205R, 37D), with 11 Representatives not voting.

Of the 228 Republicans voting, 205 (90%) voted AGAINST the Sanders amendment, and 23 (10%) voted FOR it. Of 193 Democrats voting, 156 (81%) voted FOR the Sanders amendment and 37 (19%) voted AGAINST it.

On September 27th, **Congressman Sanders** also introduced **HR.4270**, the Health Care Research and Development and Consumer Protection Act. It required **NIH** reporting on research and development expenditures for drugs approved for marketing. **HR.4270** was killed and buried in the Republican-controlled "Health and Environment" Subcommittee of the Republican-controlled House Commerce Committee on October 11, 1996.

On February 8th, 1999, **Sanders** and 35 other Representatives (including one or two Republicans) introduced **H.R.626** - the Health Care Research and Development and Taxpayer Protection Act. **HR.626** again called for "reasonable pricing" on prescription drugs developed with Federal taxpayer dollars. Again, the bill was killed and buried in the "Health and Environment" Subcommittee, this time on February 24th, 1999.

The Republican Representatives of the Pharmaceutical Industry in 1999:

House Commerce Committee - The 16 Members of the Republican Majority on the "Health and Environment"

Sub-Committee -- Michael Bilirakis, (R-FL) Chairman; Tom A. Coburn, (R-OK) Vice Chairman; Brian P. Bilbray, (R-CA), Ed Bryant, (R-TN) ,Richard Burr, (R-NC), Barbara Cubin, (R-WY), Nathan Deal, (R-GA), Greg Ganske, (R-IA), James C. Greenwood, (R-PA), Rick Lazio, (R-NY), Charlie Norwood, (R-GA), Charles "Chip" Pickering, (R-MS),John B. Shadegg, (R-AZ), Cliff Stearns, (R- FL), Fred Upton, (R-MI), Ed Whitfield, (R-KY)

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STATEMENT OF SENATOR BIRCH BAYH TO THE
NATIONAL INSTITUTES OF HEALTH

MAY 25, 2004

Thank you very much for allowing me to speak to you this morning about the intent of the Bayh-Dole Act. I am accompanied by Joe Allen, currently President of the National Technology Transfer Center, and formerly my primary staffer working on this law.

As Sen. Bayh has done my remarks are limited to addressing the contention that Bayh-Dole gives NIH the ability to control the prices of products arising from its extramural research. I am not at all familiar with the specifics of the drugs in question, so I will make no comment on the merits of these particular cases.

I feel compelled to tell many well-intended supporters of this petition that I must disagree with their conclusion that the law gives government the ability to regulate the price of products arising from Bayh-Dole. It does not.

Before Bayh-Dole was written government funded inventions were rarely commercialized. The federal agencies, such as NIH, are typically funding very early stage research far removed from a commercial product. As Thomas Edison said so well: "Invention is 1% inspiration and 99% perspiration." With regard to publicly funded research, government typically funds the inspiration and industry the perspiration.

NIH itself realized this before Bayh-Dole. The law was based on a very successful administrative policy that was implemented here because no new products were coming out of your extramural research. When the Carter Administration later decided to abruptly halt this policy, Senator Dole and I began hearing from our constituents that many promising inventions would never be developed unless the situation was remedied.

When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear we included the march-in provisions that are the subject of today's meeting.

The clear intent of these provisions is to insure that every effort is made to bring a product to market. If there is evidence that this is not being done, the funding agency can "march-in" and require that other companies be licensed. If the developer cannot satisfy health and safety requirements of the American taxpayer, agencies may march-in.

In those rare cases where the federal agencies are funding both "inspiration and perspiration," Bayh-Dole allows agencies to opt out of its coverage under the

"Exceptional Circumstances" provisions.

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Senator Dole and I believed that rather than price controls, the greater public good is achieved by creating new products from federally funded R&D with new jobs in the U.S. by making the products here. Bayh-Dole also requires that the resulting royalty payments go back to the public sector to fund more research, and reward our university inventors for their contributions.

At the time, no one really knew whether industry-university partnerships would form or not under our law. Recently, **The Economist Technology Quarterly** called Bayh-Dole "Possibly the most inspired piece of legislation to be enacted in America over the past half century."[1]

The **Economist** estimated that Bayh-Dole created 2,000 new companies, 260,000 new jobs, and now contributes $40 billion annually to the U.S. economy. Perhaps we didn't do too badly after all.

It is certainly fair to second guess us and say that we should have allowed the government to have a say in the prices of products arising from federal R&D as well. However, we are a nation of laws and, if changes are believed warranted, we have a process for doing so. That is to amend the law. You simply cannot invent new interpretations a quarter of a century later. I fear that this is what is being proposed.

It was first brought to my attention that attempts were underway to rewrite history when I saw an article in the **Washington Post** on March 27, 2002, entitled *Paying Twice for the Same Drugs.*. The crux of the article was that:

> Bayh-Dole ... states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and if refused, license it to third parties that will make the drug available at a reasonable cost.[2]

This view mistakes how our law works. Bob Dole and I responded in a letter to the editor of the **Washington Post** on April 11, 2002 setting the record straight.[3]

You can imagine my surprise when I heard that the same arguments were being formally

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[1] "Innovation's Golden Goose," The Economist 14 Dec 2002: 3.

[2] Peter Arno and Michael Davis, "Paying Twice for the Same Drugs," Washington Post 27 Mar. 2002: A21.

[3] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post 11 Apr. 2002: A28.

presented in a petition to NIH in an attempt to control drug prices. The current petition says: "The clear language of the Bayh-Dole act requires reasonable pricing of

government supported inventions."[4] It later adds: "The legislative history evidences an intent to require that government supported inventions be priced reasonably."[5]

When there is doubt about what Congress intended in enacting legislation, you must look at the legislative history on the law. This includes the law itself, the Committee report of the bill, and floor debate on that particular bill. *Legislative history does not include debates on other bills that were not enacted.*

All but one of the citations in the petition used to conclude that march-in rights were intended to control prices actually refer to hearings on bills other than Bayh-Dole. While perhaps interesting, these are not pertinent legislative history. I could only find one citation from the real legislative history. Here it is:

> This consensus was recorded in the Senate's Committee Report on the bill, which explained that march-in rights were intended to insure that no 'windfall profits,' or other "adverse effects result from retention of patent rights by these contractors."[6]

The petition footnote on this section adds "statement of Senator Bayh that the march-in provisions were meant to control the ability of 'the large, wealthy, corporation to take advantage of Government research and thus profit at taxpayers' expense.'"[7]

These quotes didn't sound right, so I looked them up. Rather than being a statement of fact, my quotation is actually taken from a question I asked the Comptroller General on another topic altogether.

The language taken from the Committee report mixes up references to two different sections of the law so that the original meaning is unrecognizable.

Let's see what happens when the quotes are placed in their proper context. In my written statement I highlighted the language referred to in the petition as it appears in the actual text.

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[4] Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Essential Inventions, Inc., 2004) 9.

[5] Ibid., 10

[6] Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Washington: Essential Inventions, Inc., 2004) 10.

[7] Ibid.

With regard to the petition's footnote,

During his testimony, I asked Elmer Staats, then the Comptroller General of the United States, a question about concerns expressed about the Bayh-Dole bill. Here it is:

> The other criticism comes from those that feel that this bill is a front to allow ***the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense.*** We thought we had drafted this bill in such a way that this was not possible. Would you care to comment on this scenario as a valid criticism?
>
> Mr. Staats: Of course, this is the key question. There is no doubt about that. In my opinion, the bill does have adequate safeguards.... It preserves the idea, the concept, that the Government will still have the rights to come in and require the exploitation of a patent. It cannot be just locked up. It also preserves the idea, which the Commission endorsed , that if there are substantial profits involved, then the Government would share in those profits...
>
> I think that you have to look at this issue not in terms of giving something away which is valuable property; it is a question of really making sure that the Government's investment has been translated into beneficial effects from the point of view of the impact on the economy.[8]

To put this in context, what Mr. Staats is referring to when we discuss "substantial profits" is not that they be regulated. He is discussing a provision in the original bill that required universities and small companies to "pay back" part of their income to the sponsoring agency. This is quite a different concept than price controls, isn't it?

The Language from the Senate Judiciary Committee Report

also

?

The petition mixes up language describing two unrelated parts of Bayh-Dole. Here's how the report actually reads with the petition extract highlighted:

> The agencies will have the power to exercise march-in rights to insure that no

[8] United States. Congress. Senate. Committee on the Judiciary, University and Small Business Patent Procedures Act: Hearings before the Committee on the Judiciary, United States Senate, Ninety-sixth Congress, first session, on S.414...May 16, and June 6, 1979 (Washington: U.S. Government Printing Office, 1979): 44.

[9] United States. Congress. Senate. Committee on the Judiciary, University and Small Business Patent Procedures Act: Report of the Committee on the Judiciary, United States Senate, on S.414 (Washington:

adverse effects result from the retention of patent rights by these contractors.[9]

-5-

That was the language on section 203, the march-in rights provision. The report continues:

> The existence of section 204 of the bill, the Government pay back provision, will guarantee that the inventions which are successful in the marketplace reimburse the Federal agencies for the help which led to their discovery. Although there is no evidence of "***windfall profits***" having been made from any inventions that arose from federally-sponsored programs, the existence of the pay back provision reassures the public that their support in developing new products and technologies is taken into consideration when these patentable discoveries are successfully commercialized."[10]

Thus, it is only by inappropriately combining language describing an entirely different section of the law that the words **"windfall profits"** can be made to refer to march-in rights. They clearly do not. Such a representation is highly misleading.

When read in context, the real meaning could not be clearer. Rather than controlling product prices, the language actually provided that the Government should be able to recoup a percentage of its investment when an invention from its extramural funding hits a home run in the market.

The payback provision was later dropped because the agencies said that the administrative costs of tracking university royalties would far outweigh any monetary benefits from the one-in-a-million breakthrough invention.

Now for those who really want to explore the fine points of Bayh-Dole, it is instructive that when we clearly intended to trigger agency actions related to the financial success of an invention, the language of the "pay back" provision was very specific. We said in black and white how much money would trigger this action.

If we had intended for agencies to control product prices, we would not do so in hidden code words suddenly unearthed like the Rosetta stone 25 years later. We would have told agencies precisely what we meant. That no such language exists is evident. Such a construction can only be made by Alice in Wonderland contortions of the record.

Again, it is fair to look back in hindsight and say that we were wrong to not control prices. Congress is certainly empowered to amend the law to do so, but we also have clear

U.S. Government Printing Office, 1979) 30.

[10] Ibid.

evidence that such actions may not have the intended result.

We need look no further than NIH itself. Under pressure, in 1989 NIH placed a provision in its intramural collaborations with industry that resulting inventions must demonstrate "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public."[11]

When industry collaborations began evaporating, and NIH explored the reasons and found:

> Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.[12]

If NIH found that price controls on its intramural research are "contrary to the Bayh-Dole Act," how can the same provisions be applied to extramural research?

If Congress does decide to amend Bayh-Dole someone clearly define what is a "reasonable price." Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that "bet the farm" on one or two patents. Copycat companies are always waiting until an entrepreneur has shown the path ahead. They can always make things cheaper since they have no significant development costs to recover.

What will happen to the start up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over their heads? What evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened to NIH.

NIH wisely realized that the greater good is to allow American taxpayers to have access to important new products and processes, along with the new jobs and taxes they create than to try and regulate prices.

Bob Dole and I made the same choice in 1980. I still believe that we were correct.

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[11] National Institute of Health, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (Washington: U.S. Government Printing Office, 2001) 9.

[12] Ibid., 8.

Thank you

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Arno, Peter and Michael Davis. "Paying Twice for the Same Drugs." Washington Post 27 Mar. 2002: A21.

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STATEMENT OF SENATOR BIRCH BAYH TO THE
NATIONAL INSTITUTES OF HEALTH

MAY 25, 2004

Thank you very much for allowing me to speak to you this morning about the intent of the Bayh-Dole Act. I am accompanied by Joe Allen, currently President of the National Technology Transfer Center and formerly my primary staffer for the Bayh-Dole Act.

I want to make quite clear that I only want to address the contention of the present petition that Bayh-Dole gives NIH the ability to control the prices of products arising from your extramural research. I am not at all familiar with the specifics of the drugs in question, so I will make no comment on the merits of these particular cases.

Quite frankly, I have mixed emotions about being here today. While I am very proud of what has been accomplished under this landmark law, today I feel compelled to tell many well-intended supporters of this petition that I must disagree with their conclusion that the law gives government the ability to regulate the price of products arising from Bayh-Dole. It does not.

I would like to briefly address what Senator Dole and I did intend in drafting the law, what the law's real legislative history says, and touch on why I continue to believe that attempting to use technology transfer legislation to control prices is not a good idea.

Let me start with why Bayh-Dole was written. Before this law, government funded inventions were rarely commercialized. The federal agencies, such as NIH, are typically funding very early stage research far removed from a commercial product. The risk and expense of taking such concepts through development and into the marketplace are enormous. Under our system of Government, industry bears these risks and expenses. Experience proved that unless companies could protect their investments they simply would not be made.

NIH itself realized this before Bayh-Dole. The law was based on a very successful administrative policy that was implemented here because no new products were coming out of your extramural research. When it was later decided in the Carter Administration to abruptly halt this policy, Senator Dole and I began hearing from our constituents that many promising inventions would never be developed unless the situation was remedied.

The purpose of Bayh-Dole was to create partnerships between the U.S. public and private sectors so that promising discoveries would not die on the shelves of federal agencies. That to me is a tremendous benefit to the American public. Bob and I also focused our attention on where we thought new products were most likely to be brought aggressively

to market. We focused our bill to inventions made by universities and small companies. The law requires universities to give domestic small companies preferences when they license their inventions. Today about 80% of university inventions are licensed to small companies.

A fear was expressed when Congress was debating our approach that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear we included the march-in provisions that are the subject of today's hearing.

This is how the Senate Judiciary Committee report describes the intent of Bayh-Dole's march-in rights:

> Section 203 establishes situations in which the funding agency may require small business firms or nonprofit organizations, or their assignees or licensees, to license subject inventions, to which the contractor has retained title. The Government may "march-in" if reasonable efforts are not being made to achieve practical application, for alleviation of health and safety needs, and in situations when the use of the invention is required by Federal regulations. Finally, a march-in is included that ties into the U.S. manufacture requirement of section 205.
>
> March-in is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third parties will be the basis for the initiation agency action.
>
> (Report of the U.S. Senate Judiciary Committee on the University and Small Business Patent Procedures Act, Report 96-480, pp. 33-34)

The clear intent of these provisions is to insure that every effort is made to bring a product to market. If there is evidence that this is not being done, the funding agency can "march-in" and require that other companies be licensed.

At the time we passed Bayh-Dole, no one really knew whether industry-university partnerships would work or not. **The Economist Technology Quarterly** of December 14, 2002 summarizes well what happened. Particularly pertinent to today it begins: "The reforms that unleashed American innovation in the 1980's, and were emulated widely around the world, are under attack at home."

It then continues:

> Remember the technological malaise that befell America in the late 1970's? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later things were very different. An exhausted Soviet empire threw in

> the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.
>
> Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole act of 1980.... More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.
>
> Before Bayh-Dole, the fruits of research supported by government agencies had belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.
>
> The result was that inventions and discoveries made in American universities, hospitals, national laboratories and non-profit institutions sat in warehouses gathering dust. Of the 28,000 patents that the American government owned in 1980, fewer than 5% had been licensed to industry. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.
>
> The Bayh-Dole act did two things at a stroke. It transferred ownership of an invention or discovery from the government agency that helped pay for it to the academic institution that carried out the actual research. And it ensured that the researchers involved got a piece of the action.
>
> Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and their graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,000 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the American economy. Having seen the results, America's trading partners have been quick to follow suit. Odd then, that the Bayh-Dole act should now be under attack in America.

This was the intent of Bayh-Dole. To provide incentives for universities and small companies to aggressively move their inventions made from federal research into the marketplace. Along these lines, Senator Dole and I provided that the federal agencies could march-in if good faith efforts were not being made to develop products so that the American public could benefit from them. Commercial availability, not pricing was our focus.

It is certainly fair game to second guess us and say that we should have allowed the government to have a say in the prices of products arising from federal R&D. I respectfully disagree.

Government is typically funding very early stage research. As described above, any company seeking to take such ideas to market faces a long, uncertain road. The odds are probably 100-1 that any particular invention made under Bayh-Dole will be a commercial success, and considerably higher that it will be a huge success. Rather than drafting our law for these rare exceptions, we designed it to work that vast majority of the time. I believe that it does so.

Again, others are certainly free to disagree with me. However, we are a nation of laws and if changes are believed warranted we have a process for doing so. That is to amend the law. You simply cannot invent new interpretations a quarter of a century later and retroactively impose them on those who successfully ran the product development gauntlet. I fear that this is what is being proposed today.

It was first brought to my attention that attempts were underway to rewrite history along these lines when I saw an article in the **Washington Post** on March 27, 2002, entitled *Paying Twice for the Same Drugs.*. The crux of the article was that:

> Bayh-Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and if refused, license it to third parties that will make the drug available at a reasonable cost.

Bob Dole and I agreed that we could not sit idly by while this novel interpretation was floated, and so we wrote a joint letter to the editor of the **Washington Post** on April 11, 2002 saying:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the purpose of the act was to entice the private sector to seek public-private research collaborations rather than focusing on its own proprietary research.
>
> The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of the company that commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

You can imagine my surprise when I heard that the same arguments were being formally presented to in a petition to NIH in an attempt to control drug prices. The current petition says: "The clear language of the Bayh-Dole act requires reasonable pricing of government supported inventions." It later adds: "The legislative history evidences an intent to require that government supported inventions be priced reasonably."

When there is doubt about what Congress intended in enacting legislation, you must look at the legislative history on the law. This includes the law itself, the Committee report of the bill, and floor debate on that particular bill. *Legislative history does not include debates on other bills that were not enacted.*

It is by mixing up the two that the current conclusions on the intent of the Bayh-Dole Act are justified in the petition. Let's take a closer look at these allegations on what we meant in writing the bill.

If you read the specific citations in the petition used to conclude that march-in rights were intended to control prices, all but one actually refers to hearings on other bills than Bayh-Dole. While perhaps interesting, these are not pertinent legislative history. I could only find one citation from the real legislative history. Here it is.

> This consensus was recorded in the Senate's Committee Report on the bill, which explained that march-in rights were intended to insure that no 'windfall profits,' or other "adverse effects result from retention of patent rights by these contractors."

The petition footnote on this section adds "statement of Senator Bayh that the march-in provisions were meant to control the ability of 'the large, wealthy, corporation to take advantage of Government research and thus profit at taxpayers' expense.'"

These quotes didn't sound right, so I looked them up. The footnote refers to a question I asked the Comptroller General in the hearing on another topic altogether. The language from the Committee report mixes up references to two different sections of the law so that the original meaning is unrecognizable.

Let's see what happens when the quotes are placed in their proper context. In my written statement I highlighted the language referred to in the petition as it appears in the actual text.

The Footnote

During his testimony, I asked Elmer Staats, then the Comptroller General of the United States, about two concerns expressed about the Bayh-Dole bill. One was that we gave a preference to small companies. Now I'll quote directly from the hearing. I pose the following question to Mr. Staats:

> The other criticism comes from those that feel that this bill is a front to allow ***the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense.*** We thought we had drafted this bill in such a way that this was not possible. Would you care to comment on this scenario as a valid criticism?
>
> Mr. Staats: Of course, this is the key question. There is no doubt about that. In my opinion, the bill does have adequate safeguards.... It preserves the idea, the concept, that the Government will still have the rights to come in and require the exploitation of a patent. It cannot be just locked up. It also preserves the idea, which the Commission endorsed , that if there are substantial profits involved, then the Government would share in those profits. You might quarrel about the particular figure which is used in your bill, but I would not. I think that a fair judgment has been made with respect to the cutoffs here.
>
> I think that you have to look at this issue not in terms of giving something away which is valuable property; it is a question of really making sure that the Government's investment has been translated into beneficial effects from the point of view of the impact on the economy.
>
> You also have to look at it also in terms of being sure that the Government does not have to pay twice. This bill does preserve that right.
>
> So I am not concerned about the concern which might be expressed that this is giving away something which ought not to be given away. I don't look at it that way. I don't believe that it would be a fair way of looking at it."
>
> (Hearings before the Committee on the Judiciary, U.S. Senate on The University and Small Business Patent Procedures Act, May 16, and June 6, 1979, p. 44)

To put this in context, what Mr. Staats is referring to when we discuss "substantial profits" is not that they be regulated. He is discussing a provision in the original bill that required universities and small companies to "pay back" part of their profits back to the sponsoring agency!

The Language in the Senate Judiciary Committee Report

The petition's quotes come from the *Conclusion* section of the report. Here is what the report actually says:

> The agencies will have the power to exercise march-in rights to insure that no **adverse effects result from the retention of patent rights by these contractors.** The existence of section 204 of the bill, the Government pay back provision, will guarantee that the inventions which are successful in the marketplace reimburse

> the Federal agencies for the help which led to their discovery. Although there is no evidence of "***windfall profits***" having been made from any inventions that arose from federally-sponsored programs, the existence of the pay back provision reassures the public that their support in developing new products and technologies is taken into consideration when these patentable discoveries are successfully commercialized."
>
> Report 96-480 of the Senate Judiciary Committee on the University and Small Business Patent Procedures Act, p. 30.

Thus, it is only by inappropriately combining language describing an entirely different section of the law that the words **"windfall profits"** be made to refer to march-in rights. They clearly do not. Such a representation is highly misleading.

When read in context, the real meaning could not be clearer. Rather than controlling product prices, the language actually provided that the Government should be able to be recoup a percentage of its investment when an invention from its extramural funding hits a home run in the market.

The pay back provision was later dropped because the agencies said that the administrative costs of tracking university royalties would far outweigh any monetary benefits from the one in a million breakthrough invention.

Now for those who really want to explore entrails of Bayh-Dole, it is instructive that when we clearly intended to trigger agency actions related to the financial success of an invention, the language of the "pay back" provision was very specific. We said in black in white how much money would trigger the provision.

If we had intended for agencies to control product prices, we would not do so in hidden code words suddenly unearthed like the Rosetta stone 25 years later. We would have told agencies precisely what we meant. That no such language exists is evident. Such a construction can only be made by Alice in Wonderland contortions of the record.

Again, it is fair to look back in hindsight and say that we were wrong to not control prices. Congress is certainly empowered to amend the law to do so, but we also have clear evidence that such actions may not have the intended result.

We need look no further than NIH itself. Under pressure, in 1989 NIH placed a provision in its intramural collaborations with industry that resulting inventions must demonstrate "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public."

When industry collaborations began evaporating, and NIH explored the reasons is found:

> Both NIH and its industry counterparts came to the realization that this policy had

> the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.
>
> (NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected, July 2001, A Plan To Ensure Taxpayers' Interests are Protected, p. 8).

If NIH by its own words found that trying to impose price controls on its intramural research is "contrary to the Bayh-Dole Act," I would be very interested, indeed, to see how a conclusion can be reached that the same provisions that failed internally could be applied to extramural research.

If Congress does decide to amend Bayh-Dole someone wiser than me must lay out in clear language what is a "reasonable price." They must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that "bet the farm" on one or two patents. Copycat companies are always waiting until an entrepreneur has show the path ahead. Copycats can always make things cheaper since they have no significant development costs to recover.

What will happen to the more than 2,000 start up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over its head? What evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened here when you tried this experiment in 1989.

NIH wisely realized that the greater good is to allow American taxpayers to have access to important new products and processes, along with the new jobs and taxes they create than to try and regulate prices.

Bob Dole and I made the same choice in 1980. I still believe that we were correct.

Thank you

Re: Senator Bayh should get a call from Associated Press reporter, Theresa Agovino

She will essentially ask: Why should Americans pay the highest drug prices in the world, particularly when the drugs were made from government research?

Suggested response: Drug pricing is a very complex issue that is outside my expertise. Quite frankly, Sen. Dole and I were focused on a more fundamental problem. Before our law, no drugs were being made at all from government-supported research. I'm proud that many of our citizens are alive today because this is no longer the case.

Thomas Edison said the invention is 1% inspiration and 99% perspiration. In the case of Government R&D, Government funds the inspiration and industry supplies the perspiration.

Evidence suggests that attempting to control prices of products resulting from federal R&D simply does not work. When NIH tried to impose price controls on development of their own research in 1989, industry simply walked away. That to me is the worst-case scenario. Wisely, NIH reversed course and got things back on track.

Developing early stage inventions is incredibly risky and expensive, since this burden is on the private sector, they simply will not allow government to try and impose prices on the rare occasions when they succeed.

Rather than price controls, Bob Dole and I thought the better return to the taxpayer was:

1. That new products be developed through public-private sector partnerships.
2. That the best minds in our public and private sectors work together to solve important natural problems.
3. That preferences be given to small businesses to develop such products whenever possible.
4. That resulting products be manufactured in the United States.
5. That the universities receive royalties back from successful products to fund more public sector research.
6. When companies commercialize new government inventions, they create new jobs and pay taxes.
7. Now we see new companies being formed around university technologies. We are the only country in the world where this is happening and our rivals now seek to copy our model. Japan just implemented their own Bayh/Dole Act.

Bob and I also made provisions that if government was funding both the "inspiration and perspiration," these highly unusual circumstances could be exempted from Bayh/Dole as "exceptional circumstances," because government was assuming the risk. In these cases, agencies can determine different patent ownership rules.

There are also protections under Bayh-Dole. We said if companies license university technologies "sit on them", that the funding agencies could "march-in" and require the university to license other developers.

Additionally, if a developer cannot meet national needs for health or safety, agencies can also march-in.

However, the law does not provide that agencies can march-in because the developer has met the requirements I outlined, but the agency doesn't like the price.

Now I may be naive, but I do expect companies developing important therapies to be good citizens as well.

I'm testifying at the NIH hearing on May 25th not to represent either party, but simply to remind everyone of the rules of the game.

You don't change the rules in the 8th inning because you don't like the score. If Congress feels that Bob and I made the wrong decision and that government should regulate prices in addition to the benefits we now receive, fine, it can do so.

They should then also be prepared to assume responsibility for changing what the Economist called "the most inspired legislation of the past half century". However, this requires an Act of Congress, not suddenly turning Congressional language on its head to "discover" a meaning that Bob and I did not intend.

BACKGROUND FACTS:

More than 80% of inventions licensed under Bayh/Dole go to small companies.

- Universities received $997,830,761 gross license income in FY 2002
- NIH received $53.7 million in royalties in FY 2003
- More than 2,000 new small companies formed under Bayh/Dole
- Estimate that of the 5,000 – 10,000 new drug compounds entering the drug development pipeline, only one will emerge as a new drug.
- Average cost of new drug development estimated between $850 million to $1.7 billion, industry pays this investment.
- A successful drug must also pay the investment cost of the 4,999 that failed in development.

Economic Impact of the Licensing of Technologies Developed at Academic Institutions FY 1999 (taken from AUTM—Association of University Technology Managers)

"Licensing of innovations made at academic institutions contributed over **$ 40 billion** in economic activity and supported more than **270,000 jobs** in Fiscal Year 1999. In addition business activity associated with sales of products is estimated to generate **$ 5 billion in U.S. tax revenues at the federal, state, and local levels."**

The licensees of academic institutions introduced 417 new products in Fiscal Year 1999."

"Survey participants reported that 344 new companies were formed during the year."

"Over 3,900 licenses and option agreements were reported for Fiscal Year 1999, and more than sixty percent of these commercial agreements were made with small companies."