REPORT

of the

UNIVERSITY PATENT POLICY AD HOC SUBCOMMITTEE

of the

EXECUTIVE SUBCOMMITTEE

of the

COMMITTEE ON GOVERNMENT PATENT POLICY, FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY

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#### REPORT OF UNIVERSITY PATENT POLICY AD HOC SUBCOMMITTEE

#### 1. THE SUBCOMMITTEE'S ASSIGNMENT

The President's Statement on Government Patent Policy stresses that inventions resulting from research funded by the Government constitute a valuable national resource, and that the public interest requires that efforts be made to encourage the expeditious development and civilian use of these inventions. The Subcommittee was established to recommend a patent policy which the Government should follow in its research and development activities with universities and other nonprofit organizations.

The importance of this assignment is evidenced by the substantial amount of research funded by the Government at universities and nonprofit organizations.1/ For example, in Fiscal Year 1972, the Government spent approximately \$3.1 billion of the total \$12 billion expended on research and development outside its own laboratories on grants and contracts to universities.2/

1/ For convenience, "Universities and nonprofit organizations" shall hereafter be referred to as "universities". In this regard, see APPENDIX B, "Issues Upon Which the University Patent Policy Ad Hoc Subcommittee Voted", where the Subcommittee discussed this matter and voted to afford universities and nonprofit organizations the same treatment. However, also note Section 9(d) (11) of the Federal Nonnuclear Energy Research and Development Act of 1974, which, while affording special treatment to universities, makes no mention of nonprofit organizations.

2/ The distribution of such funds on an agency basis was as follows:

HEW	÷.	\$1,109,000,000	USDA	-	\$75,000,000
AEC	· _ ·	\$532,000,000	EPA	· ·	\$31,600,000
NSF		\$449,000,000	Interior	-	\$31,000,000
NASA	•••	\$288,000,000	DOT	<b>—</b> '	\$26,000,000
Air Force	-	\$228,000,000	Commerce	-	\$9,000,000
Navy	-	\$172,000,000	Justice	-	\$6,500,000
Army	••	<b>\$97,000,00</b> 0	HUD	-	<b>\$5,000,</b> 000

National Science Foundation Report - 1972 NSF 71-35, Table C-9

## 2. <u>CURRENT PRACTICES OF THE AGENCIES</u><sup>3/</sup>

**Except** for the agencies discussed below, Executive agencies have traditionally interpreted the provisions of the President's Statement on Government Patent Policy or applicable statutes to require the use of patent rights clauses in grants or contracts with university sities to provide for either title in the Government in the invention generated in performance of such grants or contracts or a deferred allocation of patent rights. The deferred allocation clause provides for deciding the allocation of patent rights until after an invention is identified. Under this policy, after the making of the invention, the university may seek to retain principal rights in the invention, subject to the funding agency's agreement. Where a title clause is used ownership to resulting inventions are acquired by the Government. However, in many cases the clause, like the deferred clause, may permit the grantee or contractor to request and retain the principal rights in the invention after the invention has been identified with the agency's agreement.

The Department of Defense (DOD), the Department of Health, Education, and Welfare (DHEW), and the National Science Foundation (NSF) have each adopted special patent policies and regulations vis-a-vis universities. DOD has applied the "special situations" provision of section 1(c) of the President's Statement, and allows universities with "approved patent policies" to retain title provided the award does not fall within section 1(a) of the Statement. DHEW and NSF have both adopted special policies for universities implemented by Institutional Patent Agreements (IPA) with qualified universities, which provide that such universities may retain title subject to various conditions and limitations.4/ In the case of DHEW, its special policy applies only to grants. Inventions generated under DHEW contracts are subject to a deferred allocation policy. The NSF special institutional policy applies to grants and contracts. In any case, NSF and DHEW may except specific awards from the operation of their institutional agreements.

3/ The Subcommittee at the outset of its assignment conducted a survey of agency policies and practices vis-a-vis university patent policy. The survey was previously submitted with the Subcommittee's August 2, 1972, Report, and has been changed only by the formalization of the NSF Institutional Patent Policy in 39 F.R. 41982-41985 and 40 F.R. 12819.

<sup>&</sup>lt;u>4</u>/ Copies of the DHEW and NSF IPA's are set forth in APPENDIX A of this report.

Both NSF and DHEW consider their university policies consistent with section 1(a) of the President's statement, based on an early interpretation of this provision by the Patent Advisory Panel of the Federal Council for Science and Technology.<sup>5</sup>/ The Subcommittee gives it great weight as a contemporaneous interpretation by persons who were closely involved with its original development.6/

Of course, DOD, DHEW, and NSF continue to use essentially a deferred determination approach with universities which do not have IPA's or qualified patent policies.

- 5/ The Panel's interpretive statement, set forth in the 1965 Annual Report on Government Patent Policy, reads as follows: "Examples of exceptional circumstances of the type contemplated by section 1(a) might be . . . where the public interest will be advanced by leaving principal or exclusive rights to a nonprofit educational institution that agrees to administer inventions in a manner deemed by the agency to be consistent with the public interest."
- 6/ The President's Patent Policy is founded on the concept that the allocation of patent rights should be determined at the time a contract or grant is awarded. This policy contemplates a review at the time of each award to determine whether Section 1(a) or 1(b) is applicable. Some agencies have adopted specific procedures to conduct this evaluation. (See ASPR 9-107.4(b) and DOD Form 1564, noted in ASPR 9-107.4(a)). Other agencies whose programs fall basically under Section 1(a) have not adopted procedures for reviewing each award in the light of the President's Statement, but have operated on a presumption that all their awards are under the title portion of Section 1(a). Only where a special patent **rights** problem arose was a specific determination made. Agencies which have adopted the "exceptional circumstances" interpretation of the President's Statement to include universities with approved patent policies have also utilized the concept of a presumption that all awards to such universities fall within "exceptional circumstances" subject to a specific review or procedure for exempting specific awards where the agencies determine that exceptional circumstances are not present. The utilization of this presumption for "exceptional circumstances" is considered to be consistent with the interpretation of and procedures utilized by the agencies under the President's Statement.

#### 3. THE GOAL OF UNIFORMITY

Four basic approaches are now being used for the allocation of patent rights under university grants and contracts, i.e., deferred allocations; title in the Government, with or without provision for the contractors to request and retain principal rights after the invention has been identified; recognizing universities under 1(c) as a special situation, (DOD); and the DHEW/NSF Institutional Patent Policy approach with selected universities. Yet one of the basic considerations underlying the President's Policy is the need for a "Government-wide policy . . . reflecting common principles and objectives, at the same time recognizing that need for uniformity in the area of patent rights must be subservient to the missions of the respective agencies." In framing its recommendation, the Subcommittee has considered the differing missions of the respective agencies and the types of university research which they support. In the Subcommittee's opinion, the differing missions of these agencies do not support the wide differences in treatment of a particular university doing similar work for different agencies, although it is recognized that some agencies may be governed by statutory requirements that hamper implementation of the recommendations made in this report.

Furthermore, the need to arrive at a uniform university patent policy is supported by Governmental policies in addition to the President's Statement of Government Patent Policy.

74 For example, the following directive from Federal Management Circular 73-7 was considered by the Subcommittee to be a further mandate to seek a uniform Government patent policy as applied to universities:

"Differing administrative policies and practices associated with Federal grants and contracts for supporting research at educational institutions create confusion and additional administrative effort for educational institutions, cause conflict between the university community and the Federal Government, and reduce the effectiveness of the institutions in performing the desired research.

Since many Burdensome inconsistencies in Government Administrative policies and practices can be removed without jeopardizing the effective pursuit of the research efforts, it is in the interest of both the Government and educational institutions to remove such inconsistencies wherever feasible."

FMC 73-7, Administration of College and University Research Grants - December 19, 1973. This was formerly OMB Circular A-101.

Accordingly, the Subcommittee has formulated guidelines to implement a uniform Government patent policy for universities.

#### 4. <u>CRITERIA CONSIDERED BY THE SUBCOMMITTEE IN ARRIVING AT ITS</u> RECOMMENDATIONS

In arriving at its recommendations, the Subcommittee has attempted to devise a uniform university Government patent policy within the framework of the President's Statement that emphasizes allocation of patent rights at the time of contract or grant utilization of inventions while reducing the administrative burden to all parties involved. At the same time, the Subcommittee made efforts to ensure that the public interests would be protected.

#### 5. THE FRAMEWORK FOR COMMERCIALIZATION OF UNIVERSITY INVENTIONS

In order to arrive at a uniform patent policy covering the inventive results of university research, an understanding of the nature of this research and the inventions which flow therefrom is imperative. Accordingly, various characteristics of technology transfer of inventions from universities to the marketplace and barriers thereto were examined. Some of the factors which were considered by the Subcommittee are set forth in this section.

#### A. The Need for Commercialization by Industry

The most obvious fact that influences the utilization of university inventions is that these institutions do not engage in the direct manufacture of commercial enbodiments, and it is industry which must bring the university inventions to the marketplace. However, it is the observation of many who have studied the technology transfer process that inventions resulting from university research have not been delivered to the public by industry to the extent or in the time expected when considering the amount of research being conducted at universities.

8/ For example, as early as 1912, Dr. Frederick Cottrell, whose gift of patent rights provided the original endowment for Research Corporation, spoke of this concern for "an intellectual by-product of immense importance" that was largely going to waste. This by-product of college and university work, recognized by Dr. Cottrell, is "the mass of scientific facts and principals developed in the course of investigation and instruction, which through lack of the necessary commercial guidance and supervision never, or only after unnecessary delay, reaches the public-atlarge in the form of useful inventions, and then often through such channels that the original discoverers are quite forgotten."

Address before the 8th Annual Congress of Applied Chemistry, N.Y., 1912, as reported in Research Corp., Quarterly Bulletin, Summer 1974

The President's first message on Science and Technology on March 16, 1972 expressed concern about this matter. For example, among the "urgent situations" that led to and were reflected in this Message was:

> "Continuing failure of industry, universities and Government to cooperate in developing civilian technology in the way they produced defense, space and atomic tools."9/

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The Subcommittee believes that as to universities this failure can be attributed to the lack of an adequate mechanism to facilitate the transfer of the inventive research results to industrial concerns. Even where universities have patent protection, they may well fail to encourage the utilization of their inventions if an adequate, organized effort to communicate with industry is not made. 10/

- "Scientists Meet on U.S. Woes", <u>The Washington Post</u>, p. A-1, Feb. 18, 1972. This article is based on a series of meetings between the then President's Science Advisor, Dr. David, and leading scientists and engineers. According to the White House fact sheet issued with the President's Message, the message was based, in part, on those discussions. Also, see Dr. David's article originally appearing in <u>The Wall Street</u> <u>Journal</u> and reprinted in <u>The Washington Star</u>, August 4, 1974, entitled "Making the Most of Our Progress in Technology", in which he finds that "U.S. taxpayers deserve more dividends" from Government-supported research and development.
- 10/ For example, see the Proceedings of the Conference on Technological Transfer and Innovation, National Science Foundation - NSF '67 -May 15-17, 1966, where various participants observed: "To transfer scientific or technical information into specific innovations requires a certain amount of organized effort." Further: "The mere existence of a body of research outputs and other technical knowledge is not, in itself, enough to result in significant industrial innovation." And: "In sum, a good communications system does not just happen accidentally; management must take deliberate, specific action to devise and keep open necessary communication channels. It must also give explicit attention to its goals."

#### B. Current University Technology Transfer Programs

Most universities transfer technology through personal contacts between scientists, attendance at professional meetings, and scientific publications. But in many cases the mere disclosure or publication of technology may not attract the expenditure of private capital to promote utilization. A few universities recognize the inadequacy of publications or personal contacts to achieve utilization and have established an inhouse management mechanism to transfer their inventive results to industry. Another fairly large group of universities obtain similar services through outside patent management organizations, such as Research Corporation and Battelle Development Corporation. However, many of these universities do not have techniques to identify or report inventions. The lack of concerted efforts to obtain invention disclosures, coupled with the lack of a patent management organization to promote inventions, has in the opinion of the Subcommittee resulted in less effective technology transfer than has occurred at universities with active in-house patent management programs.

There are indications that a number of universities, which heretofore have been relatively inactive in this area of technology transfer, are considering taking more active roles. For example, several universities have initiated new efforts in the area, and several others will be participating in a "patent awareness program" with Research Corporation, which is being partially supported by the National Science Foundation and the Department of Commerce. The interest that has been manifested in these and other ways has been sufficient for instance, to lead the National Association of College and University Business Officers (NACUBO) to prepare and distribute recently a set of guidelines for formulating university patent policies. <u>11</u>/

C. The Need for Strong Patent Management Capability to Transfer University Technology

<u>11</u>/Patent at Colleges and Universities, <u>Guidelines for the Develop-</u> <u>ment of Policies and Programs</u> - Committee on Governmental Relations -NACUBO, 1974

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The need for a strong patent management capability or "technical entrepreneurs"12/ in technology transfer is especially acute in the university setting because of (1) the characteristics of the inventions coming out of university research efforts, (2) the "publish or perish" ethic, and (3) industry attitudes towards university inventions.

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But before discussing these factors, one point should be emphasized. This is that the patent rights retained by the university will almost always be critical to the undertaking by the university to interest industry in the further development or commercialization of an invention. This is because, for all practical purposes, the main right the university can utilize as negotiating leverage is its exclusive right in a patent. And since it would be unreasonable to expect an industrial organization to be willing to risk its financial resources to develop new technology without satisfactory means of protecting its investment, it is obvious that the question of patent ownership is critical to any university's efforts at technology transfer.

12/"If any suggestion were to be made as to what should be done to promote innovation, it would be to find -- if one can, "technical entrepreneurs".

Battelle Columbus Laboratories, <u>Science</u>, <u>Technology</u> and <u>Inno-</u> vation, Summary Report - February 1973, p.8.

#### (1) Characteristics of University Inventions

The Subcommittee considers the following characteristics to be significant.

#### (a) Basic and Applied Research

Most of the university work performed under Governmentsponsored grants and contracts is basic research. Inventions arising out of such research are normally incidental to the research and at most involved compositions of matter with no clear utility, prototype devices, or processes that have been tried only in the laboratory. Yet it has been estimated that the cost of bringing the typical invention (both university and industry) to the marketplace is ten times the cost of making the invention.<sup>13</sup>/ It would be rare for a university to be in a position to bring an invention beyond the initial theoretical or laboratory stage. It has neither the facilities nor a reason to attempt to perform the engineering effort necessary to design and manufacture commercial embodiments of their inventions nor, of course, the marketing resources.

**Even where** a university undertakes "applied" or "directed" research, the situation is not much different, since university inventions that result from applied research normally reach only the laboratory model stage.

#### (b) Isolation of Inventions

University inventions, unlike those of industrial firms, normally stand alone  $\frac{14}{4}$ 

13/ U. S. Department of Commerce - <u>Technological Innovation: Environ</u>ment and Management, at 8-9.

<u>14</u>/ As explained in a Harbridge House study prepared for the National Science Foundation:

"Their isolation is a major obstacle to utilization since most inventions are not marketable products in themselves. The industrial product is often protected by a cordon of patents, as illustrated by the list of patents on a packet of Polaroid film. A university invention, on the other hand, is a one-shot patent. Even if the patent specification discloses an ingenious invention, the patent claims which define the scope of monopoly are likely to be narrowly drawn. Whereas industry will add to its patent arsenal as a product is improved, a university patent, if it is to be licensed at all, must be licensed on the initial effort."

Harbridge House, Inc, Legal Incentives and Barriers to Utilizing Technological Innovation, p. 11-13 (March 1974). Further, university inventions must be licensed for royalties only. Universities, unlike manufacturing firms, cannot transfer their technology through cross-licensing arrangements, since the university has no need to obtain the right to manufacture the inventions of others.

#### (2). The "Publish or Perish" Ethic

The tradition of publication reflects the belief in the academic world that publication is central to scholarly pursuit. The goal is publication in the learned journals or books. Patents, on the other hand, have traditionally been regarded by the university community as irrelevant at best and, at worst, as an indication of unworthy commercial motives. These factors led Harbridge House to the conclusion that "perhaps the single most difficult task of a university patent administrator was the solicitation of invention disclosures." 15/ And they found it not uncommon that even where disclosure and cooperation was obtained, the disclosure was often not reported until many months after publication. Obviously, therefore, there is an acute need for efforts to be made to obtain early reporting if technology is to be transferred at the optimal rate. Such efforts, however, require strong management.

Because the one-year period for the filing of patent applications has often begun to run by the time university administrators receive invention disclosures, or soon thereafter, university patent managers must be prepared to act quickly to protect inventions once they are identified. Moreover, they need to be able to overcome the reluctance of many faculty members to concern themselves with these efforts. Further, universities, even if predisposed to do so, cannot deal in trade secrets since "publish or perish" is the rule and therefore, universities cannot control publication by its faculty.

It also should be noted that even if a domestic patent application is filed within the one-year statutory filing period initiated by publication, such publication before filing will bar issuance of valid patent protection in most of the important industrialized foreign countries. This may detract from the "product" that the university has to offer industry and adversely affect our balance of trade.

15/ Id at II-14.

#### (3) Industry Attitudes Towards University Inventions

Universities attempting to transfer university technology must also overcome certain attitudes of their potential industrial transferees. The existence of these attitudes (or organizational barriers) is understandable. But they again highlight the need for a strong and aggressive patent management capability at the universities. Among these industrial attitudes are the following:

(a) The "Not-Invented-Here" Syndrome

Industrial organizations have commercial interest in most areas of their research. Accordingly, there is an in-house incentive and capability for such organizations to further pursue the results of their research. This incentive stems from the organizations' ability to continuously evaluate this research through all stages of its development. There is a lesser incentive for industry to further pursue the results of university research where such research was not under the organizations' initial sponsorship. This bias towards investment in further development of its own ideas, rather than ideas from outside sources, is commonly referred to as the "not-invented-here" syndrome.

(b) The Desire for Patent Rights in Collaborative Situations

In some situations, industry has refused to collaborate in bringing university inventions to the marketplace unless provided some patent protection as <u>quid pro quo</u> for the investment or development effort. This has been substantiated by a Harbridge House and a General Accounting Office (GAO) study both of which found an industry-wide reluctance by pharmaceutical firms to test compositions of matter synthesized or isolated by grant-supported investigators.<sup>10</sup> This was found to be due to DHEW's

16/ Harbridge House, Inc. - Government Patent Policy Study - Final Report to Committee on Government Patent Policy, FCST, May 17 1968; and GAO Report, Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry August 12, 1968.

Harbridge House, for example, found:

"In both cases [referring to university and nonprofit inventions] the inventions most frequently arise from basic research and require substantial private development before reaching the stage where they are commercially useful. Some measure of exclusive rights appears necessary to motivate licensees to invest in the work necessary to commercialize these inventions." (Bracketed added.) Note 13 at p. 11 of first cited report. restrictive implementation of its patent policy which normally resulted in title in the Government. Industry argued that such implementation failed to take into consideration industry's large private investment before such compositions could be successfully marketed as drugs. Although not extensively documented, similar situations have occurred in the area of medical hardware devices.

In view of the university's past experience in dealings with the pharmaceutical and medical device industry there will probably be other situations where industry would be reluctant to collaborate with universities in bringing a high-risk invention to the marketplace if some patent exclusivity is not first provided to the developer.

#### (c) Contamination

As used by industry, "contamination" means the potential compromise of rights in proprietary research resulting from its exposure to ideas, compositions, and/or test results arising from Government-sponsored research at universities. For example, if a company were to incorporate into its research program some of the research findings of a university doing parallel research and then develop a product patentably distinct from the university's invention, the company might rightfully fear that a competitor might assert the Government's rights as a defense if the competitor manufactured an infringing product.

#### 6. CONCLUSIONS OF THE SUBCOMMITTEE

#### A. <u>Creation of University Technology Transfer Capabilities</u> Should be Encouraged

Because of the various factors enumerated above, the Subcommittee is persuaded that the Government needs to create an atmosphere conducive to the transfer of inventive results from universities to industry. It appears essential that the Government induce universities to provide an internal mechanism that will serve as a focal point for receipt of the inventive results of university research for later dissemination to those industrial concerns most likely to utilize such results.

Government patent policy can play a most critical role in creating the necessary atmosphere for this transfer. As previously noted, patent rights are essential if a university is to have an inducement to undertake the efforts needed to produce commercialization of their inventions by industry. The President's Message on Science and Technology provides a clear mandate to make use of such an opportunity. As urged by the President: "... we must develop careful strategies for pursuing those goals, strategies which bring together the Federal Government, the private sector, the universities, and the States and local communities in a cooperative pursuit of progress."

#### B. <u>Agreements Permitting Qualified Universities to Retain</u> <u>Title to Inventions Would Create an Incentive to Develop</u> <u>University Technology Transfer Capabilities</u>

It is our conclusion that the maintenance or creation of university technology transfer mechanism can be encouraged to a substantial degree by permitting qualified universities to retain principal rights in Government-supported inventions. The specific recommendation to accomplish this is set forth more precisely in section 8 below. The retention of principal rights by qualified universities carries with it the right to license commercial concerns, thus creating the incentive necessary to induce universities to seek industrial development of their inventions and overcome the industry attitudes discussed above.

Of course, universities without a satisfactory program would continue to be subject to patent rights provisions providing for allocations of rights by the Government after the invention has been identified.

17/ Others have also noted the important role that the Government can play in bringing about technology transfer of university research. See, e.g., OECD, <u>The Conditions for Success in</u> <u>Technological Innovation</u>, Paris, 1971, in which it stated "In cases where the requirement for university/industry relations is not met in a satisfactory manner, Government can have an important role to play as a catalyst or 'impresario' in creating the framework within which regular contacts take place between university and industry."

#### C. <u>Additional Benefits Would Flow if Qualified Universities Retain</u> Principal Rights to Resulting Inventions

In addition to the creation of a strong incentive for transfer of the results of Government-supported university research, other benefits would flow from the retention of principal rights in inventions to qualified universities. The following are examples of such benefits.

#### (1) Recognition of Co-sponsor Equities

The Government often does not provide the total costs of research projects conducted at universities. Universities in many cases assume part of the costs of such projects, and may also receive support from other sources, such as private foundations and industrial organizations. The Subcommittee's proposal permits, to the extent possible, recognition of the equities of the universities and other groups making contributions to university research projects by permitting the benefits which enure to such universities to be shared with co-sponsors.

The Subcommittee believes in the absence of an IPA, a co-sponsor's equity could be considered under the exceptional circumstances provision of 1(a) of the President's Statement, which provides additional support to the Subcommittee's position that its recommendation also falls within such provision.

#### (2) Ease of Administration

By eliminating case-by-case decisions on individual requests for patent rights, administrative work on the part of both the universities and the Government would be diminished.

(3) Use of Royalties for Support of Scientific Research and Education

Universities would be entitled to retain income generated from their patents. Such income would be used to cover the costs of patent administration and invention incentive awards programs. Any remaining income would be available for support of education and scientific research at universities. These are purposes which are clearly in the public interest.

The Subcommittee did consider the question of whether the Government should share in the income generated. However, it was concluded that this would create a disincentive to universities to establish or maintain technology transfer programs by making the likelihood of operating in the black even lower than it currently is.

#### (4) Use of Management Capability for All Inventions

Once a university has established a management capability to transfer technology, it is presumed that all inventions made at the university, whether they be Government-supported or not, will be promoted in the same manner. This, of course, would expand utilization of not only Government-funded inventions, but all other inventions generated at universities.

#### (5) Training of Future Technology Transfer Managers

A few universities have experimented with courses that utilize the services of students in their business, engineering and law schools to exploit university inventions. Presumably the practical experience gained by such students is in the public interest. It would seem reasonable to expect an increase in the opportunities for such a learning experience if more universities were able to retain rights to inventions.

## 7. ALTERNATIVE APPROACHES CONSIDERED 18/

No serious support was voiced for a policy of Government acquisition of title to all university inventions followed by its dedication to the public or the granting of only nonexclusive licenses therein by the Government, since this would eliminate the stimulus envisioned by the **patent** system. However, much discussion centered on a uniform policy of deferring the allocation of rights or the acquisition of title by the Government for later licensing of the invention by the Government. Such licensing would include the possibility of exclusive licensing after a determination that nonexclusive licensing would not likely result in expeditious commercial use. (The latter policy will hereafter be referred to as the "Government licensing policy".) It was argued that either of such policies would permit the Government to identify and evaluate the invention prior to making any determination that exclusivity was necessary as an incentive to further development. It was agreed that such policies might maximize the possibility of "competition" since exclusivity would be granted only when it is shown that it is the determining factor in bringing the invention to the marketplace. It was also concluded that such policies would afford the Government greater control over the terms of any licenses to be granted.

18/ Appendix B contains a discussion of some of the specific issues considered by and voted upon by the Subcommittee.

#### A. Shortcomings of a Deferred Allocation Policy

As already noted, inventions resulting from research at universities ordinarily require extensive development prior to their marketing, with little expectation that such development will be funded by the Government. Accordingly, it appeared that in a large proportion of cases, a deferred allocation would merely delay a decision that could have been made at the time of funding, thus acting against the expeditious development and utilization of inventions. Administrative costs of both the Government and universities would be unnecessarily increased by the need to prepare, review, and respond to requests for rights on a caseby-case basis.

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In addition, the uncertainties involved in deferring the allocation of rights would discourage active collaboration between universities and industry prior to the actual decision that rights are to be retained by the universities, whereas in the case where the university retains rights at the time of contracting, patent applications might be filed promptly and negotiations immediately commenced with prospective licensees. In fact, in the latter case, collaborative arrangements could be made wherein industry participation is protected before it is even clear whether or not inventions will be made.

Furthermore, because of the pressures for publication noted earlier, the time required for deferred allocations may in many instances result in the failure of the university to file patent applications within the statutory period initiated by publication due to a reluctance to commit funds prior to having its rights established. Thus, incentives to seek commercialization could be destroyed in some instances.

#### B. <u>Shortcomings of Acquisition of Title by the Government</u> <u>Coupled with Government Licensing</u>

The Subcommittee also concluded that a "Government licensing policy", as identified above, was not an adequate substitute to ownership in universities if the private undertaking of extensive development and marketing of university inventions is to be encouraged. While possibly appropriate in situations where a given university's patent managerial capabilities does not include administering patent rights or transferring technology, a "Government licensing policy" is not deemed an adequate substitute for an effective university patent management organization.

The above conclusion took into consideration that a "Government licensing policy" would -

(1) Increase the administrative burden of agency patent staffs by necessitating the filing of a much larger number of patent applications to protect all inventions that might have some degree of commercial potential.

(2) Be handicapped because the Government would have a more difficult time obtaining the services and cooperation of the inventor, who is not an employee of the Government.

The fact that the inventor employed by the university has a physical proximity to the university is a significant factor, since the cooperation of the inventor, both in preparing patent applications and in formulating a marketing strategy, is generally essential to a successful licensing effort.

19/ Inventors would not be willing to spend considerable time working with distant Government personnel on these matters which are outside the mainstream of their research and teaching efforts. Universities, however, can obtain such cooperation through a system of incentive awards to the inventor, as well as through day-to-day contact. It is important to note that a "Government licensing policy" could result in disincentive on the part of university researchers to report inventions other than those having clear economic significance. It seems likely that with the discovery that the reporting of inventions resulted only in additional work with nothing in return, disclosures would diminish. The facts and economics of the situation appear to be such that if the inventors cannot be induced to identify and report potentially significant inventions, normally they will not be identified by anyone else.

<u>20</u>/Dr. David, in his article, <u>supra</u>, note 9, observed:

"The most vital factor in technology transfer is people. There's nothing like a committed, enthusiastic engineer or scientist to carry the message and know-how far. If convinced of the merit of an idea or a project, he will travel at night, work on weekends, uproot his family and fall exhausted across the finish line to advance it. Yet sustaining these qualities requires special care and feeding." (3) Deprive universities of the opportunity to develop through their collaborative efforts ideas which do not at first evidence commercial potential, since it would be the Government which would ultimately decide what should be patented and protected through its licensing program.

(4) Entail considerable delay, since it seem unlikely that the Government will have the same flexibility in carrying out difficult negotiations as do universities.

(5) Would require time-consuming negotiations in exclusive licensing situations, the terms of which will vary from invention to invention. Moreover, if the program is to be successful, a "marketing" type of organization would have to be developed and funded by the Government.

#### 8. <u>SPECIFIC RECOMMENDATION -- ADOPT A POLICY THAT QUALIFIED UNIVERSITIES</u> MAY RETAIN TITLE IN INVENTIONS UNDER INSTITUTIONAL PATENT AGREEMENTS

It is recommended that the various executive agencies be advised to adopt policies and regulations recognizing that the public interest will normally best be served by allowing educational institutions with a technology transfer program meeting the general criteria set forth below to retain title to inventions made in the course of or under any Government research grant or contract. These policies and regulations should require the use of Institutional Patent Agreements (IPA'S) with universities that are found to have an established technology transfer program that is administered consistently with the stated objectives of the President's Memorandum and Statement of Government Patent Policy.

In general, the Subcommittee believes adoption of the recommendation would:

Implement to the extent possible the emphasis of the President's Statement on Patent Policy that the allocation of patent rights be made at the time of contract or grant;

Eliminate to the extent possible the wide differences in treatment of a particular university doing similar work for different agencies; **Create an incentive for prompt reporting;** 

**Promote the expeditious commercial utilization** of the inventive results of university research; and

Reduce the administrative burden on all the parties involved.

However, the agency should reserve the right to exempt specific grants and contracts at the time they are awarded from the operation of the Agreement, since there may be instances where exclusions from the normal policy are warranted as being in the public interest. Examples of this might include a contract for operating a Government-owned facility or an award involving extensive development work on a specific product or process that could be of major economic significance. Such reservation further supports the Subcommittee's conclusion as reflected on pages 2 and 3, <u>supra</u>, that its recommendation is consistent with section 1(a) of the President's Statement on Patent Policy.

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Further, the Subcommittee recommends that the IPA's be entered into for designated periods of time, at the end of which the university will be required to report on its progress. Renewal of the IPA by the Government for additional periods should only be made if the Government is satisfied with the university's performance. In addition, the length of such periods can be made dependent on the capability of the university.

IPA's should be extended to universities only after Government review of the adequacy of their technology transfer capability. The Subcommittee concluded that public interest is better served by a deferred allocation policy in situations where the university has not initiated a technology transfer program.

APPENDIX C to this report contains a list of the type of information that should be sought from universities in considering whether an Institutional Patent Agreement is justified. The information generated by APPENDIX C will provide the Government with the facts necessary for determining whether the university has a satisfactory patent technology transfer program which includes at least: A formal patent policy which is administered on a continuous basis by an officer or organization responsible to the institution;

Assurance that university employees will be legally obligated to assign to the institution or the Government any inventions made by them under Government grants or contracts;

An invention disclosure system; and

A program for the licensing and marketing of inventions.

After the Government concludes that the university can satisfactorily perform in a manner that would maximize the transfer of its inventive results to the public, the Government and the university should enter into the IPA whereby the university retains principal rights to all inventions made in performance of their Government-funded research on which the university elects to file a patent application.

However, any agreement utilized to implement the Subcommittee's recommendations should include at least the following provisions in order to protect the public interest:

A requirement for the prompt reporting of all inventions to the applicable agency along with an election of rights;

**Reservation** of all the rights specified in paragraphs (e)-(h) of the 1971 President's Statement on Government Patent Policy;

A requirement that licensing by the universities will normally be nonexclusive except where the desired practical or commercial application has not been achieved or is not likely to be expeditiously achieved through such licensing;

A condition limiting any exclusive license to a period not substantially greater than necessary to provide the incentive for bringing the invention to the point of practical or commercial application and to permit the licensee to recoup its costs and a reasonable profit thereon; A restriction that royalty charges be limited to what is reasonable under the circumstances or within the industry involved;

A requirement that the university's royalty receipts after payment of administrative costs and incentive awards to inventors be utilized for educational or research purposes;

A provision enabling the agency to except individual contracts or grants from the operation of the agreement where this is deemed in the public interest; 21

A requirement for progress reports after designated periods and re-execution of the agreement only if the Government deems the university's performance to be satisfactory;

A prohibition against assignment of inventions without Government approval to persons or organizations other than approved patent management organizations subject to the above conditions; and

A provision permitting termination for convenience by either party upon thirty (30) days' written notice.

The Subcommittee also suggests that the agencies which implement this recommendation form an interagency committee under the Executive Subcommittee of the Committee on Government Patent Policy for the purpose of encouraging uniformity in the criteria for the selection of universities eligible to receive IPA's. Such an interagency committee could also work towards common administrative procedures and practices. For example, often university inventions are made under multiple agency support. Procedures for assigning a single agency primary responsibility in such cases might be developed.

#### 9. SUMMARY

By way of summation, the Subcommittee agrees that inventions made at universities with Government support constitute a valuable national resource, but these inventions normally will benefit the public only if there is a sufficient incentive to make them known to private industry for their further development for the marketplace. The Subcommittee views the Government's role in the national research effort as complementing the activities of other elements within our society, both public and private, that also support research and development. It appears to the Subcommittee that the interests of the American people are best served when the various elements of this research structure can interact. The most effective interrelationship results when the particular capabilities of the various elements, Federal and non-Federal, can be utilized to the fullest extent. Universities, being not-for-profit, public-interest-oriented organizations, can most effectively promote the development and the ultimate utilization of inventions by industrial organizations. They can obtain such development and utilization while at the same time, due to their unique character, safeguarding the public interest. This opportunity should not be lost. Issues upon which the University Patent Policy Ad Hoc Subcommittee Voted

(a) Should the Subconnittee treat "public institutions" differently from industrial concerns?

This, of course, was the major issue under consideration and the report reflects the majority view that special policies should be utilized for public institutions.

(b) Should the Institutional Agreement approach be utilized as the mechanism for providing special treatment to public institutions?

The Subcommittee was unanimously in favor of the Institutional Patent Agreement espoused by the report.

(c) Should universities and other non-profit institutions be afforded the same treatment?

As reflected by the report, the majority of the Subcommittee felt that since universities and other non-prefit institutions both required industrial aid in bringing their inventive results to the marketplace, the proposal should treat them equally. However, two members of the Subcommittee felt differently. It was their opinion that the line between non-profit and profit organizations has clouded in recent years, with many non-profits actually functioning as profit-usking organizations. Further, since non-profit organizations have no educational mission, none of the royalty returns could be utilized for that purpose. They also wondered whether those organization tions were strongly motivated to utilize royalty receipts for research purposes. The majority of the Subcommittee felt that these concerns could be resolved on a case-by-case basis at the time a non-profit organization was negotiating for an Institutional Patent Agreement. Any agreement negotiated would, of course, set forth the monner in which royalty receipts could be utilized.

(d) Should the Institutional Patent Agreement be limited to designated "fields of technology"?

As reflected by the report, the majority of the Subcommittee did not believe the Institutional Patent Agreement should be so limited. However, four members of the Subcommittee felt that the Agreement should be limited to those inventions falling within technological areas in which the institution had a demonstrated expertise.

hat thre could it be determined what field of technology it mose Further, the majority felt that the "fields of technology" d not be defined with any accuracy, which could result in prolonged ment as to whether an invention fell within or out of a particular the invention was identified, since only such a condition would make a determination at that time could it be decorained what impossible until The majority feit that cunerchip could not be argument as ficld. in. ii O

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in the report practices (c) Should the results of the survey of agency and statistics conducted by the Subcommittee be included

However, Surrey. sho...ld also agreed that no comments would be made regarding the survice numerous differing interpretations that could be attached Ligures the Survey, sthe Report.). Under any circumstances, no comparible 110 are available regarding industry generated inventions. Subcommittee, felt that чн О the Text u i  $\sim$ Footnote the The rajority of (See it was also agreed statistics. be incluced. to to to the duc

(f) Should an interagency panel have the responsibility for reviewing and approving Institutional Patent Agreements for purposes of uniformity?

an interacency panel review of requests for Institutional Fatant Agreements, value will serve to achieve uniform treatment of individual institutions The Subconnittee was unanimously in favor of throughout, the Government.

aricing Should any distinction be made between inventions' or contracts? ප from grants

 $\hat{\phantom{a}}$ the inventions Further, the Subcommittee determined that there or utilized Luventi en should te require position is reflected in the report aguncies. This position is reflected in the verore to make a distinction between grants and contructs. functing es . agreed that there vas no clear definition of grant or contract acceptable. distinction made between grants and contracts, since Suigaird that arise from either instrument would in mort industrial aid in completing, development and bri Subcorrittee manimously to the marketplace. The failure all the ou

included under ](a) and/or l(c) of the Presidential Policy Statement? Agreement be Patent Should the Institutional Ē

stances" language of Paragraph 1(a) or under the "special situation" The Subcommittee unanimously agreed that the Institutional circun-Agreement should be justified under the "enceptional provision of Paragraph 1(c) of the President's Statement. Patent

#### APPENDIX C

#### MODEL IPA SUPPORTING INFORMATION

An Institution desiring an Institutional Patent Agreement should supply the following:

1. General information concerning your institution, including:

(a) Copies of Articles of Incorporation;

(b) The institution's purpose and aims;

(c) Source of funds.

2. A copy of your institution's formal patent policy, together with the date and manner of its adoption.

3. Name, title, address, and telephone number of institutional official responsible for administration of patent and invention matters and a description of staffing in this area. Also identify any other institutional offices, institutes, etc., which also contribute to your institution's patent management capabilities.

4. A description of your institution's procedures for identifying and reporting inventions.

5. A copy of the form of agreement required to be signed by faculty and other employees of the institution engaged in research, indicating their obligation in regard to inventions made at your institution. 6. A copy of the invention report form or outline utilized for preparation of invention reports at your institution.

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7. Advice as to whether your institution has a formal agreement with any patent management organizations, such as Research Corporation, Battelle Development Corporation, or other organizations. A copy of any agreement in effect should be enclosed.

8. A description of the efforts which the institution would expect to make in bringing to the marketplace inventions to which it retains title.

9. A general description of the institution's past patent and invention licensing activities, including the following:

(a) Number of inventions reported to the institution during each of the past ten years;

(b) Number of patent applications filed during each of the past ten years;

(c) Number of patents obtained during each of the past ten years;(d) Number of exclusive licenses issued during each of the past ten years;

(c) Number of nonexclusive licenses issued during each of the past ten years;

(f) Gross royalty income during each of the past ten years;

(g) A general description of royalties charged, including minimum and maximum royalty rates. 10. A list of subsidiary or affiliate institutions, hospitals, etc., which would be covered by an agreement signed by your institution.

11. If your institution is a subsidiary or affiliate of another organization, state name and describe relationship.

12. The amount of Government support currently being administered by your institution, giving agency breakdown.

13. Do you have an Institutional Patent Agreement with DHEW, NSF, or any other Government agency? If so, please supply a copy of the Agreement and any annual or other periodic reports describing activities under the Agreement which were submitted to the Agency within the last three years. 14. If not set forth elsewhere, state your policy as to sharing of royalties with faculty and other employces.

15. Describe the uses made of any net income generated by your patent management program.