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Committee on the
Interplay of Engineering with
Biology and Medicine

Government Patent Policy

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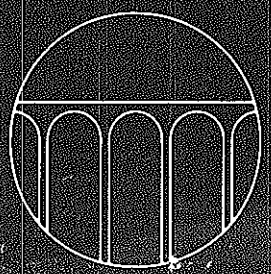
Report

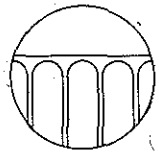
Subcommittee on Interaction with Industry



NATIONAL ACADEMY OF ENGINEERING

GOVERNMENT PATENT POLICY

Report of Workshop
September 29, 1969
Washington, D.C.



Subcommittee on Interaction with Industry

Committee on the Interplay of Engineering
with Biology and Medicine

NATIONAL ACADEMY OF ENGINEERING
Washington, D.C.
1970

SUBCOMMITTEE ON INTERACTION WITH INDUSTRY
Committee on the Interplay of Engineering with Biology and Medicine

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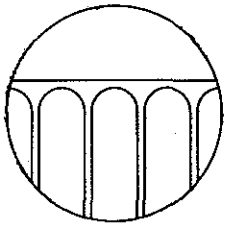

The National Academy of Engineering was established in December 1964. The Academy is independent and autonomous in its organization and election of members, and shares in the responsibility given the National Academy of Sciences under its congressional act of incorporation to advise the federal government, upon request, in all areas of science and engineering.

The National Academy of Engineering, aware of its responsibilities to the government, the engineering community, and the nation as a whole, is pledged:

1. To provide means of assessing the constantly changing needs of the nation and the technical resources that can and should be applied to them; to sponsor programs aimed at meeting these needs; and to encourage such engineering research as may be advisable in the national interest.

2. To explore means for promoting cooperation in engineering in the United States and abroad, with a view to securing concentration on problems significant to society and encouraging research and development aimed at meeting them.

3. To advise the Congress and the executive branch of the government, whenever called upon by any department or agency thereof, on matters of national import pertinent to engineering.

4. To cooperate with the National Academy of Sciences on matters involving both science and engineering.

5. To serve the nation in other respects in connection with significant problems in engineering and technology.

6. To recognize in an appropriate manner outstanding contributions to the nation by leading engineers.

FOREWORD

In June 1967, the National Academy of Engineering established the Committee on the Interplay of Engineering with Biology and Medicine under a contract with the Office of Program Planning of the National Institutes of Health. The broad purpose of the committee is to delineate clearly the ways in which the national engineering capability and modern engineering theory and practice can be applied to the problems of biology and medicine.

On the basis of its deliberations and study, the committee is expected to recommend future directions of study on:

1. The difficult basic problems connected with trying to influence the developmental phase of engineering in medicine and biology.

2. The limitations imposed on engineering in the fields of biology and medicine by the existing social and economic environments into which new products are introduced.

3. The constraints resulting from the academic separation of engineering and biomedical fields and the present privately based medical care system.

The committee has undertaken a two-pronged approach to acquire the information necessary to develop recommendations relevant to these issues. In one approach, the committee contracted with a group of universities for separate studies of the ways in which engineering schools could respond to the pressing national needs in the field of biomedical engineering. Institutional involvements in this area were examined for the committee by six universities: Harvard-MIT, Johns Hopkins, Ohio State, Carnegie-Mellon, University of Washington, and University of Virginia, and resulted in the preparation of prototype plans for the development of biomedical engineering in the university setting. A distillation and analysis of the plans prepared by the six subcontractors is included in the report Prototype University

Plans for the Development of Biomedical Engineering prepared by the Committee on the Interplay of Engineering with Biology and Medicine and available from the National Academy of Engineering.

The other approach taken by the committee emphasizes pertinent industrial aspects of the interplay of engineering with biology and medicine. The Subcommittee on Interaction with Industry, chaired by Dr. Murray Eden of the Massachusetts Institute of Technology, was formed in 1968. Its broad purpose is to show how industry can more effectively interact with government research, development, and service programs in order that the resources of industry might more effectively be brought to bear on the solution of urgent health problems.

In carrying out its mission, this subcommittee is:

1. Examining the organizational mechanisms utilized by the federal government in the development of medical instruments and medical instrument systems.

2. Examining how various industrial firms are organized to work with government agencies and with the health care systems.

3. Examining how government, the university, industry, and civic organizations can most effectively work together to provide solutions to urgent health problems.

4. Evaluating the results of the examinations in 1, 2, and 3 above.

5. Recommending appropriate courses of action to be followed to couple industry more effectively into the health care system.

The subcommittee has conducted specialized workshops for the purpose of obtaining the information on which to base its recommendations and conclusions. The first of these was the Workshop on Government Patent Policy, held at the National Academy of Engineering on September 29, 1969. The second was the Workshop on Federal Agency Development Programs, held at the National Academy of Engineering on September 30 and October 1, 1969.

Further, acting on a request of the National Institutes of Health, the committee is currently engaged in an in-depth survey of fifty selected corporations that provide biomedical devices and technical services. This study, intended to reveal factors that inhibit and/or enhance the application of the nation's industrial resources to health care, is scheduled for completion in late 1970.

Based upon these various activities, recommendations will be made by the committee to provide appropriate courses of action for the National Institutes of Health to couple industry more effectively to the health field.

W. Robert Marshall, Jr., Chairman

Committee on the Interplay of
Engineering with Biology and Medicine

This workshop and report by the
Committee on the Interplay of Engineering with Biology and Medicine
of the National Academy of Engineering were supported by the
National Institutes of Health under
Contract No. PH-43-64-44, Task Order No. 39,
June 28, 1967.

CONTENTS

INTRODUCTION

The Committee on the Interplay of Engineering with Biology and Medicine recognized the need for the development of incentives and suitable organizational mechanisms to encourage a vigorous industrial participation in the development of medical instruments. Accordingly, the CIEBM Subcommittee on Interaction with Industry was asked to consider how industry might more effectively interact with government programs, the academic community, and the health field generally. In the course of its deliberations and in interviews with representatives of industrial firms, the subcommittee concluded that government patent policy is believed by many to be a major deterrent to the allocation of important industrial resources to the health field. Misunderstanding of government patent policy appeared to be commonplace. Considerable confusion was apparent concerning the practices and procedures followed by the Department of Health, Education, and Welfare (HEW) in the administration of its patent program. A communications gap existed, which should be closed, and the Workshop on Government Patent Policy was organized to help accomplish this objective.

The Workshop on Government Patent Policy, held on September 29, 1969, brought together some 67 representatives of government, the university, and industry in a program designed to elucidate the patent issue. The oral presentations made in the formal program engendered considerable discussion from workshop participants and produced a broad perspective of the patent policy issue. The formal papers and the impromptu discussions are contained in these proceedings. The attendance list of the workshop is included as Appendix A.

Sweeping changes in government patent policy were not suggested by the workshop. Its deliberations, as reflected in these proceedings, however, produced information of considerable value to those persons who are uncertain about government patent policy and what that policy means to their institution. It is abundantly clear, for example, that government

patent policy is neither rigid nor monolithic. There are nearly as many policies as there are government agencies. Further, the standard against which different agencies measure their patent policy--the Presidential Patent Policy of 1963--is flexible and under constant review. Indeed, recommendations made by the Federal Council for Science and Technology in its annual report for 1968 would give substantially greater patent rights to a contractor than previously.* These recommendations are found in the presentation by O. A. Neumann.

The workshop showed that the nuances in government policy are matched by differing views concerning appropriate patent positions for industry and the universities.

Formal recommendations regarding patent policy were not made at the workshop, nor were any anticipated. As contained in these proceedings, however, several aspects of patent policy and its administration were stressed by the participants, and are summarized below.

GOVERNMENT

The Department of Health, Education, and Welfare should greatly augment its patent staff. Unreasonable delay in obtaining a decision on patent rights is an impediment to industrial participation in the health field.

A continuing examination of how patent policy serves the public interest is essential. Should all patents obtained on government contracts be placed in the public domain for all to use on a royalty-free basis? Or would public interests be served better by granting an exclusive license for a limited period of time, thereby providing some protection from unreasonable competition?

UNIVERSITY

Universities are well advised to adopt the HEW institutional patent agreement, which conveys certain patent rights to an invention before it is

* Annual Report on Government Patent Policy, Federal Council for Science and Technology, December 1968.

made. The university, like government, does not have facilities to produce products and should be enabled to arrange for exploitation of inventions through a royalty arrangement with a commercial firm.

Universities should make a thorough study of their mission and take it into consideration in formulating an employee patent policy.

INDUSTRY

Manufacturers of medical instruments should obtain firsthand information on government patent policy and should not rely on hearsay about dealing with HEW.

In some instances it is possible for a commercial firm to obtain greater than a nonexclusive license to patentable inventions from the HEW at the time of contract award, rather than for the determination of patent rights to be made after disclosure of an invention.

The factors involved in screening, developing, and testing the efficacy of a drug are different from those involved in the development of a medical instrument. Procedures followed in the development of a new drug as an approved marketable product are unique to the pharmaceutical industry. Government patent policy should be drafted to accommodate the differences.

The National Academy of Engineering Workshop on Government Patent Policy provided a forum where knowledgeable persons were able to elucidate that policy. These proceedings will carry the information to a wide audience and serve to reduce the misunderstanding that existed in the past. Perhaps the single most important factor that was discussed at the workshop concerned the plurality and flexibility of government patent policy. These features allow reasonable men to let common sense prevail.

Special acknowledgment and thanks are given to Mr. Gerald D. O'Brien and Mr. O. A. Neumann, whose skills as moderators were aptly demonstrated as they guided the spirited discussions about a controversial issue. We are grateful to all the participants who gave so graciously of their time in helping to assure the success of the meeting. The many hours which Mr. Gilbert B. Devey devoted to the editing of these proceedings and the diligent labors of Mrs. Dorothy Campbell and Mrs. Ernestine Pierce in preparing the typescript are also greatly appreciated.

Murray Eden, Chairman
Subcommittee on Interaction with Industry

SUMMARY AND CONCLUSIONS

Murray Eden, Chairman

We convened here today to learn something about government patent policy, and we have clearly accomplished that purpose. In addition, we have generated some concepts and indicated directions that will be useful to the committee as it formulates recommendations on patent policy with respect to biomedical engineering devices, a problem much more sharply focused than government patent policy, university patent policy, and patent policies of the business community.

It does seem that the standardized institutional agreement now used by HEW has gone a long way to dissipate some of the confusion in this area. And eventual adoption of the recommendations of the Patent Advisory Panel will go even further in this regard. From Mr. Hiller's comments, it is clear that a number of universities are anxious to adopt the institutional agreements.

The question of adequate staffing to handle the HEW patent program is a serious one. It seems to be clear that the staff should be augmented.

Clearly the question of exclusivity and the period of exclusivity are important and controversial issues. The seriousness of this issue seems to vary with the character of the invention and the industry involved, indicating the need for continued flexibility in policy administration.

The question raised as to whether the university should have an active or a passive patent program is also serious. Should the university faculty have an expansive attitude about inventions? Is it true that the university researcher thinks first of publication of his results and does not concern himself with the question of invention exploitation? Should he be more aware of the fact that the device on which he is working

has an eventual practical value and that, at least in some measure, it is his business to see that it moves ahead? Why should a university worry about whether a faculty member receives royalties and whether those royalties give him more incentive to work? University research work should not be covered by the feeling that "there is money in it for me if I go ahead." The issue is highly complicated. Inevitably a research project involves graduate students. What are their rights in an invention situation?

From the presentations and discussions at this workshop, it is clear that little is to be gained from a uniform government patent policy. The interests and missions of government agencies are just as diverse as those of their varied clientele. The adjudication of these interests might be formalized in some way--in arrangements such as those offered by Research Corporation, Battelle Memorial Institute, and others. What is needed is flexibility, with a measure of consistency.

PART ONE

PATENT POLICY

Collision or Cooperation?

GOVERNMENT VIEW

Manuel B. Hiller
U. S. Department of Health, Education, and Welfare

This workshop session on "Patent Policy: Collision or Cooperation?" brings into sharp focus the controversy over government patent policies that has simmered and boiled for many years. Touched off, perhaps, by the Attorney General's report in 1947 in which he advocated what has since become identified as the "Title" policy, the arguments pro and con have been articulated in the loudest voices and with the deepest conviction. There has been much testimony from government agencies, industry, academia, and the patent bar before the concerned committees of Congress; there have been numerous scholarly articles in law journals, industry publications, news magazines; and much debate is now recorded in the Congressional Record. One view often heard is that wherever the government pays the cost of research, the taxpayer is entitled to the free and unrestricted benefits of the results of such efforts--the essence of the so-called "title" policy. It would seem, however, that for every valid contention advanced to support such a policy, the advocates of a "license" policy--which provides that the grantee or contractor shall retain the principal rights to inventions subject only to a license to the government for governmental purposes--counter with an argument similarly deserving of consideration.

A few of the arguments in support of the government taking title include (1) the inequity of the taxpayer paying a second time to procure what his tax dollars have already bought; (2) the overemphasis of the value of patents in our current technological society, where a patent so often constitutes merely an incentive to a competitor to design around the claims; (3) recognition that the patent system no longer can protect, nor its benefits inure to, the individual inventor in our system of corporate research that involves the collaborative efforts of the team approach.

Those who advocate the license policy contend that (1) government ownership does not result in the effective utilization of inventions; (2) private ownership is consistent with the constitutional guarantees applicable to the fruits of intellectual endeavor; (3) patent ownership provides a means for new and small research organizations to compete with the giants of industry that have, over the years, built large patent portfolios; (4) government ownership dissuades the private sector from accepting government contracts or participating in government research and development or, at least, utilizing less than the best research talent of the organization to perform the research work on government-financed projects.

The diversity of views was reflected in a variety of government patent policies and practices ranging from the reservation of a mere governmental license at one end of the spectrum to, at the other end, reserving to the government all rights to foreground inventions, rights to background inventions of the contractor, and recovery of the government's cost of research from contractor sales. Apart from philosophic considerations, the missions of the departments and agencies heavily engaged in the business of sponsoring research and development have figured prominently in the formulation of their policies and practices.

It was not at all surprising, therefore, that those engaged in performing research and development for the government, whether under grant or contract, became confused and irritated by being subjected to almost as many different policies, or even variations of the same basic policy, as the number of agencies and departments for which they were performing research.

And to exacerbate further an already oversensitive area, Congress has, on occasion, enacted legislation that prescribed patent policy and procedures. To the end that a more consistent patent policy in government might be achieved, and to take into account the variety of issues that comprise that nebulous concept known as the "public interest," in October 1963 President Kennedy issued his statement of government-wide patent policy. It is not the purpose of this paper to make value judgments concerning that statement, only to summarize briefly its basic elements.

The Presidential Statement of Government Patent Policy

There are three major guidelines for the allocation of invention rights between the government and its contractors in the absence of specific statutory authority. As used in the statement, the term "contractor" includes "grantee." The first guideline is found in section 1(a) of the statement and provides for government acquisition of the principal rights, or for the deferral of the determination concerning such rights until invention disclosure where:

(1) A principal purpose of the research support is to create, develop, or improve products, processes, or methods that are intended for commercial use by the general public or that will be required for such use by government regulations.

(2) The principal purpose of the support is for exploration into fields that directly concern the public health or welfare.

(3) The research work is in a field of science developed almost exclusively by work funded by the government.

(4) The services of the contractor are for the operation of a government-owned research or production facility or for coordinating or directing the work of others.

The provisions of section 1(b), the second guideline, become available only if the situation at hand does not fall within any of the four categories of section 1(a); if the purpose of the contract is to build on existing knowledge or technology, to develop information, products, or methods for use by the government; and if the work called for by the contract is in a field in which the contractor has acquired technical competence and has an established commercial nongovernmental position. In that event, the contractor may acquire principal rights subject to the governmental license and other conditions protective of the public interest provided for elsewhere in the statement.

Where the situation does not fit the criteria of either 1(a) or 1(b), then section 1(c), the third guideline, controls. That section provides for deferral of the determination of the respective rights until after the invention has been identified and for disposition of the rights therein in a manner that best serves the public interest, taking into account the contractor's intention to develop the invention commercially.

The statement also contains provisions for exceptions to accommodate special circumstances under the first two sections.

Sections 1(e) through 1(g) provide for the imposition of certain requirements and limitations, where the contractor acquires principal rights, which are calculated to safeguard the interests of the public. These include such features as compulsory licensing in the event of need for public use by government regulation, to fulfill a health or other public purpose, or for failure to have taken effective steps to bring the invention promptly to the point of practical application, known as the "march-in" rights.

Results of the President's Statement

The President's statement has, over the past few years, influenced the patent policies of federal agencies both by its terms and through the activities of the various committees and subcommittees organized under the Patent Advisory Panel established pursuant to section 3 of the statement. The statement has provided to some extent a common meeting ground for the diverse patent policies. Agencies that previously reserved only a license to the government have moved toward acquisition of title in some instances, while so-called title agencies found reason to make exceptions to the taking of title where flexibility comports with objectives set forth in the statement.

The Department of Defense, whose policy called for governmental license except in special situations, has moved substantially toward acquisition of title in research and development contracts under the guidelines of section 1(a). Thus the incidence of DOD use of the title clause increased in frequency from 0.5 percent prior to issuance of the President's statement to 25 percent since the statement. The Atomic Energy Commission, required by statute to take title in those contracts involving nuclear materials, tightened up its policy on

"outfield" inventions (to which rights had previously been relinquished) by providing for the acquisition of title where the purpose of the contract falls under one or another of the situations described in 1(a). The National Science Foundation, which operated under a license policy until 1965, departed from that practice at least to the extent that it defers determinations until after inventions are identified. On the other hand, NASA has moved in the opposite direction. Required by statute to take title at the time of contracting with the right to waive title, NASA has amended its regulations, which formerly permitted waiver of rights in favor of the contractor only after inventions have been identified, to provide for waiver of title at the time of contracting.

Because of emphasis in the President's statement on commercial utilization of government-sponsored research, the Department of Health, Education, and Welfare, identified as a title agency, has given greater weight and emphasis to considerations of commercial exploitation and the adaptation of the advances in technology to consumer products.

Also, the safeguards keyed into sections 1(e) through 1(g) of the President's statement for application when principal rights are left to a contractor have moved HEW in the direction of greater flexibility in administering its title policy.

An intensive review of the presidential statement after five years of experience thereunder has prompted the patent advisory panel to recommend amendments to the statement that would provide for issuance of exclusive licenses under government-owned patents. This would give a wider latitude to agency heads, permitting contractors to retain greater rights than a nonexclusive license to identified inventions when the agency head determines that to do so would enhance commercial utilization or give recognition to equitable entitlements of the contractor's contribution.

HEW Policy and Practice

HEW is probably the source of the largest amount of research grant and contract support to academic and other nonprofit institutions. Therefore, it is important that the Department's patent policy and practices are well understood, particularly the more recent revisions that have been made.

Consistent with the Department's statutory responsibility for the advancement of science and knowledge and the dissemination to the public of the results of research, it has been the general policy of the department that the results of department-financed research should be made widely, promptly, and freely available to other research workers and to the public. Where the results of research constitute inventions, this availability is achieved either by dedication of the invention to the public through publication, or by royalty-free licensing under protective patents, although our regulations now permit exceptions to this where the development and practical application of inventions can best be promoted through other means to serve the public interest.

Part 8 of the HEW regulations, which are codified in title 45, CFR, governs inventions resulting from research grants, fellowship awards, and contracts for research. As to research grants, the regulations provide:

> That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs).

The criteria upon which that determination is to be made, set forth in section 8.2, are similarly calculated to secure wide availability of the invention.

Institutional Patent Agreement

The HEW regulations also provide that where a grantee institution has patent policies and procedures consonant with the policy objective of the Department, it may apply for an institutional agreement under which invention rights are left to the grantee. Such agreement, which has been standardized, would then govern inventions deriving from work under subsequent research grants awarded by HEW to that institution. Such agreements are executed only where there is assurance that any invention resulting from the project will be made available to the public without unreasonable restriction or excessive royalties.

Use of these agreements, which had been limited to the Public Health Service only, has been broadened since the presidential statement to include the following points:

(1) Nonprofit institutions other than educational institutions will be included.

(2) Use of the agreements will apply to grants made by all of the agencies of the Department.

(3) Any such applicant willing and able to comply with our standard agreement is now eligible, even though that institution has no history of patent administration oriented in the public interest.

Since standardization of the agreement in December 1968, 21 educational institutions have entered into such agreements as compared to the 17 agreements that had been in effect since 1955. There are on hand applications from 56 institutions for such agreements. The agreement provides, among other things, for reservation of a license to the government for governmental purposes as defined in the presidential statement and contains the various safeguards set out in that statement. It also permits the grantee to issue exclusive licenses to profit-making organizations for a limited period of time for purposes of achieving prompt exploitation.

One should be aware of a provision in HEW regulations that permits leaving principal rights to a grantee institution after the invention has been identified, if by so doing the invention will thereby be more adequately and quickly developed for widest use. Although this provision was used in only five instances during the 12-year period from 1953 to 1965, determinations were made to leave invention rights to grantee institutions in 13 cases in calendar year 1968 alone. The greater use of this provision reflects the Department's recognition of the public interest that is served by recourse to a mechanism to provide incentive for prompt and intensive efforts to bring an invention to commercial utilization.

21 19 30

Summary and Conclusion

From the foregoing it will be seen that the HEW traditional title policy now is being administered more flexibly in order that the objective of achieving fullest exploitation of inventions may be attained as set out in the presidential statement.

As HEW becomes more deeply involved in the fields of applied research and hardware development--whether in terms of air pollution processes, artificial organs and cardiovascular assist devices, or teaching machines--problems will arise more frequently concerning background rights relative to contractor or grantee inventions developed prior to receipt of HEW support or contractor's proprietary data. HEW regulations do not specifically address themselves to this issue. Consequently, a substantial body of opinion exists that assumes that contracting with HEW involves surrender of such background rights. Nothing could be farther from the fact.

Under current practices, in providing support for additional research and development on a contractor's background invention, HEW requires assurance that reduction to practice of any foreground improvement, system, process, or device developed under the HEW contract will not be impeded by the unavailability of the contractor's background invention only to the extent necessary to the practice of the foreground invention.

If we can overcome the understanding gap that has characterized the relationship of academia and industry to the requirements of government patent policies, we shall have taken one great leap toward establishing a more productive relationship between all parties involved in the business of research and development.

UNIVERSITY VIEW

Harry L. Baker, Jr.
Georgia Institute of Technology

Raymond J. Woodrow
Princeton University

(The presentation at the workshop was made by Mr. Harry Baker and is based on a statement prepared by the Subcommittee on Patents and Copyrights of the National Association of College and University Business Officers Committee on Governmental Relations. This statement is given in Appendix B.)

Why Should Colleges and Universities Have Patent Programs?

Universities have an obligation to serve in the public interest. In order to do this effectively, it is necessary for the university to have a patent program that will promote effective development and utilization by the public of inventions made in university-supported research projects.

Promotion and remuneration of faculty members are largely independent of the value of inventions they make, in contrast to a commercial research organization where inventiveness is encouraged and monetary rewards often are made to the contributing employee. The interest of university faculty members, on the other hand, lies primarily in the open publication of research results, with effective utilization of the invention being of secondary importance. Nearly all universities provide for a share of any royalties received from patent licenses to be paid to the inventor. This helps to assure that the publication of research results does not lead to the loss of important benefits to the public. The possibility of royalty income acts as an incentive for the inventor to devote the time and effort necessary to disclose an invention properly, to participate in invention evaluation, to assist patent attorneys in the preparation of patent applications, to respond to Patent Office actions, and often to provide information and assistance to potential or eventual licensees. Experience shows that few inventions are disclosed where there is an inadequate incentive to the inventor.

Every grant or contract for research projects made by the federal government, most of those made by industry, and even some made by private foundations and similar non-profit organizations include requirements concerning the disposition of inventions and invention rights. In order to fulfill these requirements, it is essential that the university have a formal patent program. Agreements must be made with potential inventors concerning the disclosure of inventions and the disposition of invention rights. There must be a follow-up procedure to assure prompt disclosure of inventions, sponsors must be supplied with adequate information, and licenses or assignments must be made expeditiously.

The university should share in the proceeds resulting from an invention made in a project under the aegis of the institution. The proceeds partially defray the cost of a patent program, but more importantly they can be used to strengthen the academic program and expand the research activities of the university. This is in recognition of the substantial investment in facilities and personnel, without which inventions could not be made.

Why Should Universities Retain Rights to Inventions Made in Government-Sponsored Research Projects?

An invention is a useless thing until it is developed to the point of utilization and availability to the public. Ownership of patents resulting from inventions made in university programs enables the institution to seek the best-qualified firms to develop the invention to a useful product. The university is interested in making the end results of research available in the widest possible way. Patents are not obtained by the university as a defensive measure to protect a commercial position; there is no incentive to withhold the results of research. Thus the university with a sound program of patent administration can maintain due diligence in following the development and eventual utilization of inventions.

Few inventions are commercially useful in the form in which they are conceived. Reduction to practice in the university setting usually produces a primitive product that requires substantially more development before it becomes commercially practicable. Few commercial organizations are willing to assign the necessary investment to make the invention

commercially useful unless they obtain some protection for that investment. When it is known that the university retains patent rights to its inventions, arrangements can be made for licensing agreements with commercial firms even before it is clear whether a patent is likely to be issued. The certainty of the university holding patent rights means that patent applications may be filed promptly and that negotiations for licenses can quickly begin after an invention is made, all of this with the active assistance of the inventor.

When the government retains title to inventions, making them available on a royalty-free basis to all, many inventions will never be utilized and the public will not benefit. This is because commercial firms are unwilling to make the substantial investment necessary to develop products to the point of commercial practicability unless there is some measure of protection for the investment. When the government determines the disposition of title to inventions on a case-by-case basis, a complicated, costly, and lengthy procedure must be followed for the university to obtain ownership rights. Inevitably development is delayed, and it is entirely likely for the time limit for patent application to expire. The inventor's interest in reducing his invention to practice will thus wane before a final determination to title is made.

Inventors within the university need an incentive to devote the necessary time and effort to invention disclosure and later follow-up with the development organization, just as the developing organization requires an incentive to justify the commitment of its resources in product exploitation. The only practicable way to provide such incentive to the inventor is in his participation in royalties. This can best be arranged when the university retains patent rights. Administration of a government agency licensing program that would include the payment of royalties to the inventor would require a vast, inflexible, and impersonal organization and the program would be largely self-defeating.

As mentioned earlier, the university can use its share of royalty income to pay for its patent program and to contribute to the operating expenses of the educational and research programs involved in higher education.

Conclusions

The government does not contract for inventions when it sponsors research projects within a university; inventions are by-products of this research. Furthermore, salaries paid to university faculty members are not determined as a result of the value of inventions made by the faculty. Therefore, tax money is not being inappropriately used and the public is not being cheated when a portion of the selling price of a product resulting from government-sponsored research is paid to the university as a royalty. For all the reasons mentioned above, without the payment of a royalty, it is very probable that the invention would not have been made available to the public at all.

INDUSTRY VIEW

Richard V. Holmes
Smith, Kline and French Laboratories

The purpose of this presentation is to describe the impact of the government's patent policy on the drug industry and to suggest ways to increase industry involvement in the screening of compounds developed under projects having government support. The drug industry is a special situation; it does not benefit from government-sponsored research in the same way that other industries do. In marked contrast with other fields, government health-related research funds do not generally go to a contractor capable of exploiting the invention. The money normally goes to a university or other nonprofit institution that, like the government itself, does not have the facilities for making the invention available for general use by the public.

In the pharmaceutical field it is necessary to draw a sharp line between the research leading to the invention--mostly done by the nonprofit institution--and the development of the invention into a useful product, which can be done only by a pharmaceutical company. The unusual difficulty involved in proving the efficacy and safety in humans often alters the government-financed "invention" to merely a research "lead." The basic research funded by the government most often is a minor part of the expense of the overall project. The major part of the financial burden must be assumed by the product development organization, the pharmaceutical manufacturer.

As an example, let us assume that a scientist working for a nonprofit institution supported by government funds has discovered a patentable compound that may have a medicinal use. This medicinal use, however, will never become an actuality until the compound is screened, tested in animals, tested in man, and embodied in a satisfactory pharmaceutical preparation approved for marketing by the Food and Drug Administration. The logical developer for this new compound is a pharmaceutical

company. The screening, testing, and development are exceedingly expensive and time-consuming. People and facilities must be diverted from other projects. The substantial investment that is required to bring a new product to the marketplace necessitates that a reasonable period of marketing exclusivity be granted to the developing firm in the event that the utility of the compound is established.

A competitor entering the market after a new product is introduced can afford to sell profitably at a fraction of the price established by the firm that incurred the enormous development costs. The competitor's plant cost undoubtedly will be lower and his research expense nil. Additionally, the newcomer does not face the expenses involved in introducing a new chemical entity, including the education of physicians about the new preparation. The original manufacturer is unable to meet such price competition until his development costs are recovered. Rather than do so, it is only natural that attention will be concentrated on products that offer a long period of exclusivity.

Since 1962, university scientists working under government grants have found it difficult to make arrangements for the evaluation of their compounds. The present policy of the Department of Health, Education, and Welfare (HEW) requires that compounds developed under government support, and which are screened by pharmaceutical companies, be still subject to title disposition by the government. Current HEW regulations may be interpreted by some observers to allow the grant of exclusive patent rights for long periods of time. In practice, however, the maximum period of exclusivity that is guaranteed in advance is for only three years. Few pharmaceutical products can return a profit on their investment in only three years.

The three-year maximum period of exclusive protection applies to all compounds and products in the health field. There is a basic inequity involved in applying the same maximum period of exclusivity to products requiring only minor development at low cost and those requiring many years of development at a substantial cost.

The period of exclusivity granted by HEW should be long enough to permit the manufacturer to achieve the following:

(1) Reimbursement for the expenditures incurred in establishing the utility of the compound and in carrying it through the various steps necessary to obtain FDA approval for marketing. The time required for this process has increased by a factor of 3 or 4 in the last decade.

(2) Reimbursement for a share of the expenses incurred in connection with research on products (chemical compounds) that prove to be unsuccessful.

(3) Reimbursement for expense of explaining to physicians the use of the new drug.

(4) A profit that will justify the expenditure of large sums of capital for a business involving the following increasingly important uncertainties and risks:

    (a) Inability to obtain FDA approval after a substantial investment in the compound.

    (b) Withdrawal from the market after FDA approval because of new data on safety or effectiveness.

    (c) Obsolescence resulting from the introduction of superior products by competitors.

Expenditures incurred by the pharmaceutical manufacturer in bringing a new product to the marketplace may well amount to millions of dollars, far in excess of the financial contribution made by the government. Where this expenditure is so great that the contribution on the part of the government becomes inconsequential by comparison, the manufacturer should receive the full benefit of the patent even though the basic invention belongs to the government.

The government's patent policy should be changed to permit the granting of licenses up to the full patent term where necessary to attract the large amount of capital necessary to develop a new drug. Five- to seven-years time and costs

ranging from $2,500,000 to $4,500,000 are required to develop one marketable product. That one product must also bear the cost of the many developments that abort along the path to the marketplace. In practice, the useful life of a patent for a privately developed product is apt to be limited to 12 or 13 years following FDA approval. The situation may be worsened if the patent term becomes 20 years from the filing date as has been proposed in the Patent Reform Bill (S.2756).

The exclusive license feature should be contained in the agreement negotiated between the manufacturer and the (government-supported) grantee institution before the commencement of screening, i.e., before the establishment of utility. This agreement should be approved by HEW, or in the alternative, the current standard form of institutional agreement could be amended so as to give the institution the authority to convey exclusive patent rights for the full patent term. The agreement might also provide for the payment of royalties to the government by the manufacturer as reimbursement of the dollar amount of grants for research leading directly to development of the compound. A repayment period not to exceed five years is reasonable. Thereafter, royalties would be payable to the grantee institution to fund further research. The repayment to HEW would provide an answer to the possible criticism that the pharmaceutical manufacturer acquires the benefit of the government's invention without due consideration.

We view the existing government patent policy as being shortsighted; it removes the incentive for investment that is fundamental to the patent system.

Drug research program administrators in industry can turn to a number of sources to obtain new chemical compounds for development into marketable products:

(1) In-house research normally produces many interesting compounds. Some firms probably have such a backlog of new compounds that they need not seek other sources of supply.

(2) Foreign drug manufacturers may be willing to license their compounds for use in the United States.

(3) Rights to manufacture and market compounds may be obtained from institutions and scientists in foreign countries.

(4) There may be a few United States institutions or scientists who have developed interesting compounds free of "contamination" by government funds.

(5) United States chemical concerns that do not have the facilities for drug development might grant a license to produce a compound discovered by them.

Conclusions and Recommendations

The public interests are being harmed by the present government patent policy in the following ways:

(1) The government finds its compounds gathering dust on the shelves of the scientists it supports.

(2) Both academic and industrial researchers suffer from the resulting breakdown in collaborative programs.

(3) The public receives a minimal return from tax dollars invested in scientific research.

(4) Patients are suffering from the lack of the drug that "might have been."

A major step could be taken toward improving the government's patent policy. This is to revise the October 1963 presidential statement to improve the position of the health industry. The statement is being revised, but will the special circumstances concerned with inventions in the pharmaceutical industry be given the proper weight?

Will the government still expect to obtain the principal or exclusive rights for inventions in the health field? The fact that the contractor may acquire greater rights under certain circumstances is not much help since these rights cannot be obtained until after the invention is identified. As mentioned above,

the invention is often not identified until the manufacturer has invested much time and effort in screening in order to determine the utility of the compound. At present, greater rights than a nonexclusive license cannot be negotiated until a substantial investment has been made.

Other negative features of the policy are the failure to specify that the greater rights may last throughout the term of the patent and the proposed extension of the compulsory licensing provisions to include situations where the "public interest" otherwise would suffer.

The public interest already suffers because of the lack of incentive for the pharmaceutical industry to make the very substantial investment needed to develop government-sponsored compounds that may cure dread diseases.

GOVERNMENT PATENT POLICY STUDY: THE HARBRIDGE HOUSE REPORT

James E. Denny
National Aeronautics and Space Administration

Government patent policy is one of the most studied of contemporary policy issues, an issue that remains unresolved and controversial. During the past decade we have witnessed a dozen congressional hearings on government patent policy, about thirty reports and studies have been made by the Congress, three study groups were appointed by the executive branch of the government, and Congress has considered several legislative proposals designed to clarify patent policy on a government-wide basis as well as for individual government agencies. The legislative action to date has resulted in inconsistent patent policy pertaining to different agencies.

In 1965 the Federal Council for Science and Technology established an interagency committee on government patent policy. The membership of this committee included policy-making officials from the major federal research and development sponsoring agencies, with the Departments of State and Justice also holding membership. The committee's assignment was to assess President Kennedy's October 1963 patent policy statement and to determine its effectiveness. The committee was instructed to obtain additional data that, upon analysis, would provide a data base useful in the reexamination of the policy. It was believed that this reexamination would provide the information needed for new patent legislation. Harbridge House, Inc., was commissioned by the committee to collect and evaluate the required data and to submit a report to the Federal Council for Science and Technology.

The Harbridge House report* is certainly the most extensive study ever conducted on government patent policy.

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* Government Patent Policy Study for the Federal Council for Science and Technology, Vols. 1-4, Harbridge House, Inc., Boston, Massachusetts, May 17, 1968. (Washington, D.C.: Government Printing Office, 1968.)

During the conduct of this study, it was assumed that an ideal patent policy would balance the following three basic objectives:

(1) To expedite the development and commercial utilization of inventions made under government sponsorship.

(2) To obtain the cooperation of industry to assist the government in its research and development efforts.

(3) To maintain competition in the commercial marketplace.

There were two main phases to the Harbridge House study. The first phase was a collection and analysis of information pertaining to a large sample of patents that resulted from government-sponsored research to see whether they were used commercially and to determine why or why not. The second phase of the study consisted of in-depth evaluations of selected patents and contracting situations. It was felt that the large sample of specific inventions would be statistically meaningful and that the in-depth analysis would give a more detailed understanding of the situation. Harbridge House examined more than two thousand patents on inventions that had been made under projects supported by the government. These patents were owned by government contractors and the government. Over two hundred in-depth studies were made.

The Harbridge House report clearly shows that a uniform and inflexible government patent policy is impractical. We cannot operate under a patent policy that always gives rights to the government or under one that always gives rights to a contractor.

The Harbridge House study also showed that consideration of several interrelated factors will assist in determining the possible allocation of patent rights. These are the government agency involved, the type of government contractor involved, and the particular invention involved.

The factors concerning a particular government agency were found to be:

- The mission of the research-sponsoring agency.
- The invention promotional activities sponsored by the agency.

The Department of Defense and the Tennessee Valley Authority represent opposites in this area. DOD's research is directed toward resolving military problems, the results of which may have little or no commercial application. In addition, DOD presently has no program (or mission) to encourage civilian utilization of their research.

On the other hand, TVA research is directed toward resolving specific problems presently confronting a sector of our economy. TVA keeps in constant touch with this private sector and has extensive programs for promoting commercial use of its research results within the sector. TVA has actually produced and marketed products that result from their research to show industry that the product could be exploited commercially.

The factors surrounding the type of contractor were found to be:

- The prior commercial experience of the contractor.
- The size of the contractor's private research and development efforts.
- The contractor's attitude and capability to commercialize inventions.

These factors determine the patent sensitivity of the contractor. That is, on one extreme were research and development firms who had no interest or capability to commercialize inventions, but merely sought to perform research and development for their clients. At the other end were commercial firms who have extensive private research and development programs and who were very concerned with the ownership of patent rights to protect their proprietary work.

And finally, the factors that were found to relate to the individual inventions were:

- The commercial applicability of, and the market potential for, the invention.
- The extent to which the invention was developed under government sponsorship.

- The size, nature, and research orientation of the industry that would be using the invention commercially.

It was found that some inventions, such as specific military inventions, had no commercial application at all. Other inventions, although they could be used commercially, had little or no market potential because of their expense or complexity. Also, some inventions were found to be very basic and needed extensive follow-on development before they could be used, while others were completely developed and ready for use.

The Harbridge House study concluded that all of these factors were found to be interrelated. They produce different circumstances that forbid a single rigid patent policy.

The Harbridge House Report and the National Institutes of Health

The National Institutes of Health has probably the most difficult and complex combinations of the above-mentioned patent policy considerations of all government agencies. NIH deals in the general area of public health where the President's policy suggests government acquisition of patent rights. However, much of this work is for basic research where resulting inventions normally need substantial development work and where exclusive patent rights would normally be required to encourage private industry to undertake this development. Additionally, NIH deals primarily with universities, which are not in a position to perform the development work themselves and in general have a past history of being insensitive to patents. And finally, the biggest problem is that the pharmaceutical industry, which hopefully will conduct the required follow-on development, is extremely sensitive to patent rights.

As a result of these conflicting factors, Harbridge House found that the problems involving patent policy all but stopped the cooperative efforts between the university investigator, who was supported by NIH, and the pharmaceutical industry in screening and testing compounds synthesized under NIH grants. The Comptroller General of the United States also studied the same problem and arrived at the same conclusion (see Comptroller General Report, B-164031(2), August 12, 1968).

CASE HISTORY OF ARTHUR D. LITTLE, INC.

Alfred R. Johnson

This workshop presents several points of view concerning government patent policy: government, university, and industry. Arthur D. Little, Inc., is neither government, university, nor industry. We do not manufacture a product; we can perhaps be best categorized as a pseudo-university-business organization. A. D. Little is a profit-seeking firm that does research and development work for clients, be they private businesses or a government agency. Being in business to make a profit, we resemble a manufacturing firm, but because we do not manufacture or sell an end product, we somewhat resemble a university.

It is routine with A. D. Little to cede all patent rights to the client, whether a commercial firm or a government agency. In general, then, ADL subscribes to the concept that when the government pays for the development of a new drug or a new medical device, the government unquestionably can acquire all the patent rights deriving from work conducted under its sponsorship. Often work done for the government has brought on additional work to ADL that yielded patent rights we ordinarily would not obtain. When there are background patents or patent applications to which we wish to retain title, we clearly cite this in our proposals to a government agency and reserve these rights to ADL.

ADL does not refuse to accept a contract from a government agency because of a patent policy. We are not aware of negative aspects to government patent policy, and actually we have benefited by it. For example, the National Aeronautics and Space Administration has agreed to pay a 5 percent royalty to us on equipment covered by patents where we have reserved rights. This royalty amounts to added income to ADL, since the provision was incorporated in our contract proposal. Perhaps the reservation of patent rights may exclude us from being the

successful bidder in the future, but to date this has not occurred. To cite another example, ADL once developed a new chemical for medical purposes for the Department of Health, Education, and Welfare. The chemical was believed to be valuable as an insecticide and for other purposes. At our request, HEW gave us rights for these purposes, rights that we normally would not obtain from the business community. Work done for the Department of Defense, where we synthesized a number of chemical compounds, resulted in our retention of title to these compounds. After having them classified into several chemical groups, three of the compounds showed promise to be revolutionary new drugs, and we are now working with several pharmaceutical companies to evaluate them further. To note another example, on an Army contract, ADL developed a filter paper to remove particulate matter. Following this work, the Atomic Energy Commission contracted with ADL to modify the filter paper to be suitable for their use; patents were obtained on these projects. Once the filters were developed, it became necessary to find the means to produce them. Neither the government nor ADL possessed facilities in which the filters could be manufactured. ADL arranged for production of the filter both for governmental and industrial uses. The manufacturing know-how was made available to another company, at the request of the AEC, to assure a second source of supply. Now several firms are manufacturing the filter, which is standard equipment for "clean rooms."

In light of our fortunate experience, we find it difficult it criticize the patent policies of the several federal agencies. It certainly can be contended that the government does not promptly and efficiently convert patents to which it holds title into freely available and useful commercial products. However, that is another matter.

CASE HISTORY OF GENERAL ELECTRIC COMPANY

Maurice Sapienza

The experience of the General Electric Company with Department of Health, Education, and Welfare contracts is quite limited. Our Research and Development Center has engaged in a few small contracts with HEW involving implantable electrical energy sources. In these contracts, HEW retained the right to determine unilaterally the disposition of foreground inventions, and in addition acquired certain rights to background inventions. General Electric has not been greatly concerned with HEW's acquisition of rights with respect to background inventions because there is a provision for the payment of reasonable royalties and the rights were narrowly limited in the field of application.

Before 1969, General Electric was able to negotiate contractual provisions to assure the company of not less than the right to use its foreground inventions nonexclusively and royalty-free. HEW changed its policy in June 1969. A contractor now has a choice between having no assurance that he will have the right to use any of his foreground inventions or having at most, when the contract is awarded, the assurance of exclusivity for a maximum of three years plus the pendency time of the patent on his foreground inventions.

HEW has explained that the change to a restrictive policy on foreground inventions was made to enable HEW to grant exclusive licenses under such inventions. Also, HEW can better control the requirements for clinical tests on foreground inventions prior to introduction in the marketplace. It does not seem that the prospect of HEW denial to a contractor of the right to use his <u>own</u> invention made under a government contract will stimulate either inventiveness or participation in government-sponsored projects. If there is going to be an incentive, it must be adequate and it must be assured at the very onset of the contract.

CASE HISTORY OF GENERAL MOTORS CORPORATION

George E. Frost

Why should a representative from General Motors be involved with a workshop on government patent policy devoted to medical instrumentation? Having been associated for a number of years with the pharmaceutical industry, I naturally understand and appreciate its patent problems. Several years of experience in the automobile industry have revealed an astonishing parallel of problems faced by both industries. The automobile industry encounters health problems and conducts research and development projects that lead to inventions in the health sciences. Two examples are the problem of noxious emissions from the internal combustion engine and the problem of highway safety.

In presenting one point of view of industry, Mr. Holmes was quite persuasive in suggesting the need for an appropriate period of exclusivity under a patent license agreement to provide an opportunity to recoup the substantial developmental expenses involved in bringing a new chemical compound to the marketplace. The drug industry has an extremely strong case in this respect. However, other cases might be cited.

Recently there has been considerable publicity pertaining to the air bag for use as a safety device in motor vehicles. The practicality of this device has yet to be proved. However, the automobile industry is very much interested in it because, if practicable, it would be a boon to automotive safety and would enhance the image of the automobile industry in the eyes of the public.

The government recently has shown a substantial interest in the air bag as a safety device in automobiles, whereas the concept was first evaluated as a safety device for commercial and military aircraft by the Martin Marietta Corporation operating under a National Aeronautics and Space Administration contract. The Martin project extensively explored the basic

aspects of air bag restraints, including full-scale tests when full-size aircraft were purposely crashed to test the efficacy of the device. Following the work conducted by Martin, the air bag idea was adopted by a components parts supplier to the motor vehicle industry and is something that is being commercially promoted.

The National Highway Safety Bureau is concerned with the evaluation of restraining devices and has conducted very expensive tests using live baboons as subjects. These tests involve highly sophisticated instrumentation and a very expensive test facility to record and evaluate the effect of the decelerating forces inflicted on the baboons as the sleds come to a stop. Often the baboons are sacrificed. This example is one where the capital investment in development of a product was made largely by the government, first through Martin and then through the National Highway Safety Bureau.

In this case the NHSB needed an example of a restraining device. Also, a business concern was interested in promoting the concept and was willing to provide a few air bags for test purposes as well as to assign several engineers to conduct the tests.

What can we learn from this example? All of us realize that inventions are not nearly as easy to handle legally as is the title to real property such as a house or automobile. Quite often it is very difficult to determine who made the invention, where the invention was made, and why it was made. We know that when a group of people work together, inventions will be made. Therefore, most business concerns execute patent agreements before the fact because it is well understood there is a high probability of an invention being made. In the case of the air bag, which was conceived under a government contract and later evaluated under another government contract, it is likely that the provisions of the 1966 Car Safety Act would be applied. That is, the government is required to take title when the government's investment in an invention is more than minimal.

What can we learn from this example? The drug industry representative has persuasively pointed out their need for exclusivity as an incentive to invest in product development. On the other hand, there appears to be little incentive for a

business firm to obtain a strong patent position on a product that the National Highway Safety Bureau prescribes as being required for general use. Why is patent protection an incentive to invest in product development when the Secretary of Transportation announces that the device is something that will be required in two-years time? What more incentive is needed? Will a patent make one iota of difference? The motor vehicle industry is most serious in its efforts to meet safety requirements and is expending enormous sums on research and development projects, sums that dwarf anything spent in the past; patent protection as such is immaterial. In other words, when a federal regulatory agency requires that a particular device be utilized, patent protection plays a secondary role.

The case of the air bag device illustrates that inventions can arise in quite unexpected ways. It is doubtful that the people concerned with the original Martin-NASA contract had the slightest idea that a few years later their device might be specified for use by a government regulation.

Compulsory licensing and payment of royalties often is considered as the way to eliminate the monopoly aspect of patent exclusivity. We must be careful not to look upon this as a panacea for our difficulties. In a recent instance, a government agency sought to rely on a compulsory licensing policy to eliminate the possibility that a monopoly position would develop. Unfortunately the royalty to be paid was an exorbitant 10 percent! In the appliance field and in the automobile industry, 10 percent royalties are out of the question. We must be quite certain that the term "reasonable royalties" takes into account all aspects of each individual case.

CASE HISTORY OF KONIGSBERG INSTRUMENTS, INC.

Eph Konigsberg

The foregoing presentations of case histories have focused largely on products with annual sales ranging in the millions of dollars. This presentation is made from the viewpoint of a small firm engaged in the development of medical instrumentation, a field noted for being fragmented and having a low sales volume for many of the companies selling to this market. A recent study showed that 80 percent of the companies engaged in medical instrumentation have sales less than a million dollars per year. The percentage of the total market served by these small firms was not disclosed.

It is important to realize that changes occur very rapidly in the instrument field, with the useful life of a new product being about five years. Thus, the value of an invention to a firm is not nearly as important as the experience the firm gains in the marketplace as a result of the invention. In my opinion, the market position of the Statham Instrument Company is a good example of what is meant by this. Statham pressure transducers are protected by several United States patents. Transducers delivering performance equivalent to the Statham unit are, or could be, readily available from competing firms. However, Statham has a dominant position brought about by its expert knowledge of the market. It also developed a know-how in solving problems while serving the clinical and research communities. Statham's dominant position in the line of pressure transducers results as much from an overall business acumen and experience as from the protection granted by their patents; Statham understands the problem better than many of its competitors.

As a young and small business firm, Konigsberg Instruments, Inc., does not object to abandoning exclusive rights to patents when it contracts with the National Institutes of Health because we believe that the rights that are relinquished

are not nearly as important to our success as is the knowledge gained by working with the research community on the problems posed by the contract.

Whereas patent rights are freely relinquished in contracts with the Department of Health, Education, and Welfare, we are more circumspect in our working relationships with the university community. Often the university investigator is not clear about patent rights under HEW contracts and grants. This presents a considerable problem. A substantial amount of research in instrumentation techniques is conducted in the university setting, and we can logically expect, in time, to obtain information that would be of great value to our corporation. But it is difficult for us to go through the process of obtaining licenses and paying a royalty on an invention made in the university setting only to learn, after expending substantial sums on development, that the university had no rights to assign! If we wish to improve the prospective success of commercializing university research, we should have the cooperation of the original technical personnel involved. But to obtain this cooperation and assistance, we would have to intrude on their time--which might detract from their further research. In all fairness, they need to be recompensed for this, which does imply licensing, royalties, or some other arrangement. And, concomitantly, if we are to invest time and money, we need some assurance that our investment is protected.

The patent problems that arise between the university and industry can be solved by the government. It seems desirable for the government to clarify the rights that the university obtains when it performs work in which government financial aid is involved. The standardized institutional patent agreement now utilized by HEW might accomplish this purpose. Were the government to recognize university rights for developments arising from government grants, to whatever moderate degree, it would encourage universities and their personnel to spend further effort--beyond the scope of the grant--to work with industry in bringing the fruits of research to the public as expeditiously as possible.

CASE HISTORY OF PERKIN-ELMER CORPORATION

Edward R. Hyde and Kendall Preston, Jr.

Perkin-Elmer is a major producer of a variety of analytical chemical instruments. Some time ago, under a government contract, a situation arose with respect to a patentable invention; that case is still pending.

The case in point developed from a contract awarded to Perkin-Elmer by the National Cancer Institute in 1967. The work to be accomplished under the contract was in the form of a study of automatic methods and apparatus for scanning blood smears on a glass slide. In conducting the study it became apparent that the development of an instrument that would automatically scan the samples was insufficient; an automatic apparatus was required to prepare the blood samples for subsequent scanning.

The conventional way to prepare a blood sample is to place a drop of blood on a glass slide. Then, using a straightedge, such as another glass slide, the blood is spread over the first slide to produce a thin layer of blood that can be readily scanned when viewed by a human through a microscope or by an automatic instrument. Disadvantages inherent in the present procedure are that certain blood cells are likely to be distorted or damaged, and there is not a uniform thickness of blood on the slide.

The invention made at Perkin-Elmer involved the preparation of blood samples by spinning the slide after the drop of blood was placed on the glass surface; centrifugal force spreads the blood in a uniform layer. Indeed, this technique provided a uniform monolayer of undamaged blood cells. We concluded that significant patent protection would be obtained on the method of preparing the blood samples and on the apparatus itself. Since this invention was reduced to practice under a National Institutes of Health contract, rights to the invention

were determined by the HEW patent contract provision existing at that time. In short, the NIH reserved the right to determine the disposition of title to the patent.

An engineering study and a market analysis were made of the invention. We concluded that we must have exclusive patent rights to justify assignment of the scarce corporate resources needed to bring the new product to the marketplace. The engineering investment in the product actually was quite small. It was a simple mechanism; a motor with a tray on top in which the slide was placed for spinning. However, it was believed that a substantial investment would be made in market development, and laboratory technicians would have to be educated to the automated method, which was radically different from the old manual way of smearing the blood sample. We concluded that as soon as someone (Perkin-Elmer) expended the necessary effort to develop the sales, competitors then could readily enter the market in the absence of sound patent protection. Furthermore, the total market is relatively small and does not justify a multitude of suppliers.

A formal request was directed to the NIH to grant an exclusive license or title to Perkin-Elmer for a limited period of time. This request was made in January 1968, and the patent application was filed in March 1968. Although on a number of occasions we have inquired into the status of this request, to this date no decision has been made (September 1969). Our petition happened to be made during a period when HEW was reappraising patent policies; we understand this is the principal reason for the delay in making a determination. Whatever the reason, work in developing a potentially useful product has been in limbo during this extended period of time.

This is another example of products resulting from government contracts that will not be placed on the market or that will be late in being produced, unless the inventor is granted some period of exclusivity to permit him time to exploit the invention.

GENERAL DISCUSSION

MR. WILLARD MARCY, Research Corporation, Inc.: Research Corporation, Inc., is not a profit-seeking firm, nor does it conduct research projects. It is, in reality, a nonprofit foundation operating much like a charitable organization. For the last three decades one of our major activities has been to provide expert service in the processing of patent applications and in the negotiation of licenses for inventions. Our work is done on behalf of institutions such as the Sloan-Kettering Foundation, the Mayo Clinic, hospitals, nonprofit research organizations supported by industry (e. g., the International Sugar Research Foundation), and universities.

Our work places us in contact with many government agencies. We must conform to the regulations prescribed by the several different government granting agencies that have supported our clients in research projects. The formal presentations of this workshop have not stressed sufficiently the vital need for an organization to act as a buffer between the granting agency and the inventor (or institution where a formal patent agreement exists with the inventor).

The processing of a patent and the negotiation of a license agreement require constant and almost unlimited patience. Little progress can be made in bringing an invention to a practical reality unless there is involved an organization that acts in an unbiased manner, one that is effective in making compromises to bring people to a meeting of the minds. Research Corporation is such an organization and possesses considerable experience in this area.

It is important to realize that each patentable invention is a case unto itself. Rigid rules cannot be devised to accommodate each and every case that arises. Transferring an invention from its original primitive nature to something that is introduced into the marketplace to benefit the public requires substantial effort--the accumulation of a vast amount of knowl-

edge about complex patent laws and about business operations, something that requires unlimited patience.

MODERATOR GERALD D. O'BRIEN, The Bendix Corporation: Some government agencies not only go through the process of securing a patent, but also try to exploit inventions and have them developed for commercial uses. For example, the National Aeronautics and Space Administration has a technology utilization program for this purpose. Several exclusive licenses have been granted on inventions made under NASA contractual support. The few cases where this has occurred do not suggest a great effectiveness for commercial utilization, whether exclusive or nonexclusive licensing is involved.

MR. ROLAND A. ANDERSON, Atomic Energy Commission: Research Corporation performs a useful function, but why does it not share royalty income with the government? In negotiating a royalty agreement, Research Corporation provides for the inventor, the university, and itself, but it is unwilling to share income with the government.

MR. MARCY: Research Corporation has considered approximately 8,000 inventions from universities and nonprofit institutions during the past 25 years. Only about 850 of the inventions were accepted as having some promise of commercial utility. It is an expensive matter to perform just the initial screening and select the approximately 10 percent of the total number for further consideration. Research Corporation resources also are used in applying for patents on the 10 percent of the inventions that remain following the initial screening. In addition to a full-time staff, patent attorneys are retained and their services used as required. Of the 800-plus inventions on which we filed patents during the past 25 years, licenses have been negotiated on about 80 of them. In other words, Research Corporation must recoup its original investment from about 1 percent of the inventions originally considered.

Of the 80 or so licenses that were negotiated, only about one in ten yields a return of $10,000 per year or more. In 1968, for example, Research Corporation had about $1.5 million royalty income, of which 90 percent came from one invention! In the general case, then, there is very little in the way of royalties to share with anyone.

MR. ANDERSON: The question of sharing royalties is really one of economics. There is indeed a tremendous amount of effort and investment required to follow 8,000 inventions to obtain royalties on a mere 80 of them. The question, then, is whether the royalties received on the 80 successful inventions are such as to justify the effort that was required to handle the other 7,920 cases. It is understood that Research Corporation arranges for certain royalty payments to be made to the inventor and that the balance of the payments is split equally with the university. This eliminates government participation in royalties from inventions derived from government-supported research projects. The government should receive a share of such royalties.

MODERATOR O'BRIEN: If a university has a patent program with Research Corporation, can it still work with the Atomic Energy Commission?

MR. ANDERSON: Yes, the AEC paid for the research work and it is interested to see that inventions resulting from that research are utilized. It is possible that Research Corporation might make an agreement with a firm on an exclusive licensing basis. It might be that the public interest would best be served by encouraging competition for the product.

MR. MANUEL B. HILLER, U. S. Department of Health, Education, and Welfare: The Department of Health, Education, and Welfare is a giant organization that supports research in many areas. Originally the research program of HEW was largely centered on the problem of alleviation of diseases, drugs, and therapeutics. There has been a huge expansion of research into many other areas. HEW supports research on air pollution processes and devices, medical devices, teaching machines, computer development, and laboratory instrumentation. One must keep in perspective the application of patent policies to one major segment of HEW programs, namely, the area of drug research, development, screening, and testing.

As Mr. Konigsberg pointed out, in this fast-moving technological era, new products often have useful lives limited to four or five years, whether patented or not. This lends support to one of the arguments for government patent policy; a patent in our fast-changing technological world has almost become a license to design around the patent claims.

For many years government agencies have taken the view that exclusive licenses cannot be issued except as authorized by Congress under specific legislation. This is based upon an opinion of the Attorney General that dates back to 1924. Much thought and consideration has been given to the validity of this long-held interpretation. Whether government agencies in the future will engage in exclusive licensing cannot now be predicted.

HEW's basic policy has always been to issue nonexclusive licenses to all who apply for them. Recently there have been requests from contractors for the inclusion in the contract terms of assurance that an irrevocable nonexclusive license would be granted. The HEW patent regulations and procedures have been modified to accommodate these requests.

Let us assume that a legal basis for the issuance of exclusive licenses might be determined and that HEW patent regulations therefore would be amended to that effect. It then should be possible to provide an opportunity for the contractor making the invention to apply for an exclusive license, in the event that neither he nor others would undertake to develop the invention on a nonexclusive basis. Naturally the inventing organization would be best suited and the most likely firm to proceed with development of a product on the basis of a nonexclusive license, having been responsible for the development of the invention in the first place. However, if the inventing organization is not inclined to pursue the development of the product on a nonexclusive licensing arrangement, then others should be given the opportunity to do so on the same basis. In the absence of any indication that others would develop the invention on a nonexclusive basis, with other things being equal, then an exclusive license could be issued to the inventing contractor.

MR. EDWARD R. HYDE, Perkin-Elmer Corporation: A number of nations attempt to exploit their patents outside their own country. Does our government patent policy give consideration to the exploitation of United States inventions in foreign lands?

MR. HILLER: HEW has too few people to cope with our domestic patent situation let alone enough to attempt to handle the complexitities of foreign rights. Therefore, we relinquish foreign rights to contractors, to grantees, and on occasion even to employees.

MR. ANDERSON: The AEC is active in filing for patent applications in an attempt to protect United States industry abroad. The imposition of royalties depends upon patent policy of the nation in which the application is filed. Most of the industrial nations of Europe charge royalties to United States firms for the use of their inventions, and consequently we charge royalty payment for the granting of United States licenses in those nations. The AEC permits its contractors to make foreign patent applications; when they do not file, the AEC is apt to do so. The AEC has achieved some success in that cooperative international agreements have been made based on the exchange of patent rights concerning atomic energy technology.

MR. JAMES E. DENNY: National Aeronautics and Space Administration: NASA is attempting to be highly selective and to file patent applications in other countries on a few inventions having a high probability of utilization. Recently, an exclusive license was negotiated. Ordinarily NASA does not grant nonexclusive licenses in other countries simply because there is no mechanism available for enforcement.

Other government agencies sometimes acquire title to inventions that are directly related to commercial use. For example, inventions controlled by the Department of Agriculture and by the Tennessee Valley Authority have received worldwide acceptance. If patent coverage had been obtained in foreign countries to these inventions, it might have been possible to utilize the royalties therefrom in the balance-of-payments problem or in providing assistance to developing nations. Perhaps there is potential benefit in this, but there has not been an attempt to start a trial program to determine the feasibility of the concept.

MR. EPH KONIGSBERG, Konigsberg Instruments, Inc.: When a profit-seeking firm works under a contractual relationship with the NIH, there is ample time for it to achieve a commanding lead over competition in the marketplace, for such products as may be developed under the contract. A considerable amount of development is possible on inventions made during the course of the contract. By the time a final report is published and a patent is filed, the original contractor has gained a reasonable lead over potential competitors.

The profit-seeking firm, however, faces a different situation in working with some universities. First, university investigators are prolific writers and like to "spill" all they know as soon as possible. Secondly, a third party, the government, is usually involved, which complicates the situation. Thirdly, the transfer of technical know-how between the university and an industrial firm is quite difficult to accomplish.

Time is of the essence if one is to exploit certain types of inventions, because certain technologies decay at a faster rate than others. When a university is involved with a private contractor, it must be given a reasonably free hand to negotiate patent licensing arrangements.

MR. HILLER: The HEW standardized institutional agreement has recognized this very problem. That agreement permits a university that does not itself have the capability for patent management and patent exploitation to assign the entire patent rights, if need be, to an organization such as the Research Corporation, provided there exists an agreement between the university and the patent management organization that has been approved by HEW prior to the assignment. HEW has approved the standard form of Research Corporation agreement used in the promotion of university inventions. At this time, any university that does not itself have patent management capability may enter into an institutional agreement with HEW provided that it assigns its patent management operations to an appropriate firm.

MR. G. W. FORNELL, University of Minnesota: The University of Minnesota concluded one of the early HEW institutional patent agreements in 1954 and now operates under the new standardized agreement. In working with the National Association of College and University Business Officers, it became apparent that misunderstandings of patent policies were not confined to HEW and the universities, but existed to a large extent between universities. The University of Minnesota patent policy differs from that of the Georgia Institute of Technology, which is different from that of the California Institute of Technology, and so on. Even with these differences, HEW now is able to conclude standardized institutional agreement with nearly all of the universities.

If the pharmaceutical manufacturers, the government, and the universities are to work together effectively, we must all bear in mind that our uppermost consideration is to serve

the public, the ultimate user of our inventions and our products. Each group must modify its policies a little, as the universities have, to accept the institutional agreement. HEW altered some policies to meet the universities halfway. The fact that a three-party situation is involved certainly complicates the issue. What is necessary is for the three parties to get together and develop a reasonable screening agreement. Each pharmaceutical firm has different patent policies. However, an agreement developed through the joint efforts of the Pharmaceutical Manufacturers Association, the National Association of College and University Business Officers, and the Department of Health, Education, and Welfare should minimize the effect of the variations in company patent policies. Then we can move new products into industry under an approved screening arrangement and the public will benefit thereby.

MR. ANDERSON: What is the patent policy followed by the universities? University policy seems to be a confused collection of individual views of the patent-conscious people in the universities.

Should one of the purposes of the university be to promote inventions, or is this a digression from the research functions of a university? When a university acquires rights in inventions, should it provide a reward to the individual inventor? Does a reward program or a royalty-sharing program create animosity among those who are not involved? Does the head of the department always want his name on a patent to be sure to share in royalties? Do the patent policies of a university affect the relationship between fellow professors and associates? Does the promotion of a patent affect the relationship between those in the Engineering School and those in the Liberal Arts School where the professors do not have opportunity to acquire extra outside income from inventions?

At some universities there is no patent policy; at others all inventions become the property of the university.

The AEC is searching for an optimum solution to the university patent situation, bearing in mind that the conduct of the fundamental research at the university should be the paramount goal and not the side effects of patents.

When the AEC negotiates a contract with a university, it is generally necessary to have a separate patent agree-

ment with each individual who works on the contract to assure compliance with the patent provisions of the contract. There are universities whose patent policy provides nothing for the inventor, more or less similar to the policy of the industrial profit-making organization. Then there are universities who share royalties with the inventor.

How much money has really been made by universities from patents? Is too much emphasis being placed by universities on the commercial aspects of patents? How much money has been spent by universities in obtaining patents? Is it a case where the costs to obtain the patents or administer a patent program exceed the return from royalty income? The university group should examine these and similar questions, not the government.

Can there be a uniform university policy? If not, must not the government have a flexible policy to meet the needs of the government and the general public, recognizing that there is no one uniform university policy?

MR. RICHARD V. HOLMES, Smith, Kline and French Laboratories: The present institutional agreement limits the period of exclusivity to a maximum of three years. The institutional agreement provides that the three-year period of exclusivity begins to run from the date of first commercial sale, or, in the alternative, eight years from the date of the granting of the exclusive license, thereby providing a five-year period in which time the manufacturer can do all of the developmental testing and screening work. Further, the terms of the institutional agreement permit an extension of these time periods when the university and the licensee demonstrate a valid and reasonable basis for the need for additional time.

MR. JOHN S. LACEY, The Johns Hopkins University: Recently we produced an invention made under an NIH grant. The university also provided support for the project. In this instance we asked the NIH to grant title to the invention to the university.

One of the questions raised by the NIH is something like: "If you receive title to the invention, will you promise not to ask NIH for additional funds?" The implication was that in receiving title to the invention, we would relinquish the right to ask NIH for the funds to use in further development of the invention.

MR. HILLER: HEW does not give title to an invention when the inventor plans to seek grant support to develop the very invention on which he is seeking title. If the government is going to pay for the further development of an invention, what justification is there for leaving the title and subsequent royalty payments to the university?

MR. LACEY: Even if the university were to utilize the government funds in developing a patentable invention, there still is much work required by industry before a marketable product results.

MR. HILLER: Unfortunately, at the time the inventor seeks both the title to the invention and additional support money for its development, we do not know whether the combination of those two factors will result in an invention ready for commercial utilization. In an analogous situation, if HEW were to do all of the testing and screening of drugs, then there would be no need to grant exclusive licenses.

MODERATOR O'BRIEN: The artificial heart program at the NIH encounters a number of inventions during the course of its work program. What is the effect of federal patent policy on these activities?

DR. LOWELL T. HARMISON, National Heart and Lung Institute: The Artificial Heart Program seeks solutions to problems that encompass existing as well as new technologies. Some of these problems do not have readily available answers. The Artificial Heart Program has a number of pioneering projects in which there exist considerable background patent information and proprietary rights that may or may not hold keys to the solution of some of the problems. In our program, we attempt to recognize the role and need of the profit-seeking organization. We try not to preclude future developments by highly competent organizations simply because of a controversy over background and proprietary rights.

One of the big problems to overcome in patent policy is for all parties to stop taking sides and to try to decide what the problem really is--to state the problem in soluble terms. Industry, universities, and the government must cooperate to as-

sure that new products become available for general medical use. This should include (1) industrial opportunity to contribute technically without compromising background rights in the specific area, and both background and foreground rights in other nonrelated areas; (2) opportunity for the university to apply its special research capability without compromising patent rights; and (3) government rights to background and foreground rights on the specific area funded by the government (with background rights solely limited to the application funded), and complete foreground rights when totally funded by the government.

MR. GILBERT B. DEVEY, National Academy of Engineering: Mr. Denny mentioned that the entire Department of Health, Education, and Welfare has only two or three patent attorneys. If this deplorable situation exists, then it is clear why the HEW requires so much time to handle new patent problems. Mr. Hiller, is the size of your staff inadequate?

MR. HILLER: Historically, HEW has not been at all conscious of inventions or patent rights as a significant part of a research program. Patents were considered to be a fallout from research projects about which nobody wanted to get very excited. The development of an awareness of the significance of inventions and patents has only recently come to HEW. However, staff ceilings in government being what they are, all of the awareness in the world does not necessarily bridge the gap between the need and available manpower resources. There is the problem of educating the budget people and the manpower requirements people as to the need for adequate staffing to handle properly the present overwhelming weight of business. The standardized institutional patent agreement will relieve us of some of the day-to-day work, but this is by no means the total answer to coping with our rapidly increasing workload.

All of the HEW patent attorneys currently work under the office of the General Counsel, a centralized office. We look to the outside for counsel in patent prosecution work, because we cannot possibly handle it ourselves. But even so we are limited, because we are not able to obtain an adequate budget to provide for services by a sufficient number of patent lawyers to handle the workload.

QUESTION: Is HEW giving consideration to negotiating institutional patent agreements with industry?

MR. HILLER: No, we have not considered any institutional agreements with profit-seeking organizations.

QUESTION: If a government agency cannot grant an exclusive license without special legislative permission, is there any question about the consitutionality of the standardized institutional patent agreement?

MR. HILLER: In considering whether an exclusive license can be granted by the government, it must first be determined that the government holds ownership of the invention. In a 1924 decision, the Attorney General stated that issuance of an exclusive license disposes of an element of government property for which only Congress has the authority.

The standardized institutional agreement is predicated upon the concept that a contractual agreement exists before an invention and prior to the time that any rights to future inventions can possibly have been vested in the government. So the government is not giving away anything that it owns at that time; therefore an unauthorized disposal of government property does not occur.

PART TWO

THE PRESIDENT'S PATENT POLICY

Has it furthered or failed to achieve
uniformity of government agency policy?

PROPOSED CHANGES IN THE PRESIDENT'S PATENT POLICY

O. A. Neumann

The 1968 Annual Report on Government Patent Policy* in which changes in government patent policy were recommended is now before the Federal Council for Science and Technology (FCST) for approval. This report includes patent data for fiscal years 1967 and 1968. An appendix to the report includes the numerous statutes, regulations, orders, manuals, directives, and statements that control the patent policies of government agencies. It shows whether an agency operates its patent policy under specific statutory authority, what other regulations might apply, how each agency has interpreted and implemented the October 1963 presidential policy statement, and how the patent policy is administered within each agency. The 1968 report also includes a brief description of the past activities of the FCST Committee on Government Patent Policy and the Patent Advisory Panel.

Of the proposed changes to the presidential patent policy statement, the most significant is the suggested amendment to the so-called "greater rights" provision of section 1(a). Under the 1963 policy the government could grant title to a contractor if an invention required further risk capital to bring it to the marketplace, but only if the invention was not a primary object of the contract. Since inventions resulting from research and development actually are normally directly related to the primary object of the contract, title cannot be granted to the contractor even though further risk capital is required to develop the invention to a practical device. To overcome this shortcoming, the recommended change under section 1(a) will permit a contractor to retain greater rights than a nonexclusive license when the head of the contracting agency determines that to do so would enhance commercial utilization of the invention or that equity considerations would entitle the contractor to such rights.

* Annual Report on Government Patent Policy, Dec. 1968 [with bibliography, 1970] [Federal Council for Science and Technology]. (Washington, D.C.: Government Printing Office, 1968.)

Another significant change that has been proposed is the opportunity for government agencies to grant exclusive licenses. For example, if an in-house invention is made at the National Institutes of Health, an industrial firm could apply to NIH for an exclusive license to develop the invention into a marketplace product. Under the proposed presidential patent policy statement, NIH (through HEW) would be in a position to issue an exclusive license to an industrial firm after waiting an appropriate period of time to determine that no firm would develop the product on a non-exclusive license basis.

The third change proposed to the patent policy would provide government agencies with additional authority under section 1(g) to require contractors who retain title to inventions to license others when the public interest would otherwise suffer.

The Patent Advisory Panel and the Committee on Government Patent Policy of the Federal Council for Science and Technology were reorganized during this past year. The two organizations were merged into a single body that will carry out the functions spelled out by section 3 of the presidential patent policy statement. The reorganized committee is supported by an executive subcommittee that will plan and steer the work projects of the three standing subcommittees: the Implementation Subcommittee, the Data Collection and Analysis Subcommittee, and the Patent Management Subcommittee. In addition, there are two ad hoc subcommittees working on the questions of background patent rights and university patent policy.

DEPARTMENT OF DEFENSE

Walter Henderson

This presentation is addressed to the question of how existing Department of Defense patent policies were changed to conform to the President's patent policy statement of 1963.

If one compares the old armed services procurement regulations (ASPR) with the presidential statement, one notes that much of the policy was already included in the ASPR. Therefore, changes in DOD policy were less than the changes in the practice resulting from that policy. There have been some procedural changes.

Before the 1963 presidential patent policy statement, the ASPR instructions to DOD contracting officers spelled out that if the contracting officer believed the circumstances were appropriate for the license clause to leave the title with the contractor, he would use that clause as a part of the contract terms. If, on the other hand, the contracting officer believed that one of the criteria for government title holding applied, then the contract was processed for a "deviation." The processing of a deviation involves red tape. That is, when a deviation is requested, the contract must be referred to higher authority for approval, in the example cited, in order to include the clause to vest title in the government. Under the 1963 statement, the contracting officer could insert the title clause without the need to obtain approval from higher authority.

There was little utilization of the title clause by the DOD before the presidential policy statement, perhaps being used less than 1 percent of the time. Since then, there has been a marked increase in the use of the title clause by the DOD. In fiscal year 1966, 24 percent of all research and development contracts included either the title clause or the deferred clause, meaning that the government automatically took title to inventions or reserved its decision to take the principal rights in inventions. In

fiscal year 1967, this increased to 25 percent of the cases. The analysis is not yet complete for contracts let in fiscal years 1968 and 1969, but available information indicates there was a substantial increase in the use of title clause: 30-32 percent for the Navy and 23-27 percent for the Army.

DOD experience with nonprofit laboratories and with universities indicates that the patent motive is not strong in such institutions. However, where a university or nonprofit research laboratory has a formal patent policy, it is regarded as any other contractor who might qualify under the license laws. Upon DOD approval of the institution's patent policy, that institution is then placed on a list of universities and nonprofit organizations that qualify for the license clause at the time a contract is issued. After nearly six years of operations under the President's patent policy, only about 100 institutions are involved, a relatively small number of the nonprofit and educational institutions with which the DOD does business. This is another indication of the relative lack of interest in patents on the part of most such institutions.

The presidential policy statement implies that the government acts on behalf of the public, that is, in evaluating drugs, the Department of Health, Education, and Welfare deems itself to be doing so on behalf of the public for the public health. The Interior Department contracts on behalf of the public in its saline water program; the FAA similarly does so in its supersonic transport program; etc. All involve the public as the "user." The Department of Defense is an exception to this concept, for the public is not the "user" of weapon systems. This helps to shape the DOD patent policy, and we rely on section 1(b), which involves contractors who have nongovernmental commercial positions. This simply means that if a contractor has a nongovernmental commercial position, it is implied that he is the one best able to utilize the inventions, and we will utilize the license clause with him. Most of the inventions made are associated with weapons hardware and therefore have little utility in the public sector. A small percentage of such inventions might be of use to the public, and the contractor is best able to recognize the commercial potential of these items.

VETERANS ADMINISTRATION

Eugene F. Murphy

The Prosthetics and Sensory Aids Service is the only organizational element of the Veterans Administration with a significant contract research program. In general, the scientific officer seeks agreement in preliminary negotiations with potential prosthetics contractors to use the so-called "short form" in which complete rights and title to inventions are vested in the government. Also, a modified short form can now be used that gives the contracting officer the right to determine disposition of title either to the government or to leave it in the hands of the contractor, or to determine other suitable equitable arrangements.

The "long form" patent clause, now relatively unused, was developed originally for use in the National Academy of Sciences prosthetics program. This clause rests more in government than does the short form; it provides royalty-free license for government use and also provides royalty use to background patents held by a contractor that might be needed to practice the inventions made under the prosthetics research contract. The contractor might issue royalty-free licenses under both subject inventions and background patents. Thus, using the long-form patent clause, the contractor holds the naked title to the subject invention. The contractor could not receive royalties from any government use or from nongovernment use related to the utilization of the inventions in the field of prosthetics. The long form is silent on the possible use of such an invention in fields other than prosthetics.

A special patent clause, utilized in the case of a contract with the University of California, provides the same royalty-free licensing of inventions utilized in prosthetic devices as does the short form or the long form, but it does not extend to control of background patents. It also defines the title for use in nongovernment purposes other than prosthetic devices, whereas the long form is silent on this point.

The follow-up of patents in the prosthetic field is done in a rather informal manner. The field is small enough that we are able to keep abreast of progress on a day-to-day basis. It is unlikely that anyone would deliberately or inadvertently pay royalties on an invention that belongs to the government or that should have been usable on a royalty-free basis. Our general policy is to publish progress reports on research in prosthetics semiannually in our own Bulletin of Prosthetics Research and in numerous other media. There are relatively few patents in this field. The Veterans Administration scientific officer rarely determines that the filing of a patent application is more important than its immediate publication. He considers the probable utility of the invention, the government's patent position in relation to others, the novelty, and consequently the probable scope of claims in making his decision. It is fully recognized that publication alone does not provide complete protection inasmuch as others could file a patent claim within a year following publication.

Prosthetics and sensory aids are so vitally important in their rehabilitation of the severely disabled that the general policy of government ownership or control of patents derived from government support in this field seems to be warranted and equitable. In practice, patent policy plays only a minor role in the business relationships between research contractors and the Veterans Administration.

U. S. ATOMIC ENERGY COMMISSION

Roland A. Anderson

Has the President's patent policy statement failed to achieve uniformity? The answer to that is simple: Yes. The policy statement was not intended to bring about uniformity between the several government agencies but to provide for a flexible and consistent treatment. If uniformity is desirable, then legislation should be enacted, which was noted by Congress at the time the statement was issued. The statement was to be an interim policy with legislation to be enacted by Congress.

The policy was designed to permit flexibility in the administration of patent policies while at the same time effecting a consistency in the treatment of the inventions and patents resulting from the various research and development contracts to which the government is a party. Today there is definitely a closer association and working relationship between the patent administrators in the government agencies and departments than before. Patent regulations have been issued by agencies where such regulations did not exist. And there is a degree of consistency, and in some areas uniformity, in the way the regulations are being administered.

Did the presidential policy statement affect the AEC? Section 152 of the Atomic Energy Act of 1954, as amended, provides that rights are vested in the government in inventions made or conceived in the course of or under a contract or other arrangement with the AEC, whether funded by the government or not, if the invention pertains to, relates to, or is associated with the production or utilization of special nuclear material or atomic energy. Consequently, the AEC must take title in those situations unless the Commission waives. AEC has not waived rights by contract. The AEC has used what is referred to as the "deferred clause." This means that after an invention is reported to the AEC, a determination is then made as to the assignment of rights. However, AEC generally has taken title.

Has section 1(a) of the President's policy statement affected AEC? Yes, in certain areas where AEC might have permitted the retention of exclusive rights by contractors, this no longer could be done. Under section 1(a) (1), where the principal purpose of the contract was to develop a product, process, or method that was intended for commercial use by the general public, we are required to relate the purpose of the contract to disposition of patent rights. Prior to the presidential policy statement, if the contractor had a background patent and industrial position in a field other than atomic energy, he might be permitted to retain exclusive rights in such field. Now, however, if the principal purpose of the contract is for development of commercial items in the nonatomic energy field, any exclusivity would have to be under the "exceptional circumstances."

Has AEC policy affected reporting of inventions? In the past year the AEC was responsible for approximately 8.7 percent of federal funds spent on research and development. Interestingly, it happens that 8.8 percent of the inventions reported to the government resulted from AEC contracts. But there is another aspect of patents. The government is spending approximately $16 billion per year on research and development with something like 20,000 inventions reported per year. The private sector of the economy, however, spends much less on research and development but produces more patents. Why is this? Is it the private incentive that is responsibile for creativity? On the other hand, one must remember that a large part of the $16 billion is for development and not for research; i.e., it is "programmatic" and may not be conducive to the creation of inventions.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

James E. Denny

The patent policy of the National Aeronautics and Space Administration is controlled by legislation. Section 305(a) of the Space Act requires that, in general, inventions made under NASA support become the exclusive property of the government, unless rights to the invention are waived by the administrator. Under section 305(f), the administrator may waive government rights to an invention if "the interests of the United States will be served thereby."

The legislation under which NASA and AEC operate prescribes different patent policies. AEC must take rights to inventions in one specific field only. NASA, on the other hand, legislatively is supposed to take rights in all fields, but these rights can be waived.

Before the 1963 presidential policy statement, NASA regulations did not allow waivers if an invention was especially useful in space activities. Waivers for other inventions were granted under circumstances based on equities of the contractor and the need for special incentives to assure commercial development of the invention.

The 1964 NASA patent regulations incorporated the guidelines of the presidential policy statement insofar as permitted by the Space Act; NASA would grant advanced waivers in contracts where the criteria of section 1(a) of the President's policy were not present and where the criteria of section 1(b) were present. Also, NASA waived rights to an invention on a case-by-case basis where section 1(a) did not apply and where it was believed that a waiver would be an effective incentive toward commercial development of the invention.

From NASA's inception through 1968, approximately 15,000 inventions were disclosed by NASA contractors. Waivers

were granted on 475 of these--less than 4 percent. Since the issuance of the 1964 regulations, NASA has granted 215 advanced waivers--less than 1 percent of the contracts to which they could be applied. Under these 215 advanced waivers, 105 inventions have been waived.

GENERAL DISCUSSION

DR. EUGENE F. MURPHY, Veterans Administration: Perhaps what we need is not uniformity of policy, but uniformity of equity. How are uniform rules made for determining the equities in individual circumstances?

MR. T. L. STAM, California Institute of Technology: The question of equity is perhaps overemphasized. Much has been said about benefit to the public and the rights of the inventor. The real benefit comes only when an invention is made available to the public. Inflexible rules must not be adopted. What is required is to examine the nature of the invention and to determine what arrangements must be made to have it produced so that it will be made available to the public.

DR. MURRAY EDEN, Massachusetts Institute of Technology: It is clear to me that no rigid structure will do what you want; the Subcommittee on Interaction with Industry is well aware of this. Perhaps patent questions are irrelevant to many biomedical engineering developments. Often the numbers of instruments required are small; there is no money to be made from them. How does one provide incentives for government or industry to carry the idea through to the ultimate utilization under such circumstances?

DR. MURPHY: The field of prosthetics is an excellent example of the problem Dr. Eden has mentioned. We typically must "prime the pump." After a long development and evaluation period during which the Veterans Administration purchases and tests the first few versions of an invention, we finally obtain a useful device. Even then it may be necessary to purchase another 100 or so items in order to conduct a clinical applications trial. The manufacturer of those items then typically becomes the only firm producing that device.

MR. STAM: But this is not typical of other government agencies when a "barefaced" invention has not been reduced to practice.

DR. LESTER GOODMAN, National Institutes of Health: For the past several years I have heard repeatedly that federal patent policy and the implementation of that policy are one of the major impediments to research, development, and exploitation of medical devices. Has this workshop resolved the issue? Perhaps I missed something, but it seems to me that the major issue remains unsolved: Is industry suffering under delusions? Is the federal system suffering under delusions? Is or is not government patent policy a serious impediment to research and development in the medical device field?

DR. EDEN: It seems to me that in a number of instances the answer is that government patent policy is not an impediment. In the drug industry, however, it appears that government patent policy is an impediment to development. A small firm engaged in medical instrumentation development, a characteristic of this field, recognizes that it can live perfectly well with the existing government patent policy.

DR. GOODMAN: Perhaps you are suggesting that, as Mr. Hiller mentioned, there is a communications gap and that the federal patent policy is not so severe as some people believe it to be. If they had a better understanding of the policy and the possible privileges that are available and were well guided in taking advantage of them, this enormous barrier might fast disappear. Is this so?

MR. T. R. FERRELL, Eastman Kodak: Federal patent policy is an impediment to the extent that people who are dealing with it feel it to be an impediment. If people in industry believe it is an impediment, then it is an impediment, even if people inside government believe it to be otherwise. Those who are revising the President's policy statement should seek comments from both industry and the universities before making a final policy pronouncement. Otherwise, a new policy statement may still be considered to be an impediment. One must obtain some concurrence of the people outside of government who will be affected by the policy in order to have a viable working arrangement.

MR. HOLMES: Agreed. Smith, Kline and French has several operating divisions. The research administrators in each of these divisions have different ideas of what government patent policy should be. In the drug area, exclusivity is important. In the medical device area it is normally not so important. It all depends upon the invention, the type of product that will result. The total problem cannot be solved with an inflexible policy.

DR. EDEN: With respect to Dr. Goodman's question, however, it appears that in specific cases where particular issues must be resolved, there may be impediments. At the same time, we have heard here today that the HEW does have a mechanism whereby these impediments may be adjudicated. There appears to be a variety of flexible guidelines that can be applied and agreed to in advance of a particular contractual obligation. To repeat, there may be impediments to drug development where the issue of the length of the period of exclusivity is clearly a serious one. With regard to medical devices, disagreement has not been apparent.

DR. GOODMAN: Many, many people visit my laboratory at the NIH to discuss medical devices and their development. Often they seek a government grant or contract to help support their work and, typically, they express considerable concern over the issue of patent rights. Such concern seems to be conspiciously absent in the discussions here today. I am still not certain whether it is a matter of understanding or a matter of fact that keeps the patent rights question as a burning issue.

Even if adjudication mechanisms do exist, is it reasonable for an industrial firm to invest money in development of a product if it takes a near eternity to obtain a decision on their patent rights? Mr. Hiller mentioned before that his group is completely bogged down. Excessive time delay is a crucial element of the patent problem, even though, in principle, mechanisms do exist to remove impediments.

MR. KONIGSBERG: We in industry have the impression that we get rights from the government on an ad hoc basis. Why should industry become involved in a program with the government, which is unpredictable, when we could put our time and energies in something where we have more control over the outcome?

DR. JACK H. IRVING, The Aerospace Corporation: This workshop has limited its discussion largely to cases in which a university stands between government and industry in the process of moving knowledge gained from research projects into utilization in the form of a patentable invention, or to the case in which an invention has occurred as an unanticipated result of the research program. Suggestions made for the establishment of a common policy for dealing directly with contracts with industry rejected

exclusive licensing. If, as has been suggested by several speakers, the medical instrumentation business is not likely to be profitable, then we will need a large amount of government money to prime the pump for development of medical devices. If the amount of government money required is to be minimized, then it is necessary to attract risk capital, which is more likely to be available if an exclusive licensing arrangement can be devised.

Perhaps there are but two courses of action to be taken. Either the government foots the whole bill down to the point of manufacture, in which case all risk is removed and private investment is not required, or government pays part of the bill and grants an exclusive license as an incentive to industry to pay the rest of the bill.

Somehow it seems to be immoral to use government money where it would eventually lead to profit for a specific company. But the ultimate beneficiary of this process is the public who now spend in excess of $50 billion a year for medical services. If we are really going to make progress, then I think we need to offer as much incentive as we can. One such incentive is a more attractive licensing policy.

MR. HILLER: There is no doubt that a general impression has existed to the effect that government policy represents an obstacle; this is a misunderstanding, as today's sessions have abundantly demonstrated. The one area in which an obvious collision exists between the HEW patent policy and industry is that of drug testing and screening. We have encountered no real difficulty in the other areas. For example, at a bidder's conference on a procurement for microfilm readers, the question of patent rights, including foreground rights, was an issue of discussion. I explained exactly what HEW patent policies are and how the policies would apply both to background patent rights and to any new inventions or improvements that might be made under the procurement contract. There was the usual cry as to why anyone should enter into such a contract that would jeopardize background rights. About forty responses were received to the subsequent invitation to bid. Although at the bidder's conference there was an emotional discussion of HEW patent policy, the actual response to the request for proposal produced an adequate number of capable bidders.

There are areas in which patent rights are significant. A number of industrial firms will not enter into a contract

with a government agency because of patent policy, but there are many variations of industrial patent policy and there are many variations in the interpretation and administration of government patent policy. A categorical answer cannot be given.

I believe that with the availability of institutional patent agreements, with the availability of after-disclosure determinations of patent rights (which would leave rights to institutions that had not entered into institutional agreements), and with the provision of exclusive licensing, HEW policies as a title agency are far more liberal toward industry and the university community than most government agencies.

DR. IRVING: There is an important operational difference between HEW and DOD, NASA, and the AEC, brought about by the nature of each agency's programs. The DOD, NASA, and AEC not only sponsor research and development projects, but go through the point of production. HEW typically does not sponsor much production. Considerable concern has been expressed in meetings of the Committee on the Interplay of Engineering with Biology and Medicine that there does not seem to be a mechanism for carrying out the transition from research through production in the field of medical devices. We now depend on private industry to effect this transition, and there simply is not the government assistance such as would be the case in the development of a space station. Somehow, HEW should assume more responsibility in stimulating private industry to carry out those additional steps beyond research to bring a product into practical utilization.

MR. HILLER: Neither the Congress, HEW, nor NIH has believed that it is the role of HEW to provide support that would carry a concept from the basic research stage through to its becoming a commercial product. This is a matter of basic philosophy on which Congress has laid down the rules. Congress has not seen fit to convert HEW into an agency to provide a mechanism for industrial exploitation of inventions.

APPENDIXES

APPENDIX A

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APPENDIX B

ACADEMIC INSTITUTIONS AND THE PATENT FIELD*

Why Should Colleges and Universities Have Patent Programs? And Why Should They Retain Rights to Inventions Made in the Course of Government Sponsored Research?

THE STATEMENT that follows was prepared earlier this year by the Subcommittee on Patents and Copyrights of the NACUBO Committee on Governmental Relations--a subcommittee under the chairmanship of Mr. Raymond J. Woodrow, of Princeton--to describe explicitly and in simplest terms the interest that academic institutions have, and necessarily must have, in the field of patent policy. Because the statement will be of interest and importance to institutions of higher education at large, the NACUBO Board of Directors has approved its publication here for the information of representatives of all National Association member institutions.

A. Why a Patent Program?

1. Universities by their very nature have an obligation to serve the public interest. In order to do this effectively, it is necessary that they have a patent program which will make inventions arising in the course of university research available in the public interest under conditions that will promote effective development and utilization.

2. University personnel, as compared with those in a commercial research organization, are employed and pro-

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moted with salaries which give no recognition to the value of any inventions which they make. Their interests lie primarily in the publication of research results in the open literature. In order to insure that this does not lead to the loss of important benefits to the public, practically all universities provide for a share of any royalties received to be paid to the inventor, as the incentive for him to spend the time and effort necessary to disclose an invention properly, to participate in invention evaluation, to work with patent attorneys on patent application and response to Patent Office actions, and in many cases to provide information and assistance to potential or eventual licensees. Without this incentive, and it must be an adequate incentive, experience shows that few inventions are disclosed and the amount of persuasion which a university can effect with members of the faculty for disclosure is very limited.

3. Every grant or contract for research from the Federal Government, most of those from industry, and even some from foundations and similar nonprofit organizations, contain many various requirements as to the disposition of inventions and invention rights. In order to fulfill these requirements, it is essential that a university have a patent program, obtain agreements from potential inventors as to disclosure and disposition of invention rights, and have a follow-up procedure to insure disclosure of inventions and transmittal to sponsors of adequate data and the execution of appropriate licenses or assignments.

4. Finally, it is entirely appropriate and in fact desirable that universities should share in the proceeds of any invention, to help pay for the costs of a patent program and also for the advancement and encouragement of education and research, in recognition of the institutions' investment in facilities and personnel without which such inventions would not have been possible.

B. Why Should Universities Retain Rights to Inventions in Government Sponsored Research?

1. Essentially the sole reason why universities have an interest in inventions and patents is to see that they are licensed and developed to the point of utilization and availability. Universities do not apply for patents as a defensive measure to protect a commercial position, since they have no commercial position to defend. By nature they are interested in the widest possible distribution and with no incentive for withholding of results of their re-

search. Thus the institution can objectively seek the best qualified sources of development and can monitor in the public interest, to which they are dedicated, the diligence of development and utilization.

2. Few university inventions are commercially practicable in the form in which they are conceived or reduced to practice in the university. Many if not most are in fact unanticipated by-products of the research effort. Usually, therefore, further investment is necessary in order to have the invention become commercially practicable, and it is difficult to see what organization would be willing to make the necessary investment to make the invention commercially practicable without any protection for such investment. If the university retains patent rights, patent applications may be filed promptly and negotiations immediately commenced with prospective licensees, with the active assistance of the inventor. In the drug field particularly, agreements can be entered into for the testing of compounds with some protection for the testing firm's investment before it is even clear whether or not there is a patentable invention. As a result, the public will benefit.

3. If the Government retains title to inventions and makes them available to all royalty-free, many university inventions will never become available to the public because no one will make the investment necessary to bring them to the point of commercial practicability. If decisions on disposition of title are made on a case by case basis, a complicated and costly petition must be prepared, and there will inevitably be delays in development, probable delays in publication or otherwise the time limit for patent application will expire, and finally the inventor's interest will wane.

4. As stated earlier, university inventors need an incentive to disclose inventions and put in time and effort to follow-up. The only practicable way to provide such incentives is a share of royalties, which can best be provided by permitting the university to retain patent rights. Were the Government to undertake a licensing program on a royalty basis, with a share of royalties paid to the inventor, the vast, inflexible and impersonal nature of the undertaking would be largely self-defeating.

5. Universities need a share in any royalties received in order to help pay for a patent program which, among other things, is necessary to meet the requirements of research

sponsors. Any additional income they receive for education and research can help, albeit in a small way, to alleviate the enormous fiscal pressures on higher education.

6. Finally, the public is not being cheated when it pays a royalty as part of the price of a product which incorporates an invention resulting from Government sponsored research. The Government when it sponsors research is not contracting for an invention or inventions--inventions are by-products of the research. And university salaries do not include any allowance for the value of inventions made. For the reasons stated earlier, it is very probable that the invention would not have been available to the public at all without a royalty.