Presentation of Norman J. Latker before the

Commission on Government Procurement, July 29, 1971

The opinions expressed are my own and not necessarily those of the Department of Health, Education, and Welfare.

General

The topic of my presentation is the evolution of the Institutional Patent Agreement, a device now peculiar to the Department of Health, Education, and Welfare, but one which I hope will eventually be utilized by all of the departments and agencies of the Executive.

The Institutional Patent Agreement

In the main, our Institutional Patent Agreements provide to universities and other non-profit institutions a first option to administer title to all inventions made under DHEW grants, subject to conditions considered necessary in the public interest. Among these conditions are the reservation of a royalty-free license to the Government for Governmental purposes; a requirement that non-exclusive licensing by the university or non-profit organization be considered prior to any exclusive licensing, and if not deemed feasible the right to grant an exclusive license for a period of less than that of the full patent grant; a restriction that the substantial portion of royalty receipts be utilized for educational or research purposes, with a lesserportion for distribution to inventors; and march-in provisions similar to those required by the President's Statement on Patents. This first option is offered with knowledge that a substantial portion of the inventions that

will be generated will arise under grants whose principal purpose is exploration of public health and welfare and are therefore subject to disposition under section 1(a), the title section of President's Patent Statement. Permitting public institutions a first option to such inventions is considered justified under the exceptional circumstances language of paragraph 1(a) since most inventions spring from basic research and are at early stages of development. Institutional Patent Agreements are given to selected institutions who have demonstrated that they have the management capability and tools to administer patent rights. If these Agreements were extended to all institutions receiving grant funds from DHEW, the results of over 600 million dollars of HEW research would be subject to the conditions of the Agreements. Presently the Institutional Patent Agreement has been granted to 37 universities with a number of applications pending.

As noted, Institutional Patent Agreements extend only to grant-supported research at universities and non-profit organizations. In the Department's opinion there is a fundamental difference between Government-supported research projects funded by grant rather than contract. Research performed under DHEW grants is substantially basic in nature, while that research funded under contract is ordinarily applied. Review of the results of grant research indicates that most inventions generated by grant involve at most compositions of matter with no clear utility, or prototype devices, both of which require much additional development. Public institutions themselves do not undertake to complete development

of such inventions to bring them to the point of practical application as development leading to commercial marketing is not ordinarily within the scope of their missions. Likewise, financing of the type of development work that might be accomplished by such institutions is generally not available from the Government. Consequently, complete development in such cases would generally be accomplished only where an industrial organization has an incentive to utilize its risk capital to bring such inventions to the marketplace.

The Need for an Incentive to Develop University and Non-Profit Institution Inventions

DHEW has noted situations of industry refusal to collaborate with public institutions in bringing these inventions to the marketplace without some degree of patent protection as a quid pro quo for the additional investment and development required. This was further substantiated by the Harbridge House study and the GAO Report ("Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry." dated August 12, 1968.) Both of these studies indicated an industry-wide reluctance by pharmaceutical firms to test compositions of matter synthesized or isolated by DHEW grant-supported investigators due to DHEW's patent policy, which industry indicated failed to take into consideration the large private investment before such compositions could be marketed as a drug.

I would note that similar evidence regarding medical hardware devices has not been extensive, but I believe without the extension of use of our Institutional Agreements the situation might well be

or come to parallel that existing in the area of potential therapeutic compositions; due to cases such as AMP v. Gardner 389 Fed. 2nd 825. This case upheld the Food and Drug Administration contention that a medical device used in contact with the human body is a drug that must be cleared for safety and efficacy. This added requirement for clinical data places manufacturers of such devices in a position similar to those of the pharmaceutical industry, and may generate attitudes regarding patents similar to those of the pharmaceutical industry. (No device legislation at this time -- but coming).

Examination of Methods for Creating an Incentive for Further Development

Recognition of these facts had the effect of persuading the Department that a monolithic policy of dedicating the results of its grant research to the public through Government patenting or publication was not in all instances sufficient to transfer the results of such research to the marketplace, and that further thought need be given to creating the necessary incentives for development through the granting of patent rights in appropriate situations.

Of course, as noted above, the Department review of the above situation led to the expanded use of Institutional Patent Agreements to all qualified institutions. However, prior to the determination to pursue this course, other plans which might create an incentive for development were extensively considered. It was suggested that as an alternative to leaving ownership of inventions to public institutions at the time of funding, a policy

of deferred determinations or exclusive licensing by the Government would be more in the public interest. It was argued that either of such policies would permit the Government to identify and evaluate the invention prior to making any determination that exclusivity was necessary as an incentive to further development. It was also felt that such policies would afford the Government greater control over the terms of any license to be granted.

Pursuing a course of deferred determinations would have permitted assignment of inventions to public institutions for administration after the inventions have been identified and where adequate justification for such assignment could be shown to exist. Justification would ordinarily require a showing that an incentive for further development is necessary and that such development was not to be funded by the Government. As already noted, inventions resulting from grant research ordinarily require extensive development prior to their marketing with little expectation that such development will be funded by HEW. Accordingly, it appeared that in a large proportion of cases a deferred determination would merely delay a decision that could have been made at the time of funding. Further militating against a deferred determination policy was the fact that such policy would act against the expeditious development of inventions. It was concluded that the uncertainties involved in after-the-fact determinations would discourage active collaboration between public institutions and industry prior to the actual waiver of rights to the institutions. The time delays

involved were expected to cool the enthusiasm of prospective collaborators. It was felt that where the institution knows what patent rights it has to offer, it would be in a position to seek out collaboration and possible support during the early stages of development by making specific licensing commitments.

It was also concluded that a Government exclusive licensing policy was not the best mechanism for creating an incentive for further development of HEW funded inventions made at public institutions. While possibly appropriate in situations where a public institution's managerial capabilities did not include administering patent rights, an exclusive licensing policy was not deemed an adequate substitute for an enthusiastic university or non-profit institution's patent management organization. The conclusion took into consideration the following:

1. Exclusive licensing would increase the administrative burden of the Government patent staff by necessitating the filing of a much larger number of patent applications to protect all inventions which might have some degree of commercial potential. In addition, the staff would need to negotiate exclusive licenses which will vary from invention to invention.
2. Government patent personnel often are not in as favorable a position to appreciate the importance of novel ideas that do not initially manifest commercial potential or to accord the necessary priority in seeking patent protection on these more basic concepts, or attuned to the peculiarities involved in transferring more basic technology from the institutions to the commercial developer.

3. Exclusive licensing cannot be utilized for potential inventions that fall within the drug area because before property rights could be established for licensing it is necessary to comply with Patent Office rules of evidencing medicinal utility with test data. The Harbridge House Report indicates that obtaining such test data from commercial organizations has not been possible without a guarantee of some exclusive patent rights.

4. Exclusive licensing would deprive institutions of the opportunity to develop through their collaborative efforts ideas which do not at first evidence commercial potential, since it would be the Government which would ultimately decide what should be patented and protected through the licensing program.

5. An exclusive licensing policy carries with it the same time delays associated with the deferred determination policy.

Summary of HEW Patent Policy as it Relates to Public Institutions

In summary, it was agreed that inventions made at public institutions under Government-funded research constitute a valuable national resource, and that DHEW had a responsibility to foster the fullest exploitation of such inventions for the public benefit. Although a substantial amount of DHEW funded research is conducted at public institutions, such institutions, as a general rule, do not have the capability of transferring inventions resulting from this research to the marketplace. Inventions made at public institutions will benefit the public only if there is a sufficient incentive for them to be utilized by private industry. DHEW

views its role in the national research effort as complementary to the activities of other elements within our society, both public and private, that also support research and development related to health. It seems to us that the interests of the American people are best served when the various elements of this medical research structure can interact. The most effective interrelationship results when the particular capabilities of the various elements, Federal and non-Federal, can be utilized to the fullest extent. A Government patent policy should serve to encourage such interaction. The public institution, being a not-for-profit, public interest-oriented organization, can effectively promote the development and ultimate exploitation of inventions by industrial organizations. It can do so by providing the unique competence of obtaining such development and exploitation, while at the same time, due to its character, safeguarding the public interest.

In general, DHEW has determined that it is feasible to permit ownership of inventions resulting from its grant research to reside in public institutions, while utilizing a deferred determination policy to make disposition of ownership to inventions resulting from research contracts at institutions. The dichotomy of policies is, of course, based on the difference in inventions resulting from grants and contracts. As noted above, inventions resulting from grant research ordinarily require extensive further development which will not be supported by the Government, while contract

inventions may be the direct object of the work supported, and therefore be closer to complete development than a grant invention. I would also add that the DHEW patent policy as it relates to grants has been scrutinized with greater intensity due to the Department's choice to fund basic research to a greater extent than applied research. In fiscal year 1970, something over 600 million dollars of research at public institutions was funded through the grant mechanism, whereas the contract mechanism was utilized in this same fiscal year to disperse approximately 37 million dollars. From these figures, it seems apparent that if patent problems exist, they would occur with greater frequency in the grant area, which in fact has been the case. Accordingly, the Department has not at this time felt it necessary to extend its Institutional Patent Agreement policy to cover contracts at public institutions.

The Incentive to Utilize the Results of Industry Research Differs from that to Utilize the Results of Public Institution Research

I believe that it is of great importance to stress the fact that public institutions occupy a position that differs significantly from profit-making industrial organizations engaged in Government-financed research. Industrial organizations, in many cases, have considerable know-how relating to such areas. There is an incentive for such an organization to further develop the results of its commercial position. This incentive stems from the organization's continuous contact with such research from its inception. There is a lesser incentive for industry to further develop the results of public institutions' research, for such research was not under its review or control from inception. It is reasonable to assume

that an industrial organization would be biased towards investing toward further development of its own ideas, rather than in ideas from outside sources. This merely recognizes the "not invented here" problem as applied to public institution research. These facts, plus the fact that the public interest and the nature of public institutions require their best efforts to accomplish the transfer of technology from their inventors to industry, weigh in favor of such institutions' ownership of inventions for licensing of industry. This should not be interpreted to mean I believe there are no meaningful reasons why industrial concerns should not retain title to health inventions made in performance of Government-funded contracts in certain instances. It is only intended to stress the fact that public institutions have an even greater need to retain the results of grant-generated research if these results are to be ultimately utilized by the public. Accordingly, it is recommended that the Commission pay careful attention to DHEW's Institutional Patent Agreement policy and make no recommendations that would nullify its thrust. In my opinion, it would be in the best interests of the public if the Commission would recommend a policy which would enable the departments and agencies of the Executive to adopt and utilize the theories embodied in the DHEW policy whether the inventions involved fall within the technological areas specified within paragraph 1(a) of the President's Statement or not.

To emphasize the importance of this matter, I would impress upon the Commission that in Fiscal Year 1970 approximately 3 billion

dollars of the 12 billion spent by the entire Government outside its own laboratories was utilized by universities and non-profit organizations in performance of Government grants or contracts. It appears to me that substantially all inventions which may have commercial application generated at public institutions will require the collaborative aid of commercial organizations to bring the invention to the marketplace. Under the best of circumstances the public institution is faced with the "not-invented-here" problem. The further inability to transfer some meaningful patent rights to a prospective collaborator may mean that any invention having an element of risk attached to its further development and marketing will not pass beyond the early stages of its development and the investment in this public institution research will be lost to the public.

Contracts with Commercial Organizations

I would like now to direct a few words to situations where DHEW contracts directly with commercial concerns. As previously noted, DHEW utilizes the contract mechanism where it has a specific object in mind--for example, the need for a small pump driven by atomic energy for use in artificial hearts; the desire for materials compatible with the human body for use in fabricating artificial organs; or the clinical testing of compositions of matter which have evidenced therapeutic activity. Although our contracting activities with commercial concerns have steadily increased from a total of 21 million dollars in Fiscal Year 1963 to the 63 million

dollars in Fiscal Year 1970. This figure is far exceeded by our funding of basic research through grants. At present the Department requires that any invention conceived or first actually reduced to practice in performance of such contracts be reported for Department disposition. There is little indication of a reluctance on the part of industry to accept this type of provision with the possible exception of contracts for drug development. In the area of development of hardware devices, commercial concerns in many instances produce prototypes of the item in interest at their expense prior to entrance into the contract. This, of course, establishes the contractor's proprietary position. There is no Department policy which would preclude contracting to enhance, test, or improve such proprietary items. With this understanding, DHEW has been able to obtain the services it desires when needed.

Drug development programs funded by contract have posed a more difficult problem. Although there has been no extensive funding of this area, with the exception of the Cancer Chemotherapy Development Program, on the few occasions that the Department wished to proceed in developing therapeutic agents through contracts with the pharmaceutical industry, the industry has indicated a reluctance to make proposals without some guarantee of patent rights to foreground inventions at the time of contracting. Although the pharmaceutical industry recognizes that their background compounds will remain proprietary, they point out a possibility that patentably distinct analogues of background compounds may evolve in performance

of a contract. Industry feels that disposition to the Government of a compound which has greater efficacy than a company's background compounds will negate the company's proprietary position.

The extent to which DHEW will directly contract with the pharmaceutical industry outside Cancer Chemotherapy has not yet crystalized. Therefore, it cannot be stated with any accuracy whether the industry's reservations will influence their contracting with HEW. It should be noted, however, that in regard to the Cancer Chemotherapy Program the pharmaceutical industry was able to persuade the Department to give the contractor the first option to inventions resulting from this program.