STATEMENT

submitted to

SUBCOMMITTEE ON MONOPOLY AND ANTICOMPETITIVE ACTIVITIES
SELECT COMMITTEE ON SMALL BUSINESS

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by

American Association of Community and Junior Colleges
American Association of State Colleges and Universities
American Council on Education
Association of American Universities
Association of Jesuit Colleges and Universities
National Association of College and University Business Officers
National Association of Independent Colleges and Universities
National Association of State Universities and Land-Grant Colleges
National Catholic Educational Association, College and University Department

Inventions resulting from federally funded research constitute a valuable national resource. The large amount of federal funds supporting research dictates the necessity of examining the government's patent policy in order to ensure that inventive results are being delivered to the public and that the equities of all parties involved are being protected. Because of their special mission, colleges and universities have unique patent concerns which warrant a detailed exploration, particularly with regard to ownership of patent rights developed on campus under federal contracts and grants.

The federal government sponsors research in universities to expand the boundaries of existing knowledge in areas or on problems deemed to be in the public interest or to be related to national goals. Universities are free to publish research results which are generally made available to all. The right to publish is normally preserved in the negotiation of grants and contracts, as is the sponsoring agency's right to receive agreedupon reports.

The generation of inventions is almost never the main objective of the research conducted with federal agency funds; rather, an invention generally is an incidental "byproduct" of the research activity, largely attributable to serendipity and/or the personal creativity of the investigator backed by his years of professional training and experience, and to the scholarly environment and research resources provided by the university. When patentable discoveries occur, the equities to be considered include those of the inventor, the university, and, very properly, the sponsors providing financial support for the particular research project most closely related to the discovery.

When a patentable invention is made by an investigator in an academic institution with the help of federal funds, rarely, if ever, are the federal funds the sole or even the major factor contributing to the invention. Beyond the critical

contribution of the investigator, the university itself virtually always helps to finance the laboratories, equipment and personnel contributing to an invention. It also provides a scholarly atmosphere, and often the infusion of funds obtained from nongovernment sources. Accordingly, each of the parties has a claim in equity.

A policy which assigns patent rights to the government for all federally supported research, however large or small the federal contribution, eliminates the universities' ability to recognize the equities of other sponsors who contributed to the discovery of the invention as well as the contributions of the institutions themselves.

Since inventions resulting from research sponsored by federal agencies involve equities of the government, the contractor (on his own behalf or as the result of intermingled funds derived from other than federal agency sources), and the inventor, many factors must be considered in making a decision as to where the primary right in such inventions should be vested. In making that decision only one consideration should be paramount, and that is in whose hands will the vestiture of primary rights serve to most quickly and economically transfer the invention technology to the public for its use and benefit.

Educational institutions are, of course, not organized either to manufacture or produce and market a patentable invention. Accordingly, if university-generated inventions are to be used, such institutions must seek to interest those in the industrial world who have the commercial capability for invention development and also, very importantly, market development, which the university lacks. This is often a difficult task, since few inventions coming out of university research offer readily recognizable prospects of a large market or a high return on investment. University-based inventions, since they most often correlate with the results of fundamental

research, tend to be, at best, in the early stages of development, and therefore require the investment of substantial private risk capital to develop the invention to the appropriate state for introduction into the market.

At the same time, universities are in a unique position to objectively seek the best qualified industrial developer and under appropriate licensing arrangements monitor the diligence of developmental efforts by such a developer. If universities cannot furnish, if appropriate, an exclusive license to developers for a limited period and thereby secure the investment of necessary capital, inventions resulting from government contracts are less likely to be developed to the point of marketability, and thus the public is less likely to receive the benefits from such inventions, or at least may not receive them as quickly as otherwise would be the case.

When the right to seek patents resides in universities, appropriate patent applications can be filed promptly and negotiations immediately commenced with prospective developerlicensees, with the active assistance of the inventor. When this right does not exist at the time of contracting, but must await a determination after the invention has been identified, substantial time is usually required to prepare the necessary documentation for the sponsoring agency and for the agency to make a determination. While awaiting the outcome of such administrative process, the invention lies dormant, with the attendant risks that the inventor's interest in assisting in the development becomes attenuated and that intervening rights of others may foreclose successful transfer of the invention to the public.

Since deadlines for domestic and foreign patent applications are affected by publication of patentable ideas in scientific journals, delays in determining the disposition of rights to an invention can result either in delay of publication of research results or risk of expiration of the time limit in which patent applications can be filed. Neither choice is beneficial to the public interest.

Although the university's primary motivation in filing and prosecuting applications for patents is the timely promotion of actual availability of new products or processes to the general public, if, in the course of such transfer, income to support further research at the institution can be generated, the public benefits a second time.

The public obtains the benefit of universitygenerated patents through the efforts of those sponsoring agencies which offer adequate inducement to those who can bring the fruits of basic research into a form useful to the consuming public. Mere exclusivity in patent rights does not ipso facto create artificially high prices for related products and royalties generally represent only a very small fraction of the retail price of marketed goods. Moreover, one must face the inescapable conclusion that the development of inventions under a reasonable government patent policy will benefit the public by making available products that would otherwise not have been available at any price.

Without exclusivity to some degree, private sources are unlikely to have sufficient incentive to invest in the effort necessary to develop an invention available to all into a product or process actually available to the public. Indeed, the investment required to bring a product or process to a marketable condition and to introduce it into the market is almost always far greater than the investment in original research from which the invention results.

To bring an invention to public use, further deveopment or engineering usually is required, such as testing or "screening" a prototype of the new product or process. Before the efforts and expenses incident to testing or screening are undertaken, investors need to know who has the title to or ownership of the invention (i.e., the right secured to inventors and their assignees or licensees, for limited times, as provided in the Constitution).

Sometimes prospective licensees have refused to undertake the testing, screening or development of inventions unless the licensor would grant an exclusive license for commerical sale or use. In some cases, no viable alternative has been available and, in the absence of an exclusive license, the use of the product, process or machine has been denied to the public.

Universities usually do not possess the resources, critical facilities, or controls necessary to bring drug products, for example, through the clinical testing stages to marketability. Thus, it is imperative that they be in a position to supply an incentive under appropriate licensing arrangements to those organizations which have those facilities and control capabilities.

Since government personnel would not be as intimately familiar with an invention as those that have developed it in a university, they would be in a much less favorable position to ascertain or pursue the commercial marketability of such an invention and it is feared that the time that would have to be invested in such activity could well cause a significant reduction in invention disclosures from university researchers, with a consequent reduction in public access to potential fruits of research.

Thus, the primary result of the economic stimuli afforded by a realistic licensing policy is a public benefit the production and introduction of a good or service that otherwise might not become available in the context of our free enterprise system.

Under the policies of some governmental agencies, the agency, on behalf of the government, normally asserts its rights to ownership of any inventions and patents generated in the course of research sponsored and funded by the agency but does have regulations under which such right can be waived to the contractor or grantee. If an institution desires to acquire title to a particular invention, it must request a waiver in accordance with the regulations of such agency. The granting of a waiver generally depends on a determination by the agency, based upon evidence submitted by the contractor or grantee, that the invention will be more adequately and quickly developed in the public interest if title to the

invention is waived to the contractor of grantee. Such waivers are given with a reservation of a license to the government to practice the invention for governmental purposes and with other provisions which adequately protect the public interest.

An alternative to the "waiver" approach is the "Institution Patent Agreement" approach, available since 1978. [1] This approach, endorsed by a 1968 GAO Report,[2] permits the grantee institution to retain title and to administer the principal ownership rights in inventions made under department grants and awards, clearly defines the rights of the parties with respect to such inventions, and sets forth general guidelines governing the licensing of inventions. It includes limitations on the duration of exclusive licenses to be granted, it reserves a royalty-free license to the government for governmental use, and it provides other appropriate safeguards to protect the public interest. These latter safeguards include a reservation to the government of the right to require the granting of additional licenses on royaltyfree basis or on other terms that are reasonable under the circumstances, where such licenses are necessary to fulfill public health, welfare or safety requirements.

With the active assistance of inventors, the universities are in a better position than the federal government to transfer technology to the public through the economy. A government "title" policy, however, would preclude the university from recognizing the equities of others, including inventors and nongovernmental sponsors, and would fail to acknowledge the benefits that now accrue to the taxpaying public for its contribution to the institutions' research efforts.

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1. "Institutions Patent Agreement Governing Grants and Awards from the Department of Health, Education and Welfare" HEW Standard Form Rev. 8/26/68.

2. Report to the CongressProblem Areas Affecting Usefulness of Results of GovernmentSponsored Research in Medicinal Chemistry -Comptroller General of the United States -B 1640 31(2), 1968

Consequently, qualified universities that have developed a technology transfer capability should be granted, with the award of a contract or grant, a first option to title in inventions generated on their respective campuses with federal funds with appropriate safeguards to prevent abuse of patent rights retained by any such institution and to minimize any anticompetitive effects.