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U.S. GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

FOR RELEASE ON DELIVERY
Expected At 9:30 a.m.
Wednesday, May 16, 1979

STATEMENT OF

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COMPTROLLER GENERAL OF THE UNITED STATES

BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE SEN02500

ON

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S.414--THE UNIVERSITY AND SMALL BUSINESS PATENT PROCEDURES ACT

Mr. Chairman and Members of the Committee:

We are pleased to appear today to comment on the University and Small Business Patent Procedures Act. The proposed Act would establish a Government-wide patent policy for Federal agencies to follow in dealing with small business and nonprofit organizations performing Government supported research and development (R&D). It would also establish a framework for the licensing of Government-owned inventions.

I will briefly discuss the patent policy position of the Commission on Government Procurement and the findings of the Committee on Government Patent Policy. I will also summarize our recently completed review of the patent policies

Testimony
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and procedures of four Executive agencies that was conducted at your request.

I will also submit for the record a short background paper on past efforts to set Federal patent policy, including the 1963 and 1971 Presidential Memoranda and Statements of Government Patent Policy.

NEED FOR UNIFORM PATENT LEGISLATION

There have been a number of attempts to establish a uniform patent policy for the Federal Government. Foremost among them have been the Presidential Memorandum and Statement of Government Patent Policy first issued in 1963 and revised in 1971. These attempts have been relatively unsuccessful and policy has developed over the years on an agency-by-agency basis. There are wide variances in the way agencies have interpreted the Presidential policy, which embodies both title-in-the-Government and title-in-the-contractor policies. Additionally, piecemeal legislation has made uniform implementation by the agencies increasingly difficult. As a result, today there are approximately 20 different patent arrangements employed by the various Executive agencies.

The proposed legislation would, in our opinion, go a long way in overcoming this confusion. It deals explicitly with licensing and sets forth ownership provisions for small business and nonprofit organizations. However, the treatment

of other business entities would still be governed by Presidential policy or statute.

COMMISSION ON GOVERNMENT PROCUREMENT

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The bipartisan Commission on Government Procurement, which included members from the Senate, House, Executive Branch agencies, and the private sector, was established to recommend improvements in all aspects of procurement policy. A major task group of the Commission reviewed Government patent policy.

The Commission placed considerable importance on the need for Government patent policies to stimulate commercialization of inventions. Its December 1972 report stated that effective patent policy must take advantage of the fact that development will be promoted by those having an exclusive interest; at the same time, the policy must provide for others to exploit the invention if an exclusive interest does not produce the desired result.

The Commission was skeptical of the Presidential policy because it relied on after-the-fact disposition of patent rights. They saw that policy as causing delayed utilization of discoveries, increased administrative costs, and a lessening in the willingness of some firms to participate in Government research work.

Nevertheless, the Commission recommended prompt and uniform implementation by the Executive agencies so that further assessment could be based on actual experience. If

such an assessment revealed weaknesses in the policy, the Commission suggested a legislative approach which would permit retention of title by contractors, subject to march-in rights and other safeguards. It also recommended enactment of legislation granting all agencies clear-cut authority to issue exclusive licenses.

The Commission considered the Committee on Government Patent Policy to be in the best position to assess agency progress in implementing the revised policy.

COMMITTEE ON GOVERNMENT PATENT POLICY

The Committee on Government Patent Policy was established by the Federal Council for Science and Technology to fulfill a requirement of the 1963 Presidential Statement. The Committee was to analyze the effectiveness of Federal patent policy and recommend revisions or modifications.

The Committee, which included representatives from most of the R&D agencies, evaluated Executive agency experience under the Presidential policy and concluded, in 1975, that it had not been effectively or uniformly implemented. The Committee found that patent policy legislation was needed to unify agency practices for allocating rights to contractor inventions and to clarify agency authority to grant exclusive licenses for Government-owned inventions.

The Committee's conclusion that legislation was needed appears to have been influenced by two situations. First, there was the enactment of patent legislation applicable to individual agencies, particularly Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, with title-in-the-Government orientation. The same language has since been incorporated by reference in other acts affecting various agencies' R&D programs, such as the water resources and solid waste disposal acts.

The second situation was the confusion created by two lawsuits brought against the Government, by Public Citizen, Inc., that questioned the authority of Federal agencies to exclusively license inventions and allow Government contractors to retain title to inventions. Because both suits were dismissed for lack of standing to sue, and not on their merit, the issue was not resolved.

EXECUTIVE AGENCIES PROCEDURES AND PRACTICES

The need for legislation is also supported by our review of current patent procedures and practices at selected agencies. We expect to report the details of our findings to this Committee by the end of June. We found that the Presidential policy has not been implemented uniformly. Agencies, in establishing procedures for determining rights to inventions, are often free to move in almost any direction.

The most notable recent changes have taken place at the Department of Health, Education, and Welfare and the Department of Defense with respect to nonprofit organizations.

These two agencies follow the policy established by the the Presidential Memorandum and Statement as revised in in 1971. During fiscal year 1978 they provided over 60 percent of Federal R&D funding for colleges and universities.

We will also discuss the Department of Energy and the National Aeronautics and Space Administration, both of which operate under policies established by statute.

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Department of Health, Education, and Welfare

Administrative developments during the last 2 years at the Department of Health, Education, and Welfare (HEW) appear to be leading to a reversion to policies and practices followed at the Department prior to GAO's 1968 report to the Congress.

At that time we reported that HEW was taking title for the Government to inventions resulting from research in medicinal chemistry. This was blocking development of these inventions and impeding cooperative efforts between universities and the commercial sector. We found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry because manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of a promising product.

To correct this, we suggested to the Secretary that HEW expedite determinations of rights and use Institutional Patent Agreements (IPAs) which would permit universities with

approved technology transfer programs to retain title. HEW followed our suggestions and, as of October 1978, had implemented agreements with 72 institutions. The National Science Foundation, another major agency supporting R&D at colleges and universities, began using these agreements in 1973. IPAs were endorsed for Government-wide use by the Committee on Government Patent Policy in 1975 and Federal Procurement Regulations on IPAs were issued in 1978.

In July 1978 HEW's Office of General Counsel circulated for comment a patent policy draft report recommending that the Department's use of IPAs be reconsidered because IPAs delegate to grantee institutions power over the desirability, method, and pace of development of inventions. This, the report stated, was conceptually inconsistent with any HEW objective other than rapid commercialization.

Beginning in November 1977, the HEW Assistant General Counsel for Business and Administrative Law had begun delaying review of case-by-case determinations of rights prepared by the Patent Branch. In a statement issued August 15, 1978, the General Counsel acknowledged that a backlog of cases existed and said it resulted from a more

careful review. The purpose of this review, according to the General Counsel, was to make sure that assignment of patent rights to universities and research institutes did not stifle competition in the private sector in those cases where competition could bring the fruits of research to the public faster and more economically.

We found that the Assistant General Counsel's review of draft determinations during this time was averaging 6 months. We examined four cases in some detail. In three, the review affirmed the correctness of the Patent Branch's determination to grant title to the contractor. These reviews took from 8 to 15 months to complete. Review of the fourth case took about 14 months, reversing the determination of the Patent Branch and retaining title for the Department.

The Pharmaceutical Manufacturers Association is concerned about HEW's delays in processing individual cases, reevaluation of patent policy options, and possible reversion to patent practices and procedures used prior to our 1968 report. In a recent letter to the Secretary of HEW, the Association stated that the research-based prescription drug industry feels more strongly than ever that an exclusive interest is essential if Government-financed new drug compounds are to enter clinical programs funded by the private sector. The Association argued, "In our view, HEW's patent policy should not be structured so as to 'restrain or regulate' the availability of inventions

resulting from HEW research. This strikes us as truly an attempt to suppress technology to the detriment of the public."

Department of Defense

The policies and regulations of the Department of Defense are based on the Presidential policy. Most Defense contracts allow contractors with an established commercial position to retain title to their inventions.

Because nonprofit institutions generally lacked an established commercial position, Defense interpreted the Presidential policy as requiring the use of a deferred determination clause--where rights are determined after an invention has been identified. However, for many years the Department got around this by using a "special situations" section of the Presidential policy to put a title-in-the contractor type of clause in contracts with certain qualifying universities and nonprofit organizations.

In August 1975 Defense, with no advance notification, revised its regulations, discontinuing use of the "special situations" exception. Instead, it required universities which wanted a title retention clause to furnish information to the contracting officer for determining whether the work to be performed was in a field of technology directly related to an area in which the university had an effective technology transfer program or an established commercial position.

Because of the additional administrative burden, many research institutions subsequently elected not to submit the information Defense required for the title retention clause. As a result, there was an 80 percent increase in the use of deferred determination clauses by Defense during fiscal year 1976. Our review of cases processed during that year showed that, although contractors' requests for greater rights in identified inventions were approved in all cases, the Department took from about 1 to more than 7 months to make those determinations.

The University Patent Policy Subcommittee of the Committee on Government Patent Policy reported that it appeared that a deferred determination often acts against the expeditious development and utilization of inventions by delaying a decision that could have been made at the time of funding. Administrative costs of both the Government and universities are unnecessarily increased by the need to prepare, review, and respond to requests for rights on a case-by-case basis.

The Navy noted in February 1976 that not only had an additional administrative burden been placed on universities, but that the time necessary for contracting and patent officers to make a determination on the appropriate patent clause had increased drastically. In 1977 the Air

Force, after conducting a thorough review of the revised policy, determined that the practice of qualifying institutions for each contract was moving in a direction counter productive to a cost effective, reasonably acceptable policy.

To date, Defense has not implemented the use of Institutional Patent Agreements. This inaction and HEW's reconsideration of the use of IPAs are particularly difficult to understand because they run counter to the 1975 Committee on Government Patent Policy study and the considerations which led to the regulations issued in 1978.

Department of Energy AGC00912

The Atomic Energy Act of 1954 and Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, as amended, govern Department of Energy (DOE) patent policy. Section 9 is probably the most detailed, comprehensive individual statute enacted to date. It provides that, normally, the Government will take title to inventions. But, it also gives the DOE Secretary discretionary authority to waive the Government's rights in favor of the contractor if certain criteria are met.

The results of operations under the Nonnuclear Energy Act of 1974 are significant because, as I noted previously, the same language has been incorporated by reference in other statutes. DOE appears to be functioning adequately

under its legislated patent policies. However, there are problems. Our review of a recent year's cases showed that the time for determining rights to identified inventions was lengthy, averaging about 13 months. DOE recognizes that its policy creates problems for both the Department and its prospective contractors. Delays in the R&D contracting process are caused by the substantial burdens created by petitioning, negotiating, and determining waivers.

We feel that a patent policy that provides for Government ownership places a burden upon the Department to see that the resulting technology is utilized. It becomes the Government's responsibility to obtain domestic and foreign patents, to advertise their availability for licensing, to negotiate licensing agreements, to develop related technology packages, and to enforce the patents against unlicensed users. Since the Department has only limited resources to carry out these functions, it is likely the commercial potential of some DOE funded inventions may never be realized.

DOE's mission is to work in a cooperative relationship with industry to develop commercial energy alternatives. It works, therefore, in areas with high commercial sensitivity. In this respect, the Department noted that there are contractors which refuse to work with it because of its patent policies.

One other problem we noted is that DOE has taken the position that Section 9 does not allow it to use Institutional Patent Agreements whereby a contractor or grantee with an approved technology transfer program has first option to principal rights. It is possible that other agencies governed by the same statutory language may not adopt patent policies in line with the IPA approach. The proposed Act we are considering today will eliminate the uncertainty by authorizing the IPA approach.

National Aeronautics and Space Administration AGC00036

The National Aeronautics and Space Administration's patent procedures are governed by Section 305 of the Space Act of 1958. The Government obtains rights to inventions reported by NASA's contractors unless the Administrator waives these rights. These procedures are similar to DOE's except that recommendations for granting waivers are made by an Inventions and Contributions Board.

THE BAYH-DOLE BILL

The proposed legislation addresses the administrative and legislative-based problems of the agencies. It would establish uniform Government-wide procedures under which small business, university, and other nonprofit organizations could obtain title to inventions arising from Government-supported R&D. It would also establish clear authority and a uniform framework for licensing Government-owned inventions.

The proposed Act would place initial responsibility for commercializing research results on the inventing contractor--the organization or individual with the most interest in and knowledge of the invention. It would provide the Government with "march-in" rights. These rights limit the administrative burden because they would be exercised only in specified situations, such as when the agency determines that the contractor has not taken effective steps to achieve practical application of the invention.

Studies have shown that of the 8,000 inventions disclosed annually to the Government, only a handful attain commercial importance. It would be hoped that an easing of the red tape leading to determinations of rights in inventions would bring about an improvement of this record.

The Act should solve a number of significant problems not currently satisfied by the Presidential policy. This is especially true in regard to agencies' dealings with universities and nonprofit organizations. While it is not the uniform Government-wide policy envisioned by the Procurement Commission in that it does not assign patent rights for larger contractors, it is a clear legislative mandate establishing policy that is badly needed.

The Act would also provide authority and a legislative framework for the licensing of Government-owned inventions

(proposed sections 208-211). Its statutory guidelines would make clear the authority of all agencies to issue exclusive licenses under patents held by them.

Under a uniform Government-wide title-in-the-contractor policy, this licensing authority would generally apply only to in-house inventions of Federal employees. However, the bill's licensing provisions are applicable to all inventions when the Government retains title, including those of larger contractors not assigned title by the bill. I would be concerned if the Federal agencies were to use this licensing authority as a reason for retaining title to inventions of contractors which do not qualify as small business or nonprofit organizations.

This is not to say that there will be no situations in which contractors' inventions will require Government licensing to bring them to application. But it has been the experience of agencies with policies of granting title to the contractor that a willing contractor-inventor is more likely to expeditiously commercialize an invention than a Government licensee.

Section-by-section comments on the proposed Act are submitted for the record. However, I want to comment at this time on section 202(b). This section establishes an over-

sight role for GAO. GAO would be notified of agency determinations when the agency retains title. If our monitoring revealed a pattern of nonconformity with the spirit of the Act, we would so notify the head of the agency and request an explanation. At least annually, we would be required to report to the Judiciary Committees on the Act's implementation by the agencies.

Our preference is to not be required to monitor patent policy implementation in this particular manner. We prefer to consider this aspect of an agency's operation as part of our overall reviews of procuring and contracting functions and R&D programs. As you know, we normally inform agency heads and the Congress when we find agencies not properly fulfilling their statutory responsibilities. The implementation of this Act by the agencies and the efficiency of the agency's own monitorship would be included in our normal oversight reviews.

In summary, we believe a clear legislative statement of a uniform, Government-wide patent policy is long overdue. While the proposed Act is limited to small business and nonprofit organizations, in our opinion it provides a legislative basis for progressing to a uniform policy for contractors. With these reservations, we believe the Act

will go a long way to clarify the muddled patent situation that presently exists. It will provide the Federal agencies with a clear statement of the policy supported by the Congress to ensure the expeditious commercialization of discoveries from Government funded R&D.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you or the members may have.