COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-133386 July 17, 1979

The Honorable Birch Bayh
United States Senate

Dear Senator Bayh:

On September 15, 1978, you and Senator Dole wrote that you had introduced a bill to establish a uniform Federal patent procedure for small business and nonprofit organizations and intended to hold hearings in the 96th Congress. You asked that we provide testimony, including a discussion of the procedures of the Departments of Energy and Health, Education, and Welfare for determining the patent rights for inventions arising from Government supported research and development. The procedures of these departments were to be contrasted with those of other Federal agencies.

As a result of discussions with representatives of your office and Senator Dole's, and your letter of January 8, 1979, we also obtained information on the patent policies and procedures of the Department of Defense and the National Aeronautics and Space Administration.

We gave testimony before the Senate Judiciary Committee on May 16. A background paper on Government patent policy and detailed comments on the bill were submitted for the record. Answers to your questions were furnished for the record on June 21.

A summary of the patent policies and practices of the four agencies are included as enclosures to this letter. We obtained this information by working with patent officials of the respective agencies, but we did not ask the agencies for formal review or comment. The material is also being furnished to Senator Dole. This completes our work to satisfy your request. We are pleased to have been able to support your efforts toward a uniform Federal patent policy.

Sincerely yours,

Comptroller General
of the United States

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ENCLOSURE I

DEPARTMENT OF ENERGY
PATENT POLICIES AND PROCEDURES

The Department of Energy's (DOE) patent policy is based on Section 152 of the Atomic Energy Act of 1954, as amended; Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974; and, to the extent not inconsistent with these statutes, the Presidential Memorandum and Statement of Government Patent Policy as revised August 23, 1971. Title 41 of the Code of Federal Regulations, Part 9-9, implements these statutory and Presidential guidelines.

DOE patent policies require the Government to acquire title to subject inventions made under contracts, grants, and other arrangements for research, development, and demonstration, but also provide for waiver of certain rights. When the Government retains title, the contractor retains a nonexclusive, revocable, paid-up license in the invention and the right to file and retain title in any foreign country in which the Government does not elect to secure patent rights.

The Department's policies provide that the Secretary may waive the patent rights of the Government to any invention made or to be made under contract with DOE if he determines that the interest of the United States and the general public will best be served by such waiver. There are two types of waivers--advance and individual. An advance waiver is requested at the time of contracting. If granted, the waiver results in a contract provision in which DOE waives its patent rights to all inventions made or conceived under the contract. An individual waiver is requested when a particular invention is made or conceived under a contract.

DOE's legislation established four objectives in making waiver determinations:

--Making the benefits of the energy research, development, and demonstration programs widely available to the public in the shortest practicable time;

--Promoting the commercial utilization of such inventions;

--Encouraging participation by private persons in DOE's energy programs; and,

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--Fostering competition and preventing undue market concentration or the creation or maintenance of other situations inconsistent with antitrust laws.

DOE's regulations implementing its legislation also provide 13 specific criteria for the Secretary's consideration in granting advance waivers and 12 specific criteria for individual waivers.

WAIVER OF RIGHTS TO UNIVERSITIES AND SMALL BUSINESSES

Specific criteria in DOE's legislation and implementing regulations (issued July 13, 1977) provide for preferential treatment for small businesses and nonprofit education institutions. Waivers are generally granted to small businesses if the contract involves their privately developed technology.

For advance waivers, DOE considers approved technology programs the equivalent of manufacturing and marketing capabilities, thus providing universities an equal footing with industry in requesting advance waivers. However, an approved program is not sufficient in itself to justify an advance waiver. The waiver request must be considered in light of the four objectives and 13 criteria established by the regulations.

DOE does not usually grant individual waivers to contractors, including small businesses, for identified inventions if DOE continues to fund development. The only basis for considering an exception is the extent to which the contractor will cost share development. DOE places great weight on cost sharing in making its waiver decisions.

For nonprofit educational institutions with technology transfer programs and capabilities that have been approved by DOE, the Department also generally grants individual waivers when it does not continue funding development after an invention is identified.

DOE's decision on each waiver request is supported by a "Statement of Considerations" which spells out the reasons for either granting or denying the waiver. Each statement cites at least one objective and the specific criteria mandated by the legislation, and explains the basis for the recommended determination. All waiver determinations are coordinated with and concurred in by the appropriate program division.

INSTITUTIONAL PATENT AGREEMENTS

DOE interprets its legislation as prohibiting the use of institutional patent agreements for waiving title to universities having approved technology transfer capabilities. The rationale for the Department's interpretation is founded on its waiver policies which are derived from the legislation discussed above.

However, for universities having DOE approved technology transfer programs, the Department adopted an abbreviated waiver petition in April 1979. This petition was developed to limit the information universities would have to submit when petitioning DOE for waiver of domestic patent rights to an identified invention.

PROCESSING ADVANCE AND INDIVIDUAL WAIVERS

As of December 31, 1978, DOE had received 422 petitions for waivers from about 5,600 invention disclosures made on more than 6,000 contracts. The Department granted 216, or 51 percent; denied 46, or 11 percent; and closed or had withdrawn 48, or 11 percent. The remaining 112, or 27 percent, were in process. These consisted of 54 petitions for advanced waivers and 58 for individual waivers.

Three hundred of the 422 petitions received by DOE were for advance waivers and 122 for individual waivers. DOE gives processing priority to advance waiver petitions because they usually are made prior to contracting and, therefore, could affect contract negotiations. Thus, only 18 percent of the advance waiver petitions were in process on December 31, 1978, while 48 percent of the individual petitions were in process. With a caseload of 112 waiver petitions in process at the end of 1978, DOE was about one year behind in processing.

We analyzed processing time on 30 individual waivers which DOE identified as calendar year 1977 cases. The Department's processing time for closed cases ranged from three to twenty-five months, averaging about 13 months. Determinations on seven cases had not been rendered as of December 31, 1978. These petitions had been outstanding from 14 to 29 months, averaging 19 months from the date the petition was received by DOE.

Analysis of DOE's 1977 and 1978 determinations disclosed that 121 waivers were granted and 49, or 40

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percent, were to small businesses and universities. During this same period DOE denied 17 requests, of which 5, or 29 percent, were petitions of universities. Two university petitions were denied without prejudice because the Department was continuing to fund the invention. No small business petitions were denied.

CASE STUDIES

We reviewed 13 cases where contractors or inventors petitioned DOE for waiver of rights to identified inventions. Two cases were reviewed at the request of the Senate Subcommittee on the Constitution. The other 11 cases were selected because they were the oldest cases open when our review commenced in October 1978. During our review, 10 of the 13 petitions were approved, one was denied without prejudice (the contractor can petition again after DOE ceases project funding) and one was closed because the inventor failed to submit the required information. The remaining case also was closed because the petitioner did not submit required information but was reopened upon request for reconsideration. The time required to make determinations on the cases ranged from 10 to 41 months, averaging about 22 months from the time DOE received a formal petition.

We found the reasons for the delays in making determinations varied from case to case. In three cases the delays were attributable to DOE.

One case involved a vortex gas liquid heat exchanger developed by an employee of Sandia Laboratories. The inventor filed a waiver petition in February 1976. In June 1976, the Division of Military Applications informed the General Counsel's office at headquarters that the invention was not a subject invention conceived with DOE funding and that neither the Department nor Sandia planned to further develop or commercialize it. DOE, however, did not notify the inventor until almost two years later, in February 1978, that it would assert no rights in the invention. DOE personnel attributed the delay to an administrative oversight caused by the press of other business. They also pointed out that the inventor did not pressure DOE to resolve the case.

In another case, Texas instruments, Inc. invented a material for solar absorption surface panels and petitioned for a waiver in September 1975. In November 1976, the Department's Chicago patent office recommended to the General Counsel's

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office that a waiver be granted. The Chicago office believed that a waiver would make the invention available to the public in the shortest time and would also promote the commercial utilization of the invention. However, the waiver was not granted until February 1979, or 41 months after it had been requested. A significant portion of the delay was attributed to obtaining the program office's assessment of DOE's plans for further funding and concurrence in the waiver.

In the third case (selected by the Subcommittee), Stanford University requested a waiver in November 1976 to a fast transient digitizer device developed by an employee at the Stanford Linear Accelerator Center. In its petition, Stanford claimed that the device was not a subject invention. The University, however, had not previously informed DOE of this in its invention disclosure report. In response to a Department inquiry, Stanford advised in April 1977 that it wanted full domestic and foreign rights to the invention but was not sure whether filing patent applications would be economically justified. During the same month, DOE's California patent office recommended to its General Counsel's office that the waiver be granted. The office noted that the invention was being fabricated and tested for potential use in the Department's weapons testing program under a contract with EG&G, Inc., at a DOE-owned, contractor operated facility. EG&G, however, was not developing the device to the point of commercial application and did not plan to commercially manufacture the device.

In August 1978, DOE informed Stanford that its refusal to file a patent application on the invention until after the waiver determination could be viewed as a lack of intent to commercialize. DOE subsequently denied the waiver without prejudice on January 3, 1979, on the basis that it was still funding the invention. Case records indicate that nothing occurred on this case for a ten month period (October 1977 through July 1978), and the invention was being developed by EG&G largely due to the inventor's efforts. Over 25 months elapsed between Stanford's request for waiver and DOE's denial.

The second case identified by the Subcommittee for our review involved Purdue University. Purdue requested a waiver on September 29, 1977, to an invention made under a DOE contract and a National Science Foundation (NSF) grant. The invention consisted of a selective solvent extraction process utilizing cellulosic materials.

In October 1977, Dow Chemical expressed commercial interest in the solvent involved in the process. In a letter to the inventor in January 1978, DOW reaffirmed its interest in the solvent technology, but stated that it would prefer to wait until it had a clearer definition of the patent situation from DOE and NSF before beginning work. Purdue did not inform DOE of Dow's interest in the solvent.

In January 1978, DOE's Chicago patent office, recommended to the General Counsel's office that the waiver be granted. However, in February 1978, the Division of Solar Technology objected because the Division had awarded Purdue a new $220,000 contract to further develop the invention.

NSF released its interests in the invention to DOE in April 1978. Congressman Fithian of Indiana informed DOE in April 1978 of the State of Indiana's interest in the invention and urged that the waiver be granted. Also, in April 1978, an Indiana based firm informed DOE that it had indicated to Purdue that it would commit $3.8 million to build a plant to prove the commercial feasibility of the invention. According to Congressman Fithian, this firm had also applied for a Federally guaranteed loan for this purpose.

In June 1978, Congressman Fithian informed DOE that the State of Indiana would make $750,000 available to Purdue on July 1, 1978, to pursue scaled-up research on the invention. On July 24, 1978, or 10 months after Purdue petitioned, DOE granted the waiver contingent upon the State of Indiana granting the $750,000. Purdue accepted the terms of the waiver on August 21, 1978. Dow Chemical had informed Purdue on August 11, 1978, that it was no longer interested in licensing the solvent technology.

Delays on the remaining 9 cases were attributed as follows:

--For 5 cases, after requesting waivers, the petitioners submitted unsolicited proposals to DOE for funding to further develop the inventions.

--In 2 cases the petitioners failed to provide the required information.

--In 1 case there were problems in getting the Department of Defense to lift a secrecy order imposed by the Navy on the patent application.

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--In another case the inventor failed to obtain invention release from his employer, file a complete petition, and notify DOE of change of address.

LICENSING

DOE does not actively promote licensing of its 4,244 domestic patents and patent applications. As of March 31, 1979, 435, or about 11 percent of its inventions, had been licensed. The Department had issued 1,211 nonexclusive and 2 exclusive licenses. Because DOE does not follow-up with its licensees, the Department does not know how many of its inventions are being developed and marketed.

Foreign patent applications are filed by DOE on less than 20 percent of its domestic patents. The Department maintains approximately 2,000 foreign patents on about 500 of its inventions. In calendar year 1978 DOE's royalties from foreign licenses on eight inventions totaled about $174,500. Domestic patents are licensed royalty-free.

MARCH-IN RIGHTS

The Nonnuclear Energy R&D Act specifies the minimum rights DOE must acquire under each waiver. These include the following march-in rights:

--The right to require the contractor to license others at reasonable royalties if the invention is required for use by Government regulation, or is necessary to fulfill health, safety, or energy needs;

--The right to terminate the waiver in whole or in part if the contractor is not taking effective steps necessary to commercialize the invention, or will not take such steps within a reasonable time; and

--The right to require licensing at reasonable royalties, or to terminate the waiver in whole or in part if it is shown at a public hearing held 4 years after the grant of a waiver that the waiver had tended to violate the antitrust laws, or the contractor has not taken, and is not expected to take, effective steps to commercialize the invention.

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DOE's nuclear activities are also covered because similar provisions are a basic part of the Presidential Memorandum and Statement of Government Patent Policy and the Federal Procurement Regulations.

DOE's regulations stipulate that the normal exercising of its march-in rights requires the licensing of others rather than terminating the waiver. Contractors have maintained that the possibility of DOE terminating the waiver serves as a deterrent for investing risk capital in commercialization. DOE believes, however, that if the contractor is investing money in the development of the invention, it should feel assured that the waiver cannot be terminated unless there is a violation of the antitrust laws. DOE said that, overall, its contractors have not found march-in rights retained by the Government particularly objectionable and declared that these provisions are not a serious impediment to the Department's contracting function.

DOE said that march-in rights to protect the public's interest were developed to take care of and address the patent policy issues of contractor windfall profits, suppression of technology, and the detrimental effects to competition from granting contractors rights to inventions. The Department believes that march-in rights, although available to the Government for more than 10 years, have not been utilized because such problems are illusionary and not actual. If and when negative effects result from allowing a contractor to retain title to an invention of commercial importance, march-in rights are there to address them. Otherwise, DOE believes they will never be used.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PATENT POLICIES AND PROCEDURES

On April 11, 1953, the Federal Security Agency and other related agencies were consolidated into the Department of Health, Education, and Welfare (HEW). The patent regulations of the Federal Security Agency served as the model for the Department's existing regulations (45 C.F.R. Parts 6-8). Although the Department's regulations have been revised to incorporate the objectives of the Presidential Memorandum and Statement of Government Patent Policy and other special provisions affecting HEW, the regulations have not changed philosophically from their early years.

In general, HEW's regulations provide discretion to the Assistant Secretary for Health to

1) Permit an organization (whether or not for profit) to retain rights to inventions identified during the performance of either HEW grants or contracts.

2) Enter into an Institutional Patent Agreement (IPA) with a nonprofit organization whose patent policies are consistent with HEW's aims and the public's interest. An IPA provides the organization first option to future inventions made under HEW grants.

In 1958 the Department's regulations were amended to permit commercial concerns to retain the first option to future inventions when conducting cancer chemotherapy drug research under HEW contracts. This step was needed to help ensure the participation of the best qualified pharmaceutical firms, following indications that the industry would not participate without such an amendment. This exception, however, has been denied to newer drug development programs in the National Institute of Drug Abuse and the National Institute of Child Health and Human Development. According to HEW, industry participation has been difficult to obtain because of the Institutes' inability to guarantee rights to future inventions.

The Department's regulations also parallel and incorporate by reference Executive Order 10096, which governs allocation of Government employee inventions. Disposition of substantially all HEW employee inventions results in Government ownership. These inventions comprise a major portion of the Department's patent portfolio and are available for licensing.

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GAO REPORT ON HEW PATENT PRACTICES

A long period of HEW uncertainty over the discretionary allocation to the innovating organization of inventions resulting from Department funded grants and contracts was brought to a close by GAO's report to the Congress, "Problem Areas Affecting Usefulness of Results of Government Sponsored Research in Medicinal Chemistry", August 14, 1968.

GAO reported that HEW's practice of retaining title-in-the-Government for inventions resulting from research in medicinal chemistry was blocking development of these inventions and cooperative efforts between the university and commercial sectors. GAO found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry because these manufacturers were unwilling to undertake the expense without some possibility of obtaining on a timely basis exclusive rights to further development. GAO criticized HEW for its failure to use the discretion permitted by its regulations in either entering into IPAs or making timely determinations on requests for greater rights after identification of inventions.

In response, the Department reinstated its IPA program, revising and standardizing its agreement to ensure uniform treatment of institutions. In September 1975 the Federal Council for Science and Technology endorsed a modified HEW IPA program for discretionary use by all Executive Branch R&D agencies and a July 1978 Federal Procurement Regulation provided guidance on IPA use. As of December 1978 the Department had implemented IPAs with 75 institutions.

In 1974 HEW surveyed individual petitioning institutions and institutions with IPAs which had obtained greater rights to inventions in the performance of HEW-funded research since the GAO report. The institutions reported that 78 exclusive and 44 nonexclusive licenses had been negotiated under patents and applications filed on 329 inventions. HEW estimated that the licensees committed approximately $75 million of private risk capital to develop these inventions. By the end of fiscal year 1976 the number of HEW-funded inventions held by institutions had increased to 517.

The institutions also reported, however, that the rights to over 60 percent of the inventions they retained had not been licensed and may never be licensed. Thus, the retention of rights by institutions does not guarantee that the inventions will be developed and marketed.

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Following the GAO report, the Department's regulations were amended to provide for exclusive licensing. As of December 1978, 19 exclusive and 90 nonexclusive licenses had been granted. HEW's Patent Branch said that, although it has done its best to license the Department's patent portfolio, it has not been able to duplicate the technology transfer accomplished by the universities. Successful technology transfer, the Branch said, requires the presence and cooperation of the inventor and/or inventing organization as an advocate of its invention or the possibility of licensing is severely decreased.

CASE STUDIES

We reviewed five cases at the request of the Senate Subcommittee on the Constitution. One involved HEW's licensing of a small business firm. The other four cases concerned individual waivers to nonprofit institutions.

Licensing Case

American Science and Engineering (AS&E), a small business firm, petitioned HEW in September 1976 for an exclusive license to its circle array tomography (CAT) scanner system and associated cable handling mechanism. In November 1976 the National Cancer Institute (NCI), which had funded the project, favored issuance of a nonexclusive license to AS&E. In December NCI requested that an exclusive license be granted. This request followed a meeting between the HEW Patent Branch, NCI, and AS&E officials where the company contended that their new type CAT scanner could not be easily and cheaply adapted by other manufacturers. Also in December, AS&E petitioned HEW for foreign patent rights, which the Assistant Secretary for Health granted in January 1977.

In an internal memorandum dated February 1977, the National Institute of Neurological and Communicative Disorders and Stroke questioned the proposed issuance of an exclusive license to AS&E because another company had developed a similar system. The Office of the Assistant Secretary for Health, however, following the recommendation of the National Institutes of Health Inventions and Patents Board, advertised in the Federal Register on April 7, 1977, that it intended to grant AS&E an exclusive license unless, before June 6, 1977, the Department received either statements as to why the license would not be in the best interests of the United States or applications for nonexclusive licenses.

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Although statements and/or license applications and notices of interest in filing applications were received from seven firms (none of which were small businesses), the National Institutes of Health Inventions and Patents Board recommended at a meeting on June 10, 1977, that a 3-year limited exclusive license be granted to AS&E. After granting the license on June 17, 1977, the Assistant Secretary for Health cancelled both the license and AS&E's foreign rights on July 21, 1977.

Regarding cancellation of the license, the Assistant Secretary wrote:

> I am compelled to take this action because the limited exclusive license was granted in violation of the applicable policies and regulations. Under the Presidential Statement on Government Patent Policy (36 F.R. 16887, August 26, 1971) and the Federal Procurement Regulations (41 CFR 1-9.107-3 (a)) which implement that Policy Statement, the Department did not have authority to grant AS&E a limited exclusive license to practice the inventions developed under its contract with the National Cancer Institute unless that license was a necessary incentive to bring the inventions to the point of practical application or unless the Government's contribution to the inventions was small compared to that of AS&E. The responses to the notice of intent to grant an exclusive license to AS&E, which appeared in the Federal Register (42 F.R. 18151, April 7, 1977), established that an exclusive license was not a necessary incentive to bring the inventions to the point of practical application. The contract under which the inventions were made was fully funded by the National Cancer Institute and thus the Government's contribution to the inventions was not small compared to that of AS&E. The exclusive license to AS&E was therefore granted without authority and in violation of the Presidential Statement on Government Patent Policy and the Federal Procurement Regulations.

The General Accounting Office believes the AS&E case demonstrates that an agency operating under the Presidential

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policy can move in almost any direction when determining rights to inventions.

Waiver Cases

One case involved two inventions by University of Texas scientists relating to the hormone thymosin used for treatment of malfunctioning immune systems which can make people susceptible to arthritis and several kinds of cancer. These inventions were made with National Institutes of Health (NIH) funding and reported to HEW in September 1977, when the University also petioned for rights. This was over four months after the University obtained a patent on one invention and over 10 months after it filed a patent application on the second invention.

HEW's Patent Branch received NIH comments in October and November 1977 and sent a determination to the Assistant General Counsel for review in December. This determination granting rights to the University was not acted on by the Assistant General Counsel until August 30, 1978, when it was sent to the Assistant Secretary for Health, who signed it in September.

It appears that development of the inventions was not impaired because the Assistant General Counsel delayed granting rights to the University. In July 1977 the inventor reported that a drug firm's studies of the invention showed that the compounds are not toxic.

In another case a Columbia University scientist with an NIH grant invented a solution for treatment of persons with severe burns. Although the University filed a patent application in December 1974 and the invention was published in International Surgery's June-July 1975 issue, the invention was not reported to HEW until March 1976.

Research Corporation, an invention management firm, together with Columbia petitioned HEW for rights in October 1976. Research Corporation estimated that it would take from 5 to 8 years and an investment of about $850,000 to market the invention. Therefore, a time limited exclusive license would have to be offered before a commercial firm would make such an investment.

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NIH informed HEW's Patent Branch in December 1976 that it did not object to Columbia and Research Corporation retaining title, but the Patent Branch did not send such a determination to the Assistant General Counsel until October 1977. Patent Branch officials could not explain why this delay occurred.

The Assistant General Counsel then delayed the determination another 11 months until September 1978 when it was sent to and signed by the Assistant Secretary for Health.

A third case involved an invention entitled, "Undecapeptide and Tumor Assay." This invention, discovered by the Weizmann Institute of Science under an NIH contract, could be useful in a follow-up for post-operative diagnosis and prognosis on cancer patients. The Institute first reported the invention to HEW in 1974, when the Department decided that patent protection was not warranted. Subsequently, in June 1976, the full results of the research were published in scientific journals.

The following October a drug firm approached the Weizmann Institute indicating it would be willing to prepare, file, and prosecute a U.S. patent application as consideration for an option to an exclusive license for some limited period. The Institute requested HEW's permission to file a U.S. application in November 1976. The Department granted permission on December 1, 1976, and the application was filed later that month. Through Yeda Research and Development Company Ltd., its patent agent, the Institute petitioned HEW for rights in February 1977. In the petition, Yeda stated its intention to grant the drug firm exclusivity as an incentive to market the invention.

In response to a HEW Patent Branch request for additional information, Yeda informed the Department in August 1977 that from two to three years and from one to five million dollars would be required to develop the invention to the point of submission to the Food and Drug Administration. NIH, in its comments to the Patent Branch in September 1977, stated that it was virtually impossible to predict the usefulness of the invention and its role in diagnostic testing. NIH said that it had no objection to permitting Yeda to retain title and that it was unlikely that the invention would be developed without an exclusive license to a potential manufacturer. On November 4, 1977, the Patent Branch sent a determination granting rights to Yeda to the Assistant General Counsel for review.

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However, on September 8, 1978, the Assistant General Counsel sent a determination retaining title for the Government to the Assistant Secretary for Health. The Assistant General Counsel found no legal justification for the waiver, noting that Yeda had not promoted the invention and would not supply any of the risk capital needed to develop it. The drug firm had assisted Yeda with the patent application and waiver petition and would develop the invention. The Assistant General Counsel further found that exclusive licensing appeared necessary and recommended retaining title for the Government. On January 24, 1979, the Assistant Secretary denied Yeda's petition.

In the remaining case two University of Arizona scientists invented a potential method for testing the effectiveness of drugs in individual cancer cases without administering the drugs to the patient. The University reported the invention to HEW's Patent Branch and requested a waiver in July 1977. The invention was also published in the July 1977 issue of Science.

NIH in September 1977 informed the Patent Branch that it did not object to the University retaining title to the invention, but added that it had contracts with other institutions for related research and that commercial interest would be high enough that an exclusive license would not be needed to stimulate development of a marketable product. In reply to a Patent Branch request, the University in October 1977 provided additional information for NIH evaluation, estimating that development would take from 3 to 5 years and would cost a licensee from $2,250,000 to $5,000,000. In November NIH informed the Patent Branch that the University's petition should be granted even though many questions regarding the invention's clinical utility were still unanswered. The Patent Branch on December 29, 1977, sent a determination granting title to the University to the Assistant General Counsel for review.

The Assistant General Counsel's office advised the Patent Branch in April 1978 that the petition would not be favorably considered in the near future and in September 1978 returned the determination to the Patent Branch for further evaluation. Meanwhile, in July 1978 the Patent Branch had learned of a potential licensee's interest in funding development of the invention in return for an exclusive license. The Patent Branch returned the determination to the Assistant General Counsel in November 1978. This determination, granting title to the University, was approved by the Assistant Secretary for Health on March 23, 1979.

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DEPARTMENT OF DEFENSE
PATENT POLICIES AND PROCEDURES

The policies and regulations of the Department of Defense (DOD) are based on the Presidential Memorandum and Statement of Government Patent Policy. Most DOD contracts allow contractors with an established commercial position to retain title to their inventions in accordance with Section 1(b) of the Presidential Policy.

Because nonprofit institutions lacked an established commercial position, DOD 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 the "special situations" provision of Section 1(c) of the Policy to put a title-in-the-contractor type of clause (license clause) in contracts with universities on a DOD list of nonprofit organizations with "approved" patent policies.

On August 29, 1975, DOD, with no advance notification, issued Defense Procurement Circular (DPC) 75-3, revising its Armed Services Procurement Regulation (ASPR). This circular terminated the Department's use of its list, and thereby did away with the approved patent policy concept as a special situation under Section 1(c). In lieu thereof, the circular provided that any prospective contractor having an effective program for the transfer of technology, as demonstrated by its licensing of inventions, would be entitled to a license clause in a contract where a deferred patent rights clause would otherwise be appropriate.

Educational and nonprofit institutions were required to demonstrably have such programs in order to be entitled to the license clause, whether or not their patent policies had previously been approved. Additionally, the revision required that the work to be performed under the contract must be in a field of technology directly related to an area of technology in which the university had an effective licensing program.

The Senate Subcommittee on the Constitution asked GAO to examine DOD's decision to discontinue its special situations treatment of nonprofit institutions. We found that the DOD revision was intended to implement the revised Presidential Memorandum and Statement of Government Patent Policy and was the subject of an ASPR case established in March 1975.

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At an ASPR Committee meeting in May 1975, the Patents Subcommittee Chairman briefed committee members on the proposed revisions. The case record shows:

> The OASD (I&L) Staff Representative present indicated that he no longer objected to the publication of the revised ASPR provision and recommended that the normal requirement for Industry comments be waived. The Subcommittee Chairman then briefly described the differences between the proposed ASPR coverage and the recently published FPR coverage. As a result of the discussion at this meeting, the Committee agreed that the finally approved coverage should be published in the next DPC; that a letter should be prepared by the Subcommittee Chairman to the Industry Associations normally solicited for comment, informing them that their comments were not requested prior to publication because the ASPR coverage parallels the FPR and Industry was provided two opportunities to comment on that coverage. Moreover, DOD representatives were part of the group that developed the FPR coverage and therefore were able to review the Industry comments on that coverage.

On July 9, 1975, the Committee approved the ASPR revision, and reviewed and approved the letter to industry. This letter, subsequently dated August 29, 1975, was sent to educational and nonprofit institutions on DOD's list of universities with approved patent policies. The letter, which was signed by the Department's representative serving on the Committee on Government Patent Policy, did not explain DOD's rationale for not obtaining comments prior to publication of DPC 75-3.

In September 1975 the Committee on Government Patent Policy adopted the recommendations of its University Patent Policy Ad Hoc Subcommittee. That report basically recommended that all agencies of the Executive Branch provide universities and nonprofit organizations a first option of title retention to substantially all inventions generated by them with Federal support if they are found to have an established technology transfer capability.

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In November 1975 the California Institute of Technology replied to DOD's letter:

> ***the University community is confused and surprised by the fact the DPC 75-3 appears to move in substantially the opposite direction to the philosophies of and proposals made in the July 1975 report of the University Patent Policy Ad Hoc Subcommittee***. It is our understanding that DOD has strong representation on said Ad Hoc Committee.

The Institute also commented on DOD's implementation of the revised ASPR:

> We have already had several instances of attempting to qualify for a "license" clause in connection with individual contracts and grants. Apart from the fact that these procedures will materially increase the work load of contracting personnel on both sides, it would appear that the criteria being utilized in this area is counterproductive. Specifically, we are being required to indicate successful past licensing in the specific field of technology of each proposal. The net result, particularly in universities engaged in basic research and continually moving into new fields, will be to slowly diminish the areas in which a university contractor might qualify for advance waiver. It should be recognized that a successful licensing activity at a university provides a capability in all fields and that industrial representatives seeking new technology at universities are interested in all fields of technology in which the university may be involved. It is strongly urged that the Department of Defense reconsider the narrow interpretation placed upon the expression "directly related to the field of technology" as currently applied by Contracting Officers and DOD Patent Counsel, and accept the much more practical proposition that a well-organized and proven patent licensing program at a university can be effective in all fields of technology.

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Because of the additional administrative burden, many research institutions subsequently elected not to submit the information DOD required for the title retention clause. As a result, statistics published in the Federal Council for Science and Technology's Report on Government Patent Policy showed that there was an 80 percent increase in the use of deferred determination clauses by DOD 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 1 to more than 7 months to make those determinations.

The University Patent Policy Ad Hoc 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.

Despite its representation on the Ad Hoc Subcommittee which endorsed them, DOD has not implemented the use of Institutional Patent Agreements.

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
PATENT POLICIES AND PROCEDURES

NASA patent policies and practices are based on Section 305 of the National Aeronautics and Space Act of 1958, the 1971 Presidential Memorandum and Statement of Government Patent Policy, and Executive Order 10096. Section 305 provides that any invention conceived or first reduced to practice in the performance of work under a NASA contract becomes the exclusive property of the Government, unless the NASA Administrator determines that the interests of the United States will be served by waiving all or part of the Government's rights. Rights to inventions made in-house by NASA employees are determined by the agency pursuant to provisions of Executive Order 10096, dated January 23, 1950.

REPORTING AND EVALUATING INVENTIONS

Section 305 of the Space Act provides that NASA contracts contain provisions requiring reporting of inventions, discoveries, improvements, and innovations. NASA evaluates those for which it has or may acquire the right to file for a patent. This evaluation is basically a two step process and applies to both contractor inventions and inventions of its own employees.

The first step, basically a technological evaluation, is to determine the technical significance of the invention, its potential use by or for the Government, and its commercial potential. If further interest is justified, it is then evaluated for patentable novelty. This is basically a legal evaluation to determine whether a patent can be obtained, and if so, its scope. The determination to file for a patent is based on a composite of these two evaluations and is made by the NASA Patent Counsel. Once a domestic patent application is filed there is a review to determine whether foreign patent protection should be sought, and if so, in what countries.

As an incentive for the reporting of inventions, NASA makes a monetary award for each invention on which a patent application is filed. The amount of the award is based on consideration of such factors as the technological significance of the invention, its value to NASA in carrying out its programs, and the commercial use or potential of the invention.

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For calendar years 1959 through 1978, 37,474 invention disclosures were reported to NASA and 3,302 patents were issued. Excluding the 1,043 invention disclosures still being processed at December 31, 1978, NASA had obtained one patent for about each eleven inventions reported by its employees and contractors.

Section 305 also establishes a procedure for NASA to review all patent applications pending in the U.S. Patent and Trademark Office on inventions which appear to the Commissioner of Patents and Trademarks "to have significant utility in the conduct of aeronautical and space activities." Additionally, Section 305 provides procedures for a Board of Patent Interferences hearing to establish title whenever the NASA Administrator believes that an invention not reported to NASA was made under a NASA contract. From January 1959 through July 1977, NASA reviewed 9,990 applications and contested 174 of them. NASA succeeded in obtaining patent rights in 114 of these cases.

OWNERSHIP RIGHTS

NASA obtains rights to inventions reported by its contractors unless its Administrator waives these rights. The agency's waiver policy, established by Section 305 of the Space Act, is implemented by the NASA Patent Waiver Regulations (14 C.F.R. 1245.1). These regulations also incorporate the objectives and criteria set forth in the Presidential Memorandum and Statement of Government Patent Policy.

Rights to inventions made in-house by agency employees are determined by NASA based on provisions of Executive Order 10096, i.e. in the same manner as other agencies covered by this Order.

Inventions and Contributions Board

The NASA Administrator's waiver of rights may be to an individual invention or to a class of inventions, and is granted upon the recommendations of an Inventions and Contributions Board (ICB). The ICB is appointed by the Administrator and consists of a chairman and no less than six members who are senior NASA program officials. The ICB meets at least monthly and provides recommendations on waiver requests, licensing of inventions, and monetary awards.

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NASA Waiver Policy

NASA's Administrator is empowered to grant two types of domestic waivers. Advance waivers are those granted for any invention which may be made under a given contract. Individual waivers are those granted for inventions identified and reported subsequent to the start of a contract. The Administrator can also grant foreign waivers.

Advance waivers

NASA's ICB will recommend grant of an advance waiver unless

1) a principal purpose of the contract is to create, develop or improve products, processes, or methods which are intended for commercial use by the general public at home or abroad, or which will be required for such use by governmental regulations; or

2) a principal purpose of the contract is for exploration into fields which directly concern the public health, public safety, or public welfare; or

3) the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, or where the Government has been the principal developer of the field and the acquisition of exclusive rights at the time of contracting might confer on the contractor a preferred or dominant position; or

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

To recommend an advance waiver, the ICB must also find that the work called for under the contract is to build upon existing knowledge or technology; is to develop information, products, processes, or methods for use by the Government; and is in a field of technology in which the contractor has acquired technical competence directly related to an area in which the contractor has an established nongovernmental commercial position. These criteria are prescribed by the Presidential Memorandum and Statement.

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NASA's Patent Waiver Regulations also take into account the "exceptional circumstances" and "special situations" provisions of the Presidential Memorandum and Statement.

Examples of exceptional circumstances recognized by NASA include: a contract where participation of the contractor may only be secured through the grant of waiver and the contractor is deemed essential to a NASA program; a contract having as a principal objective the application of aerospace-related technology to other uses in accordance with an established NASA technology application program and where the grant of the waiver would materially advance this objective; or, a cooperative endeavor where the contract calls for a significant contribution of funds by the contractor to the work to be performed.

Also, in the case of an individual invention identified prior to contract execution, exceptional circumstances may be found (1) where waiver is a necessary incentive to call forth risk capital and expenditures to bring the invention to the point of practical or commercial application and (2) where either the contractor has established substantial equities at his own expense in the development of the invention or, the grant of an advance waiver will significantly advance availability of the invention to the general public.

Examples of special situations include: a newly formed company having a definite program for establishing a nongovernmental commercial position in the field of the contract or a directly related area; an established company lacking an established nongovernmental commercial position in the field of the contract or a directly related field, but having established plans and programs for achieving such a position; and an educational or nonprofit institution having an established patent policy and an effective program for acquiring rights to inventions and bringing the results of such inventions to commercial application by itself or through others.

For calendar years 1959 through 1978, NASA received 906 petitions for advance waivers. The Administrator granted 463. Contractors reported 216 inventions or classes of inventions (on which they intended to file patent applications) under these contracts.

Individual waivers

NASA's ICB will recommend grant of a waiver after identification and reporting where the Board makes the following findings:

1) The invention is not directly related to a governmental program for creating, developing, or improving products, processes, or methods for use by the general public at home or abroad.

2) The invention is not likely to be required by governmental regulations for use by the general public at home or abroad.

3) The invention does not directly concern the public welfare.

4) The invention is not in a field of science or technology in which there has been little significant experience outside of work funded by the Government, or where the Government has been the principal developer of the field and the acquisition of exclusive rights in the invention would not likely confer on the petitioner a preferred or dominant position.

The Board must also find that, in view of the petitioner's plans to bring the invention to the point of practical application, the incentives provided by waiver will increase the likelihood that the benefits of the invention would be readily available to the public at an early date.

If the Board is unable to make one of the four findings to support a waiver, the Board may still recommend that waiver of rights be granted by the Administrator if it finds that such waiver is a necessary incentive to call forth risk capital and expenditures to bring the invention to the point of practical application, or that the Government's contribution to the invention is small compared to that of the contractor.

NASA contractors reported 31,357 inventions to the agency for calendar years 1959 through 1978. They requested 1,366 waivers and the Administrator granted 1,035. About 3 percent of the inventions reported were waived.

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PATENT UTILIZATION

NASA believes that one of its objectives under the Space Act is to enhance the leadership of the United States in aeronautical and space activities and make the results of these activities available to the public. Thus, NASA has implemented various programs to promote the commercial development and utilization of aeronautical and space technology. NASA said its patent policies and procedures have been adopted to augment these programs and its decisions regarding the allocation and utilization of patent rights are made with this objective in mind.

Patent Utilization-Licensing

NASA's program for licensing inventions to which it has acquired title is based on Section 305 of the Space Act and is implemented by NASA Patent Licensing Regulations (14 C.F.R. 1245.2). Both nonexclusive and exclusive licenses are available.

In order to locate prospective licensees who want to commercialize an invention, NASA uses a variety of methods to inform the public of its technology available for licensing. Abstracts of the agency's inventions appear in its publications. Additionally, NASA inventions available for licensing are listed in the Federal Register and the Official Gazette of the U.S. Patent and Trademark Office.

The National Technical Information Service also publishes a weekly journal entitled "Government Inventions for Licensing" which includes NASA abstracts and licensing information. NASA said that it has not been able to identify or relate any licensing inquiries for agency owned inventions to the NTIS journal. NASA also said it holds and participates in licensing conferences and workshops and its Industrial Applications Centers disseminate both abstracts of inventions available for licensing and information on how to obtain licenses.

NASA promotes nonexclusive licenses, but may grant exclusive licenses if it determines that the invention is not likely to be brought to commercialization under a nonexclusive license or by further Government funding and that the exclusive license will provide the necessary risk capital to achieve commercial use of the invention. NASA normally does not require royalties for a nonexclusive license but may for an exclusive license.

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Domestic Licensing

Each application for a domestic license is initially reviewed in NASA's Office of General Counsel. If the application conforms to the regulations and the license requested appears appropriate, the application is forwarded to the Inventions and Contributions Board. The ICB recommends to the Administrator whether a nonexclusive or exclusive license should be granted and any terms and conditions of the license.

If a determination is made to grant a nonexclusive license, the terms and conditions are negotiated by the Office of General Counsel. If the determination is made to grant an exclusive license, notice of this intent, along with the identification of the invention, licensee, and special terms and conditions, are published in the Federal Register. The exclusive license will be granted unless, within 30 days of the notice, a statement is received from any person setting forth reasons why it would not be in the interests of the United States to grant the proposed license, or an application for a nonexclusive license is received which states that the invention is likely to be brought to practical application within a reasonable period of time.

As of December 31, 1978, NASA had 251 licenses in force on 133 of its 3,512 domestic patents and applications. Nine of these licenses were exclusive and 242 nonexclusive.

NASA negotiates a specific date for commercialization with its licensees and requires that the invention be practiced for the term of the license, which usually is less than the term of the patent. Licensees are required to report annually on their progress in commercializing the inventions. NASA recently inquired about commercialization efforts of its 242 nonexclusive licensees; 138 or 57 percent responded. Fifty, or about 20 percent of the total licensees, reported they were pursuing development and marketing efforts.

Foreign Licensing

Inventions on which NASA obtained patents in foreign countries are available for licensing in those countries. NASA's foreign licensing objectives are to further the interests of U.S. industry, enhance U.S. economic interests, and advance U.S. international relationships.

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Foreign licenses can be either exclusive or nonexclusive. In granting foreign licenses, preference is given to the applicant who has previously been granted a license for the invention in the United States. NASA requires royalties or some other consideration under all foreign licenses.

As of December 31, 1978, NASA had 787 foreign patents on 184 inventions. Fifty-nine were licensed exclusively to 7 licensees.

Patent Utilization-Waivers

Where NASA waives property rights to inventions made under its contracts, the Inventions and Contributions Board periodically monitors the waiver recipients. Through 1977 NASA waived rights to 1,046 inventions, but subsequently voided 258 of these. NASA said that 193 or about 18.5 percent of its waived inventions were utilized or commercialized.

NASA's data on 523 inventions waived prior to 1975 showed: 84 in use in a commercial process, product, or service; 15 fully developed with Government use; 91 under development; 68 available for licensing; 228 without active commercialization or licensing efforts; and 37 obsolete.

Waiver recipients reported that the 15 fully developed inventions were ready for commercial use, but they had found only Government use in addition to NASA's use.

Most of the 91 inventions under development were being developed by the waiver recipient. Where development was being done by licensees, the inventions resulted primarily from university and nonprofit research organizations.

The only effort being undertaken for 68 inventions was to find a licensee. Many of these inventions resulted from universities and research organizations which did not have manufacturing capability. In some cases where the waiver recipient was a manufacturer, the invention was reported as being outside of its business or manufacturing activity.

NASA believed the 228 inventions without commercialization or licensing activity may have some utility. The agency, however, attributed the lack of interest in these to the following: no commercial need or market; inventions too costly to develop; inventions not cost competitive; technology too sophisticated;

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market too small to justify production; funding not available; and invention shelved indefinitely because of other priorities.

Thirty-seven inventions were obsolete because (1) other or better products and methods were available; (2) they were superceded by other technology; (3) they were not compatible with present systems; or (4) the state-of-the-art had passed them by.

MARCH-IN RIGHTS

NASA includes march-in rights in its waiver instrument. The Administrator reserves the right to require the granting of a nonexclusive or exclusive license for the practice of the invention:

1) Unless, within 3 years after the patent is issued, the waiver recipient has taken effective steps to bring the invention to the point of commercial application and thereafter continues to make its benefits reasonably accessible to the public, or

2) Unless, within 3 years after the patent is issued, the waiver recipient has taken effective steps to make such patent available for licensing on terms that are reasonable, or

3) As may be appropriate to satisfy governmental regulation for public use or as may be necessary to fulfill health or safety needs or other public purposes.

Under the terms of the waiver instrument, the recipient agrees, if requested by NASA, to provide a written report to the agency not more often than annually on the commercial use of the invention. NASA evaluates these reports to ascertain compliance with conditions of the waiver.

NASA has not enforced its "march-in" rights by directing waiver recipients to license others under the conditions specified in the waiver instrument. Rather, when the recipient does not comply with requirements, the waiver is voided and title to the invention is taken back by NASA. The invention then is made available for licensing to third parties under the agency's licensing regulations. On December 31, 1977, NASA had voided

258 waivers. All of these were voluntary on the part of the waiver recipient. NASA said that most of the waivers were voided at the request of the recipient and not for failure to comply with "march-in" provisions in the waiver instrument.