"(C) waive, in whole or in part, any right of ownership which the Government may have under any other statute to any inventions made by a collaborating party or employee of a collaborating party under the arrangement; and

"(D) to the extent consistent with any applicable agency requirements, permit employees or former employees of the laboratory to participate in efforts to commercialize inventions they made while in the service of the United States.

"(3) Each agency shall maintain a record of all agreements entered into under this section.

"(b) DEFINITION.-- As used in this section, the term--

"(1) 'cooperative research and development agreement means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government provides personnel, services, facilities, equipment, or other resources (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the agency, except that such term does not include a procurement contract or cooperative agreement as those terms are used in

17 U.S.C 105 is not applicable to the results of such arrangements an

"(A) to enter into cooperative research and development arrangements (subject to such regulations or review procedures as the agency considers appropriate) with other Federal agencies, units of State or local government, industrial organizations (including corporations, partnerships and limited partnerships), public and private foundations, non-profit organizations (including universities), or other persons (including licensees of inventions owned by the Federal agency); and

"(B) to negotiate licensing agreements under section 207 of title 35, United States Code, or other authorities for Government-owned inventions made at the laboratory and other inventions of Federal employees that may be voluntarily assigned to the Government.

"(2) Under arrangements entered into pursuant to paragraph (1), a laboratory may--

"(A) accept funds, services, and property from collaborating parties and provide services and property to collaborating parties;

"(B) grant or agree to grant in advance to a collaborating party patent licenses, assignments, or options thereto, in any invention made by a Federal employee under the arrangement, retaining such rights as the Federal agency considers appropriate;

OR Copy Right

OR warning

Any assistance to House Dept of Commerce Appropriations Bill

The Search Files

It is my understanding that patent search files within the U.S. Patent and Trademark Office (PTO) are critically inadequate because of poor subject matter classification and low integrity as to content completeness. Please size this situation for me by answering the following questions as completely as you can:

How important is the search file to members of the public that need to make patent related searches?

Critically important - decisions on whether or not to invest in innovations or not are made based on its contents.

What is the potential legal effect of either the public or a patent examiner relying on a search file where documents are missing?

Invalid patents can be granted, frequency of litigation can increase and malpractive suits can result.

Does the fact that the files are missing significant numbers of documents have a negative impact upon U.S. industrial innovation?

Yes. The practical result of missing documents is a loss of confidence in the validity of patents with a consequent reduction in the effectiveness of the patent system in enhancing innovation.

Is anything currently being done to improve the integrity of the files?

Yes. The practical efforts in this area are directed towards a limited program to check and correct the integrity of some of the most active areas in the Office's U.S. patent search files and to placing security labels on all newly issuing patents in their original and cross-referenced locations in the Public Search Room file. Much more needs to be done by way of improving integrity. Other alternatives such as microform files are also continually being explored to insure that the PTO has the most efficient and effective search file system.

How often is each subclass file checked to see if any documents are missing?

Under our present program only the more active subclasses (less than 5% of all the files annually) are being checked while some of the less active areas of the search file may never be checked. If every subclass were checked in order, it would take about 20 years to review the entire search file under the present search file integrity program. Due to lack of funds, no integrity check is presently made of the foreign patents in the search file. In fact, no inventory of the contents of the foreign patent search file exists.

Are the resources adequate?

No they are not adequate to maintain the search file at an acceptable level of integrity.

In your opinion are new programs or resources necessary to upgrade the patent files within a reasonable period of time?

Yes.

What funding and headcount resources beyond that available to you now at the current budget level would you need to correct the patent files within a reasonable period of time?

To do this we would need approximately $5.5 million with about 150 additional staff years. This excludes approximately $2 million needed to initiate the development of a full text computer assisted search system.

I understand that the security system in the PTO Public Search Room was installed to safeguard against integrity degradation of the patent search files.

Please evaluate the security system?

The security system has had a salutary effect on the public search file. It has reduced the incidence of inadvertent removal of documents by the public, and in those cases involving intentional pilferage, it has established a basis for revoking the search privileges of numerous violators.

Although the public has generally responded to the security system in a highly supportive manner, the potential for abuse will always be present. Since only a small portion of the file has been brought under the system, the full impact of the system cannot be measured.

What on-going costs are incurred through its operation?

The annual cost of operating the complete security system, including guard service, sensing equipment, security labels and labor charges, has averaged approximately $145,000.

Can it be improved upon and, if so, at what level of funding and with what expected results?

Yes. A short range solution to the security of the existing search file would be to accelerate the process of affixing security labels to all patent documents that comprise the public search file. Presently only 20% of this file is protected by the security system. At the current rate less than 225,000 patent documents can be brought under the security system each year. Further degradation of the search file would undoubtedly occur during that time. The entire file could, however, be protected during fiscal year 1980 at a funding level of approximately $1.5 million.

A long range and more effective solution is dependent upon microform technology. Although several alternatives are being studied, the present state-of-the-art is such that no immediate application suitable to our requirements is likely to be found during the next several years. The microform approach has enormous potential for achieving absolute integrity of the contents of our total search file and, accordingly, will continue to be pursued.

How would you prioritize the need to correct patent search files as compared to the need to rectify other PTO problem areas?

High - at or near the top of our list of priorities.

The Patent Cooperation Treaty

The U.S. is now a participating member of the recently formed Patent Cooperation Treaty (PCT).

What impact if any do inadequate U.S. patent search files have upon the standard of effort by the U.S. in the PCT?

Adverse. Inadequate search files may result in an inability to meet minimum documentation and search requirements under the Patent Cooperation Treaty (PCT) and will reduce the usefulness of the PCT to users and patent offices.

What monies, direct and indirect, of the current PTO budget do you attribute to participation in the PCT?

$1.084 million will be spent in FY 1980 for performance of functions under the Patent Cooperation Treaty based on estimated receipts of 6600 Treaty applications.

What amount has the PTO appropriations been increased due to U.S. participation in the PCT?

Zero.

Provide any other information that you think would be helpful in my better understanding PTO related problems that are negatively impacted by inadequate funding and headcount resources. In providing such information, specify in detail the resources needed to meet a stated objective to be reached by way of a specified plan of action.

The Patent and Trademark Office budget needs relate to four goals (and problem) areas.

(1) The issuance of quality patents that will instill confidence in their validity by the patentee, the investor, the courts, etc., so that the subject of the patent will be developed and commercialized where warranted (confidence in the validity of patents is declining).

(2) The prompt issuance of patents (within an average of 18 months of filing) to speed the development of the technology and enable others to build upon it, (pendency is 20 months and rising at the rate of 2 months/year) and;

(3) adequate dissemination of new technology to users (dissemination is presently limited and of limited effectiveness).

(4) The prompt issuance of trademark registrations (within an average of 13 months of filing) to stimulate industrial innovation and facilitate the marketing of products and services (pendency is over 17 months and is projected to double by the end of FY 1980; applications filed increased 50% over the 3 year period 1975 to 1978 and are continuing to increase at the rate of 9% per year).

An additional $14,267,000 would be required in Fiscal 1980 in order to properly (1) upgrade the quality of patent examining to an adequate level ($5,575,000) (2) achieve in a reasonable period of time an average application pendency of about 18 months ($5,498,000), (3) provide for a more effective dissemination of patented technology ($1,825,000) and (4) achieve trademark pendency of 13 months over a reasonable period of time ($1,369,000). This estimate reflects a first year start-up of a long range program designed to meet the above stated objectives over a period of years, particularly in the case of achieving average patent application pendency of about 18 months. Funding in addition to the first year start-up costs identified above will be required in subsequent years. It is assumed that patent application receipts would rise slightly each year and that trademark application receipts would continue to increase at a conservative 7% rate.

The Patent Examining Corps

It is my understanding that the number of patent examiners has been decreasing for the past four years.

Why is it being done?

The number of patent examiners has been decreasing because of budgetary constraints.

This year, the time a patent application pends will increase by several months. Will the number of patent examiners decrease again this year? If so, why?

The number of examiners will decrease again in FY 1980, due to the inability of the PTO to pay for any replacements for normal examiner attrition.

Your statement says the goal of the Patent and Trademark Office is to allow patent applications to pend only 18 months. You are not meeting that goal. How many examiners are needed to meet the 18 month goal? How much additional funding would be required? How much would it cost in this regard to stabilize pendency time at 20 months?

We would have to hire about 180 examiners in both fiscal years 1980 and 1981 and hire slightly more than we have through attrition in each year thereafter and (2) provide for a full overtime program in FY 1980 and 1981 to keep pendency from rising any further and by FY 1982 begin to reduce average pendency to about 18 months by 1987. As pointed out in response to another question above, the first year cost of a program to stabilize and later begin to reduce pendency would be about $5.5 million and another $3.1 million the following year. The budget increase is spread over two years because the Patent and Trademark Office would be unable to assimilate all of the increase within one year.

When and How to File Patent Applications on University Discoveries - Considerations That Apply

1) conception (prior to or in the course of a research project)
2) documentation of the invention
   a) laboratory notebooks - witnesses
   b) invention disclosure forms - witnesses
   c) reports to sponsor, etc.
3) reduction to practice
   a) actual
   b) constructive
4) novelty search
   a) literature and open market
   b) patent art
5) evaluation of invention in view of prior art. (realistic appraisal)
   a) potential market
   b) commercial interest
6) what is to be licensed, sold, or leased - claims to cover
   a) product
   b) process
   c) royalty base
   d) royalty rate
7) decision to file -- on what and when
   a) product
   b) process or method
   c) product-by-process, etc.

NJL

RESEARCH CORPORATION

405 LEXINGTON AVENUE, NEW YORK, NEW YORK 10017

PATENT PROGRAMS
BERNARD M. KOSLOSKI
ASSOCIATE

(212) 986-6622

PATENT BRANCH, NIH

JUN 3 1976

June 1, 1976

Mr. Norman J. Latker
Chief - Patent Branch
National Institutes of Health
Room 5A-03 Westwood Building
Bethesda, Maryland 20014

Dear Mr. Latker:

Enclosed are two copies of the Proposal for our meeting on Thursday.

Sincerely yours,

B.M. Kosloski

BMK:emc

Enclosures

of basic research in colleges and universities. But not widely recognized is the need for financial support if such basic research is to be accomplished.

Because our own resources are limited, and because we are so firmly convinced of technologically-based industry's dependence on, and hence obligation to, basic research done in university laboratories, Research Corporation is engaged in a major program to enlist such industrial firms in a cooperative effort of financial support for academic basic research. By this program, a company can take advantage of the experience, effort and procedures of the foundation in searching out, identifying and supporting basic academic research, without added overhead. Within the year since the program's inauguration, one private foundation and four companies have joined such cooperative programs, and several more are actively considering participation. Opportunities are also being offered to individual donors concerned about the present state of funding for basic research, and to other foundations which may want to join in supporting fundamental scientific research.

Aiding the Transfer of Technology

Complementing its support of basic research in colleges and universities through its Grants Program, the Patent Program—the other activity in the dual role of Research Corporation—expedites and implements the practical application of such basic research for the public benefit by means of the patent system. It was Frederick Gardner Cottrell's awareness of the value of this technology transfer from university laboratory to commercial production that led him to the establishment of this foundation, and fathered our present program of contributed services to nonprofit educational and scientific institutions in evaluating inventions, prosecuting patent applications and licensing patents to industry. The demonstration by Research Corporation of the value of such technology transfer has led to the establishment of similar programs by other organizations and agencies both here and abroad. The wide range

Nominating Committee Announces Candidates

I am pleased to submit the following report of the Nominating Committee of LES U.S.A.

We propose to nominate the following slate of candidates to be elected as Officers and Trustees of LES (U.S.A.), Inc. at the Annual Meeting of the Society in Palm Beach, Florida on October 9-13, 1977. All of the candidates have been notified and have indicated their availability and willingness to serve if elected.

PRESIDENT: Leonard B. Mackey — ITT Corp.

PRESIDENT-ELECT: Niels J. Reimers — Stanford University

PAST-PRESIDENT: William Poms — Poms, Smith, Lande & Glenny

SECRETARY: Tom Arnold — Arnold, White & Durkee

TREASURER: William Marshall Lee — Lee & Smith

V.P. EASTERN REGION: David J. Mugford — Bristol-Myers Co.

V.P. CENTRAL REGION: Robert H. Johnson — Eltra Corp.

V.P. WESTERN REGION: Harry C. Donkers — Avery Products Corp.

V.P. CANADA: William S. Campbell — Consumer Glass Co. Ltd.

V.P. INTERNATIONAL: Gerard J. Weiser — Weiser, Stapler & Spivak

TRUSTEES-AT-LARGE (ONE-YEAR TERM)

Roger G. Ditzel — Iowa State University

Corwin R. Horton — Crown Zellerbach Corp.

William F. Pinsak — American Motors Corp.

Peter F. Casella — Hooker Chemicals & Plastics Corp.

TRUSTEES-AT-LARGE (TWO-YEAR TERM)

Philip J. Sperber — Cavitron Corp.

David E. Dougherty — Carborundum Co.

Robert E. Bayes — Shell Development Co.

Cyrus S. Nownejad — Oil Shale Corp.

With regard to the one-year Trustees, Roger Ditzel and Corwin Horton will be completing the second year of their two-year term, and they are therefore included above only to provide a complete listing of Trustees. Bill Pinsak and Pete Casella are being nominated to fill the remaining terms of Harry Donkers and Bob Johnson who are being nominated as regional vice-presidents.

Again this year the Nominating Committee was able to select its slate of officers from a substantial number of well-qualified and capable members. We have attempted to provide balanced representation on the board on both a geographical and employment basis. To insure a continuing flow of new ideas our nominations provide for a one-third turnover of the Board for this year. The statistics are as follows:

Geographical

6 East
6 Central
5 West
1 Canada
18

Employment

12 Corporate
4 Private Law
2 University
18

Board Status

10 Current members
2 Hold-over
6 New Members
18

We are confident that our proposed slate of officers, and particularly Niels Reimers, as President-Elect, will provide outstanding leadership for the Society. At the same time, there are a large number of active and dedicated members who were not nominated simply because we could select only one candidate for each office. This reservoir of talent bodes well for the future strength of the Society.

Respectfully submitted,
NOMINATING COMMITTEE

Norman A. Jacobs, Chairman
Homer O. Blair
Marcus B. Finnegan
Robert W. Whipple
Leonard B. Mackey (Ex-Officio)

Foundation Publishes Book on Multinationals

The National Chamber Foundation, an economic research foundation, has announced the publication of a new book, *The Case for the Multinational Corporation: Six Scholarly Views.*

Edited by former National Chamber Chief Economist Carl H. Madden, the book contains papers and discussions from the Foundation-sponsored National Conference on Multinational Corporations.

It includes original studies by six well-known authorities on international business—Robert Hawkins, Thomas Horst, Raymond Vernon, Louis Wells, Fred Weston, and Richard Cooper, the newly-designated Undersecretary of State for Economic Affairs. It also features remarks by Lee Morgan, president and chief operating officer, Caterpillar Tractor Co.

The book objectively reviews criticisms leveled against MNCs and identifies potential areas of change. Topics addressed include: Economic effects of multinationals in the U.S. and abroad; their market power; treatment of MNCs under U.S. tax policy, and their influence on developing country economies and societies.

The Case for the Multinational Corporation is a significant contribution to present literature on MNCs and is a must for the international businessman attempting to understand and respond to international public affairs and planning challenges.

Copies of the 229-page book are available to the business community for $4.95. Orders with accompanying checks payable to the National Chamber Foundation should be sent to the National Chamber Foundation, 1615 H Street, N.W., Washington, D.C. 20062.

Placement Opportunities

Jobs anyone? The services of the Placement Committee of LES U.S.A. are available to applicants looking for positions in the licensing field. Please send your resume (five copies preferably) to the Chairman of the Placement Committee:

John L. Sniado
Director,
Patents and Licensing
Kennecott Copper
Corporation
161 East 42nd Street
New York, New York 10017

Companies or firms looking for licensing personnel are invited to send their requirements in confidence to the Chairman of the Placement Committee at the above address. The Placement Committee matches the resumes received with the requirements of the various available openings. Resumes that appear to meet the requirements of any available openings are then forwarded for consideration.

Grantee investigators may also obtain screening and testing services from academic colleagues in other health-related disciplines, such as pharmacology and physiology. However, 10 of the investigators contacted told us that these services were limited in scope and that there were delays in receiving the results; limitations result from the fact that their testing needs do not always correspond to the independent research programs of their colleagues. We also have been informed that academic testing services do not provide the screening and testing necessary to develop promising compounds because their emphasis is on scientific knowledge and not on utilization.

Examples of inadequate screening and testing services

The following examples illustrate some of the adverse effects upon the medicinal chemistry research program brought about by the lack of appropriate screening and testing services for the compounds prepared by the research investigators.

1. An experienced investigator credited with the discovery of at least two drugs received a grant amounting to about $123,000 during the period 1954 to 1964 from the National Heart Institute for the study of hypotensive compounds. During the initial period of the grant, at least one highly active clinical drug resulted from this research.

   Six pharmaceutical companies expressed interest in testing compounds for the investigator, and a working relationship was established with one of these companies that promised to provide biological testing to the point of clinical investigation. The investigator informed us that, subsequent to adoption of the 1962 patent agreement, the company withdrew its testing services and that generally all companies now decline to test compounds prepared with Federal support.

   The investigator stated that adequate screening and testing had not been received on 21 compounds synthesized by him during the period 1963 to 1966 and

that he had been unable to obtain any screening for 14 other compounds. He said that some testing was available at a university medical school on an irregular basis and that CCNSC cancer test results were only indirectly related to his heart research. An article published in 1966 in the Journal of Pharmaceutical Sciences discussing potential antihypertensive agents specifically mentioned the problem of inadequate screening in this area of research and contained the following comment concerning this grant:

> "Owing to the difficulty of obtaining screening of compounds obtained under a grant from the National Institutes of Health, no data are available pertaining to the possible antihypertensive activity of the amino acid."

The investigator told us that, because he could not obtain proper screening for his compounds, he decided not to request a renewal of his heart research grant.

2. During the period 1963-65, grant awards totaling about $37,000 were made to an investigator for research in the mental health area. According to files made available to us, the investigator attempted to make testing arrangements with two pharmaceutical firms; however, both firms declined to sign the patent agreement required by PHS. Arrangements for testing were finally made with the Psychopharmacology Service Center of the National Institute of Mental Health.

Two weeks after the investigator submitted his compounds to the Center for testing, he was notified by the Center that, due to reductions in its programs, additional compounds would not be accepted. He informed us that PHS did not suggest any alternative testing facilities and that other arrangements were not made. He also stated that, following the 1962 PHS requirements for a patent agreement, scientific information formerly provided by industry

no longer made available to him. He explained that the inadequacy of available testing facilities contributed to his decision not to request a renewal of his grant after 1965.

3. Another investigator received grants totaling about $71,000 during the period 1964-66 from the National Institute of General Medical Sciences (NIGMS). About the time of the first award an official at NIGMS suggested that the investigator have his compounds tested for biological activity and especially for antiviral, anticancer, and anticonvulsant activities.

The investigator explained to us that his compounds were of the type that should receive broad biological screening. However, the only screening and testing arrangements made were with CCNSC and they did not provide for anticonvulsant screening. The investigator stated that no Government testing facility offered broad screening and that no such testing was available at any of the institutions listed in the NIH booklet "Biological Testing Facilities." He stated that he was particularly concerned about his inability to obtain anticonvulsant testing and that PHS had not assisted him.

Prior to 1962 the investigator had sent compounds to pharmaceutical companies for testing. Test results from one company showed that a compound, submitted for testing in 1955, had been subjected to at least 20 different test systems, including several in the area of anticonvulsants the latest test occurring in March 1966. The investigator stated that the inadequacy of his current arrangements influenced his decision not to request a renewal of his grant.

4. Since 1959, awards totaling about $141,000 have been made to an investigator by the National Cancer Institute (NCI). In connection with compounds produced under the grant, the investigator has made arrangements with CCNSC for anticancer testing and since 1962 has submitted over 100 compounds. His

correspondence with CCNSC indicates that his compounds might also show activity in the treatment of mental disease; he informed us that, in his opinion, the compounds should also be tested for blood pressure activity.

He advised us that attempts to make testing arrangements through the National Institute of Mental Healt were unsuccessful, and he expressed doubts to us whether adequate testing arrangements could be made with medical school facilities. The only regular testing arrangements made by him were with CCNSC, although a pharmaceutical company had provided some tests in mental chemistry prior to 1962. The investigator stated that, although anticancer activity is the main concern of the NCI, he would like to obtain broader screening of his compounds.

Change in direction of research

We found that, within the broad terms of the grants, several grantee investigators have redirected their researc efforts away from the objective of developing compounds hav ing potential new medicinal value in the prevention and tre ment of human disorders. Some investigators are concentrat on basic chemistry studies even though they had originally proposed to prepare compounds with potential medicinal valu in several areas of health. We were advised by other inve tigators that, because of their awareness of testing proble encountered by others, they intentionally directed their re search around the need for testing. The following cases il lustrate the changes being made in the direction of the research effort in certain medicinal chemistry grants as a re sult of the difficulties being encountered in obtaining ade quate screening and testing services.

1. At one university an investigator received grants o about $49,000 during the period 1962-66 from NIGMS. The investigator was preparing various kinds of potential medicinal agents when he applied for the P grant. In his application the investigator stated that he planned to obtain screening and testing fro a pharmaceutical firm.

Subsequently, he received a commitment from the firm for these services. However, in May 1962, the firm advised him that it was opposed to the signing of the patent agreement required by PHS. The investigator made alternate testing arrangements with a commercial testing laboratory and later with a university pharmacologist for specific types of tests, but not for broad screening. The investigator has informed us that he is currently interested in the study of how drugs work and that he is studying specific drugs whose medicinal value is already known, rather than concerning himself with developing new drugs.

2. Another investigator, who received grants of about $66,000 for the period 1962-66, proposed in his initial grant application to submit his compounds to routine screening in order to obtain as broad an evaluation as possible.

The investigator stated that his attempts to obtain screening and testing from the pharmaceutical industry were unsuccessful and that he finally made arrangements with a university pharmacologist who provided limited services. The investigator informed us that his current research goals were limited and that his testing needs were also limited. He said that the broad testing proposed in the original grant application was still valuable and that, if it had been obtained from industry, the direction of his research might not have changed.

On the basis of the several grants reviewed by us and of discussions with grantee investigators, it appears to us that the difficulties encountered by grantee investigators in obtaining adequate screening and testing of compounds have adversely affected the achievement of important objectives of research grants in medicinal chemistry. These difficulties, which many of the investigators attributed to the inability to obtain the cooperation of the pharmaceutical industry and the unavailability of adequate alternative sources of

screening and testing, also seem to be related to certain problems in the administration of HEW regulations concerning invention rights, which are discussed in the subsequent section of this report.

Difficulties in administration of regulations concerning invention rights

We noted certain difficulties in the administration of regulations concerning invention rights which needed resolution to facilitate the development of grantee investigators' discoveries of potential new drugs. These difficulties involved the determination of ownership and disposition of inventions conceived under PHS grants for research in medicinal chemistry, which we found was a factor contributing to the reluctance of the drug industry to provide screening and testing services to NIH-supported investigators.

It is the general policy of HEW that the results of Department-sponsored research should be made widely, promptly, and freely available to other research workers and to the public. At the same time, the policy recognizes that in some situations, and particularly where commercial development of inventions will be costly, the public interest can best be served if a developer is granted some exclusivity for a limited time. However, we were advised by HEW officials that, in view of an opinion of the Attorney General (34 Op. Atty. Gen., 320,328 (1924)), HEW could not guarantee exclusive licensing of inventions. HEW officials told us that this opinion generally had been interpreted as holding that agencies may not grant exclusive licenses under Government-owned patents without specific statutory authority.

HEW regulations (45CFR8) require that all inventions arising out of activities supported by grants shall be promptly and fully reported to the agency. The regulations, as quoted on page 6 of this report, permit a utilization of the patent process in order to foster adequate commercial development to make new inventions widely available to the general public. The regulations specify that determination of ownership and disposition of invention rights may be made by either the responsible official on a case-by-case basis (sec. 8.1(a)) or, except for foreign rights, under blanket "institutional agreements" by grantee institutions whose policies and procedures have been approved by HEW (sec. 8.1(b)).

The regulations (sec. 8.2) provide four criteria for use by the responsible HEW official in determining disposition of rights under section 8.1(a). One of the criteria (sec. 8.2(b)) states that an invention may be assigned by HEW to a "competent" organization if it will be more adequately and quickly developed for widest use, providing there are adequate safeguards against unreasonable royalties and repressive practices.

In accordance with the general policy concerning publication or patenting of inventions, we found that HEW generally followed the practice of disseminating the results of PHS-sponsored research to other research workers and to the public through publication. Publication has the effect of making the results of research freely available to all interested parties and, subject to existing patents, permits nonexclusive exploitation of the discovery. However, we have been advised by representatives of the pharmaceutical industry that, since commercial development of new drugs is generally costly, the industry will not undertake this development unless some form of exclusivity can be obtained.

During our review, several grantee investigators informed us that, in their opinion, publication of the results of their research was not an adequate means to encourage development of promising compounds into new drugs. In addition, we noted that in April 1962 the Director of the National Cancer Institute advised the Surgeon General that he was doubtful that the policy of emphasizing dedication of inventions to the public through publication would make inventions available or that such a policy would always serve the public interest. He stated that a no-patent concept delayed the marketing of inventions because there was no protection for the investment of the developer.

Assignment of invention rights by HEW

Our review showed that HEW had not taken timely action to determine the disposition of rights to certain inventions and that only limited use had been made by HEW of the authority provided in the regulations to assign invention rights to "competent" organizations, such as grantee institutions. We found that, at the time of our fieldwork in January 1967, HEW had not acted upon several petitions

had been received from grantees for assignment of rights. We found also that, from 1962 through June 30, 1965, HEW had assigned invention rights to grantees in only one situation. NIH records showed that, during the 1962-65 period, grantees had reported a total of 682 inventions resulting from NIH-sponsored research and that numerous requests had been received for assignment of rights.

Subsequent to reporting inventions, grantee organizations may petition HEW for assignment of invention rights on an individual case basis. In such instances pursuant to section 8.1(a) the responsible HEW official, in accordance with section 8.2(b) of the regulations, may assign the invention rights to the grantee for a limited period.

HEW officials provided us with a list of nine petitions received by HEW from grantees that were pending determination as of January 1967. Two of these petitions had been submitted in 1963, one in early 1965, and three others were at least 6 months old.

University and industry officials advised us that they were dissatisfied with the determination of rights provisions by the agency because the provisions did not provide criteria and guidelines for determining rights; there were uncertainties as to the determinations to be made. The following case illustrates the delays and uncertainties involved in resolving a petition for patent rights made by a university we visited during our review:

In January 1966 a university petitioned PHS for assignment of domestic rights to inventions covering steroid compounds conceived under a PHS grant. Prior to the petition the Surgeon General had permitted the university to file six patent applications. At least 14 companies expressed interest in licenses for development of the university's inventions.

We were advised, however, by a university official that no company would develop the inventions without exclusive rights to protect its investment in the development of the inventions. He stated that, as of May 1967, no development work had been done on the inventions by any of the 14

companies. The investigator informed us that he had lost interest in development of the inventions, because of the long delay. In July 1967, 18 months after the petition, the Assistant Secretary for Health and Scientific Affairs assigned domestic rights to the university and stated that the public interest would best be served by expeditious development of the inventions.

Statements made in 1965 by two organizations representing university administrators stress the importance of assigning invention rights to universities at the time of awarding research grants or contracts. The Patent Policy Subcommittee of one organization[1] stated in a position paper that the public interest could best be served by encouraging educational institutions to assume the responsibility of furthering public use of the inventions of their faculties and recommended that universities be permitted to establish the licensing arrangements necessary to encourage private companies to invest in the development of pharmaceutical discoveries.

The Chairman of the Subcommittee in commenting on the position paper advised the organization's executive secretary that the necessity to petition the sponsoring agency for the right to patent an invention, and to justify each such petition on an individual basis, introduces substantial delay and a prolonged period of uncertainty.

In 1965 the other organization[2] submitted statements to the Senate Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, which stressed that granting invention rights to universities at the time of contracting would eliminate delays in the development of discoveries and the dissemination of research knowledge and would assist the sponsoring agency charged with the task of promoting the fruits of research. This organization also

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[1] Committee on Government Relations, The National Association of College and University Business Officers.

[2] American Council on Education.

recommended that universities be permitted to use licensing incentives to attract industry investment in product development. (Hearings on Government Patent Policy, pt. 2, p. 645.)

During our review, we requested HEW to provide us with information concerning the current status of its determinations under section 8.2(b), including the nine pending cases shown in its January 1967 listing. This information, provided to us in November 1967, showed a marked increase in departmental actions, inasmuch as HEW:

1. Had signed section 8.2(b) determinations, assigning invention rights to the grantee for a limited period, in seven cases.

2. Had decided to dedicate the invention to the public in one case.

3. Was evaluating additional information received on the remaining case.

The information provided to us also showed that, since January 1967, 17 other proposals had been submitted to HEW for 8.2(b) determinations; HEW had made determinations in four cases and was evaluating the proposals received in the other 13 cases.

On the basis of our observations, we proposed to the Secretary that HEW, in line with its responsibility, should direct its efforts toward timely determination of rights to, and the appropriate disposition of, potentially patentable inventions resulting from research in medicinal chemistry reported by grantee investigators. We believe that such action would serve the public interest by reducing the uncertainties of the status of invention rights.

Use of institutional agreements

Our review showed that HEW had made only limited use of the regulation permitting the assigning of the determination of invention rights to grantee institutions whose patent policies had been approved by HEW (45 CFR. 8.1b). This regulation has been applied through the use of institutional

agreements between PHS and individual universities, and 18 such agreements, entered into between 1953 and 1958, are now in existence. At least 34 other universities have submitted requests for these agreements; however, in March 1967, we were advised by HEW officials that no additional agreements had been approved because opinions of responsible agency officials differed concerning the value of such agreements.

We found that HEW, in addition to placing limitation on the number of institutional agreements being approved, placed limitations on the institutions' administration of the agreements now in existence, because it required use of the PHS patent agreement. Some agency officials have expressed the opinion that the use of patent agreements should not be required at grantee institutions which are holding institutional agreements and that greater use of institutional agreements would help alleviate problems in obtaining screening and testing services by pharmaceutical companies.

Information obtained during our review shows that investigators from at least seven of the universities holding agreements with PHS encountered difficulties in making screening and testing arrangements with pharmaceutical companies, because of the required use of the PHS patent agreement. The following case illustrates problems encountered when screening and testing arrangements were sought:

> In November 1962 the chairman of the patent board at a university holding an institutional agreement advised an investigator, as well as university administrators, that PHS preferred to have investigators obtain screening and testing for their compounds from commercial laboratories not engaged in the manufacturing business. Testing fees were to be charged to the grant. The chairman pointed out that he had:
>
> > "*** protested this and other recent actions of the USPHS in issuing directives requiring compliance on matters contrary to established procedure within the university and the university's institutional agreement with that agency ***."

On two occasions the university advised the Deputy Surgeon General that fees for the required testing would amount from about $30,000 to $50,000 and would consume nearly all the funds of the grant. The university recommended action to permit the use of the free services of the pharmaceutical industry. The Deputy Surgeon General replied that although there was merit in this argument, PHS had no alternative but to use the amended patent agreement clause on screening compounds.

On the basis of our observations, we proposed to the Secretary that HEW clarify the intended use of institutional agreements and review the necessity for requiring the use of patent agreements by grantee institutions whose patent policies had already been approved by HEW.

Views of agency officials
and proposed actions

Recognition of problem area

We found that, prior to our review, various HEW officials had expressed their views on problems concerning the means needed to provide improved screening and testing of compounds resulting from PHS grants for research in medicinal chemistry. Cognizant HEW officials have been aware of the difficulties experienced by grantee investigators in arranging for adequate screening and testing of compounds. They also recognized that procedures implementing department policies had been unsatisfactory and had contributed to the loss of screening and testing services formerly provided by the pharmaceutical industry.

In March 1963 the Deputy Director of NIH stated in a letter to the Director that:

> "It is becoming increasingly apparent that our current patent policy does present a problem for grantees who depend upon industrial laboratories for biological testing of material produced with PHS support."

In August 1964 the Director NIH advised the Surgeon General, PHS, of the need for change in the HEW policy to permit effective collaboration with industry. He stated in the memorandum that, since early 1962, problems had increased to the point where a prompt review of the policy appeared necessary. The Director stated that investigators found the drug industry best able to accumulate the data necessary for the licensing of a new drug.

The Deputy Surgeon General, PHS, forwarded the August 1964 letter to the HEW Patent Officer and stated that:

> "*** it is preferable to create conditions that will attract private initiative rather than to undertake complete government financing of the cost of research and development of all inventions that grow out of the government's program."

In August 1965 the Director of NIH advised the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee that:

> "The uncertainties involved in after-the-fact determination have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application."

and that:

> "Compounds which show some promise in early stages of investigation may be of no benefit to the public and may not serve the public interest unless clinical testing is undertaken and the resulting drug *** marketed. *** it seems sensible to be able to involve industry in the testing and marketing phases of drug development since these firms already possess capabilities in these areas that would have to be duplicated elsewhere to accomplish these necessary purposes."

HEW views of July 1967

In May 1967 we advised the Secretary HEW, by letter, of our findings concerning the problems in obtaining appropriate screening and testing for compounds prepared under Government-sponsored research. We inquired about the steps being taken or contemplated within the Department to provide improved means for screening and testing compounds resulting from the PHS-supported program for research in medicinal chemistry.

In his reply of July 1967, on behalf of the Secretary, the Assistant Secretary for Health and Scientific Affairs informed us that, since the responsibility for patent matters was assigned to his office in October 1966, the Department's patent policies and administrative practices, including the problems relating to screening and testing of compounds, had been under continuing review.

The Assistant Secretary mentioned that a private consulting firm was studying certain patent problems related to HEW operations in connection with a contract study being undertaken for the Committee on Government Patent Policy of the Federal Council for Science and Technology[1] and that the Department intended to use the study in the formulation of any changes in policy or administrative practices found to be in order.

The Assistant Secretary further stated that two steps were under consideration to promote screening and testing of compounds identified by grantees: (1) extension of the use of blanket institutional agreements and (2) entertainment of applications by other grantee institutions under section 8.2(b) of the regulations for assignment of principal rights by HEW to such institutions on a case-by-case basis where it was determined that such action would promote more adequate and wider utilization of the compounds, including screening and testing. However, HEW had reached no final decision regarding changes in patent policies or in the above administrative practices.

HEW comments of March 1968

After we brought the matters discussed in this report to the attention of the Secretary for review and comment, we were furnished with the Department's comments, by letter dated March 20, 1968, from the HEW Assistant Secretary, Comptroller. In this letter (see app. II), we were informed essentially of four principal actions taken or being taken by the Department to resolve the problems related to the screening and testing of compounds under HEW-sponsored research.

These actions include:

1. The use of a revised patent agreement between investigator and screening and testing organization.

[1]Established by Executive Order 10807, March 13, 1959, as an interagency body representing the principal agencies with scientific or technical missions.

2. The planned use of a revised standard institutional patent agreement.

3. The more expeditious issuance of determinations permitting assignment of an invention to a competent organization on a case-by-case basis.

4. The planned issue of a comprehensive statement of the Department's policies and requirements regarding the screening and testing of compounds.

The several actions as reported to us by the Department are summarized below.

1. During 1967, HEW put into effect a revised form of patent agreement which, as pointed out by the Department, differs significantly from that required in 1962 in that it does not restrict the tester's rights of ownership to new uses of compounds which it may discover at its own expense without the participation of the NIH-supported investigator, even "where such new use is within the field of research work supported by the grant."

HEW has informed us that its records indicate that the revised agreement is acceptable to some members of the pharmaceutical industry who are interested in providing screening and testing services and that investigators and pharmaceutical companies entered into 53 agreements, using the revised form during calendar year 1967. HEW has informed us also that the form of the required patent agreement will undergo further review and that additional changes will be made, where appropriate, to ensure recognition of the respective rights and interests of HEW, the investigators, and the organizations performing screening and testing services.

In commenting on the revised agreement the president of the Pharmaceutical Manufacturers Association advised us that it was a much needed improvement to the existing arrangements, and, although recognizing that certain problems would still exist, the association endorsed it as a progressive measure.

2. HEW has reaffirmed that the use of institutional agreements, as provided for under Department patent policy, serves the public interest and should be continued. HEW has informed us that a revised standard institutional patent agreement, now in preparation, will permit the grantee institution to retain and administer the principal ownership rights in inventions made under Department grants, will clearly define the rights of the parties with respect to such inventions, and will set forth general guidelines governing the licensing of inventions.

HEW considers that the revised agreements will go far toward solving the problems encountered by investigators in connection with screening and testing and will, at the same time, fully protect the public interest.

3. During 1967, HEW has made efforts to expedite the issuance of determinations pursuant to the provision in its patent regulations that permits assignment of an invention to a competent organization on a case-by-case basis. HEW stated that it was its intent to act as expeditiously as possible on a number of requests pending for such assignment, as well as on those determinations already made since April 1967. HEW intends to use this provision of the regulations where an institutional agreement is not in effect.

4. HEW has recognized the need for a comprehensive statement of the Department's policies and requirements regarding the screening and testing of compounds arising out of Department-sponsored research. HEW has informed us that it intends to issue a statement which will outline the Department's policies and clearly set forth alternative methods of obtaining screening and testing services and that it will encourage the utilization of Government facilities whenever appropriate.

In summary, HEW expressed its recognition that newly synthesized or identified compounds resulting from Department-sponsored research constitute a valuable national resource and that their effective utilization is a part of HEW's program goals. HEW has stated that it will continue to make such changes in its practices as are necessary to foster the fullest utilization of all such compounds, in a

manner that will protect the legitimate interests of the public, the investigator, and the screening organization.

Conclusions

On the basis of information obtained from grantee investigators and cognizant agency officials, it appears that the usefulness of the HEW grant program for research in medicinal chemistry has been adversely affected because of the difficulties encountered by grantees in arranging for adequate screening and testing services. Although the research efforts of grantee investigators provide useful scientific information in the area of health-related chemistry, optimum benefits are not obtainable if compounds which may have potential medicinal use do not receive adequate screening and testing.

We believe it is important to note that, in a meeting with agency officials in June 1966, the President of the United States expressed specific interest in medicinal research and in achieving increased practical results from drug research in the form of treatment of diseases. Agency officials have advised the President that a major impediment to these goals has been the patent policy which has made it extremely difficult to make use of the resources and services of the pharmaceutical industry.

Following this meeting, the President referred to the substantial amount of funds being spent annually by NIH on biochemical research and, after mentioning the role of medical research in control of polio and tuberculosis and in psychiatric treatment, stated:[1]

> "These examples provide dramatic proof of what can be achieved if we apply the lessons of research to detect, to deter and to cure disease. The Nation faces a heavy demand on its hospitals and health manpower. Medical research, effectively applied, can help reduce the load by preventing disease before it occurs, and by curing disease when it does strike.

[1] Weekly compilation of Presidential Documents, July 4, 1966, p. 837.

"But the greater reward is in the well-being of our citizens. We must make sure that no life-giving discovery is locked up in the laboratory."

It is apparent that HEW officials have, for some time, recognized the problems discussed in this report, and we have since been informed that remedial measures are under way or under consideration, including changes in the patent agreement for screening and testing purposes, increased use of institutional agreements, and more expeditious assignment of invention rights at the time of grant award. However, until such time as the contemplated actions have been fully implemented, it is not practicable for us to assess the effectiveness of those various measures and to determine whether they will enable investigators to obtain adequate screening and testing services in connection with their HEW-supported research activities.

Recommendation to the Secretary of Health, Education, and Welfare

We recommend that the Secretary of Health, Education, and Welfare develop and put into effect such policies and procedures as are necessary to provide adequate screening and testing of compounds resulting from HEW-supported research in medicinal chemistry to facilitate the development of potential drugs for the prevention and treatment of diseases and disabilities of man.

SCOPE

Our review of the administration of HEW grants for research in medicinal chemistry included an examination into the pertinent legislation and the regulations, policies, procedures, and practices of HEW and its constituent organizations, to the extent applicable. Our work was performed at the headquarters of HEW, PHS, and NIH, and at selected educational institutions, which were recipients of PHS grants, in the States of California, Michigan, Minnesota, and Wisconsin.

We reviewed selected grants, totaling about $4.6 million, awarded during the period 1962 to 1967 to 38 research investigators at 10 educational institutions. We examined the grantees' research programs and obtained information from the investigators and university officials as to the arrangements made or available for screening and testing new compounds to determine their usefulness. Our review did not include an examination of the manner in which the funds were expended under the grants.

We met with representatives of two pharmaceutical firms and of the Pharmaceutical Manufacturers Association to determine the basis of the industry's actions discussed in this report.

We discussed with responsible agency officials pertinent aspects of the Department's policies affecting the administration of the grants and possible changes contemplated in such policies or implementing procedures.

APPENDIXES

APPENDIX I

PRINCIPAL OFFICIALS
OF
THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
RESPONSIBLE FOR THE ACTIVITIES
DISCUSSED IN THIS REPORT

	Tenure of office			
	From		To	
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:				
Abraham A. Ribicoff	Jan.	1961	July	1962
Anthony J. Celebrezze	July	1962	Aug.	1965
John W. Gardner	Aug.	1965	Mar.	1968
Wilbur J. Cohen	Mar.	1968	Present	
ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS (note a):				
Philip R. Lee	Nov.	1965	Present	
SURGEON GENERAL, PUBLIC HEALTH SERVICE:				
Luther L. Terry	Mar.	1961	Oct.	1965
William H. Stewart	Oct.	1965	Present	
DIRECTOR, NATIONAL INSTITUTES OF HEALTH:				
James A. Shannon	Aug.	1955	Present	

[a]Effective March 13, 1968, the Assistant Secretary was given direct authority over PHS and FDA. Effective April 1, 1968, the functions previously assigned to PHS were assigned to two new operating agencies--the National Institutes of Health (including the former NIH and certain additional functions) and the Health Services and Mental Health Administration (comprising all other functions previously assigned to PHS). The Surgeon General was made the principal deputy to the Assistant Secretary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

MAR 20 1968

Dear Mr. Rabel:

The Secretary has asked that I reply to your draft report to the Congress entitled, "Review of Grants for Research in Medicinal Chemistry, National Institutes of Health, Public Health Service, Department of Health, Education, and Welfare."

The effective utilization of the results of Department-sponsored research, including any compounds that may be synthesized or identified, is considered to be an essential part of the Department's program goals. The problems relating to the screening and testing of such compounds have been under continuing review within the Department. Some changes have been made in our administrative practices and procedures to encourage such screening, and additional changes will be made where found to be appropriate.

We would like to comment briefly on some significant aspects of the draft report and to bring you up to date on the status of pertinent activities within the Department. The report indicates that investigators have alleged that their collaboration with the pharmaceutical industry for screening and testing generally ended in early 1962 when the PHS required that the screening organization and the grantee institution execute a formal patent agreement. We wish to point out that this patent agreement did not involve any change in PHS policy. It merely formalized in writing the relationship and respective rights of the parties in light of the investigator's obligations to the PHS under his grant agreement.

As noted in the Report, HEW has considered a number of changes in the patent agreement required to be signed for screening. During 1967, a revised form of agreement was put into effect, a copy of which is attached.[1] The form of the agreement currently in use differs significantly from that originally required in 1962. It does not restrict the tester's rights of ownership to new uses of compounds which it may discover at its own expense without the participation or suggestion of the PHS investigator even "where such new use is within the field of research work supported by the grant." We understand that restrictions of this type in agreements formerly in use were unacceptable to a number of pharmaceutical companies.

Our records indicate that the revised agreement is acceptable to some members of the pharmaceutical industry who are interested in providing screening and testing services, and that PHS investigators and pharmaceutical companies entered into 53 agreements using the revised form during calendar year 1967. The form of the required patent agreement will undergo further review, and additional changes will be made where appropriate to assure recognition of the respective rights and interests of the PHS, its investigators and organizations performing screening and testing services.

As noted in the Report, it is the general policy of this Department that the results of Department research should be widely, promptly, and freely available to other research workers and the public. At the same time, the policy recognizes that in some situations, and particularly where commercial development of inventions will be costly, the public interest can best be served if a developer is granted some exclusivity for a limited period of time.

Section 8.1(b) of the Department Patent Regulations provides that ownership of inventions made under Department-sponsored research may be left to a grantee institution for administration in accordance with the grantee's

[1]GAO note: Attachment not included.

Mr. Frederick K. Rabel

established policies and procedures with such modifications as may be agreed upon, provided that the Assistant Secretary, Health and Scientific Affairs, finds that the policies and procedures, as modified, are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties. This aspect of Department patent policy has been undergoing review, and it was recently reaffirmed that the policy serves the public interest and should be continued.

At the present time, a revised standard basic Institutional Patent Agreement, to be utilized under Section 8.1(b), is under preparation. This Agreement will permit the grantee institution to retain and to administer the principal ownership rights in inventions made under Department grants and awards, will clearly define the rights of the parties with respect to such inventions, and will set forth general guidelines governing the licensing of inventions, including limitations on the duration of exclusive licenses that may be granted. It will also include the reservation of a royalty-free license to the Government and other appropriate safeguards to protect the public interest, including all of those specified in the 1963 Presidential Statement of Government Patent Policy. These latter safeguards will include a reservation to the Government of the right to require the granting of additional licenses royalty-free or on terms that are reasonable under the circumstances where such licenses are necessary to fulfill public health, welfare or safety requirements. As soon as the terms of this basic agreement can be fully developed, the existing agreements will be terminated and standard agreements will be entered into with qualified grantee institutions.

We consider that the Institutional Patent Agreements will go far towards solving the problems encountered by investigators in connection with the screening and testing of compounds synthesized or identified under Department-sponsored research and will, at the same time, fully protect the public interest. An Institutional Patent Agreement will

Mr. Frederick K. Rabel

authorize a grantee institution to enter into agreements with pharmaceutical companies for the screening and testing of compounds and to agree to grant limited exclusive licenses to any inventions that may result from the screening. All such licenses will be required to include the conditions and safeguards specified in the Institutional Patent Agreement.

Section 8.2(b) of the Department Patent Regulations authorizes the Assistant Secretary, Health and Scientific Affairs, to permit assignment of an invention by the inventor to a competent organization on a case-by-case basis where he finds that the invention will thereby be more adequately and quickly developed for widest use, and that there are satisfactory safeguards against unreasonable royalties and repressive practices. During 1967, efforts were made to expedite the issuance of determinations pursuant to this provision. Since April 1, 1967, fifteen determinations have been issued pursuant to Section 8.2(b) permitting assignment of inventions to grantee institutions. A number of requests are pending, and it is our intent to continue to act on such requests as expeditiously as possible. We intend to continue to utilize this provision of the Regulations where an Institutional Patent Agreement is not in effect.

During our review of the problems associated with screening and testing of compounds arising out of Department-sponsored research, it has become apparent that there is a clear-cut need for a comprehensive statement of the Department's policies and requirements regarding this subject. Therefore, it is our intent to issue a statement outlining the Department's policies regarding screening and testing of compounds and clearly setting forth the alternative methods of obtaining screening and testing services that are available to investigators supported by the Department. This statement will encourage the utilization of Government facilities, including the Cancer Chemotherapy National Service Center (CCNSC) and the Walter Reed Army Institute of Research for screening whenever appropriate.

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In summary, we consider that the results of Department-sponsored research, including newly synthesized or identified compounds, constitute a valuable national resource, and that the effective utilization of such compounds is an essential part of the Department's program goals. We intend to continue to make such changes in our practices as are necessary to foster the fullest utilization of all compounds synthesized or identified during the course of research supported by the Department in such a manner as to recognize and protect the legitimate interests of the public, the investigator, and the screening organizations.

Sincerely yours,

James F. Kelly
Assistant Secretary,
Comptroller

Mr. Frederick K. Rabel
Assistant Director
Civil Accounting and
Auditing Division
United States General Accounting Office
Washington, D. C. 20548

Attachment [1]

[1]GAO note: Attachment not included.

U.S. GAO Wash., D.C.

As former U.S. Secretary of State Henry Kissinger declared two years ago at the OECD ministerial conference, the world today needs security policies to deal with food and energy issues in parallel with armaments. He thus made a very important point, namely, that a smooth distribution of food, energy and other resources contributes, beyond contest, to the maintenance of world peace. The establishment of comprehensive security measures has thus become necessary.

Consequently all countries are confronted not only with the task of transferring existing technology but of evolving all possible means to ensure that the last quarter of the 20th Century will be one of peace. The tasks in technology transfer must be carried out in accordance with these high level aims.

Japan itself is faced with the task of finding out how much it can contribute internationally from now on to the realization of these goals. Her major contribution will be technology that in the first place seeks to realize civic objectives. I am firmly convinced that Japan can make a worthy contribution in this respect.

I also believe that those countries which until now have achieved major technological results in military or national-policy projects will be successful in transferring these results to the attainment of civic goals. It is with anticipation and eagerness that we look forward to the results of the promotion of either bi-lateral or multi-national cooperation projects in order to achieve this objective.

In the field of telecommunications in which I am engaged, I believe that the smooth exchange of information can contribute in a large way to prosperity and peace by promoting better understanding among the people in one country as well as between the various nations. I therefore consider it my mission to build and equip the infrastructure for a telecommunications system for a global society and am endeavoring to bring it to realization.

It is thus my aspiration to see achieved the transformation of our present international society, full of antagonisms and suspicions, into a peaceful world where confidence and cooperation prevail, through the solution of the problems of the economic society of today, rendering needless the current arms race. Such are my views as a private industrialist and the reason why I lay more weight on actual results than on a concept.