## December 11, 1975

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needed to carry out the purposes of this Act, he may acquire providency and other information (a) by purchase through nevolation or by donation from any person, or (b) from guother Federal agency, (emphasis added).

The emphasized language is intended to limit the Administrator to nonduplicetive energy information collection and analysis. I firmly believe that nondeplication is the intent of the Committee on Science and Technology, based on the discussions in the committee on April 23. 1975. On that date, as the transcript clearly shows, the committee without ebjection accepted a unanimous consent request by Mr. Escu to the effect that "it was the intention of the committee that to the maximum extent feasible there be a coordination of the data bank-among the various agencies-so there would not be duplication with those of Interior and others."

I also believe that it was the sense of the conference committee that there be no duplication of existing energy information activities. Section 309 of the conference bill clearly states that the Administrator "shall coordinate nonnuclear programs of the administration with the heads of relevant Federal agencies in order to minimize unnecessary duplication of programs, projects, and research facilities." The data bank is such a project and, based on the task force reports and ERDA comments, I would find, as I am sure the majority of the conferces would agree, that very little, if any, duplication of existing energy information activities can be justified as necessary. I hope that ERDA will adhere to these respective intents in its implementation of the now-narrowed statutory mandate to establish the data bank. 61

. FISCAL RESPONSILILITY

The Science and Technology Committee report on H.R. 3474 included a strong statement supporting the principle of fiscal responsibility in ERDA's accelerating energy R. & D. program

(I) BALANCING AN ACCELERATED R&D PROGRAM WITH FISCAL RESPONSIBILITY

Our Nation's energy shortcomings will not be solved by a single, spectacular breakthrough. Rather the solution lies in marshalling many smaller, individual achievements into a comprehensive energy package. Some elements of this package are already well underway; e.g. fessil energy and nuclear power. The Science and Technology Committee has undertaken to foster the development of other promising energy sources, such as solar and geothermal, which have long been known but also long neglected. To so foster these other sources and shmifteantly accelerate their development and commercial availability, the Committee has substantially increased authorizations in associated program areas, to totals in some nonnuclear R&D areas as much as two to three times LEDA requests, Euch authorizations specifically were made in the solar, geothermal and conservation programs. In each of these program areas, the Committee strongly believes that these sub-tautially increased authorirations can be encetively and productively utdieed within administrative, managerial and technical constraints for R&D of the technologies in FY 76 and the Transition Fernod.

Additionally, 'the Committee views the funds devoted to energy EAD as a national investment. Our offenal energy RAD investment will reform generous dividends. For example, each R&D dollar spent returns more

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than seven dollars in the economy over an 18-year period. This statistic is based on the runout effect of acrospace technology. The runout effect of energy R&D should be even more dramatic. Thus, the money that leaves the Treasury in the coming few years for these programs should stimulate continued prosperity and constructive growth. And eventually the initial cost will be recouped through the taxes on the increased productivity which it generates.

The Committee, however, is aware of the perennial problems faced in any accelerated RED program; e.g., additional money alone dees not guarantee success. While money can spur progress, there is a limiting point beyond which additional funds cannot be spent effectively. After that limiting point, money is wasted rather than invested. Overfunding, in fact, can be counterproductive to the extent that a finite R&D management pool in ERDA is taxed to manage marginally effective or potentially non-productive R&D and senior management attention and focus on truly promising programs is reduced. The Committee, of course, is also aware that energy R&D funding must relect overall national priorities and budget constraints. The Committee, therefore, recognizes that the funding for the significantly increased nonnuclear energy R&D programs must reflect a careful balancing of an accelerated R&D program and fiscal responsibility.

While the additional funds authorized by the Committee in the significantly increased program areas were based on the belief that they could be used effectively, supporting information and testimony for such substantial R&D acceleration is necessarily limited and, to a degree, speculative. The Committee therefore relies on the judgment of LRDA in expending this money, in the significantly increased program areas. If further scrutiny reveals that a particular topic in those program areas does not warrant continued pursuit, then the Members expect ERDA to exercise restraint and not feel bound to expend the full amount authorized and appropriated. Various provisions of the authorization bill and existing procedures provide for reprogramming within program areas and for retention of appropriated funds without fiscal year limitation until expended. The Committee expects ERDA to utilize these provisions fully in the exercise of such fiscal responsibility in those program areas. ERDA, of course, must satisfy all requirements for notification to the Committee in any exercise of restraint and utilization of reprogramming procedures.

The Committee believes the nonnuclear pertions of the ERDA authorization enables us to begin an accelerated but sensible energy R&D program. The cumulative effect of many small and diverse achievements will be an American economy free from foreign manipulation and capricious perturbation. In the end we will be a stronger and more independent Nation because of it.

Because the Fossil Fuel Subcommittee voiced concern over the fiscal responsibility comments as applied to ERDA's fossil fuel research program, the committee view was limited to nonfossil programs. I addressed their concerns in an additional view.

#### FISCAL RESPONSIBILITY

The Committee report contains an express view on the need to belance the accelerated energy R&D program with fiscal responability. The view was adopted in the Energy Research, Development, and Demonstration Subcommittee in response to total increases of two and three times the ERDA request which were finally authorized for rolar, geothermal and conservation. The Subcommittee action was a recognition that there is an informating the exact totals and the specific program accelerations which can effectively be employed in so substantially accelerating any R&D program. Dependence on ERDA's judgment as the acceleration evolves to proceed in a fiscally responsible manner in obligating these authorized (and appropriated) funds, therefore, is the only available mechanism for balanchig fiscat responsibility with this R&D acceleration. The Subcommittee specifically charged ERDA with that responsibility.

The Committee view in the report reflects that charge of responsibility and, further, directs ERDA to utilize available reprogramming and retention procedures in exercising fiscal restraint where accelerated research can no longer be justified. The Committee, however, does not intend that this guidance be used to negate the clear and obvious mandate that ERDA accelerate its program in *cach* of the specified program areas. Its single and only intention in the view is that the acceleration in each area be affected in a fiscally responsible way.

The specific language in the view refers only to "significantly increased program areas," which is defined for purposes of the discussion as solar, geothermal, and conservation areas. I am advised that this language and reference are intended to limit the Committee's view to the non-fossil programs under the Committees nonnuclear authorization jurisdiction, thereby excluding the fossil energy R&D programs from its application. I understand that opponents of the view's application to feesil research are concerned that the view could be used by ERDA or the Office of Management and Eudnet to justify arbitrarily reducing expenditures in fossil research. Such misuse of the Committee's clear direction is not the effect of the view and would not be telerated by the Committee in its oversight of ERDA.

I also understand that opponents believe that the fossil programs do not include the acceleration which the Committee has authorized in the nonfossil programs. Although the Committee did not substantially increase the ERDA fessil request, the fessil recearch programs do, in fact, equate to significantly accelerated R&D programs. Fossil programs have increased from approximately \$73 mil-lion in FY 74 to \$105 million in FY 75 to the \$435 million in FY 76 which this Committee authorized, and which the Senate will probably increase another \$75 million more. Opponents respond to these facts by arguing that the fossil programs are far better defined and therefore not subject to considerations of fiscal restraint discussed above. I am unable to caree. The fostil programs have clearly been significantly accelerated in the past 12 months, and just as clearly, ERDA should be directed to incorporate the ethic of fiscal responsibility and, where appropriate, fiscal restraint in its implementation of the fossil programs.

I urge my colleagues in the House to support the view that fiscal responsibility and the guidance included in the Committee view should apply equally to all nonnuclear programs. In light of the current economic conditions in the nation and the severely limited Federal budget, the Congress must insuro that those funds which are authorized are used effectively. Although I strongly endorso the need for an accelerated research effort to aggre sively pursue technical alternature: to continued dependence on force n oll, I cannot justify any attempt to i, nore the coextensive requirement for ficed responsibility in all of our budget actions. The balance must be struck on a continuing basis In EPDA's energy R&D program, I intend to establish this view in the Floor debate on M.R. 3474 and I urge your support, I would abo urre ERDA to fully concuter fineal re-(pon-ability in all of its nonuclear rescarca because I have no doubt the importty of the Committee supports this view. Unjustified

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ess equipment modifications, gascous\_diffution plants, the figure "\$478,100,000" and substituting therefor the figure "\$510,100,-000".

(b) Section 101 of Public Law 03-60, as amended, is further amended by striking from subsection (b)(1), project 34-1-c. cascade uprating program, gaseous diffusion plants, the figure "\$259,600 000" and substituting therefor the figure "\$270,400,000".

#### TITLE III-GENERAL PROVISIONS

PART A-PROVISIONS RELATING TO PROGRAMS OTHER THAN FOSSIL ENERGY DEVELOPMENT

SEC. 301. The Administrator is authorized to perform construction design services for any Administration construction project whenever (1) such construction project has been included in a propesed authorization bill transmitted to the Concress by the Administrator, and (2) the Administrator determines that the project is of such urgency that construction of the project should be initiated promptly upon enactment of legislation appropriating funds for its construction.

SEC. 303. Any moneys received by the Administration may be retained and used for operating expenses (except sums received from disposal of property under the Atomic Energy Community Act of 1955 and the Strategic and Critical Materials Stockpilling Act. as amended, and fees received for tests or investigations under the Act of May 16, 1910, as amended (42 U.S.C. 2301; 50 U.S.C. 96h; 30 U.S.C. 7) ), notwithstanding the provisions of section 3617 of the Registed Statutes (31 U.S.C. 424), and may remain available until expended ...

SEC. 303. Transfers of sums from the "Operating expenses" appropriation may be made to other agencies of the Government for the performance of the work for which the appropriation is made, and in such cases the suins so transferred, may be inerged with the appropriation to which transferred.

Spc. 304. Sections 301, 302, and 303 of this Act do not apply to fossil energy develop-ment programs of the Administration.

#### PART B-PROVISIONS RELATING TO NONNUCLEAR ENERGY DEVELOPMENT

SEC. 305. REPROCEMMENG AUTHORITY .-- EXcept as provided in part C of this title-

(1) no amount appropriated pursuant to this Act may be used for any nounuclear program in excess of the amount actually authorized for that particular program by this Act.

(2) no amount appropriated pursuant to this Act may be used for any nonnuclear program which has not been presented to, or requested of, the Congress,

unless (A) a period of thirty calendar days (not including any day in which either House of Congress is not in session because of adfournment of more than three calendar days to a day certain) has passed after the receipt by the Committee on Science and Technology of the House of Representatives and the Committee on Interior and Insular Affairs of the Senate of notice given by the Administrator containing full and complete statement of the action proposed to be taken and the facts and circumstances relied upon. in support of such proposed action, or (B) each such committee before the expiration of such period has transmitted to the Administrator written notice to the cilect that such committee has no objection to the proposed sellon: Provided, That the following catecomes may not, as a result of reprograming, be decreased by more than 10 per centum the sums appropriated pursuant to this Act for such categories: Coal, petroleum and natural gas, oil chaie, colar, geothermal, and conservation.

Sic. 306. The Administrator thall submit to the Committee on Prience and Technology of the House of Representatives and the Comalitice on Interior and Insular Allalis of the

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Senate a detailed explanation of the allocation of the funds appropriated pursuant to section 101(a) and 201(a) of this Act for nonnuclear energy programs and subprograms, reflecting the relationships, consistencles, and dissimilarities between those allocations and (a) the comprehensive program definition transmitted pursuant to section 102 of the Geothermal Energy Research, Development, and Demonstration Act. (b) the comprehensive program definition transmitted pursuant to section 15 of the Solar End ergy Research, Development, and Demonstra tion Act of 1974 (42 U.S.C. 5531), (c) the comprehensive nonnuclear energy recenced development, and (d) demonstrations trausmitted pursuant to section 6 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5905).

SEC. 307. When so specified in an appropril ation pursuant to this Act for "Operating expenses" or for "Plant and capital equip-inent" for nonnuclear energy may remain available until expended.

SEC. 303. The Administrator shall, by Jana 30, 1976, and by the end of each fiscal year thereafter, submit a report to the Committee on Science and Technology of the House of Representatives and the Committee on Interior and Insular Affairs of the Senate Letailing the extent to which small business and nonprofit organizations are being funded by the nonnuclear research, development; and demonstration programs of the Admin-II istrator, and the extent to which small bus. ness involvement pursuant to section 2.d) of the Energy Reorganization Act of 1974 (42 U.S.C. 5301(d)) is being encouraged by the Administrator.

SEC. 309. The Administrator shall coordinate nonnuclear programs of the Adminis-tration with the heads of relevant Federal agencies in order to minimize unnecessary. duplication of programs, projects, and research facilities.

SEC. 310. The Administrator shall, as soon as practicable and consistent with destra, economic, and feasibility studies, include in an annual authorization proposal a recommendation on construction of at least one demonstration offshore wind-electric generating facility.

SEC. 311. As a part of the annual report required by section 15(a) (1) of the Federal Nonnuclear Energy Research and Develop-ment Act of 1974 (42 U.S.C. 5314(a)(1)), the Administrator shall:

(a) detail the Solar Energy Division personnel level recommended for the current fiscal year by the Administrator and submitted to the Office of Management and Budget, and the personnel level authorized upon review by that Office; and

(b) detail progress toward completion by January 1, 1980, of the objectives of the Solar Energy Research Development, and Demonstration Act of 1974 (42 U.S.C. 5551, et seq.).

Src. 312. The Federal Nonnuclear Energy Recearch and Development Act of 1974 (42 U.S.C. 5901) is amended by adding at the end thereof the following new section: CENTRAL SOURCE OF NONNUCLEAR ENERGY

#### INFORMATION

Sec. 17. The Administrator shall promptly establish, develop, acquire, and maintain a central cource of information on all energy resources and technology in furtherance of the Administrator's relearch, development, and demonstration mission carried out directly or indirectly under this Act. When the Administrator determines that such information is needed to carry out the purposes of this Act, he may acquire proprietory and other information (a) by purchase through negotiation or by donation from any person, or (b) from another Federal agency. The fitformation maintained by the Auministrator chall be made available to the public, subject to the provisions of section 652 of title

5. United States Code, and rection 1905 of title 18, United States Code, and to other Government accueles in a mapping that all facilitate its discontination: Provided, That upon a showing natisfactory to the Adminis-Arator by any person that any information, or portion thereof, obtained under this rection by the Administrator directly or indirectly from such person, would, if made public, divulge (1) trade secrets or (2) other proprietary information of such person, the Administrator shall not disclose such information and disclosure thereof shall be punishable under section 1905 of title 13, United States Code: Provided further, That the Administrator shall, upon request, provide such information to (A) any delegate of the Administrator for the purpose of carrying ous this Act, and (B) the Attorney General, the Secretary of Agriculture, the Secretary of the Interior, the Federal Trade Commission, the Federal Energy Administration, the Environmental Protection Agency, the Federal Power Commission, the General Accounting Office, other Federal agencies, when necessary to carry out their duties and responsibilities under this and other statutes, but such agencies and agency heads shall not release such information to the public. This section is not suchority to withhold information from Congress or any committee of Congress upon request of the chairman.".

Sec. 313. The Federal Nonhuelear Ender Research and Development Act of 1974 (42 VUS.C. 5501) is amended by adding at the end thereof (after the new section added by section 612 of this Act) The following new section:

#### "ENERCY INFORMATION

"Sec. 18. The Administrator-is, upon r quest, authorized to obtain energy inform ton under section 11(d) of the Energy Su; 7 and Environmental Coordination Act C. 1974, as amended (15 U.S.C. 700(d)).".

#### PART C-PROVISIONS RELATING TO FOSSE ENTERGY DEVELOPMENT

SEC. 314. Funds appropriated pursuant this Act for "Operating expenses" for fo Ell energy purposes may be used for (1) a facilities which may be required at locations, other than installations of the Administration, for the performance of research and development contracts, and (2) grants to any organization for purchase or construction of research faculties. No such funds shall be used for the acquisition of land. Fee title to all such facilities thall be vested in the United States, unless the Administrator determines in writing that the programs of research and development authorized by this Act shall best be implemented by resting ico title in an entity other than the United States: Provided, That, beford approving the vesting of title in such entity, the Adattalstrator shall (A) transmit such determina. tion, together with all pertinent data, to the Committee on Science and Technology of the Bouse of Representatives and the Committee on Interior and Insular Affairs of the Senate, and (B) walt a period of thirty calendar days (not including any day in which either House of Congress 13 not in session because of adjournment of more than three calendar days to a day certain). unless prior to the expiration of such period each such committee has transmitted to the Administrator written notice to the effect that such committee has no objection to the proposed action. Each great shall be made under such conditions as the Administrator decins necessary to insure that the United States will receive therefrom becelly ngequate to justify the making of the grant tio such funds shall be used under clause (1) of the first centence of this section for the construction of any major facility the estimated cost of which, including collaters. equipment, exceeds \$2.0,000 unless the Ad immistrator shall (1) transmit a report of

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### STATEMENT OF NORMAN J. LATKER PATENT COUNSEL DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE BEFORE SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS COMMITTEE ON SCIENCE AND TECHNOLOGY HOUSE OF REPRESENTATIVES

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM THE PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE. MY OFFICE HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S 1.8 BILLION DOLLAR ANNUAL RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION, SINCE I HAVE HAD A DEEP INTEREST IN GOVERNMENT PATENT POLICY WHICH HAS LED ME TO SERVICE ON EVERY MAJOR REVIEW OF GOVERNMENT PATENT POLICY IN THE LAST SEVEN YEARS. IN THAT REGARD, I SERVED AS THE DRAFTSMAN FOR THE TASK FORCE WHICH DEVELOPED THE "ALTERNATE APPROACH" FOR ALLOCATING THE INVENTIVE RESULTS OF GOVERNMENT FUNDED RESEARCH AND DEVELOPMENT FOR THE 1971 COMMISSION ON GOVERNMENT PROCUREMENT. AS YOU WILL RECALL FROM HIS TESTIMONY, DR. FORMAN CONSIDERED THE "ALTERNATE APPROACH" THE CLOSEST EMBODIMENT OF HIS VIEWS AND RECOMMENDATIONS FOR CONGRESSIONAL ENACTMENT OF A UNIFORM NATIONAL GOVERNMENT PATENT POLICY. IN ADDITION, I HAVE SERVED ON THE DRAFTING GROUPS THAT DEVELOPED THE ERDA PATENT PROVISIONS, THE FEDERAL PROCUREMENT PATENT AND LICENSING REGULATIONS WHICH YOU HAVE TAKEN NOTE OF AND WHICH WERE THE SUBJECT OF THE TWO PUBLIC CITIZENS CASES. BUT MOST RELEVANT TO MY STATEMENT TODAY, I AM THE CHAIRMAN OF THE UNIVERSITY PATENT POLICY SUBCOMMITTEE OF THE NOW ABOLISHED FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY (FCST). IT IS THIS INTERAGENCY SUBCOMMITTEE THAT WAS RESPONSIBLE FOR THE FEDERAL PROCUREMENT REGULATIONS ON UNIVERSITY PATENT POLICY NOTED BY MR. WOODROW IN HIS TESTIMONY AND NOW CIRCULATING FOR PUBLIC COMMENT. I HOPE TO ELABORATE ON THE DEVELOPMENT OF THESE REGULATIONS LATER IN MY STATEMENT.

MY SERVICE WITH THESE GROUPS AND MY DAILY INTERFACE WITH INNOVATORS AND THEIR ORGANIZATIONS HAS REINFORCED MY BELIEF IN THE FUNDAMENTAL PREMISES OF DHEW PATENT POLICY WHICH GIVEN THE FACT THAT COMMERCIALIZATION OF INVENTIONS MUST BE ULTIMATELY ACCOMPLISHED BY INDUSTRY SEEM CONCLUSIVE TO ME BUT, NOTWITHSTANDING, REMAIN A SUBJECT OF CONTINUING DEBATE. THUS, THE DEPARTMENT SUPPORTS THE BELIEF THAT A GUARANTEE OF SOME PATENT PROTECTION MAY BE NECESSARY TO AN INDUSTRIAL DEVELOPER IN ORDER TO ASSURE UTILIZATION BY OR TRANSFER TO SUCH DEVELOPER OF INVENTIVE RESULTS OF DEPARTMENT SPONSORED RESEARCH. THIS IS REFLECTED IN THE DEPARTMENT PATENT REGULATIONS 45 C.F.R., PARTS 6 THROUGH 8, AND, IN PARTICULAR, SECTIONS 6.6, 8.1(b) AND 8.2(b). FURTHER, THIS GUARANTEE MAY BE NECESSARY WHETHER THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT AND COMMERCIALIZATION WAS MADE BY A GOVERNMENT, UNIVERSITY OR INDUSTRY EMPLOYEE IN PERFORMANCE OF GOVERNMENT FUNDED RESEARCH. THESE PREMISES SEEM OBVIOUS TO ME, SINCE INHERENT TO THE COMMITMENT OF RISK CAPITAL TOWARD THE COMPLETION OF DEVELOPMENT IS A DECISION ON THE PART OF THE INDUSTRIAL

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DEVELOPER ON WHETHER THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS INTERESTS. CONVERSELY, FAILURE TO PROVIDE SUCH GUARANTEE IN CASES WHERE IT IS NECESSARY MAY FATALLY AFFECT UTILIZATION OR TRANSFER OF A MAJOR INNOVATION. ACCORDINGLY, IT WOULD SEEM THAT THE RESEARCH AND DEVELOPMENT AGENCIES SHOULD BE UNDER A HEAVY OBLIGATION TO ASSURE AVAILABILITY OF PATENT PROTECTION WHEN PRIVATE RESOURCES ARE NEEDED TO ACHIEVE COMMERCIALIZATION.

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IT IS MY OWN BELIEF THAT ANY CONTROVERSY OVER GOVERNMENT PATENT POLICY, AT LEAST IN THE RESEARCH AND DEVELOPMENT AGENCIES, IS <u>NOT</u>, AS COMMONLY STATED, WHETHER THE GOVERNMENT SHOULD TAKE "TITLE" OR "LICENSE" TO INVENTIVE RESULTS IT HAD FUNDED, BUT <u>WHEN AND TO WHAT EXTENT</u> THE GUARANTEE OF PATENT PROTECTION NOTED ABOVE SHOULD BE MADE TO INDUSTRY. ACCORDINGLY, EVERY RESEARCH AND DEVELOPMENT AGENCY THAT HAS TESTIFIED, INCLUDING DHEW, BELIEVES IT HAS THE DISCRETION WHETHER DERIVED FROM STATUTE, AGENCY REGULATION OR THE PRESIDENT'S STATEMENT ON PATENT POLICY, TO WAIVE OR LICENSE PATENT RIGHTS WHEN IT IS DEEMED APPROPRIATE TO ACHIEVE COMMERCIAL UTILIZATION. IN DHEW THAT DISCRETION IS DERIVED FROM DEPARTMENT REGULATIONS AND THE PRESIDENT'S STATEMENT RATHER THAN STATUTE. THERE IS NO DIFFERENCE OF OPINION AMONG THE RESEARCH AND DEVELOPMENT AGENCIES THAT THIS DISCRETION SHOULD EXIST.

THE MORE MEANINGFUL PROBLEM IS SIMPLY THAT THE AGENCIES HAVE NOT UTILIZED THIS DISCRETION ON A UNIFORM BASIS IN SIMILAR FACT SITUATIONS TO THE EXTENT THAT SOME AGENCIES HAVE NOT FELT IT NECESSARY TO DEVELOP A

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TITLE BRI BY UTTLE

MANAGEMENT MECHANISM TO ENTERTAIN REQUESTS FOR LICENSES OR WAIVERS ON ANY BASIS. THIS IS EVIDENCED BY THE LACK OF ACTIVITY NOTED IN LICENSE AND WAIVER CATEGORIES FOR SOME AGENCIES IN THE ''ANNUAL REPORT ON GOVERNMENT PATENT POLICY'' PUBLISHED BY FCST.

I WOULD NOW TURN MY ATTENTION TO THE ALLOCATION OF INVENTIONS ARISING FROM GOVERNMENT-SPONSORED RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS. THIS IS AN AREA OF VITAL INTEREST TO DHEW, BECAUSE THE DEPARTMENT IS BY FAR THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND PROBABLY THE WORLD, AND FURTHER, BECAUSE THE SUBSTANTIAL MAJORITY OF ALL ITS RESEARCH FUNDS ARE USED TO SPONSOR RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS. WHILE THE ALLOCATION OF RIGHTS OF INVENTIONS MADE BY DEPARTMENT EMPLOYEES AND FOR-PROFIT CONTRACTORS IS AN IMPORTANT MATTER, I WILL ONLY NOTE THAT THE POLICIES COVERING THIS AREA IN THE DEPARTMENT ARE SIMILAR TO THOSE OF NASA AND ERDA. DIFFERENCES ARE EVIDENT ONLY IN APPLICATION AND RESULT.

IN THE HISTORICAL 1939 LETTER FROM DR. EINSTEIN TO PRESIDENT ROOSEVELT POINTING OUT TO THE PRESIDENT THE IMMINENCE OF THE FIRST CONTROLLED NUCLEAR CHAIN-REACTION AND THE ADVENT OF THE ATOMIC AGE, DR. EINSTEIN MADE

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THE FOLLOWING RECOMMENDATIONS WITH A VIEW TOWARD EXPEDITING THE WORK:

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"IN VIEW OF THIS SITUATION YOU MAY THINK IT DESIRABLE TO HAVE SOME PERMANENT CONTACT MAINTAINED BETWEEN THE ADMINISTRA-TION AND THE GROUP OF PHYSICISTS WORKING ON CHAIN REACTIONS IN AMERICA. ONE POSSIBLE WAY OF ACHIEVING THIS MIGHT BE FOR YOU TO ENTRUST WITH THIS TASK A PERSON WHO HAS YOUR CONFIDENCE AND WHO COULD PERHAPS SERVE IN AN UNOFFICIAL CAPACITY. HIS TASK MIGHT COMPRISE THE FOLLOWING:

a) TO APPROACH GOVERNMENT DEPARTMENTS, KEEP THEM
INFORMED OF THE FURTHER DEVELOPMENT, AND PUT FORWARD
RECOMMENDATIONS FOR GOVERNMENT ACTION, GIVING
PARTICULAR ATTENTION TO THE PROBLEM OF SECURING A
SUPPLY OF URANIUM ORE FOR THE UNITED STATES;
b) TO SPEED UP THE EXPERIMENTAL WORK, WHICH IS AT
PRESENT BEING CARRIED ON WITHIN THE LIMITS OF THE
BUDGETS OF UNIVERSITY LABORATORIES, BY PROVIDING FUNDS,
IF SUCH FUNDS BE REQUIRED, THROUGH HIS CONTACTS WITH
PRIVATE PERSONS, WHO ARE WILLING TO MAKE CONTRIBUTIONS
FOR THIS CAUSE, AND PERHAPS ALSO OBTAINING THE COOPERATION
OF INDUSTRIAL LABORATORIES, WHICH HAVE THE NECESSARY EQUIPMENT."

IN THESE FEW WORDS DR. EINSTEIN SEEMS TO HAVE PROPERLY IDENTIFIED AND ASSIGNED TO EACH ELEMENT OF THE COLLABORATIVE TEAM HE DEEMED NECESSARY TO THE COMPLETION OF DEVELOPMENT, THE DUTY WHICH EACH WOULD

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PERFORM BEST. THUS, HE SUGGESTS THAT THE UNIVERSITIES BE AIDED IN COMPLETING THEIR EXPERIMENTAL OR FUNDAMENTAL RESEARCH, THAT INDUSTRIAL LABORATORIES BE TAPPED FOR THEIR ABILITY TO BRING SUCH FUNDAMENTAL FINDINGS INTO PRACTICAL APPLICATION THROUGH THE USE OF THEIR EQUIPMENT AND THE GOVERNMENT ACT AS THE CATALYST OR IMPRESARIO IN BRINGING THESE FACTORS TOGETHER.

AS SIMPLE AS DR. EINSTEIN'S FORMULA FOR DELIVERY OF THE RESULTS OF FUNDAMENTAL RESEARCH INTO PRACTICAL USE APPEARS, THE DEPARTMENTS AND AGENCIES OF THE EXECUTIVE HAD DONE LITTLE TO FORMULIZE IT UNTIL RECENT YEARS. THE CLOSING OF THE ENORMOUS GAP BETWEEN THE FUNDAMENTAL FINDINGS OF UNIVERSITIES IN NEW FIELDS OF KNOWLEDGE AS DRAMATICALLY INNOVATIVE AS RADAR, COMPUTER MEMORY CORES, LASERS, ANTIBIOTICS, ETC., AND THEIR PRACTICAL IMPLEMENTATION BY INDUSTRY, WITH THE EXCEPTION OF THE FEW CASES WHERE THE GOVERNMENT HAS DETERMINED TO PROVIDE THE CONTINUED FUNDING TO INDUSTRY FOR DEVELOPMENT OF SUCH FINDINGS, HAS BEEN LEFT TO RANDOM AND HAPHAZARD EXECUTION.

FROM THE VIEWPOINT OF THE GOVERNMENT AND THE PUBLIC, THE STAKE IN CLOSING THIS GAP IS VERY HIGH. THE SHEER MAGNITUDE OF GOVERNMENT SUPPORT OF RESEARCH AND DEVELOPMENT AT UNIVERSITIES APPEARS TO DEMAND EVIDENCE OF USEFUL RESULTS IF IT IS TO BE CONTINUED IN THE PREVAILING COMPETITION FOR THE FEDERAL DOLLAR. IN FISCAL YEAR 1972 APPROXIMATELY \$3.1 BILLION OF THE \$12 BILLION, OR OVER ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT

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IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES. OF THE \$3.1 BILLION, THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE WAS RESPONSIBLE FOR ADMINISTERING \$1.2 BILLION.

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ON SEPTEMBER 23, 1975, THE FEDERAL COUNCIL ON SCIENCE AND TECHNOLOGY'S COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDED, ON THE BASIS OF ITS UNIVERSITY SUBCOMMITTEE'S STUDY, THAT ALL AGENCIES OF THE EXECUTIVE BRANCH PROVIDE TO UNIVERSITIES A FIRST OPTION TO SUBSTANTIALLY ALL FUTURE INVENTIONS GENERATED WITH FEDERAL SUPPORT, SUBJECT TO STATUTORY AUTHORITY TO THE CONTRARY, PROVIDED THAT THE INVENTING ORGANIZATION IS FOUND TO HAVE AN IDENTIFIED TECHNOLOGY TRANSFER FUNCTION. THIS FIRST OPTION TO OWNERSHIP IS SUBJECT TO A NUMBER OF CONDITIONS, THE MOST IMPORTANT OF WHICH ARE THE STANDARD LICENSE TO THE GOVERNMENT, A LIMIT ON THE TERM OF ANY EXCLUSIVE LICENSE GRANTED, AUTHORITY TO WITHDRAW SPECIFIED PROJECTS FROM THE OPTION, A REQUIREMENT THAT ROYALTY INCOME BE UTILIZED FOR EDUCATIONAL OR RESEARCH PURPOSES, WITH THE EXCEPTION OF A REASONABLE SHARE TO THE INVENTOR, AND THE RIGHT OF THE AGENCY TO REGAIN OWNERSHIP DUE TO PUBLIC INTEREST CONSIDERATIONS OR THE UNIVERSITIES' FAILURE TO TAKE EFFECTIVE STEPS TO COMMERCIALIZE THE INVENTION.

IN ADDITION, THE COMMITTEE ALSO DIRECTED THAT AN INTERAGENCY COMMITTEE BE FORMED FOR THE PURPOSE OF JOINT AGENCY IDENTIFICATION OF UNIVERSITIES HAVING A SATISFACTORY TECHNOLOGY TRANSFER FUNCTION. AS NOTED, IMPLEMENTATION OF THE COUNCIL'S RECOMMENDATION IS NOW BEING CIRCULATED FOR PUBLIC COMMENT IN THE FORM OF A PROPOSED FEDERAL PROCUREMENT REGULATION.

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AT THE OUTSET OF ITS STUDY, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED SOME GENERAL PREMISES FROM WHICH IT WOULD BE NECESSARY TO PROCEED. AS YOU WILL NOTE, ALL OF THESE PREMISES WERE INTUITIVELY UNDERSTOOD BY DR. EINSTEIN IN 1939.

FIRST, A SYMPATHETIC AND ENCOURAGING FEDERAL CLIMATE IS VERY IMPORTANT TO TECHNOLOGICAL PROGRESS. THUS, IN CASES WHERE THE REQUIREMENT FOR UNIVERSITY/INDUSTRY RELATIONS IS NOT MET IN A SATISFACTORY MANNER, GOVERNMENT CAN HAVE AN IMPORTANT ROLE TO PLAY AS A CATALYST OR "IMPRESARIO" IN CREATING THE FRAMEWORK WITHIN WHICH REGULAR CONTACTS TAKE PLACE BETWEEN UNIVERSITY AND INDUSTRY.

SECOND, THE UNIVERSITY COMMUNITY AND INDUSTRY, LEFT TO THEIR OWN INITIATIVES, WILL PROBABLY BE UNABLE TO GENERATE THIS ATMOSPHERE. PRIVATE BUSINESS, EVEN THOUGH CONCERNED WITH INSTITUTIONAL BARRIERS THAT PRECLUDE SYSTEMS INNOVATIONS, CAN'T DO MUCH ABOUT IT. THEY ARE RESPONSIBLE FOR OUTPUTS OF THEIR BUSINESSES AND MUST ORDINARILY WORK WITHIN THE NARROW CONFINES OF THE COMPANIES' RESPONSIBILITIES TO MAXIMIZE PROFITS AND MINIMIZE RISKS FOR THE FIRM.

THIRD, THERE APPEARS TO BE AN ABSOLUTE NEED FOR INDUSTRIAL COLLABORATION WITH UNIVERSITIES IF THE RESULTS OF GOVERNMENT-SPONSORED UNIVERSITY RESEARCH ARE TO REACH THE MARKETPLACE. THIS IS TRUE, SINCE MUCH OF THE WORK PERFORMED UNDER GOVERNMENT-SPONSORED GRANTS AND CONTRACTS AT UNIVERSITIES IS BASIC, AS OPPOSED TO APPLIED RESEARCH. INVENTIONS ARISING OUT OF BASIC RESEARCH INVOLVE AT MOST COMPOSITIONS OF MATTER WITH

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NO CLEAR UTILITY, PROTOTYPE DEVICES, OR PROCESSES WHICH USUALLY REQUIRE MUCH ADDITIONAL DEVELOPMENT. UNIVERSITIES THEMSELVES DO NOT UNDERTAKE THE COMPLETE DEVELOPMENT OF SUCH INCHOATE INVENTIONS, AS DEVELOPMENT LEADING TO COMMERCIAL MARKETING IS NOT ORDINARILY WITHIN THE SCOPE OF THEIR MISSIONS OR PHYSICAL CAPABILITY. FURTHER, FINANCING OF THAT TYPE OF DEVELOPMENT WORK NEEDED IS NOT GENERALLY AVAILABLE FROM GOVERNMENT SOURCES. THERE ARE MANY MORE INVENTIVE IDEAS THAN FEDERAL RESOURCES FOR DEVELOPMENT PURPOSES. CONSEQUENTLY, DEVELOPMENT OF SUCH INVENTIONS WILL GENERALLY BE ACCOMPLISHED ONLY WHERE INDUSTRY HAS KNOWLEDGE OF THEM AND HAS AN INCENTIVE TO UTILIZE ITS RISK CAPITAL TO BRING THEM TO THE MARKETPLACE.

LAST, THE DIFFICULTY OF COLLABORATION IS COMPOUNDED WHEN THOSE WHO NOW PERFORM ESSENTIAL PARTS OF A FUNCTION REFUSE TO MODIFY THEIR OPERATIONS TO MEET THE NEEDS OF THE WHOLE SYSTEM. (THE RESEARCH AND DEVELOPMENT AGENCIES WERE NOT EXCLUDED AS ONE OF THE PRINCIPALS WHO MUST MODIFY ITS OPERATIONS.) THESE VESTED INTERESTS CONSTITUTE THE MOST SERIOUS INSTITUTIONAL BARRIERS TO SOCIALLY IMPORTANT INNOVATIONS. ORDINARILY, THE PRINCIPALS CAN'T BE ORDERED TO COLLABORATE. NOR WILL THEY DO SO UNLESS THEY SEE SOMETHING IN IT FOR THEMSELVES. THE PROBLEM PERCEIVED WAS HOW TO PROVIDE THE MEANS FOR INDUCING THEM TO INTEGRATE VOLUNTARILY INTO A SYSTEM THAT PERFORMS A SOCIALLY DESIRABLE FUNCTION.

WITH THESE PREMISES IN MIND, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED THE FOLLOWING AS THE PRIMARY PROBLEMS THAT NEEDED TO BE OVERCOME BEFORE OPTIMUM RESULTS IN TRANSFERRING TECHNOLOGY COULD BE ACHIEVED.

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FIRST, AND THOUGHT TO BE THE MOST IMPORTANT, WAS THE CONCLUSION THAT UNIVERSITIES DO NOT GENERALLY HAVE AN ADEQUATE MANAGEMENT CAPABILITY TO FACILITATE THE TIMELY IDENTIFICATION, PROTECTION AND THE TRANSFER OF THEIR INVENTIVE RESULTS TO INDUSTRIAL CONCERNS THAT MIGHT MAKE USE OF THEM. EVEN THOSE ORGANIZATIONS HAVING THE RIGHT TO TRANSFER A DEGREE OF PATENT PROTECTION DESIRED BY INDUSTRY MAY WELL FAIL TO SUCCEED IN ENCOURAGING UTILIZATION IF AN ADEQUATE, ORGANIZED EFFORT TO IDENTIFY, PROTECT AND COMMUNICATE THESE RESULTS IS NOT MADE.

IT WAS PERCEIVED THAT THE MERE EXISTENCE OF A BODY OF RESEARCH PUBLICATIONS AND OTHER TECHNICAL INFORMATION WAS NOT ENOUGH TO RESULT IN SIGNIFICANT INDUSTRIAL INVOLVEMENT IN FURTHERING DEVELOPMENT.

SECOND, WAS THE "NOT-INVENTED-HERE" SYNDROME. INDUSTRIAL ORGANIZA-TIONS HAVE COMMERCIAL POSITIONS IN MOST AREAS OF THEIR RESEARCH. ACCORD-INGLY, THERE IS AN IN-HOUSE INCENTIVE FOR SUCH ORGANIZATIONS TO FURTHER DEVELOP THE RESULTS OF THEIR RESEARCH IN ORDER TO IMPROVE THEIR COMMERCIAL POSITION. THIS INCENTIVE STEMS FROM THE ORGANIZATION'S ABILITY TO CONTINUOUSLY EVALUATE THEIR RESEARCH THROUGH ALL STAGES OF ITS DEVELOPMENT. IT FOLLOWS THAT THERE WILL BE A LESSER INCENTIVE FOR INDUSTRY TO FURTHER DEVELOP THE RESULTS OF UNIVERSITY RESEARCH WHERE SUCH RESEARCH WILL NOT BE UNDER ITS INITIAL REVIEW OR CONTROL. IT WAS SUGGESTED THAT THIS BIAS TOWARD INVESTMENT IN FURTHER DEVELOPMENT OF ITS OWN IDEAS, RATHER THAN IDEAS FROM OUTSIDE SOURCES, MIGHT BE LESSENED BY EARLY IDENTIFICATION BY INDUSTRY OF UNIVERSITY INVESTIGATORS WHO MAY BE WORKING IN THEIR AREAS OF INTEREST.

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THIRD, WAS THE UNCERTAINTY OVER OWNERSHIP OF INVENTIONS MADE AT UNIVERSITIES THAT MAY BE COLLABORATIVELY DEVELOPED OR ARE INITIALLY GENERATED THROUGH A COLLABORATIVE RELATIONSHIP.

DHEW HAD NOTED SITUATIONS OF INDUSTRY REFUSAL TO COLLABORATE WITH UNIVERSITIES IN BRINGING DHEW-FUNDED INVENTIONS TO THE MARKETPLACE UNLESS PROVIDED SOME PATENT PROTECTION AS <u>QUID PRO QUO</u> FOR ADDITIONAL INVESTMENT AND DEVELOPMENT REQUIRED.

THIS WAS SUBSTANTIATED BY THE HARBRIDGE HOUSE STUDY AND A 1968 GAO REPORT NO. B-164031(2) ENTITLED "PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT-SPONSORED RESEARCH IN MEDICINAL CHEMISTRY." BOTH OF THESE STUDIES INDICATED A VIRTUAL INDUSTRY-WIDE BOYCOTT BY PHARMA-CEUTICAL FIRMS TO TEST COMPOSITIONS OF MATTER SYNTHESIZED OR ISOLATED BY DHEW GRANT-SUPPORTED INVESTIGATORS DUE TO DHEW'S PATENT PRACTICES AT THAT TIME. INDUSTRY FELT DHEW PATENT PRACTICES FAILED TO TAKE INTO CONSIDER-ATION THE LARGE PRIVATE INVESTMENT BEFORE SUCH COMPOSITIONS COULD BE MARKETED AS DRUGS. SIMILAR SITUATIONS HAD OCCURRED IN THE AREA OF MEDICAL HARDWARE DEVICES.

IT WAS DETERMINED FROM THE EXPERIENCES NOTED IN UNIVERSITY DEALINGS WITH THE PHARMACEUTICAL INDUSTRY AND MEDICAL DEVICE MANUFACTURERS THAT THERE WILL BE THE SAME RELUCTANCE TO COLLABORATE WITH UNIVERSITIES IN BRINGING OTHER HIGH-RISK INVENTIONS TO THE MARKETPLACE IF SOME PATENT EXCLUSIVITY IS NOT FIRST PROVIDED TO THE DEVELOPER.

FOURTH, IS THE PROBLEM OF CONTAMINATION. AS USED BY INDUSTRY AND UNIVERSITY INVESTIGATORS, "CONTAMINATION" MEANS THE POTENTIAL COMPROMISE OF RIGHTS IN PROPRIETARY RESEARCH RESULTING FROM EXPOSURE OF INDUSTRY TO

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IDEAS, COMPOSITIONS, AND/OR TEST RESULTS ARISING FROM GOVERNMENT-SPONSORED RESEARCH. FOR EXAMPLE, AN INVENTION MADE AT A UNIVERSITY UNDER A GOVERNMENT-FUNDED RESEARCH PROGRAM IS LOOKED INTO BY A COMPANY DOING PARALLEL RESEARCH. IF THE COMPANY INCORPORATES INTO ITS RESEARCH PROGRAM SOME OF THE RESEARCH FINDINGS OF THE UNIVERSITY AND THEN DEVELOPS A MARKETABLE PRODUCT PATENTABLY DISTINCT FROM THE UNIVERSITY'S INVENTION, THE COMPANY FEARS THAT THE GOVERNMENT IS IN A POSITION TO ASSERT CLAIMS TO THEIR PRODUCT.

TO OVERCOME THESE BARRIERS TO TECHNOLOGY TRANSFER, IT WAS DEEMED ESSENTIAL TO THE SUBCOMMITTEE THAT THE GOVERNMENT PERSUADE UNIVERSITIES TO PROVIDE A MANAGEMENT CAPABILITY WITHIN THE INSTITUTION THAT WILL SERVE AS A FOCAL POINT FOR IDENTIFICATION, RECEIPT AND PROMPT PROTECTION OF THE INVENTIVE RESULTS OF UNIVERSITY RESEARCH FOR LATER DISSEMINATION BY ITSELF OR OTHER MANAGEMENT ORGANIZATIONS TO THOSE INDUSTRIAL CONCERNS MOST LIKELY TO UTILIZE SUCH RESULTS. IT WAS THE CONCLUSION OF THE SUB-COMMITTEE THAT THIS MIGHT BE ACCOMPLISHED BY GUARANTEEING TO UNIVERSITIES AT THE TIME OF FUNDING, PATENT RIGHTS IN GOVERNMENT-SUPPORTED INVENTIONS IN RETURN FOR ESTABLISHMENT OF SUCH A MANAGEMENT CAPABILITY.

I BELIEVE THAT ONE OF THE PRIMARY BASES FOR THE RECOMMENDATION WAS THE REALIZATION THAT A SUBSTANTIAL MAJORITY OF INVENTIVE IDEAS REQUIRES "ADVOCATES" IN ORDER TO REACH THE MARKETPLACE, AND THAT EXPERIENCE INDICATES THAT THE INVENTING ORGANIZATION, IF INTERESTED, IS A MORE LIKELY "ADVOCATE" THAN A LESS PROXIMATE AND NOT AS EQUALLY CONCERNED GOVERNMENT STAFF. HISTORY IS REPLETE WITH EXAMPLES OF INVENTIONS NOW ACCEPTED AS PART OF OUR CULTURE, WHICH REACHED FRUITION ONLY DUE TO THE PERSEVERANCE OF AN ADVOCATE. IT IS SAID THAT THE INVENTOR OF XEROX, CHESTER CARLSON, CONTACTED OVER 100 CONCERNS BEFORE HE WAS ABLE TO OBTAIN A FINANCIAL COMMITMENT FOR DEVELOPMENT. SIMILARLY, SAMUEL B. MORSE ARGUED THROUGH FIVE YEARS BEFORE HE WAS ABLE TO OBTAIN \$30,000 FROM CONGRESS TO BUILD A TEST LINE FOR HIS TELEGRAPH BETWEEN WASHINGTON AND BALTIMORE. THERE IS NO EVIDENCE THAT A GOVERNMENT ORGANIZATION WOULD BE WILLING TO DUPLICATE THAT KIND OF EFFORT, NOR IS IT APPARENT THAT MANY ORGANIZATIONS OR PERSONS WOULD, ABSENT A PROPERTY RIGHT.

THE GUARANTEE OF PATENT RIGHTS TO THE UNIVERSITY CARRIES WITH IT THE RIGHT TO LICENSE COMMERCIAL CONCERNS, THUS CREATING THE INCENTIVE NECESSARY FOR DEVELOPMENT IN THOSE SITUATIONS WHERE COLLABORATION WOULD NOT OTHERWISE BE ACCOMPLISHED AND LESSENING OR ELIMINATING INDUSTRY FEAR OF CONTAMINATION. FURTHER, UNDER SUCH A POLICY, COLLABORATIVE ARRANGEMENTS COULD BE MADE WHEREIN INDUSTRY'S PARTICIPATION IS PROTECTED <u>BEFORE</u> IT IS EVEN CLEAR WHETHER OR NOT INVENTIONS WILL BE MADE. SUCH PRIOR ARRANGEMENTS SHOULD MINIMIZE THE PROBLEM OF THE ''NOT-INVENTED-HERE'' SYNDROME, SINCE A COLLABORATOR WOULD NOT BE VIEWED AS AN ''OUTSIDER.'' THE PROSPECT OF A ROYALTY RETURN IS MEANT TO ASSURE THE INVENTOR'S CONTINUED INVOLVEMENT.

IT IS BELIEVED THAT THE COMMITTEE'S RECOMMENDATIONS PROVIDE THE MEANS TO INDUCE VOLUNTARY INTEGRATION INTO A SYSTEM THAT WILL OPTIMIZE TECHNOLOGY TRANSFER THROUGH RECOGNITION OF THE EQUITIES OF ALL THE PARTIES.

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TO A LARGE EXTENT THE SEPTEMBER 23RD RECOMMENDATIONS OF THE COMMITTEE ON GOVERNMENT POLICY ARE A RATIFICATION OF THE PRACTICES IMPLEMENTED BY DHEW SINCE 1969 AND THE NATIONAL SCIENCE FOUNDATION SINCE 1974. THE DHEW PRACTICES, IN TURN, WERE INITIATED IN PART THROUGH THE IMPETUS CREATED BY THE CRITICAL REMARKS FROM THE 1968 GAO STUDY MENTIONED PREVIOUSLY ON THE LACK OF TIMELINESS IN PROCESSING PETITIONS FOR WAIVERS OF IDENTIFIED INVENTIONS AND THE NEED TO CLARIFY THE USE OF INSTITUTIONAL PATENT AGREEMENTS WHICH GUARANTEE FUTURE INVENTION RIGHTS TO UNIVERSITIES WITH TECHNOLOGY TRANSFER CAPABILITIES.

IN OCTOBER 1974 THE DEPARTMENT COLLECTED SOME ROUGH STATISTICS ON MANAGEMENT OF PATENT RIGHTS LEFT TO UNIVERSITIES. THIS STUDY INDICATED THAT 167 PATENT APPLICATIONS WERE FILED SINCE 1969 BY INSTITUTIONS WHO CHOSE TO EXERCISE THEIR FIRST OPTION TO INVENTION RIGHTS UNDER THEIR INSTITUTIONAL PATENT AGREEMENT. UNDER THE 167 PATENT APPLICATIONS FILED, THE UNIVERSITIES HAVE NEGOTIATED 29 NONEXCLUSIVE LICENSES AND 43 EXCLUSIVE LICENSES. SEVENTEEN JOINT-FUNDING ARRANGEMENTS WITH COMMERCIAL ORGANIZATIONS, INVOLVING ONLY THE POSSIBILITY OF RIGHTS TO FUTURE INVENTIONS, HAVE BEEN MADE. THIS IS AN IMPORTANT STATISTIC, SINCE IT INDICATES A WILLINGNESS TO MAKE ARRANGEMENTS PRIOR TO THE TIME THAT INVENTIONS HAVE BEEN MADE ON THE BASIS THAT THE INSTITUTION HAS THE FLEXIBILITY OF PROVIDING TO THE CONCERN SOME INVENTION RIGHTS IF AN INVENTION SHOULD EVOLVE FROM THE JOINTLY FUNDED EFFORT. THE INSTITUTION GAINS THIS ABILITY TO NEGOTIATE BY VIRTUE OF ITS INSTITUTIONAL PATENT AGREEMENT. WE WERE ADVISED THAT ON THE BASIS OF ALL THE AGREEMENTS NOTED,

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APPROXIMATELY 24 MILLION DOLLARS OF RISK CAPITAL MAY BE COMMITTED TO THE DEVELOPMENT OR MAKING OF INVENTIONS EVOLVING WITH DHEW SUPPORT.

UNDER OUR DEFERRED DETERMINATION POLICY, WHICH IS APPLICABLE TO ALL UNIVERSITIES WHO HAVE NOT YET ESTABLISHED A TECHNOLOGY TRANSFER CAPABILITY, IT WAS DETERMINED THAT SINCE JULY 1, 1968, 178 PETITIONS FOR WAIVER OF AN IDENTIFIED INVENTION HAVE BEEN REVIEWED AS OF OCTOBER 1974. OF THESE 178, 162 PETITIONS WERE GRANTED. UNDER THE 162 PETITIONS GRANTED, THE INSTITUTIONS INVOLVED AND RESPONDING HAVE, TO OCTOBER 1974 GRANTED 15 NONEXCLUSIVE LICENSES AND 35 EXCLUSIVE LICENSES. THESE LICENSES HAVE GENERATED A POSSIBLE COMMITMENT OF RISK CAPITAL OF AS MUCH AS 53 MILLION DOLLARS.

ONE OF THE PETITIONS GRANTED INVOLVED A BURN OINTMENT DISCOVERED AT A UNIVERSITY, WHICH WAS PATENTED FOR THE UNIVERSITY BY RESEARCH CORPORATION, LICENSED TO A PHARMACEUTICAL COMPANY, CLINICALLY TESTED UNDER THE DIRECTION OF THE COMPANY, AND CLEARED BY THE FOOD AND DRUG ADMINISTRATION ON THE COMPANY'S INITIATIVE. THE DRUG IS NOW COMMERCIALLY AVAILABLE. TO MY KNOWLEDGE, THIS IS THE ONLY DRUG OUTSIDE THE CANCER CHEMOTHERAPY PROGRAM WHICH WAS INITIALLY DISCOVERED WITH DEPARTMENT SUPPORT AND HAS REACHED THE MARKETPLACE THROUGH THE INVESTMENT OF RISK CAPITAL FROM THE DRUG INDUSTRY.

WE ARE AWARE OF AT LEAST FIVE OTHER DRUGS OUTSIDE CANCER CHEMOTHERAPY AT VARIOUS STATES OF DEVELOPMENT WHICH WERE DISCOVERED WITH DEPARTMENT SUPPORT AND ARE NOW BEING DEVELOPED WITH PRIVATE SUPPORT UNDER LICENSE, SOME OF WHICH ARE CLOSE TO MARKET CLEARANCE. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT.

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MUCH MORE SIGNIFICANT THAN THE FIGURES INVOLVED (WHICH I BELIEVE HAVE INCREASED SINCE OCTOBER 1974) IS INFORMATION PROVIDED BY THE UNIVERSITY COMMUNITY INDICATING THAT IN THE LAST FOUR YEARS INDUSTRIAL ORGANIZATIONS HAVE BEEN ACTIVELY PURSUING UNIVERSITY RESEARCH. I BELIEVE THIS TO BE CLEARLY THE RESULT OF THE UNIVERSITY COMMUNITY'S ACTIVE SOLICITATION OF COLLABORATIVE ARRANGEMENTS, WHICH IN TURN WAS PARTLY MOTIVATED BY THE FLEXIBILITY PROVIDED BY OUR PATENT POLICY.

IT IS HOPED THAT THE GROWING SUCCESS OF THE DHEW EXPERIENCE WILL BE EXPANDED TO THE REST OF THE EXECUTIVE BRANCH THROUGH THE COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDATIONS OF SEPTEMBER 23RD.

I HAVE MADE REFERENCE TO A NUMBER OF STUDIES AND REPORTS IN MY STATEMENT, WHICH I INTEND TO MAKE AVAILABLE TO YOUR COMMITTEE. I WOULD ALSO BE PLEASED TO MAKE ANY OF THESE AVAILABLE TO ANYONE CONTACTING ME AT (301) 496-7056, OR AT THE NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND 20014.

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### STATEMENT

OF NORMAN J. LATKER PATENT COUNSEL DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE BEFORE SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS COMMITTEE ON SCIENCE AND TECHNOLOGY HOUSE OF REPRESENTATIVES

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM THE PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE. MY OFFICE HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S 1.8 BILLION DOLLAR ANNUAL RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION, SINCE I HAVE HAD A DEEP INTEREST IN GOVERNMENT PATENT POLICY WHICH HAS LED ME TO SERVICE ON EVERY MAJOR REVIEW OF GOVERNMENT PATENT POLICY IN THE LAST SEVEN YEARS. IN THAT REGARD, I SERVED AS THE DRAFTSMAN FOR THE TASK FORCE WHICH DEVELOPED THE "ALTERNATE APPROACH" FOR ALLOCATING THE INVENTIVE RESULTS OF GOVERNMENT FUNDED RESEARCH AND DEVELOPMENT FOR THE 1971 COMMISSION ON GOVERNMENT PROCUREMENT. AS YOU WILL RECALL FROM HIS TESTIMONY, DR. FORMAN CONSIDERED THE "ALTERNATE APPROACH" THE CLOSEST EMBODIMENT OF HIS VIEWS AND RECOMMENDATIONS FOR CONGRESSIONAL ENACTMENT OF A UNIFORM NATIONAL GOVERNMENT PATENT POLICY.

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IN ADDITION, I HAVE SERVED ON THE DRAFTING GROUPS THAT DEVELOPED THE ERDA PATENT PROVISIONS, THE FEDERAL PROCUREMENT PATENT AND LICENSING REGULATIONS WHICH YOU HAVE TAKEN NOTE OF AND WHICH WERE THE SUBJECT OF THE TWO PUBLIC CITIZENS CASES. BUT MOST RELEVANT TO MY STATEMENT TODAY, I AM THE CHAIRMAN OF THE UNIVERSITY PATENT POLICY SUBCOMMITTEE OF THE NOW ABOLISHED FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY (FCST). IT IS THIS INTERAGENCY SUBCOMMITTEE THAT WAS RESPONSIBLE FOR THE FEDERAL PROCUREMENT REGULATIONS ON UNIVERSITY PATENT POLICY NOTED BY MR. WOODROW IN HIS TESTIMONY AND NOW CIRCULATING FOR PUBLIC COMMENT. I HOPE TO ELABORATE ON THE DEVELOPMENT OF THESE REGULATIONS LATER IN MY STATEMENT.

MY SERVICE WITH THESE GROUPS AND MY DAILY INTERFACE WITH INNOVATORS AND THEIR ORGANIZATIONS HAS REINFORCED MY BELIEF IN THE FUNDAMENTAL PREMISES OF DHEW PATENT POLICY WHICH GIVEN THE FACT THAT COMMERCIALIZATION OF INVENTIONS MUST BE ULTIMATELY ACCOMPLISHED BY INDUSTRY SEEM CONCLUSIVE TO ME BUT, NOTWITHSTANDING, REMAIN A SUBJECT OF CONTINUING DEBATE. THUS, THE DEPARTMENT SUPPORTS THE BELIEF THAT A GUARANTEE OF SOME PATENT PROTECTION MAY BE NECESSARY TO AN INDUSTRIAL DEVELOPER IN ORDER TO ASSURE UTILIZATION BY OR TRANSFER TO SUCH DEVELOPER OF INVENTIVE RESULTS OF DEPARTMENT SPONSORED RESEARCH. THIS IS REFLECTED IN THE DEPARTMENT PATENT REGULATIONS 45 C.F.R., PARTS 6 THROUGH 8, AND, IN PARTICULAR, SECTIONS 6.6, 8.1(b) AND 8.2(b). FURTHER, THIS GUARANTEE MAY BE NECESSARY WHETHER THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT AND COMMERCIALIZATION WAS MADE BY A GOVERNMENT, UNIVERSITY OR INDUSTRY EMPLOYEE IN PERFORMANCE OF GOVERNMENT FUNDED RESEARCH. THESE PREMISES SEEM OBVIOUS TO ME, SINCE INHERENT TO THE COMMITMENT OF RISK CAPITAL TOWARD THE COMPLETION OF DEVELOPMENT IS A DECISION ON THE PART OF THE INDUSTRIAL

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DEVELOPER ON WHETHER THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS INTERESTS. CONVERSELY, FAILURE TO PROVIDE SUCH GUARANTEE IN CASES WHERE IT IS NECESSARY MAY FATALLY AFFECT UTILIZATION OR TRANSFER OF A MAJOR INNOVATION. ACCORDINGLY, IT WOULD SEEM THAT THE RESEARCH AND DEVELOPMENT AGENCIES SHOULD BE UNDER A HEAVY OBLIGATION TO ASSURE AVAILABILITY OF PATENT PROTECTION WHEN PRIVATE RESOURCES ARE NEEDED TO ACHIEVE COMMERCIALIZATION.

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IT IS MY OWN BELIEF THAT ANY CONTROVERSY OVER GOVERNMENT PATENT POLICY, AT LEAST IN THE RESEARCH AND DEVELOPMENT AGENCIES, IS NOT, AS COMMONLY STATED, WHETHER THE GOVERNMENT SHOULD TAKE "TITLE" OR "LICENSE" TO INVENTIVE RESULTS IT HAD FUNDED, BUT WHEN AND TO WHAT EXTENT THE GUARANTEE OF PATENT PROTECTION NOTED ABOVE SHOULD BE MADE TO INDUSTRY. ACCORDINGLY, EVERY RESEARCH AND DEVELOPMENT AGENCY THAT HAS TESTIFIED, INCLUDING DHEW, BELIEVES IT HAS THE DISCRETION WHETHER DERIVED FROM STATUTE, AGENCY REGULATION OR THE PRESIDENT'S STATEMENT ON PATENT POLICY, TO WAIVE OR LICENSE PATENT RIGHTS WHEN IT IS DEEMED APPROPRIATE TO ACHIEVE COMMERCIAL UTILIZATION. IN DHEW THAT DISCRETION IS DERIVED FROM DEPARTMENT REGULATIONS AND THE PRESIDENT'S STATEMENT RATHER THAN STATUTE. THERE IS NO DIFFERENCE OF OPINION AMONG THE RESEARCH AND DEVELOPMENT AGENCIES THAT THIS DISCRETION SHOULD EXIST.

THE MORE MEANINGFUL PROBLEM IS SIMPLY THAT THE AGENCIES HAVE NOT UTILIZED THIS DISCRETION ON A UNIFORM BASIS IN SIMILAR FACT SITUATIONS TO THE EXTENT THAT SOME AGENCIES HAVE NOT FELT IT NECESSARY TO DEVELOP A

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MANAGEMENT MECHANISM TO ENTERTAIN REQUESTS FOR LICENSES OR WAIVERS ON ANY BASIS. THIS IS EVIDENCED BY THE LACK OF ACTIVITY NOTED IN LICENSE AND WAIVER CATEGORIES FOR SOME AGENCIES IN THE ''ANNUAL REPORT ON GOVERNMENT PATENT POLICY'' PUBLISHED BY FCST.

I WOULD NOW TURN MY ATTENTION TO THE ALLOCATION OF INVENTIONS ARISING FROM GOVERNMENT-SPONSORED RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS. THIS IS AN AREA OF VITAL INTEREST TO DHEW, BECAUSE THE DEPARTMENT IS BY FAR THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND PROBABLY THE WORLD, AND FURTHER, BECAUSE THE SUBSTANTIAL MAJORITY OF ALL ITS RESEARCH FUNDS ARE USED TO SPONSOR RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS. WHILE THE ALLOCATION OF RIGHTS OF INVENTIONS MADE BY DEPARTMENT EMPLOYEES AND FOR-PROFIT CONTRACTORS IS AN IMPORTANT MATTER, I WILL ONLY NOTE THAT THE POLICIES COVERING THIS AREA IN THE DEPARTMENT ARE SIMILAR TO THOSE OF NASA AND ERDA. DIFFERENCES ARE EVIDENT ONLY IN APPLICATION AND RESULT.

IN THE HISTORICAL 1939 LETTER FROM DR. EINSTEIN TO PRESIDENT ROOSEVELT POINTING OUT TO THE PRESIDENT THE IMMINENCE OF THE FIRST CONTROLLED NUCLEAR CHAIN-REACTION AND THE ADVENT OF THE ATOMIC AGE, DR. EINSTEIN MADE

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THE FOLLOWING RECOMMENDATIONS WITH A VIEW TOWARD EXPEDITING THE WORK:

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"IN VIEW OF THIS SITUATION YOU MAY THINK IT DESIRABLE TO HAVE SOME PERMANENT CONTACT MAINTAINED BETWEEN THE ADMINISTRA-TION AND THE GROUP OF PHYSICISTS WORKING ON CHAIN REACTIONS IN AMERICA. ONE POSSIBLE WAY OF ACHIEVING THIS MIGHT BE FOR YOU TO ENTRUST WITH THIS TASK A PERSON WHO HAS YOUR CONFIDENCE AND WHO COULD PERHAPS SERVE IN AN UNOFFICIAL CAPACITY. HIS TASK MIGHT COMPRISE THE FOLLOWING:

a) TO APPROACH GOVERNMENT DEPARTMENTS, KEEP THEM
INFORMED OF THE FURTHER DEVELOPMENT, AND PUT FORWARD
RECOMMENDATIONS FOR GOVERNMENT ACTION, GIVING
PARTICULAR ATTENTION TO THE PROBLEM OF SECURING A
SUPPLY OF URANIUM ORE FOR THE UNITED STATES;
b) TO SPEED UP THE <u>EXPERIMENTAL WORK</u>, WHICH IS AT
PRESENT BEING CARRIED ON WITHIN THE LIMITS OF THE
BUDGETS OF <u>UNIVERSITY LABORATORIES</u>, BY PROVIDING FUNDS,
IF SUCH FUNDS BE REQUIRED, THROUGH HIS CONTACTS WITH
PRIVATE PERSONS, WHO ARE WILLING TO MAKE CONTRIBUTIONS
FOR THIS CAUSE, AND <u>PERHAPS ALSO OBTAINING THE COOPERATION</u>
OF INDUSTRIAL LABORATORIES, WHICH HAVE THE NECESSARY EQUIPMENT."
(EMPHASIS ADDED)

IN THESE FEW WORDS DR. EINSTEIN SEEMS TO HAVE PROPERLY IDENTIFIED AND ASSIGNED TO EACH ELEMENT OF THE COLLABORATIVE TEAM HE DEEMED NECESSARY TO THE COMPLETION OF DEVELOPMENT, THE DUTY WHICH EACH WOULD PERFORM BEST. THUS, HE SUGGESTS THAT THE UNIVERSITIES BE AIDED IN COMPLETING THEIR EXPERIMENTAL OR FUNDAMENTAL RESEARCH, THAT INDUSTRIAL LABORATORIES BE TAPPED FOR THEIR ABILITY TO BRING SUCH FUNDAMENTAL FINDINGS INTO PRACTICAL APPLICATION THROUGH THE USE OF THEIR EQUIPMENT AND THE GOVERNMENT ACT AS THE CATALYST OR IMPRESARIO IN BRINGING THESE FACTORS TOGETHER.

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AS SIMPLE AS DR. EINSTEIN'S FORMULA FOR DELIVERY OF THE RESULTS OF FUNDAMENTAL RESEARCH INTO PRACTICAL USE APPEARS, THE DEPARTMENTS AND AGENCIES OF THE EXECUTIVE HAD DONE LITTLE TO FORMULIZE IT UNTIL RECENT YEARS. THE CLOSING OF THE ENORMOUS GAP BETWEEN THE FUNDAMENTAL FINDINGS OF UNIVERSITIES IN NEW FIELDS OF KNOWLEDGE AS DRAMATICALLY INNOVATIVE AS RADAR, COMPUTER MEMORY CORES, LASERS, ANTIBIOTICS, ETC., AND THEIR PRACTICAL IMPLEMENTATION BY INDUSTRY, WITH THE EXCEPTION OF THE FEW CASES WHERE THE GOVERNMENT HAS DETERMINED TO PROVIDE THE CONTINUED FUNDING TO INDUSTRY FOR DEVELOPMENT OF SUCH FINDINGS, HAS BEEN LEFT TO RANDOM AND HAPHAZARD EXECUTION.

FROM THE VIEWPOINT OF THE GOVERNMENT AND THE PUBLIC, THE STAKE IN CLOSING THIS GAP IS VERY HIGH. THE SHEER MAGNITUDE OF GOVERNMENT SUPPORT OF RESEARCH AND DEVELOPMENT AT UNIVERSITIES APPEARS TO DEMAND EVIDENCE OF USEFUL RESULTS IF IT IS TO BE CONTINUED IN THE PREVAILING COMPETITION FOR THE FEDERAL DOLLAR. IN FISCAL YEAR 1972 APPROXIMATELY \$3.1 BILLION OF THE \$12 BILLION, OR OVER ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT

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IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES. OF THE \$3.1 BILLION, THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE WAS RESPONSIBLE FOR ADMINISTERING \$1.2 BILLION.

ON SEPTEMBER 23, 1975, THE FEDERAL COUNCIL ON SCIENCE AND TECHNOLOGY'S COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDED, ON THE BASIS OF ITS UNIVERSITY SUBCOMMITTEE'S STUDY, THAT ALL AGENCIES OF THE EXECUTIVE BRANCH PROVIDE TO UNIVERSITIES A FIRST OPTION TO SUBSTANTIALLY ALL FUTURE INVENTIONS GENERATED WITH FEDERAL SUPPORT, SUBJECT TO STATUTORY AUTHORITY TO THE CONTRARY, PROVIDED THAT THE INVENTING ORGANIZATION IS FOUND TO HAVE AN IDENTIFIED TECHNOLOGY TRANSFER FUNCTION. THIS FIRST OPTION TO OWNERSHIP IS SUBJECT TO A NUMBER OF CONDITIONS, THE MOST IMPORTANT OF WHICH ARE THE STANDARD LICENSE TO THE GOVERNMENT, A LIMIT ON THE TERM OF ANY EXCLUSIVE LICENSE GRANTED, AUTHORITY TO WITHDRAW SPECIFIED PROJECTS FROM THE OPTION, A REQUIREMENT THAT ROYALTY INCOME BE UTILIZED FOR EDUCATIONAL OR RESEARCH PURPOSES, WITH THE EXCEPTION OF A REASONABLE SHARE TO THE INVENTOR, AND THE RIGHT OF THE AGENCY TO REGAIN OWNERSHIP DUE TO PUBLIC INTEREST CONSIDERATIONS OR THE UNIVERSITIES' FAILURE TO TAKE EFFECTIVE STEPS TO COMMERCIALIZE THE INVENTION.

IN ADDITION, THE COMMITTEE ALSO DIRECTED THAT AN INTERAGENCY COMMITTEE BE FORMED FOR THE PURPOSE OF JOINT AGENCY IDENTIFICATION OF UNIVERSITIES HAVING A SATISFACTORY TECHNOLOGY TRANSFER FUNCTION. AS NOTED, IMPLEMENTATION OF THE COUNCIL'S RECOMMENDATION IS NOW BEING CIRCULATED FOR PUBLIC COMMENT IN THE FORM OF A PROPOSED FEDERAL PROCUREMENT REGULATION.

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AT THE OUTSET OF ITS STUDY, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED SOME GENERAL PREMISES FROM WHICH IT WOULD BE NECESSARY TO PROCEED. AS YOU WILL NOTE, ALL OF THESE PREMISES WERE INTUITIVELY UNDERSTOOD BY DR. EINSTEIN IN 1939.

FIRST, A SYMPATHETIC AND ENCOURAGING FEDERAL CLIMATE IS VERY IMPORTANT TO TECHNOLOGICAL PROGRESS. THUS, IN CASES WHERE THE REQUIREMENT FOR UNIVERSITY/INDUSTRY RELATIONS IS NOT MET IN A SATISFACTORY MANNER, GOVERNMENT CAN HAVE AN IMPORTANT ROLE TO PLAY AS A CATALYST OR "'IMPRESARIO'' IN CREATING THE FRAMEWORK WITHIN WHICH REGULAR CONTACTS TAKE PLACE BETWEEN UNIVERSITY AND INDUSTRY.

SECOND, THE UNIVERSITY COMMUNITY AND INDUSTRY, LEFT TO THEIR OWN INITIATIVES, WILL PROBABLY BE UNABLE TO GENERATE THIS ATMOSPHERE. PRIVATE BUSINESS, EVEN THOUGH CONCERNED WITH INSTITUTIONAL BARRIERS THAT PRECLUDE SYSTEMS INNOVATIONS, CAN'T DO MUCH ABOUT IT. THEY ARE RESPONSIBLE FOR OUTPUTS OF THEIR BUSINESSES AND MUST ORDINARILY WORK WITHIN THE NARROW CONFINES OF THE COMPANIES' RESPONSIBILITIES TO MAXIMIZE PROFITS AND MINIMIZE RISKS FOR THE FIRM.

THIRD, THERE APPEARS TO BE AN ABSOLUTE NEED FOR INDUSTRIAL COLLABORATION WITH UNIVERSITIES IF THE RESULTS OF GOVERNMENT-SPONSORED UNIVERSITY RESEARCH ARE TO REACH THE MARKETPLACE. THIS IS TRUE, SINCE MUCH OF THE WORK PERFORMED UNDER GOVERNMENT-SPONSORED GRANTS AND CONTRACTS AT UNIVERSITIES IS BASIC, AS OPPOSED TO APPLIED RESEARCH. INVENTIONS ARISING OUT OF BASIC RESEARCH INVOLVE AT MOST COMPOSITIONS OF MATTER WITH

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NO CLEAR UTILITY, PROTOTYPE DEVICES, OR PROCESSES WHICH USUALLY REQUIRE MUCH ADDITIONAL DEVELOPMENT. UNIVERSITIES THEMSELVES DO NOT UNDERTAKE THE COMPLETE DEVELOPMENT OF SUCH INCHOATE INVENTIONS, AS DEVELOPMENT LEADING TO COMMERCIAL MARKETING IS NOT ORDINARILY WITHIN THE SCOPE OF THEIR MISSIONS OR PHYSICAL CAPABILITY. FURTHER, FINANCING OF THAT TYPE OF DEVELOPMENT WORK NEEDED IS NOT GENERALLY AVAILABLE FROM GOVERNMENT SOURCES. THERE ARE MANY MORE INVENTIVE IDEAS THAN FEDERAL RESOURCES FOR DEVELOPMENT PURPOSES. CONSEQUENTLY, DEVELOPMENT OF SUCH INVENTIONS WILL GENERALLY BE ACCOMPLISHED ONLY WHERE INDUSTRY HAS KNOWLEDGE OF THEM AND HAS AN INCENTIVE TO UTILIZE ITS RISK CAPITAL TO BRING THEM TO THE MARKETPLACE.

LAST, THE DIFFICULTY OF COLLABORATION IS COMPOUNDED WHEN THOSE WHO NOW PERFORM ESSENTIAL PARTS OF A FUNCTION REFUSE TO MODIFY THEIR OPERATIONS TO MEET THE NEEDS OF THE WHOLE SYSTEM. (THE RESEARCH AND DEVELOPMENT AGENCIES WERE NOT EXCLUDED AS ONE OF THE PRINCIPALS WHO MUST MODIFY ITS OPERATIONS.) THESE VESTED INTERESTS CONSTITUTE THE MOST SERIOUS INSTITUTIONAL BARRIERS TO SOCIALLY IMPORTANT INNOVATIONS. ORDINARILY, THE PRINCIPALS CAN'T BE ORDERED TO COLLABORATE. NOR WILL THEY DO SO UNLESS THEY SEE SOMETHING IN IT FOR THEMSELVES. <u>THE PROBLEM PERCEIVED WAS HOW TO PROVIDE THE MEANS FOR</u> INDUCING THEM TO INTEGRATE VOLUNTARILY INTO A SYSTEM THAT PERFORMS A <u>SOCIALLY DESIRABLE FUNCTION</u>.

WITH THESE PREMISES IN MIND, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED THE FOLLOWING AS THE PRIMARY PROBLEMS THAT NEEDED TO BE OVERCOME BEFORE OPTIMUM RESULTS IN TRANSFERRING TECHNOLOGY COULD BE ACHIEVED.

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FIRST, AND THOUGHT TO BE THE MOST IMPORTANT, WAS THE CONCLUSION THAT UNIVERSITIES DO NOT GENERALLY HAVE AN ADEQUATE MANAGEMENT CAPABILITY TO FACILITATE THE TIMELY IDENTIFICATION, PROTECTION AND THE TRANSFER OF THEIR INVENTIVE RESULTS TO INDUSTRIAL CONCERNS THAT MIGHT MAKE USE OF THEM. EVEN THOSE ORGANIZATIONS HAVING THE RIGHT TO TRANSFER A DEGREE OF PATENT PROTECTION DESIRED BY INDUSTRY MAY WELL FAIL TO SUCCEED IN ENCOURAGING UTILIZATION IF AN ADEQUATE, ORGANIZED EFFORT TO IDENTIFY, PROTECT AND COMMUNICATE THESE RESULTS IS NOT MADE.

IT WAS PERCEIVED THAT THE MERE EXISTENCE OF A BODY OF RESEARCH PUBLICATIONS AND OTHER TECHNICAL INFORMATION WAS NOT ENOUGH TO RESULT IN SIGNIFICANT INDUSTRIAL INVOLVEMENT IN FURTHERING DEVELOPMENT.

SECOND, WAS THE "NOT-INVENTED-HERE" SYNDROME. INDUSTRIAL ORGANIZA-TIONS HAVE COMMERCIAL POSITIONS IN MOST AREAS OF THEIR RESEARCH. ACCORD-INGLY, THERE IS AN IN-HOUSE INCENTIVE FOR SUCH ORGANIZATIONS TO FURTHER DEVELOP THE RESULTS OF THEIR RESEARCH IN ORDER TO IMPROVE THEIR COMMERCIAL POSITION. THIS INCENTIVE STEMS FROM THE ORGANIZATION'S ABILITY TO CONTINUOUSLY EVALUATE THEIR RESEARCH THROUGH ALL STAGES OF ITS DEVELOPMENT. IT FOLLOWS THAT THERE WILL BE A LESSER INCENTIVE FOR INDUSTRY TO FURTHER DEVELOP THE RESULTS OF UNIVERSITY RESEARCH WHERE SUCH RESEARCH WILL NOT BE UNDER ITS INITIAL REVIEW OR CONTROL. IT WAS SUGGESTED THAT THIS BLAS TOWARD INVESTMENT IN FURTHER DEVELOPMENT OF ITS OWN IDEAS, RATHER THAN IDEAS FROM OUTSIDE SOURCES, MIGHT BE LESSENED BY EARLY IDENTIFICATION BY INDUSTRY OF UNIVERSITY INVESTIGATORS WHO MAY BE WORKING IN THEIR AREAS OF INTEREST.

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THIRD, WAS THE UNCERTAINTY OVER OWNERSHIP OF INVENTIONS MADE AT UNIVERSITIES THAT MAY BE COLLABORATIVELY DEVELOPED OR ARE INITIALLY GENERATED THROUGH A COLLABORATIVE RELATIONSHIP.

DHEW HAD NOTED SITUATIONS OF INDUSTRY REFUSAL TO COLLABORATE WITH UNIVERSITIES IN BRINGING DHEW-FUNDED INVENTIONS TO THE MARKETPLACE UNLESS PROVIDED SOME PATENT PROTECTION AS <u>QUID PRO QUO</u> FOR ADDITIONAL INVESTMENT AND DEVELOPMENT REQUIRED.

THIS WAS SUBSTANTIATED BY THE HARBRIDGE HOUSE STUDY AND A 1968 GAO REPORT NO. B-164031(2) ENTITLED "PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT-SPONSORED RESEARCH IN MEDICINAL CHEMISTRY." BOTH OF THESE STUDIES INDICATED A VIRTUAL INDUSTRY-WIDE BOYCOTT BY PHARMA-CEUTICAL FIRMS TO TEST COMPOSITIONS OF MATTER SYNTHESIZED OR ISOLATED BY DHEW GRANT-SUPPORTED INVESTIGATORS DUE TO DHEW'S PATENT PRACTICES AT THAT TIME. INDUSTRY FELT DHEW PATENT PRACTICES FAILED TO TAKE INTO CONSIDER-ATION THE LARGE PRIVATE INVESTMENT BEFORE SUCH COMPOSITIONS COULD BE MARKETED AS DRUGS. SIMILAR SITUATIONS HAD OCCURRED IN THE AREA OF MEDICAL HARDWARE DEVICES.

IT WAS DETERMINED FROM THE EXPERIENCES NOTED IN UNIVERSITY DEALINGS WITH THE PHARMACEUTICAL INDUSTRY AND MEDICAL DEVICE MANUFACTURERS THAT THERE WILL BE THE SAME RELUCTANCE TO COLLABORATE WITH UNIVERSITIES IN BRINGING OTHER HIGH-RISK INVENTIONS TO THE MARKETPLACE IF SOME PATENT EXCLUSIVITY IS NOT FIRST PROVIDED TO THE DEVELOPER.

FOURTH, IS THE PROBLEM OF CONTAMINATION. AS USED BY INDUSTRY AND UNIVERSITY INVESTIGATORS, "CONTAMINATION" MEANS THE POTENTIAL COMPROMISE OF RIGHTS IN PROPRIETARY RESEARCH RESULTING FROM EXPOSURE OF INDUSTRY TO IDEAS, COMPOSITIONS, AND/OR TEST RESULTS ARISING FROM GOVERNMENT-SPONSORED RESEARCH. FOR EXAMPLE, AN INVENTION MADE AT A UNIVERSITY UNDER A GOVERNMENT-FUNDED RESEARCH PROGRAM IS LOOKED INTO BY A COMPANY DOING PARALLEL RESEARCH. IF THE COMPANY INCORPORATES INTO ITS RESEARCH PROGRAM SOME OF THE RESEARCH FINDINGS OF THE UNIVERSITY AND THEN DEVELOPS A MARKETABLE PRODUCT PATENTABLY DISTINCT FROM THE UNIVERSITY'S INVENTION, THE COMPANY FEARS THAT THE GOVERNMENT IS IN A POSITION TO ASSERT CLAIMS TO THEIR PRODUCT.

TO OVERCOME THESE BARRIERS TO TECHNOLOGY TRANSFER, IT WAS DEEMED ESSENTIAL TO THE SUBCOMMITTEE THAT THE GOVERNMENT PERSUADE UNIVERSITIES TO PROVIDE A MANAGEMENT CAPABILITY WITHIN THE INSTITUTION THAT WILL SERVE AS A FOCAL POINT FOR IDENTIFICATION, RECEIPT AND PROMPT PROTECTION OF THE INVENTIVE RESULTS OF UNIVERSITY RESEARCH FOR LATER DISSEMINATION BY ITSELF OR OTHER MANAGEMENT ORGANIZATIONS TO THOSE INDUSTRIAL CONCERNS MOST LIKELY TO UTILIZE SUCH RESULTS. IT WAS THE CONCLUSION OF THE SUB-COMMITTEE THAT THIS MIGHT BE ACCOMPLISHED BY GUARANTEEING TO UNIVERSITIES AT THE TIME OF FUNDING, PATENT RIGHTS IN GOVERNMENT-SUPPORTED INVENTIONS IN RETURN FOR ESTABLISHMENT OF SUCH A MANAGEMENT CAPABILITY.

I BELIEVE THAT ONE OF THE PRIMARY BASES FOR THE RECOMMENDATION WAS THE REALIZATION THAT A SUBSTANTIAL MAJORITY OF INVENTIVE IDEAS REQUIRES "ADVOCATES" IN ORDER TO REACH THE MARKETPLACE, AND THAT EXPERIENCE INDICATES THAT THE INVENTING ORGANIZATION, IF INTERESTED, IS A MORE LIKELY "ADVOCATE" THAN A LESS PROXIMATE AND NOT AS EQUALLY CONCERNED GOVERNMENT STAFF.

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HISTORY IS REPLETE WITH EXAMPLES OF INVENTIONS NOW ACCEPTED AS PART OF OUR CULTURE, WHICH REACHED FRUITION ONLY DUE TO THE PERSEVERANCE OF AN ADVOCATE. IT IS SAID THAT THE INVENTOR OF XEROX, CHESTER CARLSON, CONTACTED OVER 100 CONCERNS BEFORE HE WAS ABLE TO OBTAIN A FINANCIAL COMMITMENT FOR DEVELOPMENT. SIMILARLY, SAMUEL B. MORSE ARGUED THROUGH FIVE YEARS BEFORE HE WAS ABLE TO OBTAIN \$30,000 FROM CONGRESS TO BUILD A TEST LINE FOR HIS TELEGRAPH BETWEEN WASHINGTON AND BALTIMORE. THERE IS NO EVIDENCE THAT A GOVERNMENT ORGANIZATION WOULD BE WILLING TO DUPLICATE THAT KIND OF EFFORT, NOR IS IT APPARENT THAT MANY ORGANIZATIONS OR PERSONS WOULD, ABSENT A PROPERTY RIGHT.

THE GUARANTEE OF PATENT RIGHTS TO THE UNIVERSITY CARRIES WITH IT THE RIGHT TO LICENSE COMMERCIAL CONCERNS, THUS CREATING THE INCENTIVE NECESSARY FOR DEVELOPMENT IN THOSE SITUATIONS WHERE COLLABORATION WOULD NOT OTHERWISE BE ACCOMPLISHED AND LESSENING OR ELIMINATING INDUSTRY FEAR OF CONTAMINATION. FURTHER, UNDER SUCH A POLICY, COLLABORATIVE ARRANGEMENTS COULD BE MADE WHEREIN INDUSTRY'S PARTICIPATION IS PROTECTED <u>BEFORE</u> IT IS EVEN CLEAR WHETHER OR NOT INVENTIONS WILL BE MADE. SUCH PRIOR ARRANGEMENTS SHOULD MINIMIZE THE PROBLEM OF THE 'NOT-INVENTED-HERE'' SYNDROME, SINCE A COLLABORATOR WOULD NOT BE VIEWED AS AN 'OUTSIDER.'' THE PROSPECT OF A ROYALTY RETURN IS MEANT TO ASSURE THE INVENTOR'S CONTINUED INVOLVEMENT.

IT IS BELIEVED THAT THE COMMITTEE'S RECOMMENDATIONS PROVIDE THE MEANS TO INDUCE VOLUNTARY INTEGRATION INTO A SYSTEM THAT WILL OPTIMIZE TECHNOLOGY TRANSFER THROUGH RECOGNITION OF THE EQUITIES OF ALL THE PARTIES.

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TO A LARGE EXTENT THE SEPTEMBER 23RD RECOMMENDATIONS OF THE COMMITTEE ON GOVERNMENT POLICY ARE A RATIFICATION OF THE PRACTICES IMPLEMENTED BY DHEW SINCE 1969 AND THE NATIONAL SCIENCE FOUNDATION SINCE 1974. THE DHEW PRACTICES, IN TURN, WERE INITIATED IN PART THROUGH THE IMPETUS CREATED BY THE CRITICAL REMARKS FROM THE 1968 GAO STUDY MENTIONED PREVIOUSLY ON THE LACK OF TIMELINESS IN PROCESSING PETITIONS FOR WAIVERS OF IDENTIFIED INVENTIONS AND THE NEED TO CLARIFY THE USE OF INSTITUTIONAL PATENT AGREEMENTS WHICH GUARANTEE FUTURE INVENTION RIGHTS TO UNIVERSITIES WITH TECHNOLOGY TRANSFER CAPABILITIES.

IN OCTOBER 1974 THE DEPARTMENT COLLECTED SOME ROUGH STATISTICS ON MANAGEMENT OF PATENT RIGHTS LEFT TO UNIVERSITIES. THIS STUDY INDICATED THAT 167 PATENT APPLICATIONS WERE FILED SINCE 1969 BY INSTITUTIONS WHO CHOSE TO EXERCISE THEIR FIRST OPTION TO INVENTION RIGHTS UNDER THEIR INSTITUTIONAL PATENT AGREEMENT. UNDER THE 167 PATENT APPLICATIONS FILED, THE UNIVERSITIES HAVE NEGOTIATED 29 NONEXCLUSIVE LICENSES AND 43 EXCLUSIVE LICENSES. SEVENTEEN JOINT-FUNDING ARRANGEMENTS WITH COMMERCIAL ORGANIZATIONS, INVOLVING ONLY THE POSSIBILITY OF RIGHTS TO FUTURE INVENTIONS, HAVE BEEN MADE. THIS IS AN IMPORTANT STATISTIC, SINCE IT INDICATES A WILLINGNESS TO MAKE ARRANGEMENTS PRIOR TO THE TIME THAT INVENTIONS HAVE BEEN MADE ON THE BASIS THAT THE INSTITUTION HAS THE FLEXIBILITY OF PROVIDING TO THE CONCERN SOME INVENTION RIGHTS IF AN INVENTION SHOULD EVOLVE FROM THE JOINTLY FUNDED EFFORT. THE INSTITUTION GAINS THIS ABILITY TO NEGOTIATE BY VIRTUE OF ITS INSTITUTIONAL PATENT AGREEMENT. WE WERE ADVISED THAT ON THE BASIS OF ALL THE AGREEMENTS NOTED,

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STATEMENT OF DR. BETSY ANCKER-JOHNSON ASSISTANT SECRETARY FOR SCIENCE AND TECHNOLOGY U.S. DEPARTMENT OF COMMERCE AND CHAIRMAN OF THE COMMITTEE ON GOVERNMENT PATENT POLICY OF THE FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY PRESENTED TO THE SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY U.S. HOUSE OF REPRESENTATIVES

October 1, 1976

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to appear before the Subcommittee to give you some of my views regarding the ownership of rights resulting from Federally-funded research and development and to provide you with information concerning the ongoing work of the Committee on Government Patent Policy. I have with me, Mr. David Eden, Special Assistant to the Assistant Secretary for Science and Technology, Mr. Robert B. Ellert, Assistant General Counsel for Science and Technology, and Mr. O. A. Neumann, Executive Secretary of the Committee on Government Patent Policy.

I wish to commend the Subcommittee for scheduling these hearings whereby the patent policies, regulations, and practices employed by the Federal agencies in conducting their research and development programs may be reviewed.

#### I. BACKGROUND

In preparing this Statement, I have attempted to present new information if at all possible which has not been covered by the volumes of background material prepared by the Subcommittee and previous witnesses.

As added background, with your permission, Mr. Chairman, I would like to introduce into the record my May 7, 1975 comments made in response to four questions raised by Senator Philip A. Hart. The questions were concerned with the

- (1) desirability of uniform Government patent policy;
- (2) licensing of Government-owned inventions;
- (3) allocation of rights to inventions; and
- (4) safeguards when title or exclusive rights are retained by the contractor.

In addition, the Committee responded on June 17, 1974 to questions asked by Senator William Proxmire concerning the activities of the Committee on Government Patent Policy regarding its past published reports, actions taken to improve the transfer of technology, the comprehensive licensing program of the Federal Government which included the exclusive licensing of Federallyowned patents, the Alternate Approach of the Commission's Report, and technical data. I would also like to introduce into the record this response.

As I will show, it is becoming extremely \difficult for industry, universities, nonprofit institutions and the general public to deal with the increasingly complex and diverse patent policies, regulations, and practices of the Federal Government.

In late 1965, the Federal Council for Science and Technology established the Committee on Government Patent Policy for the purpose of assessing how the 1963 Presidential Statement on Government Patent Policy had worked in practice, to acquire and analyze additional information that would contribute to the reaffirmation or modification of the policy, and to identify principles that would underline sound legislation in this area.

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The prime impetus for creating this interagency Committee was the Federal Council's desire to formulate a uniform Federal patent policy, and the Committee, composed of policy level officials, provided a forum for developing such a position.

The major accomplishments of the Committee over the first ten years of its existence are the support of the fourvolume work of the study conducted by Harbridge House, Inc., its recommendations for revising the 1963 Statement which resulted in the issuance of the 1971 Presidential Patent Policy Statement, and the drafting of the Federal procurement and patent licensing regulations which implemented this Statement. A continuing important task of the Committee for its use in policy review is the collection of data which provide valuable insight into Federal agency patent practices, the present size of the Federal patent operations, and future trends. For the purpose of my later discussion of the more recent and, to date, unpublished data compiled by the Committee, I would like to have entered into the record a copy of Table I, showing data for fiscal years 1970 through 1975, and Table II, making a comparison and analysis of the total data accumulated during these years. While the data are lacking in some respects, they represent the most accurate information available on the subject.

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#### II. UNIFORM PATENT POLICY

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Recently, the Committee undertook the task of drafting a suggested uniform patent policy covering (1) the allocation of rights to all inventions resulting from Federally-sponsored R&D, made either by contractors or Federal employees, and (2) the protection and licensing of all Federally-owned inventions. This action was taken to respond to recommendations of the Congressionally-established Commission on Government Procurement; to overcome legal uncertainties raised by past and pending litigation regarding the Federal procurement and licensing regulations; and to provide uniformity among Federal agency practices so as to permit the public to do business with the Federal Government with greater ease and predictability.

We are now in the final stages of completing this suggested policy and with the exception of a few unresolved issues we have complete agreement within the Executive Branch. Prior to drafting this policy, the Committee considered

the concepts and options available to it. The Committee reviewed the existing policies and combinations thereof and agreed to draft a policy that, briefly, would

> permit the contractor to retain title to any inventions as long as the contractor sought patent protection and the commercialization of the inventions, and require the Federal agency to acquire all rights necessary to safeguard the public interest;

- (2) codify the basic policy concepts of Executive Order10096, add incentives, and make the law applicableto all Federal employees; and
- (3) authorize the Federal agencies to protect Federallyowned inventions, as warranted, and to license the inventions so as to enhance commercial utilization.

#### (a) Contractor Inventions

With respect to the policy concepts available with respect to contractor inventions, the Committee reviewed the various policies set forth in existing legislation, the 1971 Presidential Statement, and the Alternate Approach of the Commission's Report. In analyzing the diverse policies presented, the Committee considered the competing policy objectives of:

- encouraging the participation of the most qualified and competent contractors;
- (2) fostering competition;
- (3) promoting the widespread utilization of inventions resulting from such research; and
- (4) reducing the burden of both the Federal agencies and their contractors in the administration of invention matters.

The first three of these policy objectives were considered by Harbridge House, Inc., in conducting the Committee-sponsored study, mentioned above.

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From a review of the numerous diverse patent policy statutes and regulations printed in the background materials compiled by the Subcommittee, it quickly becomes apparent what the public must face when doing business with the Federal Government. Additional insight to the problem is possible by reviewing Section IV of Table I which shows the numerous types of patent rights clauses used by the Federal agencies in their R&D contracts and grants.

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After extensive deliberations, the Committee adopted the basic policy concepts of the Alternate Approach as the policy which best responds to all of the competing policy concepts of obtaining maximum participation, competition, and utilization, while reducing the administrative burden and maintaining, and even strengthening, the safeguards to the public interests.

The policy concepts incorporated in the Alternate Approach by the Commission on Government Procurement and endorsed by the Committee on Government-Patent-Policy would permit the contractor to retain title to all patents resulting from Federal contracts and grants, and require the contractor to license others in certain specified situations so as to safeguard the public interest. In particular, the contractor would be required to license others if he fails to commercialize an invention covered by the patent. Even where

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he commercializes his invention, the contractor would be required to license others to meet specified public interest needs such as health, safety, and welfare, or where it is necessary to correct a situation inconsistent with the antitrust laws. It is expected that in these licensing situations, the contractor would generally be willing to license third parties without a Federal agency determination requiring him to do so. Should a contractor refuse to license a third party, the Federal agency itself has the right, in appropriate circumstances, to license the third party, subject to the contractor's right to a hearing and an appeal. The proposed policy would reduce drastically the administrative burden of deciding the type of patent rights clause to be used in some 30,000 R&D contracts annually, and would obviate the need for processing waiver petitions.

#### (b) Federal Employee Inventions

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In considering how the rights to inventions made by Federal employees should be allocated, the Committee believed that the basic policy concepts of Executive Order 10096 issued by President Truman in 1950 should be codified.

Briefly, under the proposed policy, the Federal Government would retain ownership to all inventions made by Federal employees where the invention bears a relation to the duties of the employee-inventor, or is made in consequence of employment. The

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policy encourages employees to invent because of the incentive awards program and the income-sharing provision.

The Committee believed the draft policy should contain provisions for Federal employee inventions, especially since not all Federal employees are covered by the Executive Order.

## (c) Protection and Licensing Authority

The remaining aspect of the draft policy is concerned with insuring that all Federal agencies obtain adequate domestic and foreign patent protection on inventions owned by them, and that licenses are granted on a uniform basis. Such a policy would enhance the Government's ability to transfer its technology to the private sector and to commercialize the inventions which it retains.

#### III. CONCLUSIONS

In conclusion, the Federal patent policies are set out in numerous statutes, several Executive Orders, and the 1971 Presidential Memorandum and Statement of Government Patent Policy. These policies spell out which invention rights are to be acquired and which are to be retained by the contractor.

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An examination of the Federal patent policies mentioned above discloses a significant diversity in agency practices in this important area. Some agencies are obligated because of statutory requirements to use a clause acquiring title to all inventions resulting from the contract. Other agencies are required to use a clause acquiring title to all inventions made under the contract, but may waive title to the contractor under certain circumstances. In addition, other agencies may use any one of several clauses, either acquiring title, acquiring only a license, or deferring the allocation of rights determinations until an invention is made under the contract, as provided by the 1971 Presidential Statement.

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As a result of the diversity in agency practices, there is an enormous and needless administrative burden placed on both the Federal agencies and their contractors as extensive negotiations occur respecting the rights to be granted the contractors and those to be retained by the Government. This administrative burden also often deters the most qualified and competent contractors from seeking Federal R&D contracts, thus inhibiting competition and curtailing the widespread utilization of inventions resulting from such research.

We believe that a policy which leaves title in the contractor subject to strong "march-in" rights in favor of the Government will protect the public interest and reduce substantially the administrative burden of both the Federal agencies and their contractors. In addition, we believe this change will stimulate more qualified and competent contractors to participate in Federally-sponsored R&D contracts. We also believe that this policy change will be especially beneficial to individuals and small business concerns since they no longer will have to cope with the existing diversity in agency practices and often the uncertainty as to their rights to inventions which may result from the contracts.

In addition, such a single patent rights clause will provide the contractor with a greater incentive to invest his own funds to commercialize an invention resulting from the contract. This incentive is especially important as most inventions require a potential manufacturer to invest substantial development funds before the invention can be marketed. By granting the contractor a limited period of exclusivity, the government improves his ability to recover development costs, thus encouraging him to commercialize the invention. Such commercialization benefits both the Government and the contractor.

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## WASHINGTON STATE UNIVERSITY

#### PULLMAN, WASHINGTON 99163

ASSISTANT VICE PRESIDENT-FINANCE

October 5, 1976

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Mr. Norman Latker Patent Council Westwood Building, Room 5A03 C/o National Institutes of Health Bethesda, Maryland 20014

Dear Mr. Latker:

I have made a brief review of the proposed federal procurement regulation revision prepared by the Ad Hoc Committee on University Patent Policy. I have also asked for comments from some fellow administrators and faculty members here at Washington State University.

I would like to make some comment and suggestions based on our review. I support the liberalization of the exclusive license. Anything we can do to make development of our ideas more attractive to the private sector will result in an increased utilization of knowledge developed at our University.

I note that there is a new requirement that scientific employees must sign a statement agreeing to these rules. I would prefer that this be a little more liberal and would allow institutions some flexibility here. For example, we include a statement in our faculty handbook which makes it very clear that it is a condition of employment for all of our faculty and scientific personnel to adhere to our patent policy. This has worked very well and is much less expensive than a procedure which would require a signature on a statement by each individual faculty member. I am sure you are aware of the numbers of pieces of paper they are required to sign right now by other federal regulations.

I noticed also that the new draft contains some very stiff reporting requirements. What stuck in my mind mostly were the reports requiring history going back ten years on the individual university's patent program statistics. This would involve a good deal of expense and I, frankly, question the value that will be produced.

Thank you for the opportunity of reviewing this document. I hope my comments are of some help.

Sincerely yours,

Joseph D. Hamel Assistant Vice President

JDH/db cc: Members of Patent Committee

## STATEMENT OF PURPOSE AND NEED

The draft Bill, cosponsored by the Office of Science and Technology Policy and the Department of Commerce, is directed toward establishing for the first time a uniform Federal policy on patentable technology and other intellectual property resulting from Federally-sponsored research and development (R&D). To this end, the Bill sets forth a policy for the (1) allocation of rights to all inventions (contractor and Federal employee) which result from Federal R&D programs, (2) protection of these invention rights through domestic and foreign patenting, and (3) licensing and commercialization of the patented and related technology.

#### BACKGROUND

Since World War II, the Federal Government has increasingly supported the overall R&D effort of the United States, and, at least intially, the patent policies of the Federal agencies were generally fashioned without any central guidance or overall coordination.

#### Federal Employee Inventions

In 1950, President Truman, in an attempt to bring about consistency in the allocation of rights to inventions made by Federal employees, issued Executive Order 10096.1/ This Executive Branch directive, generally based upon the common law principles for allocating invention rights to employees not otherwise under contract, covered most but not all Federal employees. The Executive Order recently was challenged successfully in a District Court of Illinois.2/

#### Contractor Inventions

With the increase in size of the Federal Government's R&D effort, the individual Federal agencies reacted differently to the problem of allocating rights to inventions. Some agencies, notably the Department of Defense, acquired a royalty-free license to resulting inventions and permitted the contractor to retain title, or what might otherwise be described as exclusive commercial rights. Other agencies conducting research of interest to the private sector, such as the Department of Health, Education, and Welfare, decided to acquire full right, title and interest to inventions developed under their R&D contracts. Finally, some agencies simply ignored the issue, which, in effect, permitted the contractor to retain all rights to inventions.

As Congress became more concerned with rights to inventions, it enacted differing legislative policies for new R&D programs. In some instances, the Congress provided guidance for the entire R&D effort of an agency, while in others, for only a specified R&D program. Generally, the Congress required the Federal Government to take title to all inventions.

As the issues developed prior to 1963, most arguments, positions, and proposed solutions supported Government-take-all

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or contractor-take-all. That is, some believed that the Government should always take title to all inventions resulting from R&D contracts (normally referred to as the "title policy"), while others advocated that the Government should acquire only a license to use these inventions (normally referred to as the "license policy").

In 1963, President Kennedy issued a Statement on Government Patent Policy, 3/ to bring about more uniformity in agency practices. The policy applied to the R&D programs of all Federal agencies except where it conflicted with specific statutory requirements.

The 1963 Policy Statement took the approach of identifying certain types of contracting situations where it would appear that, under an initial presumption, the public interest would best be served by Federal acquisition of title, and other contracting situations where it would appear that such rights would best be retained by the contractor. In addition, recognizing that the policy solution was based upon basic assumptions and a limited amount of factual information, the policy specified exceptions to the general rules and provided public interest safeguards where undesirable results might occur.

An unsuccessful attempt to obtain uniformity through legislative action occurred in 1965. $\frac{4}{}$  The result of Congressional hearings on the then proposed legislation was a Bill providing for a uniform Federal policy recommending substantially the

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same criteria set forth in the Kennedy Statement. While the Bill was reported out of Committee, no further Congressional action was taken.

In late 1965, the Federal Council for Science and Technology (FCST) established the Committee on Government Patent Policy for the purpose of assessing how the Kennedy Statement had worked in practice, to acquire and analyze additional information that would contribute to the reaffirmation or modification of the policy, and to identify principles that would underline sound legislation in this area. The prime impetus for creating this interagency Committee was that the Executive Branch was being pressed for its position on a uniform Federal patent policy bill, and the Committee, composed of policy level officials, provided a forum for developing such a position.

To fulfill its originating functions, the Committee supported what is perhaps the most extensive study ever conducted on the Federal patent policy issue. The results of this study, conducted by Harbridge House, Inc., of Boston, Massachusetts, are reported in a four-volume work.5/ The Harbridge House study suggested that no single across-the-board policy is in the best interest of the public; that is, neither the "title" nor the "license" policy is a proper solution.

Based upon its analysis of the results of the Harbridge House study and the operating experience under the Kennedy Statement, the Committee concluded that the criteria specified

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in the 1963 Statement, with minor revisions, satisfied the policy needs identified by the Harbridge House study. Accordingly, in 1969 the Committee recommended that if legislation was to be proposed, it should follow the basic criteria of the Kennedy Statement. As an alternative, the Committee recommended that modifications be made to the Kennedy Statement directed primarily toward increasing the Federal agencies' flexibility under the policy, and providing direction to the agencies for the licensing of Federallyowned inventions. The Department of Justice did not concur in all the conclusions and recommendations' made by the Committee, but it was in agreement with the reissuance of the Presidential Policy Statement. The Department of Justice believed additional studies and operating experience under a new Policy Statement should be obtained before a definite position on legislation should be taken. Accordingly, legislation was not sought at that time. Instead, President Nixon issued a revised Statement on Government Patent Policy<sup>6</sup>/ incorporating the modifications recommended by the Committee.

### LAWSUITS ON REGULATIONS IMPLEMENTING THE 1971 PRESIDENTIAL STATEMENT

#### Federal Property Management Regulations (FPMR)

Section 2 of the 1971 Nixon Statement directs the Adminstrator of General Services to issue regulations for the comprehensive licensing of Federally-owned inventions. In

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January 1973, the Administrator issued an amendment to the Federal Property Management Regulations concerned with the licensing of Federally-owned inventions.7/

The validity of this regulation was challenged in a complaint filed in the U.S. District Court by Public Citizen, Inc., et al. $\frac{8}{}$  The prime allegation of the complaint was that the exclusive licensing of a Federally-owned patent constituted a disposal of property in violation of Article IV, Section 3, Clause 2 of the Constitution. The District Court found for the Plaintiffs and directed the Administrator to take immediate steps to void the licensing regulations. Accordingly, the Administrator suspended the licensing regulations thereto until further notice. $\frac{9}{}$ 

The Government appealed,  $\underline{10}$  and on June 16, 1975 the Court of Appeals adjudged that the appellees were without standing, in consequence of which it reversed the findings of the District Court. On October 1, 1975, the Administrator reinstated the licensing regulations. $\underline{11}$  It is noted that the Court did not address the merits of the allegations made in the lawsuits. Accordingly, the legality of any exclusive license which a Federal agency, not having specific legislative authority, may grant under this regulation remains untested.

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## Federal Procurement Regulations (FPR)

Following the issuance of the 1971 Statement, regulations providing for standard patent rights clauses for use by all the Federal agencies were drafted and subsequently promulgated by the Administrator of General Services in August 1973.<u>12</u>/

The validity of these regulations was also challenged in a complaint filed in the United States District Court for the District of Columbia. 13/ Plaintiffs alleged that whenever the Government acquired less than title in a Government contract, the Government was, in effect, disposing of property in violation of Article IV, Section 3, Clause 2 of the Constitution. In view of the lawsuit, the Administrator cancelled the regulations.

On July 24, 1974, the Court dismissed the complaint on the grounds that no plaintiffs had alleged sufficient standing to sue. The plaintiffs appealed the dismissal; however, on June 16, 1975, the Court of Appeals affirmed the judgement of the District Court.14/

The regulations were reissued in May  $1975; \frac{15}{}$  however, again, the court did not address itself to the merits of the allegations made in the complaint.

#### COMMISSION ON GOVERNMENT PROCUREMENT

In November 1969, Congress established, by Public Law 91-129, the Commission on Government Procurement to study and recommend

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methods "to promote the economy, efficiency and effectiveness" of procurement by the Executive Branch of the Federal Government. Industry, the trade and bar associations, individuals, members of the Executive Branch, and a full-time staff assigned to the Commission assisted in the development of the Commission Report which was rendered to the Congress on December 31, 1972. $\frac{16}{}$ The bipartisan report contains 149 recommendations, 16 of which are related to patent, data and copyright matters.

Recommendation No. 1 of Part I, Volume IV of the Report states:

"Implement the revised Presidential Statement of Government Patent Policy promptly and uniformly."

Recommendation No. 2 states:

"Enact legislation to make clear the authority of all agencies to issue exclusive licenses under patents held by them."

Recommendation No. 1 was partially implemented with the issuance of the FPMR (licensing regulation) and the FPR (standard patent rights clause). However, if uniformity is to be achieved, a corollary of Recommendation No. 1 requires the repeal of all conflicting statutory provisions. Repeal of such provisions requires legislation as does the implementation of Recommendation No. 2.

During the September 23, 1975 meeting of the FCST Committee on Government Patent Policy, it was decided to prepare drafts of an Administration Bill to implement these recommendations of the Commission's Report. In later meetings, after considering several proposals, the Committee unanimously agreed that the policy concepts of the so-called "Alternate Approach" set forth in the Commission's report should provide the basis for such legislation. Briefly, the policy concept of the Alternate Approach provides a balanced approach to the longstanding policy issue by permitting the contractor to retain invention rights subject to the usual license to the Federal Government and a requirement that third parties be licensed under resulting patents in specified public interest situations.

#### DRAFT BILL

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A summary of the draft Bill approved by the Committee on Government Patent Policy follows:

#### TITLE I--FEDERAL INTELLECTUAL PROPERTY POLICY

Title I states as the primary purpose of the Act the establishment of a Federal Intellectual Property Policy based on the findings that inventions resulting from Federal research and development constitute a valuable national resource which should be appropriately protected by domestic and foreign patents and rights therein allocated in a manner which recognizes the equities of Federal employees and contractors while pursuing the mechanism most likely to promote their utilization in the national interest.

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TITLE	II-	-FUNC	CTIONS	OF	THE	OFFI	CE (	DF	SCIENC	Ε
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Title II provides to the Federal Coordinating Council for Science, Engineering and Technology (established by Title IV, P.L. 94-282, The National Science and Technology Policy, Organization and Priorities Act of 1976) the more specific responsibilities, and the means to exercise them, of making recommendations on intellectual property matters to the Office of Science and Technology Policy for the purpose of implementing this Act and the policy objectives of P.L. 94-282. Such responsibility also includes advising on the impact of use, ownership or licensing of trademarks, copyrights, right-in-technical data and matters connected therewith on Federal programs.

In addition, Title II provides for a Board on Intellectual Property for the purpose of making determinations and hearing appeals as provided for in the Act.

#### TITLE III--ALLOCATION OF PROPERTY RIGHTS IN INVENTIONS RESULTING FROM FEDERALLY-SPONSORED RESEARCH AND DEVELOPMENT

#### Chapter 1-- Inventions of Contractors

Chapter 1 of Title III provides for a single patent rights clause that normally is to be used in all Federally-funded contracts. The clause is intended to meet the competing policy objectives of

- 1. encouraging the participation of the most qualified and competent contractors,
- 2. fostering competition,
- promoting the widespread utilization of inventions resulting from such research, and
- 4. reducing the burden of both the Federal agencies and their contractors in the administration of invention matters,

while maintaining the uniform principles called for by Title I, Sec. 101.(c)(4) of P.L. 94-282.

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Chapter 1 also establishes procedures within which the Federal agencies may modify the single patent rights clause in situations which are deemed to be outside normal expectations or pose considerations radically different from those that arise in conventional negotiations for research and development services. Notwithstanding, the procedures are designed to assure uniformity of application through regulations, publication and post review.

#### Chapter 2--Inventions of Federal Employees

Chapter 2 of Title III establishes the criteria for allocation of rights between the Federal agencies and their employees in inventions made by such employees.

Chapter 2 further provides for an Incentive Awards and/or Royalty-sharing Program to be implemented at the discretion of the Federal agencies in order to monetarily reward or otherwise recognize Federal employees, stimulate inventive creativeness and encourage disclosure of inventions for purposes of enhancing utilization.

#### TITLE IV--DOMESTIC AND FOREIGN PROTECTION AND LICENSING OF FEDERALLY-OWNED INVENTIONS

Title IV provides the authorities and responsibilities in the Federal agencies deemed necessary to administer effectively a program or programs for the domestic and foreign licensing of Federally-owned inventions. The inventions include those that contractors have assigned to the Federal agencies under the provisions of Title III, Chapter 1, due to disinterest or failure to pursue utilization, and those acquired from Federal employees under the criteria of Title III, Chapter 2.

#### TITLE V--MISCELLANEOUS

#### Chapter 1--Other Related Provisions

Chapter 1 of Title V sets forth the definitions for the purposes of this Act for, "Federal agency," "Federal employees," "contractor," "contract," "invention," "Subject Invention," "practical application," "person," "made," and "antitrust law."

In addition, Chapter 1 clearly removes any implication that the Act provides immunity from the antitrust laws.

#### Chapter 2--Amendments to Other Acts

Chapter 2 of Title V is intended to amend or repeal parts of all Acts covering similar subject matter.

#### Chapter 3--Effective Date Provision

Chapter 3 of Title V establishes the effective date of this Act.

#### CONCLUSIONS

Enactment of this Bill would resolve longstanding policy issues, answers to which Congress, the Executive Branch, Industry and the public-at-large have actively sought for approximately thirty-six years. Further the Bill is responsive to the Commission on Government Procurement recommendations, set forth in the bipartisan report to the Congress that legislation be enacted which would make uniform the Federal practices in the area of allocating the rights to contractor inventions and make clear the authority to grant exclusive licenses under Federallyowned inventions. The Bill would also codify the basic policy concepts of Executive Order 10096, the provisions of which would be uniformly applicable to all Federal employees. In addition, passage of this Bill would overcome any remaining legal questions raised by past and pending litigation.

It is anticipated that, following implementation of the Act, greater commercial use will be made of the technology and intellectual property resulting from the Federal Government's total R&D effort and this in turn will create additional employment, a higher standard of living, and an overall economic benefit to the United States and the general public.

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- 1/ Executive Order 10096: "Providing for a Uniform Policy for the Government with Respect to Inventions Made by Government Employees and for the Administration of Such Policy," President Harry S. Truman, January 23, 1950 (3 CFR, 1949-1953 Comp., p.292); as amended by Executive Order No. 10930: "Providing for the Abolishment of the Government Patents Board and Providing for the Performance of its Functions," President John F. Kennedy, March 23, 1961 (26 F.R. 2583, March 28, 1961).
- 2/ Ervin Kaplan vs. Donald E. Johnson, Administrator, and John J. Corcoran, General Counsel, Veterans Administration, No. 74-C2004, United States District Court for the Northern District of Illinois, Eastern Division, February 18, 1976.
- 3/ Memorandum and Statement of Government Patent Policy Issued by President John F. Kennedy on October 10, 1963. (Published F.R., Vol. 28, No. 200, October 12, 1963.)
- 4/ S.1809. On April 23, 1965, Senator McClellan introduced in the 89th Congress, 1st Session, a Bill "To Establish a Uniform National Policy Concerning' Property Rights to Inventions Made Through the Expenditure of Public Funds, and For Other Purposes." The Bill was amended and accepted by the Senate Judiciary Committee as the "Federal Inventions Act of 1966." (No vote by full Senate.)
- 5/ Government Patent Policy Study by Harbridge House, Inc., Boston, Massachusetts, Volumes I-IV, May 17, 1968. Superintendent of Documents, U.S. Printing Office, Washington, D. C. 20402 - Contract No. 7-35087.
- 6/ Memorandum and Statement on Government Patent Policy Issued by President Richard M. Nixon on August 23, 1971. (Published F.R., Vol. 66, No. 166, August 26, 1971.)
- 7/ Amendment A-16 to Federal Property Management Regulations Issued January 29, 1973. (F.R., Vol. 38, No. 23, February 5, 1973.)
- 8/ Public Citizen, Inc., et al. vs Arthur F. Sampson, GSA (Civil Action No. 781-73), United States District Court for the District of Columbia.
- 9/ FPMR Temp. Reg. A-10 to Federal Property Management Regulations Issued February 12, 1974. (F.R., Vol. 39, No. 34, February 19, 1974.)

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- 10/ Arthur F. Sampson, GSA, vs Public Citizen, Inc., et al. (Civil Action No. 74-1619), United States District Court of Appeals for the District of Columbia Circuit.
- 11/ Amendment A-10 to Federal Property Management Regulations Issued October 1, 1975. (F.R., Vol. 40, No. 199, October 14, 1975.)
- 12/ Amendment 116 to Federal Procurement Regulations Issued August 29, 1973. (F.R., Vol. 38, No. 170, September 4, 1973.)
- 13/ Public Citizen, Inc., et al., vs Arthur F. Sampson, GSA. (Civil Action 74-303), United States District Court for the District of Columbia.
- 14/ Public Citizen, Inc., et al., vs Arthur F. Sampson, GSA (Civil Action No. 74-1849), United States Court of Appeals for the District of Columbia Circuit.
- 15/ Amendment 147 to Federal Procurement Regulations Issued May 7, 1975. (F.R., Vol. 40, No. 89, May 7, 1975.)
- 16/ Volumes I-IV, Report of the Commission on Government Procurement, Superintendent of Documents, U.S. Printing Office, Washington, D. C. 20402. Stock Nos. 5255-00002; 5255-00003; 5255-00004; and 5255-00006.

#### SECTION-BY-SECTION ANALYSIS

#### TITLE I--FEDERAL INTELLECTUAL PROPERTY POLICY

#### Sec. 101 Findings.

Section 101 states the findings of Congress; namely, that:

"(a) The inventions in scientific and technological fields resulting from work performed under Federal research and development constitute a valuable national resource;

"(b) A Federal policy on the allocation of rights to inventions resulting from Federally-sponsored research and development should stimulate inventors, meet the needs of the Federal Government, recognize the equities of the Federal employee-inventor and the Federal Government contractor, and serve the public interest; and

"(c) The public interest would be better served if greater efforts were made to obtain patent protection, both domestic and foreign, and to promote the interests of the United State and the commercial use of new technology resulting from Federally-sponsored research and development, both in the United States and foreign countries, as appropriate.

#### Sec. 102 Declaration of purpose.

Section 102 states the purposes of this Act which are responsive to the directive of Title I, Section 101.(c) of P.L. 94-282, The National Science and Technology Policy, Organization and Priorities Act of 1976 that: "Federal patent policies should be developed based on uniform principles, which have as their objective the preservation of incentives for technological innovation and the application of procedures which will continue to assure the full use of beneficial technology to serve the public."

The declaration of purpose is to:

"(a) Establish a uniform Federal policy for matters of intellectual property arising from Federally-sponsored research and development;

"(b) Provide for uniform implementation of the provisions of this Act, and to make a continuing effort to monitor such implementation;

"(c) To allocate rights to contractor inventions which result from Federally-sponsored research and development so as to

"(1) encourage the participation of the most

qualified and competent contractors,

- "(2) foster competition,
- "(3) promote the widespread utilization of the inventions, and
- "(4) reduce the administrative burdens, both for the Federal agencies and its contractors;

"(d) To allocate rights to Federal employee inventions in an equitable manner;

"(e) To provide for a domestic and foreign protection and licensing program to obtain commercial utilization of Federally-owned inventions, with the objective of strengthening the Nation's economy and expanding its domestic and foreign markets; and

"(f) To amend all other Acts and abolish the Executive Orders regarding the allocation of rights to inventions which result from Federally-sponsored research and development and the licensing of Federally-owned patents.

TITLE II--FUNCTIONS OF THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY (OSTP) AND FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING AND TECHNOLOGY (FCCSET)

## Sec. 201 Federal Coordinating Council for Science, Engineering and Technology.

Subsections (a), (b) and (c) define the responsibilities of FCCSET and the means to carry out such responsibilities in matters regarding intellectual property. FCCSET is to make recommendations to the Director of OSTP with regard to:

- "(1) Uniform and effective planning and administration of Federal programs pertaining to inventions, patents, trademarks, copyrights, rights in technical data, and matters connected therewith.
- "(2) Uniform policies, regulations, guidelines and practices to carry out the provisions of this Act and other Federal Government objectives in the field of intellectual property.

"(3) Uniformity and effectiveness of interpretation and implementation by individual Federal agencies of the provisions of this Act and other related Federal Government policies, regulations and practices.

These responsibilities were deemed to require special emphasis due to the directive of Title I, Section 101.(c)(4) of P.L. 94-282 set out in discussing Section 102. Further, due to the anticipated need for regulatory implementation, surveillance, and reporting required under the Federal patent policy established by this Act. In carrying out its responsibilities, FCCSET is authorized to:

- "(1) Acquire data and reports from the Federal agencies on the interpretation and implementation of this Act and related policies, regulations and practices.
- "(2) Review on its own initiative, or upon request by a Federal agency, Federal agency implementation of the provisions of this Act.
- "(3) Analyze on a continuing basis data acquired by the COUNCIL.
- "(4) Consider problems and developments in the fields of inventions, patents, trademarks, copyrights, rights in technical data, and matters connected therewith and the impact of such on Federal Government policy or uniform accomodation or implementation by Federal agencies.

"(5) Publish annually a report on COUNCIL efforts, findings and recommendations.

It is anticipated that the Committee on Government Patent Policy of the former Federal Council for Science and Technology (FCST) will be reestablished under the authority of Title IV, Section 401.(h) of P.L. 94-282 to operate under the aegis of the FCCSET. The reestablished committee could be renamed the Committee on Intellectual Property to reflect FCCSET's expanded responsibilities to advise not only on patent matters affecting Federal programs but on the use, ownership or licensing of trademarks, copyrights, right-in-data, etc., affecting such programs. Staffing of the Committee on Intellectual Property will be in accordance with Title IV, Section 401.(g) of P.L. 94-282.

The responsibilities of the COUNCIL are not intended to give to the COUNCIL the role of planning, implementing, or modifying the patent, trademark, or copyright laws of the United States or other programs within the respective jurisdiction of the Patent and Trademark Office or the United States Copyright Office. Section 202 Board for Intellectual Property

Section 202 authorizes the Director of OSTP to establish or designate a Board or Boards to carry out the responsibilities provided for under this Act, as appropriate. It is the intent of this section to provide flexibility to the Director in utilizing existing organizations or mechanisms or to create

new organizations or mechanisms, whichever appears to be most suitable to carry out the responsibilities of the Board(s). This would include the authority to establish a board for intellectual property within OSTP notwithstanding the heretofore advisory nature of OSTP, or to designate existing boards with or without the standard procedures. In any event, any Board or Board(s) established or designated shall consult with the Council and other Federal authorities, such as the Office of Federal Procurement Policy (OFPP) and authorities designated to issue implementing regulations.

## TITLE III--ALLOCATION OF PROPERTY RIGHTS IN INVENTIONS RESULTING FROM FEDERALLY-SPONSORED RESEARCH AND DEVELOPMENT

#### Chapter 1--Invention of Contractors

# Sec. 311 Criteria for the Allocation of Property Rights in Subject Inventions.

Section 311 provides for a single patent rights clause which normally is to be used in all Federally-sponsored research and development contracts with the exception of those situations set out in uniform regulations based on recommendations of the Council and promulgated by GSA and DOD or those exceptions provided in Section 312.(c). GSA and DOD have been named because of their present authority to issue such regulations.

It is intended that the regulations of Section 311 may provide for the acquisition of rights greater than the Federal Government's minimum rights of Section 311.(b)(2) in certain classes of contracts where the Government has greater equities, such as, contracts for the operation of a Government-owned facility. Section 312.(c)(2) defines limited situations where the regulations may permit that the Government acquire lesser rights than those of Section 311.(b)(2). It is emphasized that the promulgation of the regulations of Section 311 is meant to assure Federal Governmentwide consistency of action.

(a) Reporting Requirements and Declaration of Intent.

Subsection (a) requires a report on any invention made by the contractor in performance of a Federally-sponsored research and development contract and an election on whether the contractor will file patent applications and seek commercialization. Subsection (a) further permits the Federal Government to defer for a reasonable time release of information disclosing a Federally-sponsored invention to permit a patent application to be filed.

(b) Minimum rights to the Federal Government and the public.

Subsection (b)(1) establishes the Government's right to ownership to those inventions which the contractor has reported but elects not to exercise his option to file a patent application and commercialize, subject only to those nonexclusive license rights normally retained by the contractor.

Subsection (b)(2) establishes the minimum rights the Government must acquire in those instances where the contractor elects to file and commercialize.

Subsection (b)(2)(A) establishes the Government's right to periodic reports on the contractor's progress toward commercialization of a reported invention. These periodic reports

are intended to provide the information necessary to determine whether a Federal agency should exercise the right of Subsection (b)(2)(C) on the basis that the contractor is not taking effective steps to commercialize.

Subsection (b)(2)(B) establishes the Federal Government's right to a nonexclusive, nontransferrable, irrevocable paid-up license for the purpose of practicing the invention for its own needs. The Agency may also include a provision to acquire a license for the needs of State, domestic local or foreign governments if it determines it to be in the National interest. The phrase "foreign policy considerations" is intended to permit an Agency to acquire a license for a lesser developed country to manufacture in its own country in competition with imports.

Subsection (b)(2)(C) establishes a Federal agency's right to acquire from the contractor whatever rights it deems appropriate, including an assignment to the Government, in order to further the commercialization of an invention by parties other than the contractor when the AGency determines that such action is necessary because the contractor is not effectively moving toward commercialization of the invention. Since there may be a reasonable disagreement on whether a contractor is taking effective steps to commercialize, the agency's determination has been made appealable to the Board.

Subsection (b)(2)(D) establishes the Board's right to require the licensing of a third party after appropriate petition, notice and hearing if it deems such action is necessary (i) to

alleviate health, safety or welfare needs, or (ii) to the extent that the invention is required for public use by Federal regulatic and where the contractor or his licensee is not satisfying the market created by such health, safety or welfare need or such regulations. It was not intended by this subsection to provide to the Board the authority to require licensing on the mere basis of a predicted or existing marketplace price differential between the contractor and a prospective licensee. However, this may be considered along with other public health, safety or welfare needs.

Subsection (b)(2)(E) establishes the Board's right to require the licensing of a third party after appropriate petition, notice and hearing if it determines that the exclusive rights to the invention in the contractor have "tended substantially to lessen competition or to result in undue market concentration in any section of the United States in any line of commerce to which the technology relates, or to create or maintain other situations inconsistent with the antitrust laws." The quoted language is derived from the "Federal Nonnuclear Energy Research and Development Act of 1974" and is discussed in the conference report on S.1283.

Subsection (b)(2)(F) establishes the Board's right commencing ten years from the date of invention or five years after first public use or sale in the United States, whichever occurs first (excepting that time before Federal regulatory agencies necessary to obtain premarket clearance), to require