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FEDERAL SECURITY AGENCY

FEDERAL SECURITY AGENCY ORDER 110-1

SUBJECT: INVENTIONS RESULTING FROM RESEARCH GRANTS

1. Policy--The Federal Security Agency each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees, to this expenditure of public funds frequently include patentable inventions.

The Agency, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

On the other hand, in some cases it may be necessary to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Agency has a responsibility to see that the public use of the fruits of the research not be unduly restricted or denied.

The following conditions have been adopted to govern the ownership of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

2. Research Grant Provisions for the Ownership of Inventions--Subject to legislative directives or executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide, as the head of the constituent unit may determine, either

(a) that the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the head of the constituent unit responsible for the grant, or

Supersedes Agency Order 110-1 dated September 15, 1952

(b) that the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the head of the constituent unit finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in section 4 below, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to subsection (b) shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be prescribed, to file foreign patent applications upon the invention.

3. Agency Determinations--Domestic Rights--The domestic rights in any invention not subject to disposition by the grantee pursuant to section 2 are for determination by the head of the constituent organization as follows:

(a) If he finds that there is adequate assurance that the invention will either be effectively dedicated to the public, or that any patent which may be obtained thereunder will be generally available for royalty-free and nonexclusive licensing, the effectuation of these results may be left to the grantee.

(b) If he finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices, the invention may be assigned to a competent organization for development and administration for the term of the patent or such lesser period as may be deemed necessary.

(c) If he finds that the interest of another contributing Government agency is paramount to the interest of the Federal Security Agency, or when otherwise legally required or in the public interest, the invention may be left for disposition by that agency in accordance with its own policy.

(d) In all other cases, he shall require that all domestic rights in the invention shall be assigned to the United States unless he determines that the invention is of such doubtful importance or the Government's equity in the invention is so minor that protective measures, except as provided in section 4, are not necessary in the public interest.

4. Licenses to the Government--Any arrangement or determination as to the disposition of rights in inventions pursuant to sections 2 and 3 shall require that there be reserved under any patent application or patent thereon a nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

5. Agency Determinations--Foreign Rights--In any case where it is determined pursuant to section 3 or 4 that domestic rights should be assigned to the Government, or that the Government should have a license thereunder, it shall further be determined in writing by the head of the appropriate office or constituent organization, pursuant to Executive Order 9865 and Government-wide regulations issued thereunder, that the Government shall reserve an option to require the assignment of such rights in all or in any specified foreign countries, the option to expire unless exercised within such period of time as may be provided by regulations issued by the Chairman of the Government Patents Board.

In any case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government, it may be determined that any application for a patent which he may file on his own behalf in such country or countries shall nevertheless be subject to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license for all governmental purposes, which reservation shall whenever practicable appear in any foreign patent which may issue.

6. Ownership of Inventions in Other Cases--In the event of an invention resulting from an employment or contract relationship or any arrangement other than a grant or contract in aid of research, and made by a person not a Government employee as defined in Agency Order 110, the ownership thereof shall be governed by the terms of the agreement or contract and shall be in accordance with any applicable law and regulations.

In the discretion of the head of the responsible constituent organization, the award of a fellowship to a person not a Government employee, as so defined, may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of subsection 2 (a) of this Order, or for its disposition by the institution at which the research was performed in accordance with its established policies, if applicable to such an invention, which with any agreed modifications of such policies, meet the requirements of subsection 2 (b) or 2 (c)

7. Decisions Regarding Patentability and Patenting--The constituent organization making a grant or contract in aid of research shall be responsible for deciding in writing whether any invention, subject to assignment to the Government under section 3 hereof or otherwise, may be patentable, and whether the Agency shall seek a domestic patent thereon, and for recommending whether it should be patented in any foreign countries. Such decisions shall be consistent with Agency policy and in accordance with pertinent law and regulations and established procedures.

All determinations pursuant to section 3, 5 or 6, together with any related decisions regarding patentability or patenting, and any assignments and licenses or other documents affecting the disposition of inventions reported under these sections which may have been received by the constituent organization, shall be transmitted to the Agency Patents Officer for the central Agency patent files and for any Agency reports or further action which may be appropriate.

Any licenses to the United States or other documents evidencing the Government's rights in reported inventions left for disposition by the grantee pursuant to section 2 shall similarly be transmitted to the Agency Patents Officer.

8. Organization and General Provisions--The provisions of Part I of Agency Order 110, as revised, relating to Agency organization and general provisions, are applicable where appropriate in connection with any invention in which the Agency has an interest.

9. Effective Date--The provisions of this Agency Order shall be applicable to determinations of ownership and other decisions concerning the disposition or patenting of particular inventions even though the invention was made prior to the date of this Order, or arose out of a grant or other transaction which was made prior thereto.

/S/ John L. Thurston
Acting Administrator

December 30, 1952

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Explanation of special applications of Agency Order 110-1, "Inventions Resulting from Research Grants"

Disposition of inventions: It will be noted in Section 2 of the Agency Order that the policy provides that inventions arising under Public Health Service grants-in-aid (and awards) are to be handled (a) by the Surgeon General on a case by case determination, or (b) by the grantee institution in accordance with its established practices and policies, after those policies with such modifications as may be agreed upon have been accepted by the Surgeon General as assuring that the invention will be made available without unreasonable restrictions or excessive royalties. Institutions desiring to be considered under (b) should advise the Division of Research Grants. It is understood that institutions which do not take such action wish to continue on the basis of case by case determinations by the Surgeon General.

Responsibility: It is the primary responsibility of the institution and not of the personnel engaged in work assisted by the grant to comply with Public Health Service patent provisions. The Service does not require the individual to sign a statement of agreement on patent rights[1] since it believes the institution should administer such matters. Accordingly a provision on patentability is contained in the grant-in-aid application blank, which is signed by an official of the grantee institution, and which may or may not be supplemented by a letter of agreement between the Division of Research Grants representing the Surgeon General, and the grantee institution. Grantee institutions are expected, therefore, to take whatever action they deem necessary to enable them to comply with the agreements they make with the Public Health Service relating to patentable inventions.

Reportability of research results as "inventions." All "inventions" developed with the assistance of Public Health Service grants-in-aid which are or may be patentable must be reported to the Division of Research Grants regardless of whether the grantee institution has the agreement of the Surgeon General to handle inventions in accordance with its own policies or whether an individual determination is to be made by the Surgeon General. The method by which such reporting is insured is at the discretion of the institution. It is not the desire of the Public Health Service to require or encourage investigators to scrutinize research results for minor patentable features. The Service will consider that the institution has discharged its duty in this respect if there are reported those accomplishments which the investigator and the institution think are both patentable and of sufficient importance to justify publication, or are of sufficient importance to justify investigation for patentability by the inventor or local institution if the Public Health Service were not concerned. It is not to be assumed in this connection that progress reports may serve as substitutes for reports of inventions.

1/ This is not true for the research fellowships and certain of the traineeships awarded by the Service, where there is a direct relationship between the Service and the fellow or trainee. In such programs the individual is required to sign a statement on inventions.

Patent provision in application blank for grants-in-aid: The patent agreement in the grant application blanks presently in use reads "(4) that if any patentable discoveries or inventions are made in the course of the work aided by any grant received as a result of this application, the applicant will, in consideration of such grant, refer to the Surgeon General of the Public Health Service, for determination, the question of whether such patentable discoveries or inventions shall be patented and the manner of obtaining and disposing of the proposed patents in order to protect the public interest." As a practical matter, this form will be continued until the supply is exhausted even though it does not provide for disposition by the institutions in accordance with their policies. In the meanwhile procedure for effecting an agreement that disposition of patent rights may be handled under institution policies will be given in the "Instructions for preparing an application for a Public Health Service Research Grant" and in the information sheets for other grants.

INVENTION AND PATENT POLICIES ACCEPTABLE
TO THE PUBLIC HEALTH SERVICE

The policy of the Department of Health, Education, and Welfare (formerly the Federal Security Agency) on "Inventions Resulting from Research Grants" recognizes the cooperative nature of research aided by Public Health Service grants-in-aid. For this reason it offers alternative conditions with respect to the handling of patentable inventions which may arise out of activities assisted by the grant. Either the Surgeon General of the Public Health Service may reserve the right to determine the ownership of the invention and its disposition or such inventions may be administered by the grantee-institution in accordance with its own patent policies and procedures, provided the Surgeon General accepts these as assuring that the invention either will be dedicated to the public or, if patented, will be made available without unreasonable restrictions or excessive royalties.

Policies and procedures outlined below are types which may give such assurance. Institutions which may not as yet have formulated a policy with respect to inventions developed from research financed in part with public funds may find this outline of some assistance in the formulation of their own procedures.

A. Dedication to the public of results of research either by publication or patenting with subsequent dedication of the patents.

The Surgeon General will accept this policy in any case wherein it is demonstrated that the grantee-institution has a responsible body or official to see that the policy is effectuated.

As stated in the Department Order on grantee inventions, dedication to the public in general seems most appropriate for many inventions developed with the assistance of public moneys. Many research institutions, particularly in so far as inventions related to health are concerned, also adhere to this principle.

B. Patenting with royalty-free licensing.

A general policy of issuing royalty-free, unconditional and nonexclusive licenses under patents obtained is equally acceptable. In administering such a policy there may be times when in the judgment of the institution the interests of the public in a particular patent will be best served by (1) conditional licensing, providing standards as to the quality of the product or the qualifications of the manufacturer, or (2) restricted licensing for a

limited period to assure the development of the invention to the point of utility and satisfactory quality. Decision as to the necessity for either such arrangement would be that of the grantee-institution, but prior to accepting the institution policy the Public Health Service would require general assurance that under the institution policy exclusive licenses would be the exception, not the rule, and that they would be for a limited period only. In the case of institutions which do issue exclusive licenses, the Public Health Service would further require full information as to the basis on which such licenses are issued and the safeguards utilized to protect the public interest.

C. Patenting with licensing on a royalty basis.

Licensing as provided in B which provides for royalties in some or even all cases will also be considered acceptable policy. In such case the royalty rates must however be reasonable and a royalty-free license to the Government with power to sublicense for all governmental purposes will be required in all cases.

The Public Health Service realizes that there are conditions at certain institutions which in the estimation of the institution make royalties desirable, if not mandatory, in order to provide reimbursement of the funds spent to secure patents, incentive awards to the inventor, and support of research. When this policy is adopted it is the view of the Service that the royalty charged should not in any case exceed the rate acknowledged as normal trade practice, and that lower rates are more appropriate for licenses issued by public institutions.

The Service believes that profits realized from these royalties should be applied to teaching and research functions except for proportionate costs of administration of institution patent business. In view of the purposes for which Public Health Service grants-in-aid funds are appropriated, it would be preferable from the Service's point of view that any profits from royalties be used to support additional research. Any policy which makes the inventor the primary recipient of royalties would not be acceptable.

D. Assignment of ownership rights to a qualified organization.

The Service will not object to policies which provide for the assigning of patent rights to a reputable organization, when the agreement between the institution and that organization gives assurance that administration of the patents will be within the limits indicated above.

GENERAL REQUIREMENTS

Before accepting the policies of an institution, the Service would like assurance that they have been formally adopted by appropriate institution officials; that an administrative body has been established, or some responsible official has been designated, to carry out the program; and that the institution's history of operation has been consistent with its promulgated policies.

PRINCIPLES OF OWNERSHIP

It is assumed that all institutions wishing to administer inventions arising under Public Health Service grants-in-aid have established principles to determine the equities of the inventor, the institution, and the sponsor therein. A number of institution policies with which the Service is familiar provide that under certain conditions the invention may be left to the inventor. The Service would consider the following criteria as satisfactory to determine the equities of the inventor and the institution. (These are the criteria applied by the Federal Government to inventions made by its employees):

(a) The institution shall obtain entire right, title and interest in and to all inventions made by any employee (1) during working hours, or (2) with a contribution by the institution of facilities, equipment, materials, funds, or information, or of time or services of other institution employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the institution, as measured by any one or more of the criteria set forth in paragraph (a) last above, to the invention is insufficient equitably to justify a requirement of assignment to the institution of the entire right, title and interest to such invention, or in any case where the institution has insufficient interest in an invention to obtain entire right, title and interest therein, the institution may leave title to such invention in the employee, subject, however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

The Service will not "second-guess" the institutions on such decisions, but it will require the same report on them as is required for all inventions, and will hold the institution responsible for seeing that the report is made and license duly issued.

REPORTS

A report will be required on all patentable inventions as discussed in "Explanation of Special Applications of Department Order 110-1." The form will not be specified for this report, but will be discussed individually with each institution with a view toward using whatever form may already be in effect. In addition to the initial invention report, an annual report, for informational purposes, of the disposition of inventions in which it has an interest is requested. It is not proposed to review the institution's decision as to whether or not patenting is desirable, unless so prescribed by the institution.

June 15, 1953