



PUBLIC HEALTH SERVICE

BETHESDA 14, MD.

NATIONAL INSTITUTES OF HEALTH OLiver 6-4000 August 13, 1959

Mr. William G. Hendrickson Director, Licensing Division Wisconsin Alumni Research Foundation P. O. Box 2217 506 N. Walnut Street Madison 5, Wisconsin

Dear Mr. Hendrickson:

Many thanks for taking care of the reservations for Dr. Burch and me for our forthcoming trip to Madison.

When you were in Bethesda recently, you indicated that it would be helpful for you to have, before our meeting on the 20th, an idea of the type of information required by the Public Health Service in considering a grantee institution's over-all patent policies and procedures, which is set forth below:

- 1. A statement of the invention and patent policies of the University of Wisconsin, including full information on reporting procedures, policy on seeking patents, licensing and royalty practices, and use of profits, if any. Specifically: (a) Are employees required to sign agreement to report all patentable discoveries to the University? (b) Is the University in general opposed to exclusive licenses? What criteria are employed in determining whether or not patents should be sought? (d) Are royalty rates consonant with normal trade practice? (e) How are profits derived from patenting and licensing utilized? (f) Is there provision for turning over rights to inventors?
- 2. A statement as to whether the University has an active policy of dedication to the public through publication in those cases on which patent is not sought.
- 3. A statement as to whether publication is delayed in order to screen research results for patentable features.
- 4. Some idea of the extent of the patent program at the University of Wisconsin; the number of patents your

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institution has obtained in the past ten years; if you have issued exclusive license, the number, terms of duration, and full information as to the basis on which such licenses were issued and the safeguards utilized to protect the public interest.

The above information is sought following the submission from a grantee institution of its formally adopted patent policy. Once all the data required is at hand, the institution policies are considered in conjunction with the criteria outlined in the attached "Invention and Patent Policies Acceptable to the Public Health Service."

If you require additional information before I leave here on August 17, please let me know.

Sincerely yours,

(Miss) Katharine A. Parent

Special Assistant to the Chief Division of Research Grants

Enclosure

VENTION AND PATENT POLICIES AC PABLE TO THE PUBLIC HEALTH SERVICE

The policy of the Department of Health, Education, and Welfare on Inventions Resulting from Research Grants, Fellowship Awards, and other Research Arrangments, 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 where 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 Regulations on grantee inventions, dedication to the public in general seems most appropriate for inventions developed with the assistance of public moneys. Many institutions, particularly insofar 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.
- 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.

REPORTS

A report will be required on all patentable inventions as described in the following discussion of special applications of Department Regulations. 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.

September 14, 1955

Explanation of special applications of Department Regulations on Inventions Resulting from Research Grants, Fellowship Awards, and other Research Arrangements

<u>Disposition of inventions</u>: It will be noted in Paragraph 8.1 of Department Regulations 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 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.