

§ 7.7

Patents, any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to issue sublicenses for use in behalf of the Government and/or in furtherance of the foreign policies of the Government.

[27 FR 7987, Aug. 10, 1962]

§ 7.7 Notice to employee of determination.

The employee-inventor shall be notified in writing of the Department's determination of the rights to his invention and of his right of appeal, if any. Notice need not be given if the employee stated in writing that he would agree to the determination of ownership which was in fact made.

[31 FR 12842, Oct. 1, 1966]

§ 7.8 Employee's right of appeal.

An employee who is aggrieved by a determination of the Department may appeal to the Commissioner of Patents, pursuant to section 4(d) of Executive Order 10096, as amended by Executive Order 10930, and regulations issued thereunder, by filing a written appeal with the Commissioner, in duplicate, and a copy of the appeal with the Assistant Secretary (Health and Scientific Affairs), within 30 days (or such longer period as the Commissioner may, for good cause, fix in any case) after receiving written notice of such determination.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Oct. 1, 1966]

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND CONTRACTS FOR RESEARCH

Sec.

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AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR, 1953 Supp. E.O. 9865, 12 FR 3907; 3 CFR, 1947 Cum. Supp. E.O. 10096, 15 FR 391; 3 CFR, 1950 Supp.

§ 8.0 Policy.

(a) The Department of Health and Human Services 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.

(b) The Department, 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.

(c) On the other hand, in some cases it may be advisable 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 Department has a responsibility to see that the public use of the fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment 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.

[20 FR 6749, Sept. 14, 1955]

§ 8.1 Conditions to be included in research grants.

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 either:

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(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 Assistant Secretary (Health and Scientific Affairs) 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 § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section 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.

[20 FR 6749, Sept. 14, 1955, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.2 Determination as to domestic rights.

Rights in any invention not subject to disposition by the grantee pursuant to § 8.1(b) are for determination by the Assistant Secretary (Health and Scientific Affairs) as follows:

(a) If he finds that there is adequate assurance that the invention will ei-

ther 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 Department of Health and Human Services, 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 § 8.3, are not necessary in the public interest.

[20 FR 6749, Sept. 14, 1955, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.3 Licenses to the Government.

Any arrangement or determination as to the disposition of rights in inventions pursuant to §§ 8.1, 8.2, 8.5 or 8.6 shall require that there be reserved under any patent application or patent thereon, domestic or foreign, a non-exclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

[22 FR 9696, Dec. 4, 1957]

§ 8.4 Option to acquire foreign rights.

In any case where it is determined that all domestic rights should be assigned to the Government, there shall

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be reserved to the Government, pursuant to Executive Order 9865 (3 CFR, 1943-1948 Comp.) and Government-wide regulations issued thereunder, an option to require the assignment of all rights in the invention in all or in any specified foreign countries. In any case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government, or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Chairman of the Government Patents Board any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to sublicense for all governmental purposes.

[20 FR 6750, Sept. 14, 1955]

§ 8.5 Fellowships.

In the discretion of the Assistant Secretary (Health and Scientific Affairs), the award of a fellowship to a person not a Government employee may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of § 8.1(a) 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 meet the requirements of paragraph (b) of such section.

[22 FR 9695, Dec. 4, 1957, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.6 Contracts for research.

(a) Contracts for research, with other than nonprofit institutions, shall provide that any invention first conceived or actually reduced to practice in the course of the performance of the contract shall be promptly and fully reported to the Assistant Secretary (Health and Scientific Affairs) for determination by him as to the manner of disposition of all rights in and to such invention, including the right to require assignment of all rights to the United States or dedication to the public. In the exercise of this power the or-

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ganization head will be guided by the policy specified in § 8.2 with respect to grants.

(b) Contracts for research with nonprofit institutions shall contain provisions as in paragraph (a) of this section except that, if it is determined that the institution's policies and procedures are acceptable as meeting the requirements of § 8.1(b) with respect to grants, the contract may provide, with such special stipulations in the contract as may be deemed necessary in the public interest, for leaving the ownership and disposition of all domestic rights for determination by the contracting institution in accordance with such policies and procedures.

[23 FR 1215, Feb. 27, 1958, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.7 Cancer chemotherapy industrial research contracts.

Notwithstanding the provisions of § 8.6, the Surgeon General in the negotiation of contracts with other than nonprofit organizations for the cancer chemotherapy research program shall be subject only to such limitations and alternatives as the Assistant Secretary (Health and Scientific Affairs) may approve for such program.

[22 FR 9696, Dec. 4, 1957, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.8 Screening of compounds generated under DHHS grants and awards.

(a) *General policy.* (1) Chemical compounds having potential medicinal and other utilities are often synthesized or identified during the course of research financed under DHHS research grants and awards. Reporting, filing patent applications on, and determining ownership in inventions relating to such compounds pose problems which require special attention. After a compound has been synthesized, it generally will not constitute a patentable invention under the patent laws of the United States until a specific utility for the compound has been established. It is the policy of the Department that all compounds synthesized or identified during the course of grant-supported research should be adequately screened

and tested in Government or non-Government facilities in order that all possible utilities may be ascertained and that any promising compounds may be fully developed for widest possible use. The Department encourages the utilization, whenever appropriate, of the screening services of the Cancer Chemotherapy National Service Center and the Walter Reed Army Institute of Research.

(2) It is the policy of the Department notwithstanding anything to the contrary under patent law of the United States or requirements of U.S. Patent Office practice, to acquire no ownership rights to inventions claiming novel methods of using compounds, where such use inventions are first conceived and reduced to practice solely by the screening or testing organization without the use of grant funds.

(b) *Screening performed with use of grant funds.* Where nongovernmental facilities are utilized for screening services to be performed and paid for by the grantee (as used in this section, the term "grantee" refers to awardees in addition grantee (as used in this section, the term to grantee institutions) with grant funds, the grantee shall obtain an agreement with the screening organization providing that the screener shall promptly report to the grantee the details of any positive findings of utility for the compound and that all invention rights relating to the compound and its utility shall, as between the grantee and the screener, vest in the grantee. Upon receipt of such report of positive findings, the grantee shall promptly forward copies to DHHS. Ownership of all invention rights to the compound or reported utilities shall be subject to the disposition by the Assistant Secretary (Health and Scientific Affairs) as provided by the terms of the grant or award in accordance with § 8.2, except that where the grantee institution has entered into an Institutional Patent Agreement with the Department pursuant to § 8.1(b), ownership of the invention rights shall be in accordance with the terms of that Agreement.

(c) *Screening performed without the use of grant funds.* Where screening is to be performed at nongovernmental facilities without the use of grant funds, the

grantee may proceed to have compounds screened under one of the following arrangements:

(1) *Institutional Patent Agreement.* Where the grantee institution has entered into an Institutional Patent Agreement with the Department under § 8.1(b) of the Department Patent Regulations, the grantee shall enter into an agreement with the screener which shall be consistent with, and will permit the grantee to fully comply with its obligations under such Institutional Patent Agreement. The agreement with the screener shall, as a minimum, provide that ownership of patent rights to inventions resulting from the screening process shall vest, depending on the law of inventorship, in the grantee, the screener, or both, except that such agreement may leave to screening or testing organizations ownership rights to inventions claiming novel methods of using compounds, where such use inventions are first conceived and reduced to practice solely by the screening or testing organization without the use of grant awards. The grantee shall administer all invention rights to the compound and all other invention rights vested in the grantee in accordance with the terms of the Institutional Patent Agreement.

(2) *Patent Agreements for Screening.* Where an Institutional Patent Agreement is not in effect, the grantee shall enter into an agreement with a screener to govern disposition of rights to inventions resulting from the screening. Such agreements shall be in the form prescribed by or as may be approved by the Department and shall be consistent with the policy set forth in paragraph (a) of this section.

(3) *Determination of invention rights prior to screening.* Where a grantee has not entered into an Institutional Patent Agreement, it may, prior to making arrangements for screening, petition the Assistant Secretary (Health and Scientific Affairs) requesting a determination that invention rights pertaining to an identified compound be assigned to the grantee for administration, pursuant to the provisions of § 8.2(b). Determinations under § 8.2(b) normally permit the grantee to grant exclusive licenses for a limited period

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of time. Such petition must demonstrate that an assignment is required in order to achieve effective screening of the compound and any resulting inventions will thereby be more adequately and quickly developed for widest use.

[34 FR 201, Jan. 7, 1969]

PART 9—USE OF HHS RESEARCH FACILITIES BY ACADEMIC SCIENTISTS, ENGINEERS, AND STUDENTS

Sec.

9.1 Purpose.

9.2 Policy.

9.3 Delegations of authority.

9.4 Criteria.

9.5 Restrictions.

AUTHORITY: 27 Stat. 395, as amended; 20 U.S.C. 91.

SOURCE: 34 FR 18938, Nov. 27, 1969, unless otherwise noted.

§ 9.1 Purpose.

To enhance the availability of DHHS scientific research and study facilities to academic scientists, engineers, and qualified students.

§ 9.2 Policy.

It is the policy of the Department of Health and Human Services in accordance with the policy of the President announced on February 21, 1969, to make research and study facilities of the Department readily available to the scientific community, especially qualified academic scientists and engineers. Unique, unusual, and expensive-to-duplicate facilities at laboratories and other study and research facilities of the Department will be made available to the national scientific community, to the maximum extent practical without serious detriment to the missions of those facilities. It is also the policy of the Department to permit qualified students and graduates of institutions of learning in the several States, and territories, as well as the District of Columbia, to use study and research facilities of the Department. When such facilities are used by academic scientists, engineers, and students, the costs incurred for the operation of the unique or unusual research

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facilities, as well as of the other facilities, should be funded by the operating agency responsible for the operation of that facility, except for any significant incremental costs incurred in support of research not directly related to an HHS mission.

§ 9.3 Delegations of authority.

(a) The heads of operating agencies are delegated authority for negotiations and decisions as to the use of Department facilities by qualified academic scientists, engineers, and students.

(b) The heads of operating agencies may (and are encouraged to) redelegate to the heads of their respective component organizations, with the power to further redelegate to laboratory directors, the authority for negotiations and decisions as to the use of departmental facilities. Appropriate use shall be made of advisory groups in formulating their decisions.

§ 9.4 Criteria.

(a) The official permitting use of Department facilities must determine that it would be consistent with the programs of his activity to participate. Facilities may be made available provided the use of such facilities will be of direct benefit to the objectives of the academic scientist, or engineer, or student, with the prospect of fruitful interchange of ideas and information between Department personnel and the academic scientist, or engineer, or student, and such use will not interfere with the Department program.

(b) The official permitting use of Department facilities will furnish the non-Government user with safety requirements or operating procedures to be followed. Such requirements or procedures are to include the requirement to report to the permitting official any accident involving the non-Government user.

(c) The official delegated authority for approving the use of Department facilities will not permit the use of laboratory facilities unless he determines:

(1) That facilities are available for the period desired; and

(2) That the proposed research will not interfere with regular Department