

## § 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.

8.0 Policy.

8.1 Conditions to be included in research grants.

8.2 Determination as to domestic rights.

8.3 Licenses to the Government.

8.4 Option to acquire foreign rights.

8.5 Fellowships.

8.6 Contracts for research.

## 45 CFR Subtitle A (10–1–96 Edition)

8.7 Cancer chemotherapy industrial research contracts.

8.8 Screening of compounds generated under DHHS grants and awards.

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