CHAPTER 6-10

# REGULATIONS AND PROCEDURES

6-10-00 Scope
.10 Regulations (from Federal Register of 10/1/66)
.20 Patent Policy Applicable to Cancer Chemotherapy Industrial Research Contracts

## 6-10-00 SCOPE

This Chapter contains:

1. Department regulations relating to inventions (a) made by Department employees, or (b) resulting from research grants, fellowship awards, or research contracts under programs administered by the Department; and

2. Department patent policy, approved 7/31/58 by the Secretary, establishing the limitations referred to in section 8.7 of the Department regulations for the negotiation of cancer chemotherapy industrial research contracts.

## 6-10-10 REGULATIONS

TITLE 45--PUBLIC WELFARE
Subtitle A--Department of Health, Education, and Welfare, General Administration

PART 6--INVENTIONS AND PATENTS (GENERAL)

PART 7--EMPLOYEE INVENTIONS

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

The following parts are Department rules and policies relating to inventions which are made by Department employees having a relation to their official duties or with some contribution from the Government or which arise from research or related activities assisted by grants or otherwise under programs administered by the Department.

### PART 6 -- INVENTIONS AND PATENTS (GENERAL)

Sec.
6.0 General Policy.
6.1 Publication or patenting of inventions.
6.2 General Responsibility.

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§6.3 Licensing of Government-owned patents.

Licenses to practice inventions covered by patents and pending patent applications owned by the United States Government as represented by this Department will generally be royalty free, revocable and nonexclusive. They will normally be issued to all applicants and will generally contain no limitations or standards relating to the quality or testing of the products to be manufactured, sold, or distributed thereunder.

Where it appears however that the public interest will be served under the circumstances of the particular case by licenses which impose conditions, such as those relating to quality or testing of products, requirement of payment of royalties to the Government, etc., or by the issuance of limited exclusive licenses by the Assistant Secretary for Health and Scientific Affairs after notice and opportunity for hearing thereon, such licenses may be issued.

§6.4 Central records; confidentiality.

Central files and records shall be maintained of all inventions, patents, and licenses in which the Department has an interest, together with a record of all licenses issued by the Department under such patents. Invention reports required from employees or others for the purpose of obtaining determinations of ownership, and documents and information obtained for the purpose of prosecuting patent applications shall be confidential and shall be disclosed only as required for official purposes or with the consent of the inventor.

PART 7 -- EMPLOYEE INVENTIONS

Sec.
7.0 Who are employees.
7.1 Duty of employee to report inventions.
7.3 Determination as to domestic rights.
7.4 Option to acquire foreign rights.
7.7 Notice to employee of determination.
7.8 Employee's right of appeal.

AUTHORITY: §§ 7.0 to 7.8 issued under Reorg. Plan No. 1 of 1953, 18 F.R. 2053, 3 CFR 1949-1953 Comp., p. 1022; E.O. 10096, 15 F.R. 391, 3 CFR 1949-1953 Comp., p. 292; E.O. 10930, 26 F.R. 2583, 3 CFR 1959-1963 Comp., p. 456.

§7.0 Who are employees.

As used in this part, the term "Government employee" means any officer or employee, civilian or military, except such part-time employees or part-time consultants as may be excluded therefrom by a determination made in writing by the head of the employee's office or constituent organization, pursuant to an exemption approved by the Commissioner of Patents that to include him or them would be

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power to grant licenses for all governmental purposes, such reservation to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b) of this section to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (1) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (2) to conduct or perform research, development work, or both, (3) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (4) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, falls within the provisions of paragraph (a) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b) of this section. Either presumption may be rebutted by a showing of the facts and circumstances and shall not preclude a determination that these facts and circumstances justify leaving the entire right, title and interest in and to the invention in the Government employee, subject to law.

(d) In any case wherein the Government neither (1) obtains the entire domestic right, title and interest in and to an invention pursuant to the provisions of paragraph (a) of this section, nor (2) reserves a nonexclusive, irrevocable, royalty-free license in the invention, with power to grant licenses for all governmental purposes, pursuant to the provisions of paragraph (b) of this section, the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

§7.4 Option to acquire foreign rights.

In any case where it is determined that all domestic rights should be assigned to the Government, it shall further be determined, 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. In 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 Commissioner of 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.

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(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.

§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.

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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.

§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 paragraph (a) of §8.1, 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.

§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 he 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.

§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.

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(1) Institutional Patent Agreement -- Where the grantee institution has entered into an Institutional Patent Agreement with the Department under Section 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 (a).

(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 Section 8.2(b) above. Determinations under Section 8.2(b) normally permit the grantee to grant exclusive licenses for a limited period 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.

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(3) Sustained concentration on the anti-cancer objective of all resources mobilized for the purposes of the contract.

c. Contractor's interests: The Surgeon General or his representatives shall maintain close consultations with the contractor concerning questions affecting the public need for the products of inventions which are subject to the limitations prescribed in the alternative clauses for the protection of the public interest with respect to their supply, price, and quality. The objective of these consultations shall be to promote a mutual awareness of such matters in order to assure to the contractor (under his right to exploit the invention) an opportunity on his own initiative to take such actions regarding them as he believes would be in his and in the public interest.

B. Contracts for research--Rights left to contractor. When the contract is for research (including contracts for product development necessary for purposes of research) to be performed by the company (with or without provision for subcontracting), the contract, as an alternative to the standard patent clauses, may provide for leaving to the contractor the right to patent and exploit any invention conceived or first actually reduced to practice in the course of the performance of the contract subject, however, to the following limitations which are deemed necessary to protect the public interest:

1. Reporting. Agreement that the contractor will report promptly to the Surgeon General any such invention and will also report promptly the filing of any domestic or foreign patent application thereon or his election not to file such application. Invention Report shall be required after the conception or first actual reduction to practice of each invention that reasonably appears to be patentable and, in any event, as soon as any evidence of utility has been developed (whether in a health or other field of use).

2. Disclosure. Reservation to the Surgeon General of the right to make disclosure of the invention, whenever he deems it in the public interest, after taking into consideration a reasonable opportunity to the contractor to protect such rights as he may have in the invention. The contract may specify that such disclosure shall not in any case, without the consent of the contractor, be made in less than six months from the time the Surgeon General determines the invention was or should have been reported.

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(1) to dedicate to the public all rights in the invention 2/ or;

(2) to issue (under or in anticipation of the issuance of any such patent) nonexclusive, royalty-free licenses (for practice of the invention for any health purpose) on a nondiscriminatory basis to all qualified applicants to use, manufacture and sell embodiments of the invention for any health purpose. 3/

c. If, within 20 days of receipt of notice, the contractor files such request for a hearing, the Surgeon General, or a representative or representatives designated by him for this purpose, shall afford the contractor a reasonable opportunity to be heard, to be represented by counsel, to present any pertinent information and argument, and to rebut any other information to be considered in reaching a decision. The findings by the Surgeon General or such representative(s) shall be in writing, shall be based solely on the material presented at the hearing, and shall be final and binding on the contractor. If the Surgeon General's decision based on these findings be that the contractor has not met the public need and that public dedication or additional licensing by the Surgeon General is necessary in the public interest, he may so dedicate or license, effective at the end of the above-provided 90-day period or at the conclusion of the hearing, whichever is later.

5. Contractor's determination not to patent—Failure to pursue application. Agreement that in the event the contractor elects, within a period (not to exceed six months after the invention was or should have been reported) specified in the contract, not to file a patent application on the invention, or, having elected to file thereafter fails to file and diligently prosecute a patent application, the Surgeon General, when he deems it necessary in order to protect the availability of the invention for health purposes, shall have the right to require the assignment to the Government of all domestic rights therein except for the reservation of a nonexclusive royalty-free license to the contractor.

2/ Such dedication to be effective against the contractor and any persons claiming from him upon filing by the Surgeon General with the Commissioner of Patents of notice of same.

3/ Either one or both of these alternatives shall be specified in the contract.

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D. Inventions by Federal Employees. Inventions made by Federal employees, or by Federal employees jointly with others, are subject to determination under applicable Executive Orders and Department regulations. Appropriate reference to this requirement will be made in connection with contracts with suppliers of chemical compounds for use in research to be conducted by the Service, and contracts for research and development in which Federal employees may in any way participate.

E. Background patents or rights. Nothing in this policy statement shall be deemed to limit the authority of the Surgeon General to negotiate for a license or other rights under existing patents or involving the use of patented or unpatented compounds or processes, as he may deem necessary for the effective prosecution of the cancer chemotherapy program.