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 Government-owned patents; licensing; dedication to the public.
6.4 Central records; confidentiality.

AUTHORITY: §§ 6.0 to 6.4 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.

§6.0 General Policy.

Inventions developed through the resources and activities of the Department are a potential resource of great value to the public health and welfare. It is the policy of the Department:

(a) To safeguard the public interest in inventions developed by Department employees, contractors and grantees with the aid of public funds and facilities;

(b) To encourage and recognize individual and cooperative achievement in research and investigations; and

(c) To establish a procedure, consistent with pertinent statutes, Executive Orders and general Government regulations, for the determination of rights and obligations relating to the patenting of inventions.

§6.1 Publication or patenting of inventions.

It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made where the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Commissioner of Patents. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

§6.2 General Responsibility.

The Assistant Secretary (Health and Scientific Affairs) is responsible for the administration of the invention and patent program of the Department and the determination of rights in inventions and patents in which the Department has an interest.

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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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impracticable or inequitable, giving the reasons therefor. A person shall not be considered to be a part-time employee or part-time consultant for this purpose unless the terms of his employment contemplate that he shall work for less than the minimum number of hours per day, or less than a minimum number of days per week, or less than the minimum number of weeks per year, regularly required of full-time employees of his class.

§7.1 Duty of employee to report inventions.

Every Department employee is required to report to the Assistant Secretary (Health and Scientific Affairs) in accordance with the procedures established therefor, every invention made by him (whether or not jointly with others) which bears any relation to his official duties or which was made in whole or in any part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information, or of time or services of other Government employees on official duty.

§7.3 Determination as to domestic rights.

The determination of the ownership of the domestic right, title, and interest in and to an invention which is or may be patentable, made by a Government employee while under the administrative jurisdiction of the Department, shall be made in writing by the Assistant Secretary (Health and Scientific Affairs), in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Commissioner of Patents as follows:

(a) The Government as represented by the Assistant Secretary (Health and Scientific Affairs) shall obtain the entire domestic right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government 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 Government, as measured by any one or more of the criteria set forth in paragraph (a) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire domestic right, title and interest in and to such invention, or in any case where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest therein (although the Government could obtain same under paragraph (a) of this section), the Department, subject to the approval of the Commissioner, shall 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

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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.

(6-10-10 cont'd) §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.

§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.

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.
8.7 Cancer chemotherapy industrial research contracts.

AUTHORITY: §§ 8.0 to 8.7 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.

§8.0 Policy.

(a) The Department of Health, Education, and Welfare 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.

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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.

(6-10-10 cont'd) §7.7 Notice to employee of determination.

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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.

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(a) The Department of Health, Education, and Welfare 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.

(6-10-10 continued)

(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.

(6-10-10 cont'd) (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.

§8.2 Determination as to domestic rights.

Rights in any invention not subject to disposition by the grantee pursuant to paragraph (b) of §8.1 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 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 Department of Health, Education, and Welfare, 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.

§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 nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

§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 be reserved to the Government, pursuant to Executive Order 9865 and Government-wide

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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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§8.8 Screening of compounds generated under DHEW 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 DHEW 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 nongovernment 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 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 DHEW. 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 Section 8.2, except that where the grantee institution has entered into an Institutional Patent Agreement with the Department pursuant to Section 8.1(b) above, 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:

(6-10-10 continued)

(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.

6-10-20 PATENT POLICY APPLICABLE TO CANCER CHEMOTHERAPY INDUSTRIAL RESEARCH CONTRACTS

A. General

1. The cancer chemotherapy program of the Public Health Service is an intensified effort, with special appropriations made available under a Congressional directive, to explore exhaustively and rapidly the potentialities of chemical compounds in the control of cancer. Because of the peculiar exigencies of this program and in order that the resources of pharmaceutical and chemical firms may be brought to bear with a minimum of delay, certain exceptions to general Department policy will be permitted in the negotiation of industrial contracts for this program.

2. Industrial research contracts for this program may contain either:

   a. the standard patent clauses, reserving to the Surgeon General the right to determine the disposition of inventions arising from the performance of the contract or, in lieu of such right,

   b. standard alternative clauses leaving the right to patent and exploit such inventions with the contractor, subject to certain limitations deemed necessary to protect the public's interest in the results of the contracted research.

3. Department policy concerning the negotiation and operation of the alternative clauses:

   a. Contract negotiations: The alternatives indicated will be made available in the negotiations with all contracting companies without discrimination.

   b. Public interest: The operation of these alternative clauses will be closely reviewed to assure that the following basic objectives are maintained in the public interest:

      (1) The availability of information concerning the results of research and the right, without undue delay, to make disclosures to the extent essential to serve the research need;

      (2) The availability for development and use of health purposes, on reasonable terms, of inventions arising from the research contract, whether actual development and production is to be made by the contractor himself or by others; and

(6-10-20.A3 continued)

(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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3. License to the Government. Reservation to the Government of an irrevocable, nonexclusive, royalty-free license to practice or cause to be practiced, by or for the Government throughout the world, each subject invention (whether patented or unpatented) in the manufacture, use or disposition according to law of any article or material or in the use of any method or process.

4. Failure to meet health needs.

a. In recognition of the Government's investment and the public interest in the results of contracted research, agreement that whenever, subsequent to the contractor's filing of a patent application for any invention conceived or first actually reduced to practice in the course of the performance of a contract, the Surgeon General, after obtaining and considering the advice of such advisory bodies or consultants as he deems appropriate and competent, has ground to believe that such invention, whether related to a product, process, or otherwise, is at such stage of development that if it were more generally available it would meet a health need and that the public interest -1/- requires the invention to be available for health purposes to others than the contractor and his licensees, he shall so notify the contractor, giving reasons therefor, and request him, within a time specified, to take appropriate steps to meet the public need, which may include the issuance of licenses to additional manufacturers of the contractor's own selection. (Such requests shall be supplementary to such informal consultations between the Surgeon General or his representative and the contractor as have taken place in accordance with the provisions of section A.3c above.)

b. If, upon expiration of the time specified, or such extension thereof as approved by the Surgeon General, the Surgeon General finds that the contractor has failed to take appropriate steps adequate to meet the public need, he shall notify the contractor, with reasons therefor, that at the end of 90 days from such notice he will exercise the rights specified below. If within 20 days of receipt of such notice the contractor fails to file a written request for a hearing as provided below, the Surgeon General shall upon expiration of the above 90-day period have the right:

1/ With respect to supply, quality, or price

(6-10-20.B4, continued)

(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.

(6-10-20B continued)

6. Foreign Rights. Similarly, agreement that if the contractor fails to file, or elects not to file, foreign patent applications which the Surgeon General determines are necessary to protect the availability of the invention for health purposes in other countries, the Surgeon General may require the assignment of the foreign rights.

7. Renegotiation on new leads. (Such a provision not mandatory). The contract may provide that if, in the course of the performance of the contract, the contractor identifies any new lead which it wishes to develop at its own expense, without utilization of facilities financed by the Government, the Surgeon General may, when he deems it consistent with advancement of the research purposes of the Government, renegotiate the application of the patent provisions of the contract to such new lead. Any modification of the terms of the contract shall be upon such consideration (which may be used to reduce the obligation of the Government under the contract) as the Surgeon General may deem equitable under the circumstances, after taking into consideration the extent of the investment of the Government in relation to the probable cost of further development.

C. Contracting with suppliers for screening and testing only.

1. When a company furnishes, for controlled screening and testing only, compounds or products not otherwise available to the Service and in which the company has a proprietary interest, the contract may provide that all rights in the compound or product shall remain in the company. It may additionally provide for confidentiality of the results for a limited period after the completion of the screening process and the report of the results by the Service to the supplier. Such period, as to results deemed significant for the research purpose, shall not exceed 12 months.

2. When the screening and testing of compounds obtained from the supplier under such a contract is carried out by an outside laboratory, the contract of the Service with the laboratory will contain provisions to safeguard the rights of the supplier under its contract with the Service.

(6-10-20 continued)

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.