(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.

(6-10-20B continued)

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 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

(6-10-10 continued)

§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 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

(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.

(6-10-10 cont'd)
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

(6-10-10 cont'd)

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.