86th Congress
1st Session

COMMITTEE PRINT

PATENT PRACTICES OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PRELIMINARY REPORT

OF THE

SUBCOMMITTEE ON

PATENTS, TRADEMARKS, AND COPYRIGHTS

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

EIGHTY-SIXTH CONGRESS, FIRST SESSION

PURSUANT TO

S. Res. 53

Printed for the use of the Committee on the Judiciary

UNITED STATES

GOVERNMENT PRINTING OFFICE

48436 WASHINGTON : 1960

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[1] The late Honorable William Langer, while a member of this committee, died on Nov. 8, 1959.

FOREWORD

Should basic Government patent policy be substantially altered by administrative action taken to accommodate a small group of research contractors? This question is raised by the action of the Surgeon General in virtually abandoning an established policy of patent dedication to the public in favor of a policy advocated by the drug companies cooperating in the cancer chemotherapy research program. Under the new policy the drug companies retain title to patents developed under this Government-financed program, subject to complex and untried provisions for compulsory licensing.

The following report was prepared by Clarence M. Dinkins of the subcommittee staff, under the supervision of Robert L. Wright, chief counsel of the Subcommittee on Patents, Trademarks, and Copyrights, as part of the subcommittee's study of the U.S. patent system, conducted pursuant to Senate Resolution 53 of the 86th Congress, 1st session. It is the seventh of a series dealing with patent practices of the various agencies. Their purpose and scope are more fully described in the forewords of the reports on patent practices of the Tennessee Valley Authority and the National Science Foundation and in the annual report of the subcommittee issued on March 9, 1959.

This report deals with the practices of the Department of Health, Education, and Welfare, an agency which spends more money on research and development than any of the other Government agencies except the National Aeronautical and Space Administration, the Atomic Energy Commission, and the Defense Department. Most of these research expenditures are in the field of public health and they are clearly intended to benefit the public at large. For this reason, HEW has traditionally pursued a policy of freely publishing its research results so as to make them widely available. It has preferred this policy to the alternative of taking out patents in the name of the Government.

However, in exceptional instances, HEW has permitted its research contractors to retain title to inventions developed with the expenditure of its funds. The most recent instance has been in connection with a series of cancer chemotherapy research contracts with leading drug companies. For the purpose of these contracts a special policy was adopted by which the drug companies could retain title to inventions made under the contracts, but the Surgeon General could compel royalty-free licensing when and if the public need for such patented products with respect to supply, quality, or price was not met. However, the participating drug concerns apparently insisted upon a further modification of this policy which established elaborate "procedural safeguards designed to protect the contractor from arbitrary action." Under these procedural provisions the Surgeon General may

not act to compel the issuance of a license until a formal notice has been issued and a hearing had.

Since this program is still too new to have brought any of these provisions into actual use it is difficult to predict what the consequences will be. However, it is clear that these new provisions impose a sharp restriction upon the rights which the Surgeon General has traditionally exercised with respect to inventions arising out of publicly financed research. The provisions also contemplate a form of compulsory licensing which is wholly untried in this country.

If the remedy of compulsory licensing is to be used as a means of insuring that the public interest in inventions produced with public funds is best served, it would seem that the standards under which such licensing may occur should be established by the Congress rather than by contracting officials. Compulsory licensing instead of Government ownership or dedication of patents as a means of making patents generally available for public use is an innovation which raises questions of public policy going far beyond the needs of the Public Health Service. Whether compulsory licensing is desirable, and if it is, what limitations should be imposed upon it appear to be matters which Congress should determine on the basis of the factual information that is now being collected in these preliminary studies.

JOSEPH C. O'MAHONEY,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate.

NOVEMBER 30, 1959.

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I. Legal Authority as to Patents

The major research and development programs of the Department of Health, Education, and Welfare are conducted by the Public Health Service and administered by the Surgeon General under the supervision and direction of the Secretary of Health, Education, and Welfare. The statutory authority of the Surgeon General includes the following:

42 U.S.C. 241—Research and investigations generally

The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Surgeon General is authorized to:

(a) Collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(b) Make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study.

(c) Establish and maintain research fellowships in the Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad;

(d) Make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Advisory Cancer Council, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or, with respect to heart diseases, recommended by the National Advisory Heart Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project;

(e) Secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

* * * * *

42 U.S.C. 282—Powers and duties of Surgeon General

In carrying out the purposes of section 241 of this title with respect to cancer the Surgeon General, through the National Cancer Institute and in cooperation with the National Cancer Advisory Council, shall:

(a) *Fosterage of research.* Conduct, assist, and foster researches, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer;

(b) *Coordination of researches.* Promote the coordination of researches conducted by the Institute and similar researches conducted by other agencies, organizations, and individuals; * * *.

42 U.S.C. 283—Administration of powers by Surgeon General; radium; technical instruction and training; acceptance of gifts; memorials; grants-in-aid

(a) In carrying out the provisions of section 282 of this title all appropriate provisions of section 241 of this article shall be applicable to the authority of the Surgeon General, * * *.

Under Public Law 85-580, approved August 1, 1958, there was appropriated to the National Institutes of Health for general research and services the sum of $28,974,000 and to the National Cancer Institute for grants-in-aid for research and training projects relating to cancer the sum of $75,268,000.

In connection with the appropriation for the National Cancer Institute the language of the statute is as follows:

To enable the Surgeon General, upon the recommendations of the National Advisory Cancer Council, to make grants-in-aid for research and training projects relating to cancer; to cooperate with State health agencies, and other public and private nonprofit institutions, and in the prevention, control, and eradication of cancer by providing consultative services, demonstrations, and grants-in-aid; and to contract on a cost or other basis for supplies and services by negotiation, without regard to section 3709[1] of the Revised Statutes, in connection with the chemotherapy program, including indemnification of contractor to the extent and subject to the limitations provided in title 10, United States Code, section 2354,[2] except that approval and certification required thereby shall be by the Surgeon General; and to otherwise carry out the provisions of title IV, part A, of the Act; $75,268,000.[3]

[1] Provides, with some exceptions, that Government contracts may be made only after advertising for proposals.
[2] Provides for indemnification of contractors for damages to persons or property arising from direct performance of contracts.
[3] 72 Stat. 469.

In addition to the statutory authority relating to the cancer research programs, there are other comparable provisions for research programs to be conducted by the National Heart Institute and other agencies of the Public Health Service.

Although patents are not specifically mentioned in these statutes, it is clear from the broad grant authority and the contractual powers given to the Surgeon General that many situations are likely to arise involving patent matters. This language has been construed by HEW as giving to the Surgeon General authority to condition grants and to execute necessary contractual provisions so as to protect the interest of the Government and the public in all patents and inventions which spring from these grants and contracts.

II. Present Practice

A. Administration

1. Personnel

The problems involved in the administration of patent matters by HEW are numerous and difficult due to the wide variety of the means used to carry on its research. HEW engages in research through its constituent agencies, by grants to individuals, universities, and other institutions, and by contracts with public and private organizations. In addition, its research programs have been substantially increased in recent years.

Regulations for handling patent matters have been issued and revised from time to time, and the office of the General Counsel of HEW has been available for consultation. The heads of the various constituent agencies in which the invention was made, or which supported the work leading to the invention, and the Department Patents Board, are primarily responsible for patent determinations (45 C.F.R. sects. 6.5, 7.3, 7.4, 8.2 and 8.4 which appear in the appendix, pp. 22–27). The Department's patent officer does not engage in policy determinations and his work, which at present is only part-time, is largely confined to determining which matters should be referred to the Department Patents Board. In November 1957 it was said:

> In the operating units of the Department some staff time is given to matters arising in connection with patent policy and the determination of rights in inventions. This does not, however, involve the preparation of patent applications or the administration of such patents as are obtained, and no full-time position wholly devoted to patent matters exists at this time within the Department [4] (report from HEW to Senator O'Mahoney attached to letter of Nov. 15, 1957).

Since November 15, 1957, with the steady increase in research and development work conducted under the auspices of HEW, some changes have been made in an effort to take care of the increasingly important patent problems which have arisen. The membership of the Department Patents Board has recently been increased from five to seven. Chapter 6–20 entitled "Department Patents Board and

[4] Letter to Hon. Joseph C. O'Mahoney, chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, from Mr. Marion B. Folsom, Secretary of Health, Education, and Welfare dated Nov. 15, 1957.

Patents Officers," as revised on April 15, 1959, giving the names and official positions of the members of the Department Patents Board, together with their duties and the duties of the Department patents officer, appears in the appendix at pages 31–33.

In commenting upon these administrative matters, Mr. Edward J. Rourke, acting patents officer of HEW, in a letter dated May 28, 1959, to the Subcommittee on Patents, Trademarks, and Copyrights, had the following to say:

> * * * While it continues true that no full-time position devoted to patents has yet been filed within the Department, a major portion of the time is devoted to patents by one person in the Office of the Surgeon General of the Public Health Service and by another in the Division of Research Grants, National Institutes of Health. From time to time many other persons in the Department are involved in considering particular situations, and the Office of the General Counsel through its several divisions advises operating officials regarding patent matters and the application or implementation of patent regulations, including those applicable to contracts. In other words, the patent aspects of research are considered as they arise at all levels involved in the conduct or support of research. This will largely continue to be true under present plans to improve the staffing arrangements for patent matters.
>
> * * * * * * *
>
> In recognition of the increasing role that patents administration is assuming in the research programs of the Department, the Secretary has approved the establishment of a full-time position of Department patents officer in the Office of the Secretary. It is expected that this position will be allocated and filled as soon as funds are available.
>
> The Public Health Service—the operating agency within the Department having by far the greatest share of patent actions to handle—has recently allocated and expects soon to fill a full-time position the major duties of which will be to handle patent matters of the Public Health Service.[5]

2. Performance statistics

The following table shows the number of Government-owned patents administered by HEW or its predecessor agency from July 1, 1937, through 1958, with issuance dates:

1938	1	1950	1
1939	2	1951	11
1940	3	1952	6
1941	1	1953	4
1942	1	1954	1
1945	2	1955	0
1947	0	1956	0
1948	0	1957	2
1949	1	1958	2

[5] Letter to Mr. Clarence M. Dinkins, assistant counsel, Senate Subcommittee on Patents, Trademarks, and Copyrights, from Mr. Edward J. Rourke, acting patents officer, Department of Health, Education, and Welfare, dated May 28, 1959.

Patent applications have never been handled by HEW. Until October 1953 the filing and prosecution of patent applications was handled for it by the Department of Justice. In this connection it was said:

> At that time the Department of Justice discontinued its service to other agencies of the Government in the filing and prosecution of patent applications, except upon a fixed-fee basis. Since that time special arrangements have had to be made by this Department whenever it has been decided to seek patent protection upon an invention.[6]

The special arrangements referred to above were of two kinds. The first involved the use of patent attorneys in the Department of the Army. This was done as a matter of accommodation where the invention was of interest to a particular military branch. The other arrangement was by contract with a private patent firm in cases where the nature of the invention or special circumstances made this course advisable.

In regard to the percentage distribution of patent matters as between the various constituent agencies of HEW, the following estimates were made, based upon representative samples covering the period 1950 through 1958:

	Percent
Public Health Service:	
National Institutes of Health	56
Bureau of State Services	17
Bureau of Medical Services	10
Total, PHS	83
Food and Drug Administration	10
Social Security Administration	7
Office of Education	0
Office of Vocational Rehabilitation	0
St. Elizabeths Hospital	0

For the 4 years prior to May 1959 all of these invention reports have come from the Public Health Service.

B. POLICY AS TO RETENTION OF TITLE

As a matter of general policy HEW favors dedication to the public through publication of research activities rather than patenting. It believes the former practice assures greater availability to the public of the invented product and avoids the administrative burden and expense involved in securing a patent. The special circumstances which HEW believes justify it in seeking to obtain patents are (1) cases where patenting is necessary to protect against patent rights being acquired by others and restricted in such manner as to impair or defeat HEW's objectives and (2) cases where the nature of the invention necessitates the maintenance of licensing control to further a health purpose, as in a case involving a narcotic drug. A list of inventions made by employees and grantees of the National Institutes of Health and dedicated to the public for the period of 1953–58 appears in the appendix at page 33. A list of the inventions on which patent applications were filed on behalf of HEW appears in the appendix at page 36.

[6] See note 4 on p. 3.

By regulations issued on December 4, 1957, HEW's general policy as to inventions developed through its resources and activities is stated as follows:

> § 6.1—*General Policy.* Inventions developed through the resources and activities of the Department are a potential source 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.
>
> § 6.2—*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 through publication. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made only if 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 Chairman of the Government Patents Board. 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.
>
> § 6.3—*Government-owned patents; licensing; dedication to the public.* All licenses under patents and pending patent applications for the administration of which the Department is responsible shall be issued by the Secretary. Licenses will be royalty-free, revocable and nonexclusive. Except in unusual cases when determined upon recommendation of the head of the constituent organization that unconditional licensing would be contrary to the public interest, licenses will be issued to all applicants and will contain no limitations or standards relating to the quality of the products to be manufactured, sold, or distributed thereunder. To reduce the need for individual license applications, patents held for unconditional licensing shall be dedicated to the public as may be feasible.[7]

1. By employees

HEW makes employee patent determinations in accordance with the provisions of Executive Order 10096.

[7] These regulations appear in full in the appendix at p. 19.

The procedure for dealing with employee inventions is stated by HEW to be as follows:

> With respect to Department employees, the procedure begins with the report by the employee-inventor to the agency of the Department which employs him. Unless the invention appears to the officer receiving the report (with the concurrence of the Department patents officer) not to be patentable, the report is forwarded with appropriate recommendations to the head of the constituent employing agency who makes in writing the following determinations: (1) whether the invention may be patentable; (2) whether circumstances of invention make the Government entitled to all rights therein; and (3) whether publication in lieu of patenting is adequate to serve the public interest. This determination constitutes the determination of the Department unless it is referred to the Department Patents Board because of questions of consistency with law or Department regulations or policy regarding patents. Notice of the determination is given the employee (unless he has previously agreed to the determination that is made), and if he is aggrieved, he has a right to appeal to the Government Patents Board pursuant to Executive Order 10096.[8]

2. By contractors and grantees

HEW believes that essentially the same basic policy should be applied to its employees as is applied to inventions arising out of research supported by grants or contracts. Thus HEW considers the public interest is in general best served if inventive advances arising from its grants or contracts are made freely available to the Government, to science, to industry, and to the general public. There are certain differences, however, between grants and contracts in the implementing methods and procedures.

a. By contractors.—The patent regulations applicable generally to contracts for research provide that the head of the HEW organization responsible for the contract shall determine the disposition of all inventions "first conceived or actually reduced to practice in the course of the performance of the contract." The reasons for this policy were stated in the following language:

> The Department of Health, Education, and Welfare as a matter of overall policy takes the position that the results of research which are developed with the aid of public funds in the field of its programs should be utilized in a manner which will best serve the public interest. It considers that the public interest will in general be best served if advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public. * * *
>
> Contracts for research, whether or not with nonprofit organizations, will be required to conform to the same departmental policy, under standard clauses adopted to 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 head of the constituent

[8] See note 5 on p. 4. The regulations on this subject appear in the appendix at p. 22.

> organization responsible for the contract, 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 organization head will be guided in general by the policies specified in departmental regulations with respect to grants.[9]

This basic policy is implemented by the Department's standard contract patent clause No. 20 which appears in the appendix, page 45. If, however, the contract is with a nonprofit institution, the contract may provide for leaving the ownership and disposition of the rights in inventions to the contractor if it is determined that the nonprofit institution's policies and procedures are acceptable on the same basis as would be those of a grantee as discussed above, pages 10 to 14. (See HEW Regulations, sec. 8.6(b) in the appendix, p. 27.)

Cancer chemotherapy contracts

On September 9, 1957, HEW adopted a special policy applicable only to cancer chemotherapy contracts with industrial profitmaking companies, and under this policy—intended to obtain extensive industrial cooperation in the synthesis and screening of possible anticancer agents—the cooperating firms are permitted to patent and exploit inventions as long as the products of such inventions are available to meet the public need with respect to supply, quality, and price. Subsequent to the adoption of this policy—

> * * * those involved in negotiating drug development contracts on behalf of the Government reported to the Department Patents Board that industry was not participating to an extent needed to meet the demands of the program, apparently due to industry concern that the "march-in" rights reserved to the Surgeon General might be exercised arbitrarily and without due regard to the real public need. It was on this basis that procedural modifications of the September 1957 policy were approved by the Secretary of Health, Education, and Welfare, July 1958. By this modification, the march-in rights were to be exercised only in accord with specified procedural safeguards designed to protect the contractor from arbitrary action.[10]

The march-in rights referred to above were those rights reserved to the Surgeon General under the special policy adopted in 1957 and applicable only to cancer chemotherapy research contracts with industry. They provided that under certain circumstances the Surgeon General may issue royalty-free licenses when he deems it necessary to assure an adequate supply of the product for health purposes at a reasonable price and of a high quality.[11]

In its latest statement of policy applicable to its cancer chemotherapy industrial research contracts, HEW has added several provisions which restrict procedurally the exercise of the right reserved to the Surgeon General to dedicate the invention or issue licenses on

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[9] "HEW Patent Policy Applicable to Research Contracts," dated Sept. 9, 1957. For complete text see the appendix, p. 42.

[10] See note 5 on p. 4.

[11] See paragraph 1(4)(a) of policy statement adopted as of Sept. 9, 1957, which appears in the appendix, p. 43.

a royalty-free basis when deemed to be in the public interest. Under these provisions the Surgeon General must give the contractor at least 90 days' advance notice that he intends to exercise his rights and if the contractor decides to contest this action he has the right to a hearing and to be represented by counsel. The findings of the Surgeon General must be in writing and are final and binding upon the contractor.[12]

A copy of a research and development contract between the Upjohn Co. and HEW was submitted as being typical of cancer chemotherapy research contracts made subsequent to July 31, 1958.[13] Instead of the so-called standard clause 20, preserving to the Surgeon General the right to determine the disposition of inventions arising in the course of the contract work, it contains substitute provisions giving the contractor the right to take title to such inventions.

Upjohn Co. (Contract No. SA-43-ph-1933)

The basic contract was made on January 1, 1958, for the period from January 1 through December 31, 1958, and provided for "the development of techniques for analysis of antitumor beers and extracts" at an estimated cost of $145,000. The original agreement gave the contractor the right to file a patent application in his own name pending the Surgeon General's determination as to ultimate disposition of the patent only when this was deemed necessary to prevent patenting of the invention by others. By a supplement dated December 1, 1958, the period of time for this research project was extended through December 31, 1959, and an additional $505,000 was obligated, bringing the total amount of this contract to $650,000. In addition, this supplement deleted in its entirety the "standard" patent rights provision and substituted a new provision which permitted the contractor to patent such inventions in his own name for the purpose of commercial exploitation.

The principal departures from the procedures provided by standard clause 20 are as follows:

If the contractor decides to patent an invention in this country and abroad, he may obtain title for himself, but this title would be subject to a royalty-free, nonexclusive license for governmental purposes. However, in the case of a domestic patent, the Surgeon General may, if he deems such action necessary to protect the availability of the invention for health purposes in a foreign country, take over all rights in foreign countries to the invention involved. The Surgeon General also may take over any invention and dedicate it to the public or issue nonassignable, nonexclusive licenses when and if he finds the contractor has not met the public need and that the public dedication or additional licensing by the Surgeon General is necessary in the public interest. However, the rights of the Surgeon General may only be exercised after he has been advised by a body of consultants and has given the contractor notice in writing of the grounds on which he expects to take over control of the invention. The contractor is then given a time specified by the Surgeon General in which to correct the deficiencies relied upon by the Surgeon General. Upon the expiration of that time, if the contractor

[12] For complete text of the patent policy announced Aug. 5, 1958, see the appendix. For the restrictive revisions referred to see paragraph B4 a, b, c, thereof.

[13] This is a cost reimbursement contract which is funded for a specified amount, but payments are made to the contractor only on the basis of actual expenditures plus an agreed upon provisional rate to cover overhead.

has not satisfied the Surgeon General, he is then given notice that at the end of 90 days from such notice the Surgeon General will exercise his rights. Within 20 days after receipt of such notice, the contractor may file a request for a hearing at which he may be represented by counsel and present testimony in his behalf. If the contractor does not elect to have a hearing, the Surgeon General will then make his findings; if a hearing is held, findings will subsequently be made by the Surgeon General. In either event, the Surgeon General's conclusions will be final and he may proceed to dedicate or license at the expiration of the time limitations.

While there is no provision for judicial review of the merits of the Surgeon General's decision, the procedural limitations noted above form an obvious basis for judicial intervention if the contractor claims that the Surgeon General acted without complying fully with these procedural requirements. Since no disputes have yet arisen under this provision, the extent to which it may lead to litigation cannot now be estimated. The provision is, in any event, a sharp restriction of the rights which the Surgeon General has traditionally exercised with respect to patents arising out of publicly financed health research.[14]

The following list sets out all of the industrial research contracts of HEW which were in effect as of February 1, 1959, in connection with its cancer chemotherapy program, classified by the form of patent clause used in each:[15]

(1) STANDARD CLAUSE

Contractor	Contract No.	Date
Bristol Laboratories, Inc.	SA-43-ph-1908	Feb. 1, 1958
Do.	SA-43-ph-2411	Sept. 2, 1958
Pitman-Moore Co.	SA-43-ph-1963	Mar. 15, 1958
The Upjohn Co.	SA-43-ph-1933	Jan. 1, 1958

(2) PROVISIONS BASED ON POLICY OF SEPTEMBER 1957

Abbott Laboratories	SA-43-ph-1910	Oct. 15, 1957
Chas. Pfizer & Co., Inc.	SA-43-ph-1926	Jan. 1, 1958
Schering Corp.	SA-43-ph-1929	Do.

(3) PROVISIONS PERMITTING APPLICATION AT CONTRACTOR'S OPTION, OF POLICY OF JULY 31, 1958

E. R. Squibb & Sons	SA-43-ph-2395	June 1, 1958
Parke-Davis & Co.	SA-43-ph-1965	Apr. 1, 1958
Merck & Co., Inc.	SA-43-ph-1886	Jan. 1, 1958
Do.	SA-43-ph-1948	Do.
Armour & Co.	SA-43-ph-1934	Do.

(4) CONTRACT PROVISIONS BASED ON POLICY OF JULY 31, 1958

The Upjohn Co.	Supp. No. 2 to SA-43-ph-1933	Dec. 1, 1958

b. By grantees.—To implement the basic policy as to grantees, about 85 percent of the research grants of the Public Health Service are governed by provisions which reserve to the Surgeon General the right to

[14] For text of substituted provisions of clause 20, see appendix, p. 46.
[15] Letter to Hon. Joseph C. O'Mahoney, chairman, Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary from Mr. Arthur S. Flemming, Secretary, Department of Health, Education, and Welfare, dated Feb. 13, 1959.

determine on an individual case basis the disposition of rights to inventions developed under the grant.[16] Department regulations set forth four alternative methods available to the head of the constituent agency for disposition of the inventions.[17]

Thus in the majority of research grant situations, upon receipt of an invention report it is reviewed by persons expert in the same field, who submit opinions as to the novelty, utility, and scientific importance of the invention, whether in their opinion publication would suffice to protect the public interest, and whether an invention should be patented. These opinions, together with other facts relating to the development of the invention, form the basis of the determination by the Surgeon General for the particular case. In the majority of the cases reported to date, the Service has determined that full application of the facts would serve to establish priority of the invention and would serve within the year as dedication of the invention to the public. Certain cases in which special arrangements or conditions have been desirable in the public interest are noted later in this report. Each case, however, is considered separately, and the Surgeon General follows the course of action deemed by him to be in the public interest.

Alternative grantee agreements

HEW regulations permit an alternative to the above general policy and procedure. Instead of the rights of disposition being retained by the head of the constituent agency, this alternative permits him to enter into an agreement with a grantee institution under which inventions arising from research grants may be disposed of by the grantee in accordance with its own established policies if they are first approved by the head of the constituent agency as in accord with Department regulations.[18] With respect to the Public Health Service, about 15 percent of the grants are covered by such agreements which, as of May 28, 1959, had been entered into with 19 universities or other nonprofit institutions.[19]

The acceptability to the Public Health Service of a grantee's patent policies and procedures is determined by comparing the grantee institution's formalized policy with the policies and procedures determined acceptable to the Service.[20] In making these agreements by which the Service consents to the administration by the grantee institution of inventions and discoveries arising from PHS support in accordance with its own policies and procedures, the Service offers the following alternatives:

A. Dedication to the public of results of research either by publication or patenting with subsequent dedication of the patents.

B. Patenting with royalty-free licensing.

C. Patenting with licensing on a royalty basis, provided the royalty is reasonable and coupled with a royalty-free license to the Government with power to sublicense for all governmental purposes.

D. Assignment of ownership rights to a patent management agent who will adhere to the standards established for the grantee.

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[16] See PHS Application for Research Grant form in the appendix, p. 37.
[17] See Regs. sec. 8.2 in the appendix, p. 26.
[18] See sec. 8.1(b) in the appendix, p. 26.
[19] For list of grantees see the appendix, p. 34.
[20] These policies appear under the heading "Invention and Patent Policies Acceptable to the Public Health Service," in the appendix, p. 38.

Before a recommendation is made to the Surgeon General as to whether an institution's policies are acceptable the following information is required from the grantee institution:

1. A statement of the invention and patent policies of the institution, with full information as to organization for handling, reporting procedures, policy as to seeking patents, licensing and royalty practices, use of profits (if any), and reward to inventor (if any).

2. The publication of research results as affected by the invention and patent policies of the institution.

3. The number of patents the institution has obtained in the past 10 years, and the number of licenses issued on each patent. If exclusive licenses have been issued, the number, terms of duration, and full information as to the basis on which such licenses were issued and the safeguards utilized to protect the public interest.

Papers relating to the University of Washington were submitted by HEW as being typical of those received from other grantee institutions. Negotiations between the Public Health Service and the University of Washington began in 1953 and the final agreement between the Surgeon General and the university was executed on October 13, 1954. A copy of this agreement is as follows:

OCTOBER 13, 1954.

MR. NELSON WAHLSTROM,
University of Washington,
Seattle, Wash.

DEAR MR. WAHLSTROM: Replying to your letter of April 10, 1953, I am pleased to advise that it has been determined, pursuant to provisions of section 2(b) of Department Order 110–1, "Inventions Resulting from Research Grants," that the ownership and disposition of all domestic rights in inventions arising under Public Health Service grants and awards made to the university shall be left for administration by the university.

It has been noted in the review of the materials submitted by you that the policy provides for a contract with Research Corp. which acts as patent management agent for the University of Washington on those inventions assigned to them for prosecution. In making my determination, therefore, I have particularly noted that the policies of both the University of Washington and Research Corp. provide for licensing on a royalty basis, and for conformance with normal trade practices insofar as royalties are concerned. I have also taken cognizance of the fact that the University of Washington is opposed to exclusive licenses, and that in the licensing arrangements entered into by the University of Washington and Research Corp. adequate safeguards are inserted to protect the public interest.

This determination is subject to the following understandings and conditions, and upon acceptance will apply to inventions under current grants and awards and to those made while it remains in effect:

(1) The university will make its determinations in accordance with the invention and patent policies as they appear in patent policy of the University of Washington, adopted by the board of regents of the university January 10, 1950, as supplemented by (*a*) your letters of April 10, 1953, and July 26, 1954, addressed to the National Institutes of Health, Division of Research Grants, and (*b*) your patent management agreement with Research Corp.

(2) The university will report to the Public Health Service on each invention which appears to be patentable and which arises under research assisted by grants or awards to the university by the Public Health Service. Such report shall be furnished immediately on the filing of a patent application on any such invention, and the university will furnish to the Public Health Service an annual report showing the disposition of all such inventions.

(3) The university will reserve to the United States in any such patent application and in any patent issued thereunder a nonexclusive, irrevocable, and royalty-free license to make and use, and to sell as provided by law, embodiments of the invention, with power to sublicense, for all governmental purposes.

(4) The university will reserve an option to the Government to file foreign patent applications on any such invention, and will convey to the Government upon demand the rights necessary to enable the Government to prosecute such applications and obtain patents in foreign countries, such option to run for 6 months from the date of the filing of a patent application in the United States. If the Government either fails (*a*) to exercise this option within the period specified, or (*b*) determines within this period not to exercise its rights to an option, the university may dispose of all foreign rights in the invention, subject to the reservation of the United States of a nonexclusive, irrevocable, royalty-free license to make, use and sell as provided by law, embodiments of the invention, with power to sublicense, for all governmental purposes.

Please have two copies of this agreement signed by an official authorized to commit the university in the space indicated below and return one copy to the Division of Research Grants, National Institutes of Health, Bethesda, Md., retaining the other for your files.

Sincerely yours,

LEONARD A. SCHEELE,
Surgeon General.

UNIVERSITY OF WASHINGTON,
By: NELSON WAHLSTROM.

C. FOREIGN FILING

1. Employees' patents

HEW's policy as to foreign patenting is stated as follows:

> This Department does not seek foreign patents. Even in those cases where it is practicable to acquire foreign rights in an invention and public policy in relation to general health objectives would point to the desirability of seeking patent or other protection abroad, the Department has neither statutory authority nor facilities for this type of activity.
>
> In the case of the invention of the antimalarial drug "Primaquine," which was recommended for foreign patent protection, the Department of Commerce arranged for its patenting abroad in a number of countries under an arrangement by which a private drug company handled the actual applications. The Department of Commerce acted at that time under Executive Order 9865 as implemented by administrative orders of the Chairman of the Government Patents Board. There is now no centralized facility for the handling

of foreign patent applications. The routine determinations and recommendations regarding foreign patenting which we now make are generally unproductive because neither this Department nor any other agency is in a position to take followup action on inventions arising from the research programs of the Department.

There have been two instances of inventions made abroad by an employee or fellow of the Public Health Service working in collaboration with employees of the British Government. In the first of these an arrangement was entered into by which rights to the invention in the United States were assigned to the United States and the foreign rights to the Medical Research Council of Great Britain, patent applications being thereafter filed in the two countries. * * *[21]

The second case involved a request from the Medical Research Council of Great Britain to the Surgeon General for consideration of a patent agreement between the Public Health Service and the Council. This request has now been studied and discussions have been held with the State Department. It is expected that an agreement may be reached sometime this year on terms acceptable to both agencies.

HEW has no information as to the extent to which employee-inventors may have sought or obtained foreign patent rights for themselves.

2. Contractors' and grantees' patents

HEW regulations provide for prompt written notice by contractors and grantees of all inventions and patent applications made by them in the course of their contract work.[22]

Upon the basis of information from its contractors and grantees relating to inventions and patent applications received to date, HEW has no information indicating that any of these contractors and grantees have made applications for patents in foreign countries. In connection with these invention reports, the following statement was made by HEW:

> * * * Since as to both contracts and grants the normal "standard" provision requires a report of invention to the Government and requires the invention to be subject to disposition and control by the Government, we have information in the form of invention reports as to grantees and certainly expect to have from the comparatively smaller and newer research contract program as and when inventions are developed under such contracts. Invention reports from grantees are regularly received and in almost all cases it has been determined to dedicate the invention to public use by full publication * * *. Under the standard provisions, therefore, the grantee or contractor has no basis consistent with his agreement with the Department on which to seek a patent for himself. Even in the two exceptional areas where title to an invention may be retained by the grantee or contrac-

[21] See note 4 on p. 3.

[22] (See par. 8.1 entitled "Conditions to be included in research grants" and 8.6 entitled "Contracts for research" contained in HEW's regulations in appendix at p. 26. See also clause 20 of HEW's general provisions entitled "Patent Rights" in the appendix at p. 45.)

tor (by special agreement with the grantee or nonprofit contractor and in cancer chemotherapy research contracts), full reports of invention are required.[23]

D. USE OF PATENTS BY PARTIES RETAINING TITLE

1. Employees

HEW has no information showing the use of patents to which employees have retained title. Employees of HEW have retained title to patents in very few cases, and only in those where Government materials, time or information has not contributed to an invention, or where the Government has insufficient interest in the invention. Under such circumstances HEW does not collect information on inventions of this type.

2. Contractors and grantees

To date there are two instances in which the Surgeon General had been requested to approve, and did approve, a disposition of grantee inventions which involved an assignment or exclusive license. The inventors were Dr. Harry S. Penn, of the University of California and Dr. Russell H. Morgan, of Johns Hopkins University. In both of these cases there was a strong showing of need of substantial additional investment in order to continue research and development to the point of wide utility.

The facts in these cases are briefly as follows:

Dr. Harry S. Penn, University of California

This invention was described as a "synthetic antigen for use in detection of cancer." The invention resulted from research which had been supported by contributions from several sources. Prior to the granting of an exclusive license, the Government had contributed approximately $87,000 from 1949 to 1953. During this period support from non-Federal sources had been approximately $143,000. The grantee institution claimed that it was unable to continue the necessary research work except by accepting an offer from a private drug firm, which was willing to contribute approximately $55,000 for continued research for several years together with the assistance of qualified technicians. This offer of the drug company was conditioned upon its receiving a 5-year exclusive license with a limit of 5 percent of net sales on any royalty charge. This arrangement was approved by the Surgeon General in March 1953, and in April 1958 a license to the Government was received under the pending patent application. In January 1959 the university notified HEW that is was abandoning all of its rights to the invention on conditions that the inventor fulfill his obligations to the Government.

Dr. Russell H. Morgan, Johns Hopkins University

This invention involved low noise amplification and was first reported to the Public Health Service in March 1955. The research work leading to the invention was supported over a period of several years by contributions of approximately one-third by the university and two-thirds by the Public Health Service. The work was directed primarily toward amplification of X-ray fluoroscopic screens. In

[23] See note 5 on p. 4.

November 1955, because of the need for further highly technical development to be undertaken by a private firm and after receiving abundant assurances that vigorous efforts would be devoted to developing the invention, the first priority being given to the field of medicine in public health, the Surgeon General determined that this firm could hold the patents until April 1965. Upon the expiration of this period of exclusivity, the owner of the patent is required to grant licenses on a nonexclusive basis with royalties limited to 6 percent, and the Government is entitled at all times to a nonexclusive, irrevocable royalty-free license, with power to sublicense for governmental purposes.

HEW has no data showing the use which grantees have made of patents which they obtained. No patent has yet been issued to which a contractor has title. In connection with inventions arising out of grants, HEW stated:

> * * * the inventions developed under grants have for the most part also been dedicated by publication or, if covered by agreement with universities, the extent of actual use would be peculiarly the knowledge of the university.[24]

3. Government

HEW has a definite policy of discouraging the acquisition and/or ownership of patents by the Government except (1) in the case of inventions of high potential significance to public health, safety, or welfare when it is deemed advisable to obtain maximum protection against potential rival claims by establishing priority of invention and diligence in reducing to practice, and (2) for reasons of health and safety when it is determined to be advisable to have legal authority to impose restrictive conditions on the use of the patents.

The present policy of HEW strongly leans toward dedication to the public, not only in the case of patented inventions, but also in the case of patentable inventions which were dedicated without making patent applications. The only patentable invention reported to HEW pursuant to a research contract is now in process of being dedicated to the public. As long as this dedication policy is continued, there will be very little need for granting licenses.

A tabulation showing, as of May 1959, all patents owned by HEW under which licenses were granted, giving patent number, dates of issue, subject matter of invention, name and address of licensee, date of license, and the name and status of the inventor appears in the appendix at page —.

Two examples of dedicated inventions which HEW believes may have had extensive commercial use are the following:

> An example of an important invention on which a patent was obtained was that of a "Method of Converting Tomatidine into Δ 16 Allopregnenolone" by a team of research workers at the National Institutes of Health. As soon as report was made of the success obtained in this research effort, numerous inquiries were received concerning the availability of the invention for commercial use. Accordingly, after the patent issued, determination was made to dedicate the patent to the public. Formal dedication was recorded in the Patent

[24] See note 5 on p. 4.

Office, and those who had inquired about licensing were notified of this action which eliminated any need for the issuance of individual licenses.

An example of an unpatented invention made by a Department employee and having substantial commercial utility was the invention in 1953 of the new insecticide "DDVP" by a team of research workers at the Technical Development Laboratories of the Public Health Service Communicable Disease Center. This invention was significant both in the field of agriculture and of public health, and as soon as reports concerning it appeared inquiries were received from a number of commercial organizations. The Department determination was in favor of technical publication, rather than patenting, and press releases were issued for the information of the public as to its potentialities and its availability for use. * * * [25]

No reports have been obtained from any HEW licensee showing the extent of commercial use.

Three examples of licensed patents were submitted as having probable commercial uses. These were:

2,178,010—Nuclear substituted derivatives of the morphine series. "Metropon" licenses to eight drug and chemical companies.

2,234,981—Formaldehyde sulphoxylate derivatives. Licenses to four drug and chemical companies.

2,604,474—"Primaquine." Licenses to five drug and chemical companies. (This highly useful invention was developed under a Public Health Service research grant to Columbia University.) [26]

III. Agency Viewpoint

A. Judgment as to effectiveness of present policy

HEW feels that its present practice regarding patent matters is working reasonably well. In this connection it was stated:

This Department has reached no conclusions as to whether greater flexibility of authority in the administration of Government-owned patents than now exists would facilitate or impede the realization of its research objectives. If, however, in the administration of more flexible authority the Department should be required to take into consideration objects extraneous to the research objective, the effect would be detrimental. In any event the building up of a system placing emphasis on patenting and the administration of patents would entail the setting up of extensive administrative machinery and personnel.

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[25] See note 4 on p. 3.
[26] See note 4 on p. 3.

As has been indicated, the development of policy in this Department has been in the other direction. While the underlying purpose here has been to make fully, freely, and promptly available the fruits of research conducted or financially aided by the Department, with restrictions limited to those involving safety factors, it has fortunately coincided with more economical administration.[27]

B. RECOMMENDATIONS AS TO FUTURE POLICY

None were offered.

[27] See note 4 on p. 3.

APPENDIX

No. 1

MANUAL—GENERAL ADMINISTRATION

Part 6—Patents and Inventions

CHAPTER 6–10

REGULATIONS AND PROCEDURES

6–10–00 Scope
6–10–10 Regulations (from *Federal Register* of 9/14/55 and 12/4/57)

[From *Federal Register*, Title 45, Subtitle A]

PART 6—INVENTIONS AND PATENTS (GENERAL)

Sec.
6.0 Definitions.
6.1 General Policy.
6.2 Publication or patenting of inventions.
6.3 Government-owned patents; licensing; dedication to the public.
6.4 Central records; confidentiality.
6.5 Procedures relating to employee and grantee inventions.
6.6 Issuance of patents on non-fee basis; certification of public interest.

PART 7—EMPLOYEE INVENTIONS

7.0 Who are employees.
7.1 Duty of employees to report inventions.
7.2 Determination as to patentability.
7.3 Determination as to domestic rights.
7.4 Option to acquire foreign rights.
7.5 Determination as to patenting.
7.6 Department review and determination.
7.7 Notice to employee of determination.
7.8 Employee's right of appeal.

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

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.

HEW TN–21 (7/31/58). Supersedes page 1, Chapter 6–10 (TN–15).

6–10–20 Patent Policy Applicable to Cancer Chemotherapy Industrial Research Contracts

6–10–00 *Scope*

A. 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.

B. The substance of the Department regulations relating to employee inventions is incorporated in a statement for the general information of supervisors and employees which was issued 10/19/56 in HEW General Administration Manual Guide No. 1.

6–10–10 Regulations (from Federal Register of 9/14/55 and 12/4/57)

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.

AUTHORITY: §§ 6.0 to 6.6 issued under Reorg. Plan No. 1 of 1953, 18 F.R. 2053; 3 CFR 1953 Supp. E.O. 10096, 15 F.R. 391; 3 CFR, 1950 Supp.

§ 6.0 *Definitions.* As used in Parts 6, 7, and 8 of this subtitle:

(a) "Department" means the Department of Health, Education, and Welfare.

(b) "Secretary" means the Secretary of Health, Education, and Welfare.

(c) "Head of constituent organization" includes the Surgeon General of the Public Health Service, the Commissioner of Education, Commissioner of Social Security, Commissioner of Food and Drugs,

the Director of Vocational Rehabilitation, and the Superintendent of Saint Elizabeths Hospital.

§ 6.1 *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, Executives orders and general Government regulations, for the determination of rights and obligations relating to the patenting of inventions.

§ 6.2 *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 through publication. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made only if 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 Chairman of the Government Patents Board. 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.

§ 6.3 *Government-owned patents; licensing; dedication to the public.* All licenses under patents and pending patent applications for the administration of which the Department is responsible shall be issued by the Secretary. Licenses will be royalty-free, revocable and nonexclusive. Except in unusual cases when determined upon recommendation of the head of the constitutent organization that unconditional licensing would be contrary to the public interest, licenses will be issued to all applicants and will contain no limitations or standards relating to the quality of the products to be manufactured, sold, or distributed thereunder. To reduce the need for individual license applications, patents held for unconditional licensing shall be dedicated to the public as may be feasible.

§ 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.

§ 6.5 *Procedures relating to employee and grantee inventions.* The Department Patents Officer, with the approval of the Department Patents Board, and the heads of constitutent organizations within their respective areas of responsibility, are authorized to issue such procedures and bulletins and take such other actions as may be necessary or desirable to supplement the provisions of Parts 7 and 8 of this subtitle.

§ 6.6 *Issuance of patents on non-fee basis; certification of public interest.* For the purpose of an application for a patent to issue under the non-fee provisions of the Patent Code (35 U.S.C. 266), a certification that an invention is used, or is likely to be used, in the public interest may be executed in behalf of the Secretary by the head of the constituent organization having admistrative jurisdiction over the inventor.

PART 7—EMPLOYEE INVENTIONS

Sec.
7.0 Who are employees.
7.1 Duty of employee to report inventions.
7.2 Determination as to patentability.
7.3 Determination as to domestic rights.
7.4 Option to acquire foreign rights.
7.5 Determination as to patenting.
7.6 Department review and determination.
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, 1953 Supp. E. O. 10096, 15 F.R. 391; 3 CFR, 1950 Supp.

§ 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 Chairman of the Government Patents Board, that to include him or them would be 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.* Any Department employee is required to report promptly to the constituent organization in which he is employed any 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 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. Reports of inventions (except for cases as to which it is decided by the appropriate office or constituent organization, with the concurrence of the Department Patents Officer, that it does not appear they are or may be patentable) shall be forwarded through appropriate channels to the head of the office or constituent organization having administrative jurisdiction over the inventor at the time the invention was made. Thereafter they shall

be forwarded with the related administrative recommendations and determinations to the Department Patent Officer.

§ 7.2 *Determination as to patentability.* Upon receiving a report of an employee invention, the head of the appropriate office or constituent organization shall make in writing the decision on behalf of the Department as to whether the results of the research, development, or other activity constitute an invention or inventions which may be patentable.

§ 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 head of the appropriate office or constituent organization, in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Chairman of the Government Patents Board, as follows:

(a) The Government as represented by the Secretary 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 Chairman, 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 power to grant licenses for all governmental purposes, such reservation, in the terms thereof, 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 shal 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 the facts or circumstances attendant upon the conditions under which any particular invention is made and, nothwithstanding the foregoing, shall

not preclude a determination that the invention falls within the provisions of paragraph (d) of this section.

(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 countires. 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 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 issue sublicenses for use in behalf of the Government and/or in furtherance of the foreign policies of the Government.

§ 7.5 *Determination as to patenting.* When the head of the appropriate office, or constituent organization, determines in accordance with the provisions of §§ 7.3 and 7.4 that the Government has rights in a patentable invention:

(a) He shall also determine whether the Department should seek to obtain a domestic patent thereon, or whether it shall be published or other action taken in the public interest, giving his reasons therefor; and

(b) He shall further recommend in writing whether the invention should receive foreign patent protection or be published abroad and, if affirmative, should specify the foreign jurisdictions in which action is recommended, giving reasons therefor, and should indicate, if possible, its immediate or future industrial, commercial, or other value, including particularly its value to public health.

§ 7.6 *Department review and determination.* The determination by the head of an office or constituent organization of the ownership of domestic or foreign rights in an invention by a Department employee shall constitute the decision of the Department unless, upon review, the Department Patents Officer questions the consistency of the determination with applicable law or regulations or with Department policy. Any question, unresolved after consultation with the originating unit, will be submitted by the Department Patents Officer to the Department Patents Board which shall either affirm or reverse the determination or return the same to the head of the constituent organization or office for further action. If the Board proposes to determine, or to approve a determination, that the invention shall be required to be assigned to the Government, it may in its discretion afford the employee an opportunity of a hearing.

§ 7.7 *Notice to employee of determination.* The appropriate office or constituent organization shall notify each employee-inventor in writing, of the Department's determination and of his right of appeal, if any. In the case of determinations made by the Department Patents Board, the notification shall be made by the Department Patents Officer. 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 Chairman of the Government Patents Board, pursuant to section 4(d) of Executive Order 10096 and regulations issued thereunder, by filing a written appeal with the Chairman, in quadruplicate, and a copy of the appeal with the Department Patents Officer, within 30 days (or such longer period as the Chairman 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 of 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, 1953 Supp., E.O. 9865; 12 F.R. 3907; 3 CFR, 1947 Supp., E.O. 19906, 15 F.R. 391; 3 CFR, 1950 Supp.

§ 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.

(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, as the head of the constituent unit may determine, either:

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the head of the constituent unit responsible for the grant, 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 head of the constituent unit 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.

§ 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 head of the constituent organization 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 Gov-

ernment'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 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 fild 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 head of the responsible constituent organization, 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 head of the constituent organization responsible for the contract, 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 organization 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.

§ 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 organiaztions for the cancer chemotherapy research program shall be subject only to such

limitations and alternatives as the Secretary may approve for such program.

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

(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.

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 as such stage of development that if it were more generaly 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 therefore, 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.)

[1] With respect to supply, quality, or price.

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) 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.

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

[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.

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.

D. *Invention 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.

No. 2

MANUAL—GENERAL ADMINISTRATION

Part 6—Patents and Inventions

CHAPTER 6–20

DEPARTMENT PATENTS BOARD AND PATENTS OFFICES

6–20–10 *Organization*

A. The Department Patents Board shall consist of a chairman and six other members of the Department appointed by the Secretary.

B. The Department Patents Officer shall be appointed by the Secretary and shall serve as a member of the Board if so designated by the Secretary. A Deputy Department Patents Officer may likewise be appointed.

6–20–20 *Assignment of Responsibilities*

A. The Department Patents Board shall:

1. Advise and consult with the Secretary and with appropriate Department personnel, including the Department Patents Officer and the Department's representatives on the Government Patents Board, on questions of patent policy affecting the Department.

2. Upon request, consult with and make recommendations to the Secretary, the Department Patents Officer, or the head of an operating agency, regarding the application of patent policies or procedures within the Department, or with respect to specific inventions.

3. In its discretion, after affording opportunity for an informal hearing, hear and determine on behalf of the Department, appeals from determinations relating to the ownership or patenting of employee inventions.

B. The Department Patents Officer shall:

1. Act as executive officer and secretary for the Department Patents Board.

2. Act either as the representative of the Department or as its alternate representative on the Government Patents Board, as designated by the Secretary; act as liaison officer for the Department with the Chairman of that Board and make such reports to him as may be appropriate; except where otherwise provided by the Secretary, represent the Department on any boards and committees and in other matters relating to inventions and patents.

3. Act as liaison officer for the Department with the Department of Justice on matters relating to patent policies and procedures.

4. Receive all determinations made by the heads of operating agency units relating to inventions made by Department employees, referring, if necessary, any such determinations to the Department Patents Board for its review and decision.

5. Receive for transmittal, with his recommendation where appropriate, matters relating to patents requiring consideration or action by the Department Patents Board or the Secretary.

6. Consult and advise, as feasible, with the various operating agency organizations and officers of the Department in the formulation and carrying out of policies and procedures relating to inventions and patents.

7. Be responsible for the maintenance of records concerning Government-owned patents for the administration of which the Department is responsible and for the handling of applications for licenses thereunder.

6–20–30 *Membership Department Patents Board and the Department Patents Officer*

A. The membership of the Department Patents Board shall consist of:

Miss Mary Switzer, *Chairman*, Director, Office of Vocational Rehabilitation

Mr. Homer D. Babbidge, Assistant Commissioner and Director of the Division of Higher Education, Office of Education

Mr. Edward B. Persons, Deputy Director, Division of Personnel Management, Office of Administration

Dr. John D. Porterfield, Deputy Surgeon General, Public Health Service

Mr. Richard L. Seggel, Executive Officer, National Institutes of Health

Mr. Dale S. Thompson, Director, Division of General Services, Office of Administration

Dr. Frank H. Wiley, Chief, Division of Pharmaceutical Chemistry, Food and Drug Administration

B. Department Patents Officer: (vacant).

Deputy Patents Officer: Mr. Edward J. Rourke, Assistant General Counsel, Public Health Division, Office of the General Counsel

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No. 3

NATIONAL INSTITUTES OF HEALTH

Inventions dedicated to the public through publication for the period 1953–58

EMPLOYEE INVENTIONS

Inventor	Title of invention	Journal reference
1953		
Crisp, Laurence R. and Stierli, Harry.	"Automatic Pipette Washing Machine."	Crisp, L. R. and Stierli, H.: Automatic Pipette Washing Machine, *Bib. Tech. Repts.*, U.S. Dept. Commerce, PB 111745.
White, WM. C.	"X-ray Sensitive Glass"	White, W. C.: Some Experiments on the Use of Glass as a Radiation Dosimeter, *Nucleonics*, (Oct.) 1953.
1954		
Steinberg, Daniel	"Split Lyophilization Flask"	Steinberg, D.: Split Lyophilization Flask, *Bib. Tech. Rpts.*, U.S. Dept. Commerce, PB 116937.
Nadel, Eli M.	"Tube-Separatory Funnel and Rocker for Rapid Extraction."	Nadel, E. M.: Tube-Separatory Funnel and Rocker for Rapid Extraction, *Chemist Analyst*, (Mar.) 1954.
Perrine, Theodore T.	"Stopcock With Needle-Valve Control."	Perrine, T. J.: Stopcock With Needle-Valve Control, *Anal. Chem.*, Vol. 28, p. 286, (Feb.) 1956.
Crisp, Laurence R. and Debroske, John M. F.	"Process of Preparation of Tooth Sections for Microscopy.	Crisp, L. R. and Debroske, J. M. F.: Process of Preparation of Tooth Sections for Microscopy, *Bib. Tech. Rpts.*, U.S. Dept. Commerce, PB 111471.
Highhouse, Frederick and Mencken, Calvin.	"Triple Automatic All-Glass Water Still."	Highhouse, F. and Mencken, C.: Triple Automatic All-Glass Water Still, *Rev. of Scien. Instr.*, Vol. 25, No. 10, pp. 1038–1039, (Oct.) 1954.
Gunkel, Ralph D.	"Self-Recording Tangent Screen for Visual Fields."	Gunkel, R. D.: Self-Recording Tangent Screen for Visual Field, *Amer. J. Ophth.*, 1955.

Inventions dedicated to the public through publication for the period 1953–58—Continued

EMPLOYEE INVENTIONS—Continued

Inventor	Title of invention	Journal reference
1955		
Brubach, Howard F.	"Dessicator Cover Remover and Sleeve Wrench."	Brubach, H. F.: Dessicator Cover Remover and Sleeve Wrench, *Science*, Oct. 21, 1955.
Bowman, Robert L.	"Spectrophotogluorometer"	Bowman, R. L.: Spectrophotogluorometer, *Science*, Vol. 122, No. 3157 (July) 1955.
1956		
Pierce, Charles E.	"Liquid-Liquid Continuous Extractor."	Pierce, C. E.: Liquid-Liquid Continuous Extractor, *Anal. Chem.*, Vol. 28, p. 2029 (Dec.) 1956.
Severinghaus, John W.	"Telecor"	Severinghaus, J. W.: Telecor, *Current Res. in Anes. and Analg.* (Apr.) 1957; *Rev. of Scien. Instr.* (Aug.) 1956.
Cole, Kenneth R.	"Bridge Circuit for Temperature Measurement with Semi-Conductors".	Cole, K. R.: Thermistor Thermometer Bridge, Linearity and Sensitivity for a Range of Temperature, *Rev. of Scien. Instr.*, Vol. 28, No. 5, 326-328 (May) 1957.
Noble, Frank W.	"Sonic Valve Catheter-Tip Manometer."	Noble, F. W.: Sonic Valve Catheter Tip Manometer, *Fed. Proc.*, Vol. 15, pp. 136-137, 1956; *Inst. of Radio Engrs. Transaction on Med. Electronics*, PGMR-8 (July) 1957.
1957		
Joram, Philip	"Vacuum Formed Disposable Paraffin Embedding Trays."	Joram, P.: Vacuum Formed Disposable Paraffin Embedding Trays, *U.S. Govt.* Res. Rpts., PB 131397.
Jenkins, Jack C.	"Invertor Rack"	Jenkins, J. C.: Invertor Rack, to be published in *U.S. Govt. Res. Rpts.*, U.S. Dept. Commerce.
Moore, John W.	"A Method for Reduction of Capacitative Currents."	(Final arrangements not completed.)
Moore, John W.	"Automatic Zero Volt Loss Current Meters."	Moore, J. W.: Automatic Zero Volt Loss Current Meters, *Rev. of Scien. Instr.* (to be published).
1958		
Cotlove, Ernest	"Automatic Chloride Titrator."	Cotlove, E.: Automatic Chloride Titrator, *J. of Lab. & Clin. Med.*, (Mar.) 1958.
Fletcher, Hewitt G., Jr. and Diehl, Harry W.	"A Simplified Preparation of 2-Deoxy-*D*-Ribose."	Fletcher, H.G. and Diehl, H.W.: A Simplified Preparation of 2-Deoxy-*D*-Ribose, *Arch. of Biochem. and Biophy.*, (Dec.) 1955.

GRANTEE INVENTIONS

1954		
Nisselbaum, Jerome S. and Bernfeld, Peter, Tufts University.	"Purification and Isolation of Proteins by Electrophoresis on a Medium Consisting of a Modified Starch Paste."	Nisselbaum, J. S. and Bernfeld, P.: Report of the Sixth Annual Meeting of the Board of Scientific Advisers of the Tufts College Cancer Research & Cancer Control Unit, *Tufts—Cancer Research & Cancer Control Unit, 5th Annual Rpt.*, (Oct.) 1953.
Litsky, Warren, University of Massachusetts.	"Rapid Pasteurization of Fluids by Continuous Passage Through a Stainless Steel Tube Which is Heated by Electrical Resistance."	Litsky, W.: An Apparatus for Establishing the Come-Up Time Process for the Heating and Pasteurization of Fluids, *Tech. Rpts.*, U.S. Dept. Commerce, (Aug.) 1953.
Green, Harold D., Wake Forest College.	"Electromagnetic Flowmeter"	Green, H.D., Denison, A. D., and Spencer, M. P.: Demonstration of Electromagnetic Flowmeter for Unopened Blood Vessels, *Fed. Proc.*, Vol. 13, No. 1, p. 643, 1954.
1956		
McShan, W. H., University of Wisconsin.	"A Simplified Procedure for the Preparation of Pituitary Follicle Stimulating Hormone."	McShan, W. H.: A Simplified Procedure for the Preparation of Pituitary Follicle Stimulating Hormone, *Proc. of Soc. of Exper. Bio. & Med.*, (Apr.) 1954.

Inventions dedicated to the public through publication for the period 1953–58—Continued

GRANTEE INVENTIONS—Continued

Inventor	Title of invention	Journal reference
1955—continued		
Nason, Alvin, Johns Hopkins University.	"Lipid Cofactor for the Enzymatic Reduction of Cytochrome C."	Nason, A.: Lipid Cofactor for the Enzymatic Reduction of Cytochrome C, *Science*, (July) 1955.
Fanta, Paul E. and Stein, Robert A., Illinois Institute of Technology.	"Synthesis with Sodium Nitromalonaldehyde."	Fanta, P. E.: Synthesis with Sodium Nitromalonaldehyde, Ph. D. Thesis, Illinois Institute of Technology, (June) 1955.
1956		
Stefanini, Mario, St. Elizabeths Hospital, Mass.	"Identification of Clot Retraction Promoting Factor in Platelets."	Magalini, S. I. and Stefanini, M.: Clot Retraction Promoting Factor (Retractin) in Platelets and Tissues, *Science*, Vol. 129, pp. 796, 796, 1956.
Price, Charles C., and Ulbright, Tilo L. V., University of Pennsylvania.	"New Compound '4-amino-5-hydroxymethyl-2-methylthiopyrimidine.'"	Price, C. C. and Ulbright, T. L. V.: New Compound "4-amino-5-hydrox"-ymethyl-2-methylthiopyrimidine,' *Chem. and Indust.*, (Sept.) 1956.
Robins, Roland K., New Mexico Highlands.	"Synthesis of 4-Amino- and 4-Substituted Aminopyrazolo (3–4–d) Pyrimidines and Several 1-Alkyl Derivatives."	Skipper, H. E., Robins, R. K. and Thomson, J. R.: Inhibition of Experimental Neoplasms by 4-Aminopyrazolo (3–4–d) Pyrimidine, *Proc. Soc. Exper. Bio. & Med.*, Vol. 89, pp. 594–596, 1955.
Burgess, Landry E., Meharry Medical College.	"An Antianemic and Growth Principle Isolated from the Developing Egg of the Grasshopper."	Burgess, L. E., Clark, S. S. and Rolfe, D. T.: Effect of Crystalline Vitamin B_{12} and of a Crystalline Grasshopper Pigment (GHP) on Experimental Anemia in Mice, *Fed. Proc.*, Vol. 15, No. 1, (Mar.) 1956; Burgess, L. E. and Rolfe, D. T.: Comparative Study of Growth-Promoting Activity of a Pteridine in Relationship to Thymidine & Vitamin B_{12}, *Fed. Proc.*, Vol. 14, No. 1, (Mar.) 1955; Burgess, L. E.: A Preliminary Quantitative Study of Pterine Pigment in the Developing Egg of the Grasshopper, *Arch. Bio.*, Vol. 20, No. 2, pp. 347–355, (Feb.) 1949.
Acheson, George A., Kahn, Julius B., and Vick, Robert L., University of Cincinnati.	"Dihydro-ousbain and dihydrodigitoxin have the characteristic effects of cardiac glycosides with a greatly increased safety margin."	Acheson, G. A., Kahn, J. B., and Vick, R. L.: Dehydro-ouabain and dihydrodigitoxin have the characteristic effects of cardiac glycosides with a greatly increased safety margin, *J. Pharm. & Exper. Therap.*, (Nov.) 1956.
1957		
Buswell, A. M., University of Florida.	"Rapid Method for Determining Optimal 'Alum' Dosages in Water Treatment."	Buswell, A. M.: Method for Automatic Control of Coagulant Dosage, *J. Am. Water Works Assn.*, Vol. 50, No. 4, (Apr.) 1958.
Morrison, Martin, Stotz, Elmer H., and Hamilton, Howard B., University of Rochester, U.S. Army (Hamilton).	"Procedure for Isolating the Enzyme, Lactoperoxidase by Ion Exchange Chromatography."	Morrison, M., Stotz, E. H., and Hamilton, H. B.: Procedure for Isolating the Enzyme, Lactoperoxidase by Ion Exchange Chromatography, *J. Bio. Chem.*, (Oct.) 1957.
Bercu, Bernard A., and Diettert, Gerald A., Washington University.	"Disposable Oxygenator"	(Final publication arrangements not completed.)
Geckeler, George D., and Burke, Norman B., Hahnemann Medical College and Hospital of Philadelphia.	"Microphone for low frequency vibrations."	Do.
1958		
Carroll, Donald W., Rollins College.	"5-N-Alyky-5-formyl-Hydantoins and Derivatives."	Henze, H. R., and Carroll, D. W.: 5-N-Alyky-5-formyl-Hydantoins and Derivatives, *J. Am. Chem. Soc.*, Vol. 76, p. 4580, 1954.
Martell, Arthur E., Clark University.	"Synthesis of New Pyridine Aldehydes as Models of Vitamin B_6."	Martell, A. E.: Synthesis of New Pyridine Aldehydes as Models of Vitamin B_6, *Tetrahedron*, (June) 1958.

No. 4

List of inventions on which patent applications were filed, as of May 1959, on behalf of HEW

Inventor(s)	Type of invention
Drs. Jesse P. Greenstein and Vincent E. Price (employee invention). Pat. Application S.N. 173,474. Filed July 12, 1950. Abandoned Sept. 25, 1952.	"Method of Resolving Racemic Amino Acids."
Drs. Lloyd W. Law and Walter E. Heston (employee invention). Ser. No. 182,084. Filed Aug. 29, 1950. Abandoned Jan. 14, 1953.	"Feed Hopper."
Dr. Milton J. Allen (employee invention) Ser. No. 201,502. Filed Dec. 18, 1950. Rejected Oct. 10, 1952.	"Preparation of Substituted Bis-Aminophenyl Ethylene Glycols."
Dr. Jonathan L. Hartwell (employee invention) Ser. No. 203,240. Filed Dec. 28, 1950. Rejected Aug. 7, 1952.	"Pelatin Derivatives."
Dr. Milton J. Allen (employee invention) Ser. No. 58,632. Issued Jan. 30, 1951—U.S. Pat. No. 2,539,338.	"Preparation of Aminoindase."
Dr. Jonathan L. Hartwell (employee) Ser. No. 223,812. Filed Apr. 30, 1951. Rejected Dec. 1, 1952.	"Quarternary Ammonium Compounds."
Dr. Simon H. Wender (grantee), University of Oklahoma U.S. Pat. No. 2,557,164. Issued June 19, 1951.	"Method of Isolating Quercitrin from Peanut Hulls."
Dr. Jonathan L. Hartwell (employee) Ser. No. 223,811. Filed Apr. 30, 1951. Rejected Nov. 8, 1952.	"Chemical Compounds."
Dr. Milton J. Allen (employee) U.S. Pat. No. 2,563,806. Issued Aug. 14, 1951.	"Preparation of Substituted Bisaminophenyl Ethylene Glycols."
Dr. Srinivasa Rajagopalan (PHS research fellow), Harvard University. U.S. Pat. No. 2,569,300. Issued Sept. 25, 1951.	"Selective Oxidation of Seroid Alcohols."
Dr. Bernard B. Davis (employee) U.S. Pat. No. 2,571,115. Issued Oct. 16, 1951.	"Isolation of Bacterial Mutants."
Drs. R. C. Elderfield and Eleanor Werble (grantees), Columbia University, New York City. U.S. Pat. No. 2,604,474. Issued July 22, 1952.	"Primaquine."
Dr. Louis J. Pecora (employee) U.S. Pat. No. 2,611,363. Issued Sept. 23, 1952.	"German-Silver Electro-Cardiograph Contact Electrodes."
Drs. Leon Levintow and Jesse P. Greenstein (employees) U.S. Pat. No. 2,616,828. Issued Nov. 4, 1952.	"Method of Enzymatic Resolution of Amino Acids."
Drs. Donald L. Snow and Cyril S. Staub (employees) U.S. Pat. No. 2,649,727. Issued Aug. 25, 1953.	"Chemical Fume Hood."
Dr. Herbert Kahler (employee) U.S. Pat. No. 2,651,236. Issued Sept. 8, 1953.	"Electrically Controlled Thermal Expansion Device."
Dr. Hugh Chaplin, Jr. (employee) Ser. No. 409,904. Filed Feb. 28, 1954. Abandoned Feb. 14, 1955.	"Preservation of Blood."
Dr. Albert E. Sobel (grantee), the Jewish Hospital of Brooklyn. Ser. No. 487,715. Filed Feb. 11, 1955.	"Collagen Chondroitin Sulfate Complexes."
Drs. Wilton R. Earle, Virginia Evans, Mr. Edward L. Schilling, Mr. Jay C. Bryant (employees). Serial No. 506,681. Filed May 6, 1955.	"Fluid Suspension Culture Method for Fixed Tissue Cells."
Dr. Joseph Portnoy (employee) Pat. Application No. 610,046. Filed Sept. 12, 1956.	Process for preparing active fraction of virulent treponema pallidum.
Drs. Ralph Jones, Jr., Charles C. Price, Achintya K. Sen (grantees), University of Pennsylvania. Ser. No. 655,452. Filed Apr. 26, 1957. Rejected Mar. 19, 1958.	"Quinoline-Type Mustards and Process for Producing Same."
Dr. Paul Talalay (employee) U.S. Pat. No. 2,796,382. Issued June 18, 1957.	"Microbiological Transformation of Steroids."
Franz J. Maier (employee) Pat. No. 2,802,391. Granted Aug. 13, 1957.	"Improved Colorimeter."
Franz J. Maier and Ervin Bellack (employees) Pat. Application 693,216. Filed Oct. 29, 1957.	"Method of Using Fluorspar for Fluoridation."
Dr. Max Strumia (grantee), Bryn Mawr Hospital U.S. Pat. No. 2,845,929. Issued Aug. 5, 1958.	"An Apparatus for the Collection and Cooling of Blood."
Drs. Wilton R. Earle and Frederick Highhouse (employees) U.S. Pat. No. 2,858,036. Issued Oct. 28, 1958.	"Culture Flasks for Use With Plane Surface Substrate Tissue Cultures."
Drs. Everette L. May and Nathan B. Eddy (employees) Ser. No. 771,165. Filed Oct. 31, 1958.	"New Benzomorphans and Preparation Thereof."
Drs. Everette L. May and Nathan B. Eddy (employees) Ser. No. 771,166. Filed Oct. 31, 1958. Preliminary rejection Mar. 16, 1959.	"Improved Analgesic Drugs (Benzomorphans)."

No. 5

Public Health Service application form for research grants

(Leave Blank) Received Date	Department of HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NATIONAL INSTITUTE OF HEALTH	(Leave Blank)
Council Assigned	Mail Completed Application to: Division of Research Grants National Institutes of Health Bethesda 14, Md.	Formerly
Action		

APPLICATION FOR RESEARCH GRANT Date

Application is hereby made for a grant in the amount of $ (omit cents) for the period from (month) (day) (year) through (month) (day) (year), inclusive

for the purpose of conducting a research project entitled (Limit to 53 typewriter spaces).

TITLE OF PROJECT:

Check One:

☐ NEW PROJECT ☐ SUPPLEMENT TO PHS GRANT NO.

☐ RENEWAL OF PHS GRANT NO. ☐ REVISION OF PHS APPLICATION NO.

Principal Investigator	Co-Principal Investigator, if any:
Name (First) (Middle) (Last)	Name (First) (Middle) (Last)
Title	Title
Dept.	Dept.
School	School
University or Institution	University or Institution
Street Address	Street Address
City and State	City and State
Name, Title and Address of Financial Officer:	Check to Be Drawn as Follows:

AGREEMENT

It is understood and agreed by the applicant: (1) That funds granted as a result of this request are to be expended for the purposes set forth herein; (2) that the grant may be revoked in whole or part at any time by the Surgeon General of the Public Health Service, provided that a revocation shall not include any amount obligated previous to the effective date of the revocation if such obligations were made solely for the purposes set forth in this application; (3) that all reports of original investigations supported by any grant made as a result of this request shall acknowledge such support; (4) that, if any invention arises or is developed in the course of the work aided by any grant received as a result of this application, the applicant institution will either (a) refer to the Surgeon General for determination, or (b) determine in accordance with its own policies, as formally stipulated in a separate supplementary agreement entered into between the Surgeon General and the grantee institution, whether patent protection on such invention shall be sought and how the rights in the invention, including rights under any patent issued thereon, shall be disposed of and administered, in order to protect the public interest.

NAME OF INSTITUTION

ADDRESS

CITY AND STATE

NAME AND TITLE OF OFFICIAL AUTHORIZED TO SIGN FOR INSTITUTION *(Please Type)*

PERSONAL SIGNATURE (This agreement must carry the actual signature of the official whose name appears on the line above.) (use ink)

PAGE 1

PHS 398 Rev. 9-57

Form Approved Budget Bureau No. 68-R249.7

No. 6

NONPROFIT INSTITUTIONS WITH WHICH PATENT AGREEMENT HAS BEEN REACHED

California Institute of Technology, Pasadena, Calif.
Cornell University, Ithaca, N.Y.
Florida State University, Tallahassee, Fla.
Harvard University, 25 Shattuck Street, Boston, Mass.
Iowa State College of Agriculture & Mechanic Arts, Ames, Iowa.
Massachusetts Institute of Technology, Cambridge, Mass.
Michigan State College, East Lansing, Mich.
Mt. Sinai Hospital, 5th Avenue and 100th Street, New York, N.Y.
Northwestern University, 619 Clark Street, Evanston, Ill.
Ohio State University, Columbus, Ohio.
Purdue University, Lafayette, Ind.
Princeton University, Princeton, N.J.
State College of Washington, Pullman, Wash.[1]
Tufts University, Medford, Mass.
University of California, 240 Administration Building, Berkeley, Calif.
University of Illinois, Urbana-Champaign, Ill.
University of Kansas (Lawrence only), Lawrence, Kans.
University of Minnesota, Minneapolis, Minn.
University of Washington, Seattle, Wash.

No. 7

INVENTION AND PATENT POLICIES ACCEPTABLE TO THE PUBLIC HEALTH SERVICE

The policy of the Department of Health, Education, and Welfare on Inventions Resulting from Research Grants, Fellowship Awards, and other Research Arrangements, recognizes the cooperative nature of research aided by Public Health Service grants-in-aid. For this reason it offers alternative conditions with respect to the handling of patentable inventions which may arise out of activities assisted by the grant. Either the Surgeon General of the Public Health Service may reserve the right to determine the ownership of the invention and its disposition or such inventions may be administered by the grantee-institution in accordance with its own patent policies and procedures, provided the Surgeon General accepts these as assuring that the invention either will be dedicated to the public or, if patented, will be made available without unreasonable restrictions or excessive royalties.

Policies and procedures outlined below are types which may give such assurance. Institutions which may not as yet have formulated a policy with respect to inventions developed from research financed in part with public funds may find this outline of some assistance in the formulation of their own procedures.

[1] Agreement reached subsequent to the Department's letter of Nov. 15, 1957.

A. DEDICATION TO THE PUBLIC OF RESULTS OF RESEARCH EITHER BY PUBLICATION OR PATENTING WITH SUBSEQUENT DEDICATION OF THE PATENTS

The Surgeon General will accept this policy in any case where it is demonstrated that the grantee-institution has a responsible body or official to see that the policy is effectuated.

As stated in the Department Regulations on grantee inventions, dedication to the public in general seems most appropriate for inventions developed with the assistance of public moneys. Many institutions, particularly insofar as inventions related to health are concerned, also adhere to this principle.

B. PATENTING WITH ROYALTY-FREE LICENSING

A general policy of issuing royalty-free, unconditional, and nonexclusive licenses under patents obtained is equally acceptable. In administering such a policy there may be times when in the judgment of the institution the interests of the public in a particular patent will be best served by (1) conditional licensing, providing standards as to the quality of the product or the qualifications of the manufacturer, or (2) restricted licensing for a limited period to assure the development of the invention to the point of utility and satisfactory quality. Decision as to the necessity for either such arrangement would be that of the grantee-instituion, but prior to accepting the institution policy the Public Health Service would require general assurance that under the institution policy exclusive licenses would be the exception, not the rule and that they would be for a limited period only. In the case of institutions which do issue exclusive licenses, the Public Health Service would further require full information as to the basis on which such licenses are issued and the safeguards utilized to protect the public interest.

C. PATENTING WITH LICENSING ON A ROYALTY BASIS

Licensing as provided in B which provides for royalties in some or even all cases will also be considered acceptable policy. In such case the royalty rates must however be reasonable and a royalty-free license to the Government with power to sublicense for all governmental purposes will be required in all cases.

The Public Health Service realizes that there are conditions at certain institutions which in the estimation of the institution make royalties desirable, if not mandatory, in order to provide reimbursement of the funds spent to secure patents, incentive awards to the inventor, and support of research. When this policy is adopted it is the view of the Service that the royalty charged should not in any case exceed the rate acknowledged as normal trade practice, and that lower rates are more appropriate for licenses issued by public institutions.

The Service believes that profits realized from these royalties should be applied to teaching and research functions except for proportionate costs of administration of institution patent business. In view of the purposes for which Public Health Service grants-in-aid funds are

appropriated, it would be preferable from the Service's point of view that any profits from royalties be used to support additional research. Any policy which makes the inventor the primary recipient of royalties would not be acceptable.

D. ASSIGNMENT OF OWNERSHIP RIGHTS TO A QUALIFIED ORGANIZATION

The Service will not object to policies which provide for the assigning of patent rights to a reputable organization, when the agreement between the institution and that organization gives assurance that administration of the patents will be within the limits indicated above.

General requirements

Before accepting the policies of an institution, the Service would like assurance that they have been formally adopted by appropriate institution officials; that an administrative body has been established, or some responsible official has been designated, to carry out the program; and that the institution's history of operation has been consistent with its promulgated policies.

Principles of ownership

It is assumed that all institutions wishing to administer inventions arising under Public Health Service grants-in-aid have established principles to determine the equities of the inventor, the institution, and the sponsor therein. A number of institution policies with which the Service is familiar provide that under certain conditions the invention may be left to the inventor. The Service would consider the following criteria as satisfactory to determine the equities of the inventor and the institution. (These are the criteria applied by the Federal Government to inventions made by its employees):

(*a*) The institution shall obtain entire right, title and interest in and to all inventions made by any employee (1) during working hours, or (2) with a contribution by the institution of facilities, equipment, materials, funds, or information, or of time or services of other institution 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 institution, as measured by any one or more of the criteria set forth in paragraph (*a*) last above, to the invention is insufficient equitably to justify a requirement of assignment to the institution of the entire right, title and interest to such invention, or in any case where the institution has insufficient interest in an invention to obtain entire right, title and interest therein, the institution may 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 power to grant licenses for all governmental purposes, such reservation, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.*

Reports

A report will be required on all patentable inventions as described in the following discussion of special applications of Department Regulations. In addition to the initial invention report, an annual report, for informational purposes, of the disposition of inventions in which it has an interest is requested. It is not proposed to review

the institution's decision as to whether or not patenting is desirable, unless so prescribed by the institution.

Explanation of special applications of Department Regulations on Inventions Resulting from Research Grants, Fellowship Awards, and other Research Arrangements

Disposition of inventions.—It will be noted in Paragraph 8.1 of Department Regulations that the policy provides that inventions arising under Public Health Service grants-in-aid (and awards) are to be handled (a) by the Surgeon General on a case by case determination, or (b) by the grantee institution in accordance with its established practices and policies, after those policies with such modifications as may be agreed upon have been accepted by the Surgeon General as assuring that the invention will be made available without unresonable restrictions or excessive royalties. Institutions desiring to be considered under (b) should advise the Division of Research Grants. It is understood that institutions which do not take such action wish to continue on the basis of case by case determinations by the Surgeon General.

Responsibility.—It is the primary responsibility of the institution and not of the personnel engaged in work assisted by the grant to comply with Public Health Service patent provisions. The Service does not require the individual to sign a statement of agreement on patent rights [1] since it believes the institution should administer such matters. Accordingly a provision on patentability is contained in the grant-in-aid application blank, which is signed by an official of the grantee institution, and which may or may not be supplemented by a letter of agreement between the Division of Research Grants representing the Surgeon General, and the grantee institution. Grantee institutions are expected, therefore, to take whatever action they deem necessary to enable them to comply with the agreements they make with the Public Health Service relating to patentable inventions.

Reportability of research results as "inventions."—All "inventions" developed with the assistance of Public Health Service grants-in-aid which are or may be patentable must be reported to the Division of Research Grants regardless of whether the grantee institution has the agreement of the Surgeon General to handle inventions in accordance with its own policies or whether an individual determination is to be made by the Surgeon General. The method by which such reporting is insured is at the discretion of the institution. It is not the desire of the Public Health Service to require or encourage investigators to scrutinize research results for minor patentable features. The Service will consider that the institution has discharged its duty in this respect if there are reported those accomplishments which the investigator and the institution think are both patentable and of sufficient importance to justify publication, or are of sufficient importance to justify investigation for patentability by the inventor or local institution if the Public Health Service were not concerned. It is not to be assumed in this connection that progress reports may serve as substitutes for reports of inventions.

[1] This is not true for the research fellowships and certain of the traineeships awarded by the Service, where there is a direct relationship between the Service and the fellow or trainee. In such programs the individual is required to sign a statement on inventions.

No. 8

Patent Policy Applicable to Research Contracts, Department of Health, Education, and Welfare Between September 9, 1957, and July 31, 1958

GENERAL

The Department of Health, Education, and Welfare as a matter of overall policy takes the position that the results of research which are developed with the aid of public funds in the field of its programs should be utilized in a manner which will best serve the public interest. It considers that the public interest will in general be best served if advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public. Regulations to secure these objectives have been developed and are controlling with respect to research within the Service and under its grant programs.

Contracts for research, whether or not with nonprofit organizations, will be required to conform to the same Departmental policy, under standard clauses adopted to 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 head of the constituent organization responsible for the contract, 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 organization head will be guided in general by the policies specified in departmental regulations with respect to grants.

CANCER CHEMOTHERAPY CONTRACTS

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.

Industrial contracts for this program may contain either (1) the standard patent clause, reserving to the Surgeon General the right to determine the disposition of inventions arising from the performance of the contract, or (2) standard alternative clauses developed to give effect to the following criteria. The alternatives indicated will be made available in the negotiations with all contracting companies without discrimination. 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 for 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

(3) Sustained concentration on the anticancer objectives of all resources mobilized for the purposes of the contract.

1. Contracts for research

When the contract is for research to be performed by the company (with or without provision for subcontracting), the contract will contain either the standard patent clauses, as indicated under "GENERAL" above, or alternative standard clauses to provide, with respect to any invention conceived or first actually reduced to practice in the course of the performance of the contract, for each of the following:

(1) *Reporting.*—Prompt reporting to the Surgeon General of any such invention and prompt report of the filing of any patent application thereon;[1]

(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 (not to exceed 6 months from the time the Surgeon General determines the invention was or should have been reported) to protect such rights as the contractor may have in the invention;[1]

(3) *Government license.*—Reservation to the Government of an irrevocable, nonexclusive, royalty-free license under any patent which may issue thereon for all uses by or for the Government of the United States throughout the world;[2]

(4) (*a*) *Reservation of right to protect the public interest.*—Agreement that if at any time, after a *minimum period* designated in the contract, but not in any case to exceed 1 year from the issuance of a patent thereon or 3 years from the date of the filing of application therefor, whichever is earlier, the Surgeon General shall deem it necessary in order to assure an adequate supply of the product for any health purposes served by the product, at a reasonable price and of high quality, the Surgeon General shall have the right to issue sublicenses (under or in anticipation of the issuance of any such patent) to other pharmaceutical and/or chemical companies to use, manufacture, and sell embodiments of the invention for any health purpose;[3]

(*b*) *Sublicensing by contractor.*—Agreement by the contractor to hold any such patent available for nonexclusive licenses to other pharmaceutical and/or chemical companies on a royalty basis not to exceed normal trade practices;[4]

(*c*) *Renegotiation provision on new leads.*—Provision that if, in the course of the performance of the contract, the contractor identifies any new lead having no apparent significance for health purposes which it wishes to develop at its own expense, without utilization of facilities financed by the Government, and for purposes other than health, the Surgeon General may, when he deems it consistent with advancement of the primary research

[1] This provision mandatory for all contracts.
[2] Provision for a license to the Government is mandatory for all contracts. However, it is permissible to provide that the license shall be for such use by or for the Government in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, including use in research conducted for such purpose.
[3] Inclusion of this provision is mandatory for all contracts.
[4] Inclusion of this provision is desirable but not mandatory. If included, the contract may provide that such sublicenses shall be (1) for all purposes or (2) for all health-related purposes.

purpose, renegotiate the application 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; [5]

(5) *Assignment of domestic rights.*—Agreement that in the event the contractor elects, within a period (not to exceed 6 months after the invention was or should have been reported) specified in the contract, not to file or continue the prosecution of a patent application on the invention, or 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 of all domestic rights therein to the Government; and [6]

(6) *Assignment of 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.[6]

II. Contracts with suppliers of chemical compounds for screening and testing only

When a company furnishes, for controlled screening and testing only, unpatented compounds or products 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.

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.

Contracts of this type are permissible only when the screening and testing is of routine and prescribed character, use of the compound under the contract is limited to such screening and testing, and the compound is not otherwise available to the Service. Nothing in this policy statement shall be deemed to limit the authority of the Surgeon General to acquire, by purchase, license or other rights under existing patents as may be necessary for the effective prosecution of this program.

[5] Inclusion of a renegotiation provision is not mandatory.
[6] This provision is mandatory for all contracts.

III. 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.

Approved:

EDWARD FOSS WILSON,
Acting Secretary.

Dated: September 9, 1957.

No. 9

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

GENERAL PROVISIONS

December 1957

Clause 20. Patent rights

(a) Whenever any invention, improvement, or discovery (whether or not patentable) is made or conceived or for the first time actually or constructively reduced to practice, by the Contractor or its employees, in the course of, in connection with, or under the terms of this contract, the Contractor shall immediately give the Contracting Officer written notice thereof, and shall promptly thereafter furnish the Contracting Officer with complete information thereon; and the Surgeon General shall have the sole and exclusive power to determine whether or not and where a patent application shall be filed, and to determine the disposition of all rights in such invention, improvement, or discovery, including title to and rights under any patent application or patent that may issue thereon. The determination of the Surgeon General on all these matters shall be accepted as final and the provisions of the Clause of this Contract entitled "DISPUTES" shall not apply; and the Contractor agrees that it will, and warrants that all of its employees who may be the inventors will, execute all documents and do all things necessary or proper to the effectuation of such determination.

(b) Except as otherwise authorized in writing by the Contracting Officer, the Contractor shall obtain patent agreements to effectuate the provisions of this Clause from all persons who perform any part of the work under this Contract, except such clerical and manual labor personnel as will have no access to technical data.

(c) Except as otherwise authorized in writing by the Contracting Officer, the Contractor will insert in each subcontract, having experimental, developmental, or research work as one of its purposes, provisions making this Clause applicable to the subcontractor and its employees.

December 1, 1958

SUPPLEMENTAL AGREEMENT No. 2

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH

Cost-Reimbursement Contract for Research and Experimental Work

Contractor: The Upjohn Co.

Address: Kalamazoo, Mich.

Place of Performance: Kalamazoo, Mich.

Purpose: To extend period of performance and provide additional funds for expansion of work.

Amount: $505,000.

Appropriation: 7590349, Allot. 92801, Proj. 95, C. Code 20106, Reqn. 202609.

Authority: Public Law 85–580, 85th Congress.

* * * * * * *

Clause 20, Patent Rights, of the General Provisions, hereby is deleted in its entirety and the attached Clause 20 is inserted in lieu thereof.

Unless otherwise amended hereby, all provisions of this contract remain in full force and effect.

No. 10

CLAUSE 20. PATENT RIGHTS

A. *Definition of "Subject Invention".* The term "Subject Invention", as used throughout this Clause, means any invention, improvement, or discovery (whether or not patentable) made or conceived or first actually or constructively reduced to practice by the Contractor or its employees, in the course of, in connection with, or under the provisions of this contract.

B. *Reports of Inventions.* The Contractor shall make a written Invention Report to the Contracting Officer promptly after either (a) the conception or (b) first actual or constructive reduction to practice, but in any event as soon as *any* evidence of utility has been developed (whether in a health or other field of use) of each Subject Invention that reasonably appears to be patentable.

(1) Such Report shall be furnished directly to the Contracting Officer, separate and distinct from and independent of any other requirement under this contract for the submission of reports and whether or not reference to such Subject Invention has been made in any progress or other report furnished to Government technical personnel.

(2) Such Report shall sufficiently describe and identify each Subject Invention, appropriately illustrated by simple sketch or diagram, to permit the invention to be understood and evaluated.

If a patent application is filed promptly by the Contractor in the U.S. Patent Office, a copy of such application furnished promptly to the Contracting Officer shall fully satisfy the reporting requirement, it being understood, however, that the Contractor shall furnish such additional information as the Surgeon General, in his sole discretion, may require for the purpose of making the disclosure provided for in paragraph D hereof.

(3) The Report may, in addition, include a statement by the Contractor specifying whether or not a United States patent application claiming such invention has been or will be filed by or on behalf of the Contractor. If the Contractor specifies that such an application will not be filed (or having specified that it will file, thereafter, notifies the Contracting Officer to the contrary), the Contractor shall promptly inform the Contracting Officer of the date and identity of any known publication of such invention made by or known to the Contractor or, where applicable, of any contemplated publication to be made by or known to the Contractor and shall, in addition, execute such documents as may be necessary or appropriate to comply with the requirements of paragraph E hereinbelow.

(4) Within 6 months from the date the Invention report required by this paragraph was in fact received or should have been received by the Contracting Officer (as determined by the Surgeon General) the Contractor shall notify the Contracting Officer in writing of his election to file or not to file a United States patent application.

C. *Certifications.*

(1) If the Contract continues in effect for more than a year, the Contractor shall submit to the Contracting Officer periodic certifications, not less often than once every 12-month period, commencing with the date of the Contract, stating whether or not any Subject Inventions reasonably believed to be patentable were conceived or first actually or constructively reduced to practice during the preceding 12 months. The Contractor shall, in such certifications,

(a) list any such inventions,

(b) give references, including date, to each written report, if any, previously submitted, and

(c) submit reports and related information as provided in B above if this has not already been done.

(2) Prior to final settlement of this Contract, the Contractor shall furnish to the Contracting Officer a final report listing all such inventions including those listed in prior reports and furnishing the information respecting such inventions required by B above if not previously furnished.

D. *Disclosure.* The Surgeon General shall have the right to publish and make disclosure of any Subject Invention, whenever deemed by him in the public interest, after either

(1) an application for a United States or foreign patent is filed, or

(2) the expiration of 6 months from date the Invention Report, provided in paragraph B of this Clause, was in fact received, or

should have been received by the Contracting Officer (as determined by the Surgeon General), whichever is earlier.

E. *Assignment of Domestic Rights.* The Surgeon General shall have the further right to require, when he deems such action necessary in order to protect the availability of the invention for health purposes, that all domestic rights in any Subject Invention, including all right, title and interest in, to, and under any patent application and patent that may issue thereon (except, however, for the reservation of a non-exclusive, royalty-free license to the Contractor) be assigned to the Government, at any time after the earlier of any one of the following occurrences:

(1) The Contractor gives the Contracting Officer written notice of election not to file, or continue prosecution of, an application for a United States Patent; or

(2) The Contractor having elected to file and having notified the Contracting Officer, in conformance with B(4) above, of such election, fails to file promptly thereafter (as determined by the Surgeon General) an application for a United States patent; or

(3) An application for a United States patent is filed but is not diligently prosecuted (as determined by the Surgeon General).

In addition, the Contractor shall, upon request of the Surgeon General, promptly furnish him with all information relating to the date and identity of any known publication of such invention made by or known to the Contractor or, where applicable, of any contemplated publication to be made by or known to the Contractor.

F. *Assignment of Foreign Rights.* The Surgeon General shall have the further right to require, when he deems such action necessary to protect the availability of the invention for health purposes in another country, or other countries, that all foreign rights in any Subject Invention, including all right, title and interest in, to, and under any patent application and patent that may issue thereon in such country or countries, be assigned to the Government, at any time, and from time to time, after the earlier of any one of the following occurrences:

(1) The Contractor gives the Contracting Officer written notice of election not to file, or continue prosecution of, an application for a patent in such country or countries; or

(2) Upon the expiration of 6 months after the right has accrued in the Surgeon General, under the provisions of paragraph E of this Clause, to require the assignment of domestic rights, application has not been filed by Contractor for patent on Subject Invention in such foreign country or countries; or

(3) Upon the expiration of 9 months after date a corresponding United States application is filed, application has not been filed by Contractor for patent on Subject Invention in such foreign country or countries.

G. *Other Notices and Inspection of Patent Application.* The Contractor shall

(1) give prompt written notice to the Contracting Officer of

(a) date and content of any publication of Subject Invention made prior to the filing of application for United States patent thereon,

(b) date Subject Invention or any embodiment thereof was first in public use or on sale in the United States,

(c) date and content of assignment of any right, title, or interest in Subject Invention, including right, title, or interest in, to, and under any patent application and patent that may issue thereon,

(d) the filing of any application for a United States or foreign patent on Subject Invention,

(e) Contractor's election not to continue prosecution of any United States patent application on Subject Invention not less than 60 days before expiration of the response period, and

(f) issuance of an United States or foreign patent on Subject Invention; and

(2) furnish promptly to the Contracting Officer on request an irrevocable power of attorney to inspect and make copies of each United States patent application covering Subject Invention.

H. *License to Government.* The Contractor shall grant, or cause to be granted, and the Contractor does hereby grant, unto the Government an irrevocable, nonexclusive, royalty-free license or licenses to practice and cause to be practiced, by or for the United States 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.

I. *Licensing by Government.*

(1) The Contractor shall grant, or cause to be granted, and the Contractor does hereby grant unto the Government, the right, subject only to the limitations provided for in subparagraph (3) of this paragraph, exercisable at any time or from time to time subsequent to the Contractor's filing of a patent application on any Subject Invention, to dedicate to the public all rights in the invention or to issue (under or in anticipation of the issuance of any patent on the Subject Invention) non-assignable, non-exclusive licenses (for the practice of the invention for any health purpose) and revocable by the Government only, royalty-free without regard to prior license or agreement which may have required payment of royalties, on a non-discriminatory basis to all applicants determined by the Surgeon General in his sole discretion to be qualified, to use, manufacture and sell embodiments of the invention, whether related to a product, process or otherwise, for any health purpose, when and if the Surgeon General finds that the Contractor has not met the public need and that the public dedication or additional licensing by the Surgeon General is necessary in the public interest.

(2) Contractor agrees that any license or other privilege of use issued to any other person under or in anticipation of the issuance of any patent, whether with or without royalty or on an exclusive or non-exclusive basis for the practice of Subject Invention, shall be made only after furnishing notice to such licensee or permitee of the terms of this Clause and shall further be made subject to the provisions hereof.

(3) The right of the Surgeon General to issue the licenses provided for in I(1) above shall be exercisable in conformance with the procedures hereinafter provided and only after:

(a) The Surgeon General has obtained and considered the advice, to the extent, on such terms, and with respect to such matters or issues as he in his sole discretion determines suitable, of such advisory bodies or consultants as he deems appropriate and competent in the particular situation; and (b) thereafter, the Surgeon General has notified the Contractor, in writing, that he has ground to believe that such invention is at such stage of development that if it were more generally available it would meet a health need and that the public interest, with respect to an adequate supply, a reasonable price consistent with normal trade practices under competitive conditions, or maintenance of quality, requires the invention to be available to others than the Contractor and his licensees and, accordingly, the public interest requires the exercise of the right provided for in I(1) above, stating the reasons therefor. Such notice shall contain a request that the Contractor, within a time specified in such notice, take appropriate steps, which may include the issuance of licenses to additional manufacturers of the contractor's own selection, to meet the public need. If, upon the expiration of the time specified, or such extension thereof as may be 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, in writing, with reasons therefor, that at the end of 90 days from the date of mailing such notice he will exercise the rights provided for in I(1) above.

If within 20 days of receipt of such notice the Contractor files with the Surgeon General a request, in writing, for a hearing, the Surgeon General, or a representative or representatives designated by him for the purpose, shall promptly afford the Contractor a reasonable opportunity to be heard (at a time and place to be selected by the Surgeon General), to be represented by counsel, to present any pertinent information and argument, and to rebut any other information pertinent to the issues. A copy of the written findings by the Surgeon General or such representative shall be furnished to the Contractor, which findings shall be based solely on the material presented at the hearing, and shall be final and conclusive upon the Contractor. If the Surgeon General's decision, based upon such findings, be that the Contractor has

not met the public need and that dedication and/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-mentioned 90-day period or at the conclusion of the hearing, whichever is later.

J. *Inventions by Federal Employees.* Notwithstanding any provision contained in this Contract, Subject Inventions made by Federal employees, or by Federal employees jointly with others, shall be submitted for and subject to determinations, procedures, and disposition under and pursuant to the terms of applicable Executive Orders and Department Regulations as in effect on the date of execution of this Contract.

K. *Conclusiveness and Implementation of Determinations by Surgeon General.* Determinations of the Surgeon General on all matters specified in this Clause as being for his determination (or in Executive Orders and/or Department Regulations referred to in paragraph J hereof) shall be accepted as final and the provisions of the Clause of this Contract entitled "Disputes" shall not apply; and the Contractor agrees that it will, and warrants that all its employees who may be the inventors will, execute all documents and do all things necessary or proper to the effectuation of such determinations.

L. *Patent Agreements Between Contractor and Persons Performing Work Under this Contract.* Except as otherwise authorized in writing by the Contracting Officer, the Contractor shall obtain patent agreements to effectuate the provisions of the Clause from all persons who perform any part of the work under this Contract, except such clerical and manual labor personnel as will have no access to technical data.

M. *Subcontract Provisions.* Except as otherwise authorized in writing by the Contracting Officer the Contractor shall insert in each subcontract having experimental, developmental, or research work as one of its purposes, provisions making this Clause applicable to the subcontractor and its employees.

N. *Effective Period of, and Required References to, Provisions of this Clause.* All provisions of this Clause shall survive and extend beyond the termination, expiration, and final payment under this Contract, any extensions or modifications thereof, and such successive contracts as may follow, and continue to be fully effective and enforceable. The exercise of any right or power by the Surgeon General or the Government pursuant to the provisions of this Clause shall in no event and in no manner be deemed as an exclusive election of rights or constitute a waiver of subsequent additional exercise thereof or of any other right or power of the Surgeon General or the Government provided in this Clause or elsewhere in this Contract. Any right, title or interest in or to Subject Invention, or in, to, or under any patent application or patent that may issue thereon, shall be subject to the provisions of this Clause, whether created by contract, assignment, license, or otherwise, and each such instrument shall so provide and include reference to this Clause; and such provision and reference shall further appear, where practicable, in any domestic patent application and patent which may issue on Subject Invention.

No. 11

Patents owned by HEW under which licenses were granted

Patent No.	Dates of issue	Subject	Name and address of licensee	Date of license	Name and status of inventor
2,207,725	July 16, 1940	Removal of fluorides from drinking water	Victor Chemical Works, Illinois	Feb. 21, 1941	Elias Elvove, PHS employee, NIH.
2,257,111	Sept. 30, 1941	Removing fluorides from drinking water	Leo Moss, Corpus Christi, Tex.	Apr. 24, 1952	Do.
2,178,010	Oct. 31, 1939	Nuclear substituted derivatives of the morphine series and methods for their preparation.	Mallinckrodt Chemical Works, 3500 North 2d St., St. Louis, Mo.	May —, 1947	Lyndon Frederick Small and Howard Montgomery Fitch, PHS employees.
2,178,010	do	do	Merck & Co., Inc., Rahway, N.J.	do	Do.
2,178,010	do	do	New York Quinine & Chemical Works, 99-117 North 11th St., Brooklyn, N.Y.	do	Do.
2,178,010	do	do	Sharpe & Dohme, Inc., 640 North Broad St., Philadelphia, Pa.	Apr. 10, 1952	Do.
2,178,010	do	do	Parke, Davis & Co., Joseph Campau St. at the River, Detroit, Mich.	Apr. 18, 1952	Do.
2,178,010	do	do	Wyeth Inc., 1401 Walnut St., Philadelphia, Pa.	do	Do.
2,178,010	do	do	American Home Products Corp., 22 East 40th St., New York, N.Y.	Feb. 24, 1953	Do.
2,178,010	do	do	Parke, Davis & Co.	Mar. 12, 1953	Do.
2,178,010	do	do	Sharpe & Dohme, Inc.	Mar. 2, 1953	Do.
2,178,010	do	do	Mallinckrodt Chemical Works	Mar. 19, 1953	Do.
2,178,010	do	do	New York Quinine & Chemical Works	Mar. 18, 1953	Do.
2,178,010	do	do	Merck & Co., Inc.	May 4, 1953	Do.
2,234,981	Mar. 18, 1941	Formaldehyde sulphoxylate derivative of diphenylsulphides, disulphides, sulphoxides, and sulphones, and methods of production.	Abbott Laboratories, Chicago, Ill.	June 18, 1940	Sanford M. Rosenthal and Hugo Bauer, PHS employees, NIH.
2,234,981	do	do	Parke, Davis & Co., Detroit, Mich.	Aug. —, 1947	Do.
2,234,981	do	do	E. R. Squibb & Sons, New York, N.Y.	Mar. 18, 1948	Do.
2,234,981	do	do	Chemo Puro Manufacturing Corp., 26-32 Skillman Ave., Long Island City, N.Y.	Jan. 15, 1952	Do.
2,280,856	Apr. 28, 1942	Benzene sulphonamidyl compounds of sulphanilamide, salts, and derivatives thereof, and methods of production.	May Chemical Corp., New Jersey.	Aug. 17, 1940	Do.
2,531,451	Nov. 28, 1950	Water purification	Leo Moss, Corpus Christi, Tex.	Apr. 24, 1952	Franz J. Maier, Division of Dental Health, PHS.
2,531,451	do	do	Robert Roseboom, 5556 Ninth Ave., North, St. Petersburg, Fla.	May 4, 1953	Do.
2,541,056	Feb. 13, 1959	Screening method for blood glucose	Macelester Bicknell Co., 243 Broadway, Cambridge, Mass.	Mar. 30, 1951	Dr. Erich Heftman, PHS employee, NIH.
2,602,252	July 8, 1952	Portable exhibiting device	Charles C. Shinn, 4006 Nicholson St., Hyattsville, Md.	July 29, 1952	Charles C. Shinn, Division of Industrial Hygiene, PHS.
2,602,252	do	do	Vemaline Products Co., Hawthorne, N.J.	Oct. 20, 1953	Do.
2,602,252	do	do	Mr. Donald O. Tarney, 1055 Santa Cruz, San Pedro, Calif.	July 2, 1954	Do.

2,602,252	----do----	----do----	Mrs. Lempi Matthews, 5155 South Christiana Ave., Chicago, Ill.	Mar. 17, 1955	Do.
2,604,474	July 22, 1952	Process for preparation and manufacture of 6-methoxy-8-(4-amino-1-methylbutylamino-quinoline)—"Primaquine."	Burroughs Wellcome & Co., Tuckahoe, N.Y.	Oct. 3, 1952	Dr. Robert C. Elderfield and Dr. Eleanor Werble (NIH grant to Columbia University).
2,604,474	----do----	----do----	The Wellcome Foundation, Ltd., 183-193 Euston Rd., London N.W. 1, England.	----do----	Do.
2,604,474	----do----	----do----	Abbott Laboratories	Jan. 1, 1953	Do.
2,604,474	----do----	----do----	Winthrop-Stearns, Inc., 1450 Broadway, New York, N.Y.	July 13, 1953	Do.
2,604,474	----do----	----do----	Chemo Puro Manufacturing Corp.	Dec. 28, 1954	Do.

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[illegible]	do.	do.	[illegible]	do.
[illegible]	do.	do.	[illegible]	do.