CHAPTER 6-20

DEPARTMENT PATENTS BOARD AND PATENTS OFFICER

6-20-10 Organization
20 Assignment of Responsibilities
30 Membership of Department Patents Board and Department Patents Officer

6-20-10 ORGANIZATION

A. The Department Patents Board shall consist of a chairman, seven other officers or employees of the Department appointed by the Secretary, and the Department Patents Officer. The chairman shall designate a qualified person to serve as executive secretary of the Board.

B. The Department Patents Officer shall be a member of the staff of the Office of the General Counsel designated by the General Counsel. A Deputy Department Patents Officer may likewise be designated.

6-20-20 ASSIGNMENT OF RESPONSIBILITIES

A. The Department Patents Board shall:

1. Upon its initiative, advise and consult with the Secretary, the General Counsel and other officials of the Department on questions of patent policy affecting the Department.

2. Upon request, consult with and make recommendations to the Secretary, the General Counsel 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. Carry out such functions, relating either to appeals from determinations relating to ownership or patenting of employee inventions or to other matters, as may be vested in the Board by Department regulations.

B. The Department Patents Officer, as the delegate of, and utilizing such assistance as may be designated by, the General Counsel, shall:

1. Represent the Department, except where otherwise designated by the General Counsel, on the Government Patents Board, on other boards or committees and with respect to other matters relating to inventions and patents.

2. Receive and review for consistency with Department policy determinations made by the heads of operating agency units relating to inventions made by Department employees.

(6-20-20 continued)

3. Receive for transmittal, with such recommendations or comment as may be appropriate, matters relating to patents requiring consideration or action by the Department Patents Board or the Secretary.

4. Consult and advise, as feasible, with the various operating agencies and officials of the Department with respect to formulation and carrying out of policies and procedures relating to inventions and patents.

5. Issue any necessary instructions or procedures relating to Department patent policies and their administration and carry out such additional functions as may be vested in the General Counsel or the Department Patents Officer by Department regulations relating to inventions or patents.

6. Maintain records concerning inventions, patents and licenses in which the Department has an interest and receive, review, and make recommendations regarding, applications for patent licenses.

6-20-30 MEMBERSHIP DEPARTMENT PATENTS BOARD AND THE DEPARTMENT PATENTS OFFICER

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

Mr. James M. Quigley Chairman	Assistant Secretary
Mr. Edward B. Persons Vice Chairman	Assistant Director Division of Personnel Management Office of Administration
Dr. Homer D. Babbidge	Assistant Commissioner and Director Division of Higher Education Office of Education
Dr. John D. Porterfield	Deputy Surgeon General Public Health Service
Mr. Richard L. Seggel	Executive Officer National Institutes of Health
Miss Mary E. Switzer	Director Office of Vocational Rehabilitation
Mr. Dale S. Thompson	Director Division of General Services Office of Administration
Mr. Frank H. Wiley	Chief Division of Pharmaceutical Chemistry Food and Drug Administration

Department Patents Officer	Office of the General Counsel
B. Department Patents Officer:	Mr. Manuel B. Hiller
Deputy Patents Officer:	Mrs. Sarah H. Spector

CHAPTER 6-30

CRITERIA FOR PATENTING OR PUBLICATION--PROOF OF INVENTION

6-30-00 Purpose
10 General Assumptions
20 Determination as to Patentability
30 Inventions of Trivial Value or Significance
40 Inventions of Substantial Value or Significance
50 Publication as an Alternative to Patenting--"Printed" Publication
60 Notebooks and Original Records--Evidence of Invention

6-30-00 PURPOSE

This chapter provides supplementary criteria for Department personnel who are charged with responsibility for making recommendations as to the patenting or publication of inventions in which the Department has an interest (45C.F.R. 7.5). It is issued, with the approval of the Department Patents Board, pursuant to Department Regulations (45 C.F.R. 6.5).

6-30-10 GENERAL ASSUMPTIONS

A. The Department's interest in inventions is almost the reverse of that which generally prompts a private patent application. Its concern is not to withhold the invention from the public or to charge royalties for its use but to assure the availability of the invention to all (45 C.F.R. 6.2). This assurance with respect to an invention may be lost if an individual claiming priority of invention files a patent application.

B. The Department therefore does have an interest, and under Executive Order 10096 it has an obligation, to take appropriate defensive action, to protect the interest of the Government and the public against potential adverse claims. Such action may take the form of initiating a patent application or by full disclosure through publication.

C. Since not all inventions are of sufficient importance to warrant the labor and expense of patenting, and since the Department does not itself maintain staff or facilities for such purpose, the need for patenting and the resources available for handling a patent application need to be weighed carefully before a determination as to patenting is made.

6-30-20 DETERMINATION AS TO PATENTABILITY

A. No recommendation as to patenting should in any case be made unless it is first determined that the invention may be patentable.

(6-30-20 continued)

B. The determination as to whether the invention "may be patentable" should identify the originality of concept, as well as the elements of novelty and usefulness, believed to be present in the invention. This is for the reason that, even though an invention is "new and useful" it is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." (35 U.S.C. 103)

C. Whether it is determined that the invention may or may not be patentable, the basis for the conclusions reached should be indicated in the determination. For example, a written report on these points by research workers who have familiarity with the art in the particular field is valuable, because it may indicate that the invention has been fully anticipated. In any event, the report itself will constitute a record bearing on the relation of the invention to the prior art, and so may serve a protective purpose.

D. The determination should set forth fully the dates of conception and of reduction to practice (or of the successful test or performance) of the invention, and of any prior disclosure (speeches, writings, printed publication, etc.) or use thereof. These are important because the invention will not be patentable if at the time of the determination it has been for more than one year either--

1. described in a printed publication in this country or abroad; or

2. in public use or on sale in this country (35 U.S.C 102(b)).

6-30-30 INVENTIONS OF TRIVIAL VALUE OR SIGNIFICANCE

A. Unless "useful" to some degree, the invention will not be patentable.

B. Even though the invention is possibly patentable, it may be recommended that title be left with the inventor, pursuant to section 7.3 (b) of the Department Regulations on grounds of "insufficient interest," subject to license to the Government under any patent which may be secured.

C. Government "interest" has two aspects. First, the Government has an interest as a potential user of the invention in its own operations or as a purchaser of products embodying the invention. Second, it has an interest (particularly strong in the field of research) of preserving for the public the products of its work and investment. Ordinarily, therefore, a recommendation of dedication to the public by publication rather than a finding of insufficient interest is appropriate in the case of all but patently trivial gadgets in which there has been no substantial investment of Government time or facilities.

D. Determinations of "insufficient interest" are subject to review by the Chairman of the Government Patents Board.

6-30-40 INVENTIONS OF SUBSTANTIAL VALUE OR SIGNIFICANCE

A. In general patenting should not be recommended when printed publication of a technically adequate description can be, or has been, arranged, or disclosure to or use by others can be, or has been, arranged under safeguards which will assure the availability of proofs as to time of conception, reduction to practice, and disclosure. (A person is not entitled to a patent if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. 102 (a).) Certainly patenting should not in the absence of unusual justification be recommended if the one year period which may elapse between a printed publication and the filing of an application has almost elapsed.

B. Patenting, however, is appropriately recommended when--

1. it is deemed advisable, in the case of an invention of high potential significance to the public health, safety, or welfare, to obtain maximum assurance against potential rival claims by establishing priority of invention and diligence in reducing to practice; or

2. it is deemed advisable, for reasons of health or safety, to retain control (beyond that afforded under the Federal Food, Drug, and Cosmetic Act, as amended, or the Public Health Service Act, as amended, or other Federal control legislation) of the invention itself, with legal authority to impose restrictive conditions on its use; or

3. other Federal agencies have such interest in the invention that they would be prepared to prosecute the patent application.

C. 1. Filing may be especially important as a protective device when there is likely to be a considerable lag between conception and actual reduction to practice and the invention is in a highly competitive field or when the invention is a basic one likely to constitue a key to subsequent advances in the art.

2. The filing of a patent application may be of great practical importance in case of competing claims because the Commissioner of Patents is under a duty to give notice and have questions of priority determined by a board of patent interferences whenever an application is made which would seem to interfere with any pending application or any unexpired patent. (35 U.S.C. 135)

3. "In determining priority of invention there shall be considered not only the respective dates of a conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, for a time prior to conception by the other." (35 U.S.C. 102 (g))

(6-30-40C continued)

4. If a patent has issued, the filing of an allowable application is regarded in litigation involving priority of invention as a constructive reduction to practice and as evidence that the inventor made his invention at least as early as the date of filing.

D. The inventor's interest, as a matter of prestige and professional reputation, in having a patent issued in his name does not justify a recommendation for a patent application to be prosecuted at the expense of the Government.

E. In order that final determinations as to ownership may not be delayed pending resolution of the question of patenting, the operating agency may make a determination to patent contingent upon the availability of timely arrangements for the prosecution of a patent application, with reliance, in the event that these are not feasible, upon publication to protect the public interest.

6-30-50 PUBLICATION AS AN ALTERNATIVE TO PATENTING--"PRINTED" PUBLICATION

A. Publication, to be effective as an anticipation, requires a full disclosure setting forth the essential elements of the invention, and the manner of making and using it.

B. Such publication may be made in a technical journal or digest, in a publication of the operating agency (e.g., Public Health Reports, Social Security Bulletin) or in any other printed publication.

C. Additionally, the Office of Technical Services in the Department of Commerce, through the monthly publication of "U. S. Government Research Reports", provides a means of achieving technical "publication" as well as a means of disseminating papers which disclose the results of research. Original reports filed with the Office of Technical Services are deposited in the Library of Congress and copies may be ordered from the Library in photocopy or microfilm. In addition, Office of Technical Services is prepared to distribute stock copies of scientific research reports for government agencies. Listing in "Research Reports", together with the deposit of a typewritten or other copy in an appropriate Federal library, and published announcement of a means provided for duplication of copies for the public have been held to constitute "printed publication" under 35 U.S.C. 102(b). An operating agency wishing to avail itself of this channel should communicate with the Chief, Technology Division, Office of Technical Services, Department of Commerce.

6-30-60 NOTEBOOKS AND ORIGINAL RECORDS--EVIDENCE OF INVENTION

A. Whether or not a patent application is filed, written records, and particularly original records, properly dated, are important evidence of invention both as to completeness and the time when made. When these exist they may be used defensively to prevent the issuance of a patent on an invention subsequently conceived, or to contest the validity of a patent which may have been granted to some other person. For such purpose, the conception should be recorded, with indication of the date of conception, and immediately corroborated by communication to a competent witness who may be asked to read and initial the record, indicating the date of his initialing. Reduction to practice should be corrobated by a witness who observes the actual test or performance. Accurate dating is an essential factor in such records.

B. The operating agency, to the extent deemed consistent with good research practice, should require of its research workers the making and preservation of records which will serve a probative purpose. This is especially desirable in the case of developments failing within section 6-30-40.B1.

PATENT ADVISOR
OFFICE OF THE DIRECTOR, NIH

JAN 6 1967

CHAPTER PHS: 6-10

REGULATIONS AND POLICIES FOR PROCESSING PUBLIC HEALTH SERVICE EMPLOYEE INVENTION REPORTS AND DETERMINATIONS

PHS: 6-10-00 Purpose
01 Definitions
02 Duty of Employee to Report Inventions
03 Conception of the Invention
04 Reduction to Practice
05 Procedure for Submitting Reports
06 Determination as to Patentability
07 Final Determination
08 Regulations and Policy

PHS: 6-10-00 PURPOSE

This chapter (1) summarizes the rights and duties of employees with respect to inventions which they may conceive while in the employ of the Public Health Service, DHEW, and (2) prescribes the procedures to be followed for submitting invention reports and making determinations as to patenting. The chapter is of special concern to employees engaged in research, or administrative work of a research nature, since they are most likely to develop or recognize work of a patentable nature. Each employee, however, should be aware of what an invention is, his duty to report it, and how to prepare the report.

PHS: 6-10-01 DEFINITIONS

A. Definition of an Employee. As used in this part, the term "PHS Employee" means any commissioned officer or employee of the Public Health Service, Department of Health, Education, and Welfare, except such 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. 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.

B. Definition of an Invention. Any process, art or method, machine, manufacture, or improvement thereof may constitute an invention if it is new and useful, and would not have been obvious to a person having skill in the art to which

PHS:
(6-10-01 continued)

it relates. A "process" may be either a connected series of steps or a new use of a process, machine, manufacture, or composition of matter. In a patent sense, the word "new" has a broader meaning than it has in common usage. The usual test of novelty applied by the Patent Office is the novelty search in which available printed matter is consulted to find if there is a previous description of the invention claimed. This search brings forth prior published knowledge. Any reference prior to the patent application is considered by the Patent Office to be prior art. A description published more than one year prior to the date of an application for patent constitutes a statutory bar to patenting. Prior unpublished experimental uses, abandoned experiments, or lost arts are not proper references.

An invention is useful in a patent sense if it is capable of performing some beneficial function.

PHS:
6-10-02 DUTY OF EMPLOYEE TO REPORT INVENTIONS

Every PHS employee is required to report promptly any invention conceived by him which bears any relation to:

(a) his official duties; or
(b) was made in whole or in part during working hours; or
(c) was made with any contribution of Government facilities, equipment, materials, funds, or information; or
(d) included time or services of other Government employees on official duty.

Even in those instances where doubt exists on the relationship of the invention to official duties, Government facilities, etc., the invention will be considered reportable. This is necessary in order to establish the circumstances surrounding the invention and make a clear determination of the employee's rights.

PHS:
6-10-03 CONCEPTION OF THE INVENTION

An invention begins with its mental visualization or conception. However, the conception must be complete and include the result as well as the means for bringing about that result. Because the conception is a mental process, it must be communicated to others

PHS:
(6-10-03 continued)

who understand it before it can be proved satisfactorily. The date of conception is the earliest date to which an inventor can be entitled for priority purposes. If the inventor can demonstrate reasonable, continuous diligence in carrying out (constructing and testing) the conceived invention, for purposes of priority, he may be considered as having made the invention when he began the continuous diligence. If this diligence began immediately after conception, then the date to which the inventor is entitled is the date on which the invention was conceived.

PHS:
6-10-04 REDUCTION TO PRACTICE OF THE INVENTION

The act of transforming an inventive concept into physical reality (construction and testing) is referred to as "reduction to practice" of the invention. The general rules of reduction to practice for the four most important classes of invention are:

(1) For a process.................. when it is successfully performed; this normally requires a test of results to demonstrate the success.

(2) For a machine.................. when it is assembled and tested or used.

(3) For an article of manufacture.. when it is completely manufactured and tested or used.

(4) For a composition of matter.... when it is completely composed and tested or used.

PHS:
6-10-05 PROCEDURES FOR SUBMITTING INVENTION REPORTS

Reports of inventions shall be prepared in at least four (4) copies on form PHS-3969 Employee Invention Report. Additional copies of the report, for internal bureau use, may be determined by the individual bureaus. An initial supply of this form is being forwarded under separate cover. Replenishment of stock will be made in accordance with the PHS Forms Catalog. If more than one person contributed to the invention, the joint inventors will also sign the invention report. The signed report, and copies, will be submitted to the immediate supervisor. When a supervisor receives a completed invention report, it will be forwarded to the bureau official (Patent Attorney, if any) responsible for reviewing and transmitting the invention report to the OSG Patent Staff.

PHS:
6-10-06 DETERMINATION AS TO PATENTABILITY

Before a recommendation as to patenting can be made, it is necessary to determine whether the invention may possibly be patentable. This determination may be made only by the PHS Patent Staff or the Bureau Patent Attorney. Even though an invention is "new and useful," it is not always patentable if "the difference between the subject matter to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." (35 USC 103). Additional guidance as to patentability may be found in the DHEW General Administration Manual, Part 6, Chapter 6-30.

PHS:
6-10-07 DETERMINATION AS TO PATENT RIGHTS

Form PHS-3968 Determination on Employee Invention will be used in preparing determinations. The forms will be prepared in an original and five (5) copies. A supply of this form may be obtained from the HEW Central Stores Section. If the recommendation to patent or publish is prepared by the Bureau Patent Attorney, the first carbon copy will be initialed by the Bureau Executive Officer or his designee and forwarded to the PHS Patent Staff. Recommendations, to patent or publish, prepared by the PHS Patent Staff will be forwarded to the appropriate bureau for initialing before processing. Following review by the bureau, the recommendation will be forwarded to the Department Patents Officer who will initial the first carbon copy prior to submitting the recommendation to the Surgeon General. The Surgeon General is the only individual in the Public Health Service with the authority to make the final determination on patent rights. The original copy will be returned to the Department Patents Officer. The remaining copies will be distributed as follows:

1st carbon copy - PHS Patent Staff

Remaining copies (Surgeon General's file
(Bureau file
(Employee (Inventor)
(Division file

PHS:
6-10-08 REGULATIONS AND POLICY

Advice and consultation on patents is available within the Immediate Office of the Surgeon General from the PHS Patent Staff. However, employees should be familiar with the following applicable

PHS:
(6-10-08 continued)

regulations and policies of the Government and the Department:

A. Government-wide Regulations. Uniform requirements applicable to all Government employees for determining the ownership of inventions made after January 23, 1960, were established by Executive Order 10096, as amended by Executive Order 10930. The provisions of these Executive Orders are administered by the Commissioner of Patents. Regulations supplementing the Executive Orders have been issued by the Commissioner in the form of Administrative Orders, together with interpretations and other procedural instructions.

B. Department Regulations. Department regulations, published in the Federal Register (20 F.R. 6747), supplement these directives for purposes of application to this Department. These regulations (45 C.F.R. 6.0 to 8.7) are reproduced in Part 6 of the General Administration Manual. Sections 7.0 to 7.8 of those regulations deal specifically with employee inventions and specify the machinery for determination by the head of the constituent agency on (1) ownership rights in the invention, and (2) disposition of the invention in the public interest.

C. Department Policy. It is the Department policy that the results of Department research should, as a rule, be made widely, promptly, and freely available to the public. Often this availability will be adequately preserved through dedication of the invention to the public by publication. At times, however, it may best be assured by patenting, and subsequent issuance of licenses or dedication of the patent to the public.