

both, or is otherwise available commercially; and

(11) Any other information which applicant believes will support a determination to grant the license to applicant.

(b) An executed CRADA which provides for the use for research and development purposes by the CRADA collaborator under that CRADA of a Federally-owned invention in the Federal laboratory's custody (pursuant to 35 U.S.C. 209 and 15 U.S.C. 3710a(b)(1)), and which addresses the information in paragraph (a) of this section, may be treated by the Federal laboratory as an application for a license.

[83 FR 15963, Apr. 13, 2018]

§ 404.9 [Reserved]

§ 404.10 Modification and termination of licenses.

Before modifying or terminating a license, other than by mutual agreement, the Federal agency shall furnish the licensee a written notice of intention to modify or terminate the license, and the licensee shall be allowed 30 days after such notice to remedy any breach of the license or show cause why the license shall not be modified or terminated.

[71 FR 11514, Mar. 8, 2006, as amended at 88 FR 17740, Mar. 24, 2023]

§ 404.11 Appeals.

(a) The following parties may appeal to the agency head or designee of the Federal agency any decision or determination concerning the grant, denial, modification, or termination of a license:

(1) A person whose application for a license has been denied;

(2) A licensee whose license has been modified or terminated, in whole or in part; or

(3) A person who timely filed a written objection in response to the notice required by § 404.7 and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action due to being denied the opportunity to promote the commercialization of the invention.

(b) The Federal agency shall establish appropriate procedures for consid-

ering appeals under paragraph (a) of this section.

[71 FR 11514, Mar. 8, 2006, as amended at 88 FR 17740, Mar. 24, 2023]

§ 404.12 Protection and administration of inventions.

A Federal agency may take any suitable and necessary steps to protect and administer rights to Government owned inventions, either directly or through contract.

[71 FR 11514, Mar. 8, 2006]

§ 404.13 Transfer of custody.

A Federal agency having custody of a federally owned invention may transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in such invention.

§ 404.14 Confidentiality of information.

35 U.S.C. 209(f) requires that any plan submitted pursuant to § 404.8(a)(8) and any report required by 35 U.S.C. 209(d)(2) shall be treated as commercial or financial information obtained from a person and privileged and confidential and not subject to disclosure under 5 U.S.C. 552.

[88 FR 17740, Mar. 24, 2023]

§ 404.15 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall remain in effect.

[88 FR 17740, Mar. 24, 2023]

PART 501—UNIFORM PATENT POLICY FOR RIGHTS IN INVENTIONS MADE BY GOVERNMENT EMPLOYEES

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AUTHORITY: Sec. 4, E.O. 10096, 3 CFR, 1949–1953 Comp., p. 292, as amended by E.O. 10930, 3 CFR, 1959–1963 Comp., p. 456 and by E.O. 10695, 3 CFR, 1954–1958 Comp., p. 355, DOO 30–2A.

SOURCE: 53 FR 39735, Oct. 11, 1988, unless otherwise noted.

EDITORIAL NOTE: At 78 FR 4766, Jan. 23, 2013, parts 500–599 were transferred from Title 37, Chapter V, to Title 37, Chapter IV. Chapter V was removed and reserved.

§ 501.1 Purpose.

The purpose of this part is to provide for the administration of a uniform patent policy for the Government with respect to the rights in inventions made by Government employees and to prescribe rules and regulations for implementing and effectuating such policy.

[61 FR 40999, Aug. 7, 1996]

§ 501.2 Scope.

This part applies to any invention made by a Government employee and to any action taken with respect thereto.

§ 501.3 Definitions.

(a) The term *Secretary*, as used in this part, means the Director of the National Institute of Standards and Technology.

(b) The term *Government agency*, as used in this part, means any Executive department or independent establishment of the Executive branch of the Government (including any independent regulatory commission or board, any corporation wholly owned by the United States, and the Smithsonian Institution), but does not include the Department of Energy for inventions made under the provisions of 42 U.S.C. 2182, the Tennessee Valley Authority, or the Postal Service.

(c) The term *Government employee*, as used in this part, means any officer or employee, civilian or military, of any Government agency, including any special Government employee as defined in 18 U.S.C. 202 or an individual working for a Federal agency pursuant to the Intergovernmental Personnel Act (IPA), 5 U.S.C. 1304 and 3371–3376, or a

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part-time consultant or part-time employee as defined in 29 U.S.C. 2101(a)(8) except as may otherwise be provided by agency regulation approved by the Secretary.

(d) The term *invention*, as used in this part, means any art or process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.

(e) The term *made* as used in this part in relation to any invention, means the conception or first actual reduction to practice of such invention as stated in *In re King*, 3 USPQ2d (BNA) 1747 (Comm'r Pat. 1987).

[61 FR 40999, Aug. 7, 1996, as amended at 78 FR 4766, Jan. 23, 2013]

§ 501.4 Determination of inventions and rights.

Each Government agency has the approval of the Secretary to determine whether the results of research, development, or other activity in the agency constitute an invention within the purview of Executive Order 10096, as amended by Executive Order 10930 and Executive Order 10695, and to determine the rights in and to the invention in accordance with the provisions of §§ 501.6 and 501.7.

[61 FR 40999, Aug. 7, 1996]

§ 501.5 Agency liaison officer.

Each Government agency shall designate a liaison officer to represent the agency before the Secretary; Provided, however, that the Departments of the Army, the Navy, and the Air Force may each designate a liaison officer.

§ 501.6 Criteria for the determination of rights in and to inventions.

(a) The following rules shall be applied in determining the respective rights of the Government and of the inventor in and to any invention that is subject to the provisions of this part:

(1) The Government shall obtain, except as herein otherwise provided, the entire right, title and interest in and to any invention made by any Government employee:

(i) During working hours, or

(ii) 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

(iii) Which bears a direct relation to or is made in consequence of the official duties of the inventor.

(2) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a)(1) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire 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 right, title and interest therein (although the Government could obtain same under paragraph (a)(1) of this section), the Government agency concerned 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. The terms of such reservation will appear, where practicable, in any patent, domestic or foreign, which may issue on such invention. Reference is made to section 15 of the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710d) which requires a Government agency to allow the inventor to retain title to any covered invention when the agency does not intend to file a patent application or otherwise promote commercialization.

(3) In applying the provisions of paragraphs (a)(1) and (2) of this section to the facts and circumstances relating to the making of a particular invention, it shall be presumed that an invention made by an employee who is employed or assigned:

(i) To invent or improve or perfect any art or process, machine, design, manufacture, or composition of matter;

(ii) To conduct or perform research, development work, or both,

(iii) To supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or

(iv) To act in a liaison capacity among governmental or non-governmental agencies or individuals engaged in such research or development work, falls within the provisions of paragraph (a)(1) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (a)(2) of this section. Either presumption may be rebutted by a showing of the facts and circumstances in the case and shall not preclude a determination that these facts and circumstances justify leaving the entire right, title and interest in and to the invention in the Government employee, subject to law.

(4) In any case wherein the Government neither:

(i) Obtains the entire right, title and interest in and to an invention pursuant to the provisions of paragraph (a)(1) of this section nor

(ii) 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 (a)(2) 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.

[53 FR 39735, Oct. 11, 1988, as amended at 61 FR 40999, Aug. 7, 1996]

§ 501.7 Agency determination.

(a) If the agency determines that the Government is entitled to obtain title pursuant to § 501.6(a)(1) and the employee does not appeal, no further review is required.

(b) In the event that a Government agency determines, pursuant to paragraph (a)(2) or (a)(4) of § 501.6, that title to an invention will be left with the employee, the agency shall notify the employee of this determination. In cases pursuant to § 501.6(a)(2) where the Government's insufficient interest in the invention is evidenced by its decision not to file a patent application, the agency may impose on the employee any one or all of the following conditions or any other conditions that may be necessary in a particular case:

(1) That a patent application be filed in the United States and/or abroad, if

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the Government has determined that it has or may need to practice the invention;

(2) That the invention not be assigned to any foreign-owned or controlled corporation without the written permission of the agency; and

(3) That any assignment or license of rights to use or sell the invention in the United States shall contain a requirement that any products embodying the invention or produced through the use of the invention be substantially manufactured in the United States. The agency shall notify the employee of any conditions imposed.

(c) In the case of a determination under either paragraph (a) or (b) of this section, the agency shall promptly provide the employee with:

(1) A signed and dated statement of its determination and reasons therefor; and

(2) A copy of 37 CFR part 501.

[53 FR 39735, Oct. 11, 1988, as amended at 61 FR 40999, Aug. 7, 1996]

§ 501.8 Appeals by employees.

(a) Any Government employee who is aggrieved by a Government agency determination pursuant to §§ 501.6(a)(1) or (a)(2), may obtain a review of any agency determination by filing, within 30 days (or such longer period as the Secretary may, for good cause shown in writing, fix in any case) after receiving notice of such determination, two copies of an appeal with the Secretary. The Secretary then shall forward one copy of the appeal to the liaison officer of the Government agency.

(b) On receipt of a copy of an appeal filed pursuant to paragraph (a) of this section, the agency liaison officer shall, subject to considerations of national security, or public health, safety or welfare, promptly furnish both the Secretary and the inventor with a copy of a report containing the following information about the invention involved in the appeal:

(1) A copy of the agency's statement specified in § 501.7(c);

(2) A description of the invention in sufficient detail to identify the invention and show its relationship to the employee's duties and work assignments;

(3) The name of the employee and employment status, including a detailed statement of official duties and responsibilities at the time the invention was made; and

(4) A detailed statement of the points of dispute or controversy, together with copies of any statements or written arguments filed with the agency, and of any other relevant evidence that the agency considered in making its determination of Government interest.

(c) Within 25 days (or such longer period as the Secretary may, for good cause shown, fix in any case) after the transmission of a copy of the agency report to the employee, the employee may file a reply with the Secretary and file one copy with the agency liaison officer.

(d) After the time for the inventor's reply to the Government agency's report has expired and if the inventor has so requested in his or her appeal, a date will be set for hearing of oral arguments before the Secretary, by the employee (or by an attorney whom he or she designates by written power of attorney filed before, or at the hearing) and a representative of the Government agency involved. Unless it shall be otherwise ordered before the hearing begins, oral arguments will be limited to thirty minutes for each side. The employee need not retain an attorney or request an oral hearing to secure full consideration of the facts and his or her arguments. The employee may expedite such consideration by notifying the Secretary when he or she does not intend to file a reply to the agency report.

(e) After a hearing on the appeal, if a hearing was requested, or after expiration of the period for the inventor's reply to the agency report if no hearing is set, the Secretary shall issue a decision on the matter within 120 days, which decision shall be final after a thirty day period for requesting reconsideration expires or on the date that a decision on a petition for reconsideration is finally disposed of. Any request for reconsideration or modification of the decision must be filed within 30 days from the date of the original decision (or within such an extension thereof as may be set by the Secretary before the original period expires). The

decision of the Secretary shall be made after consideration of the statements of fact in the employee's appeal, the agency's report, and the employee's reply, but the Secretary at his or her discretion and with due respect to the rights and convenience of the inventor and the Government agency, may call for further statements on specific questions of fact or may request additional evidence in the form of affidavits or depositions on specific facts in dispute.

[53 FR 39735, Oct. 11, 1988, as amended at 61 FR 41000, Aug. 7, 1996]

§ 501.9 Patent protection.

(a) A Government agency, upon determining that an invention coming within the scope of §§ 501.6(a)(1) or (a)(2) has been made, shall promptly determine whether patent protection will be sought in the United States by or on behalf of the agency for such invention. A controversy over the respective rights of the Government and of the employee shall not unnecessarily delay the filing of a patent application by the agency to avoid the loss of patent rights. In cases coming within the scope of § 501.6(a)(2), the filing of a patent application shall be contingent upon the consent of the employee.

(b) Where there is an appealed dispute as to whether §§ 501.6 (a)(1) or (a)(2) applies in determining the respective rights of the Government and of an employee in and to any invention, the agency may determine whether patent protection will be sought in the United States pending the Secretary's decision on the dispute. If the agency decides that an application for patent should be filed, the agency will take such rights as are specified in § 501.6(a)(2), but this shall be without prejudice to acquiring the rights specified in paragraph (a)(1) of that section should the Secretary so decide.

(c) Where an agency has determined to leave title to an invention with an employee under § 501.6(a)(2), the agency will, upon the filing of an application for patent, take the rights specified in that paragraph without prejudice to

the subsequent acquisition by the Government of the rights specified in paragraph (a)(1) of that section should the Secretary so decide.

(d) Where an agency has filed a patent application in the United States, the agency will, within 8 months from the filing date of the U.S. application, determine if any foreign patent applications should also be filed. If the agency chooses not to file an application in any foreign country, the employee may request rights in that country subject to the conditions stated in § 501.7(b) that may be imposed by the agency. Alternatively, the agency may permit the employee to retain foreign rights by including in any assignment to the Government of an unclassified U.S. patent application on the invention an option for the Government to acquire title in any foreign country within 8 months from the filing date of the U.S. application.

[61 FR 41000, Aug. 7, 1996]

§ 501.10 Dissemination of this part and of implementing regulations.

Each Government agency shall disseminate to its employees the provisions of this part, and any appropriate implementing agency regulations and delegations. Copies of any such regulations shall be sent to the Secretary. If the Secretary identifies an inconsistency between this part and the agency regulations or delegations, the agency, upon being informed by the Secretary of the inconsistency, shall take prompt action to correct it.

§ 501.11 Submissions and inquiries.

All submissions or inquiries should be directed to the Chief Counsel for NIST, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1052, Gaithersburg, MD 20899-1052; telephone: (301) 975-2803; email: nistcounsel@nist.gov.

[78 FR 4766, Jan. 23, 2013]

PARTS 502-599 [RESERVED]

CHAPTER V [RESERVED]