

**§ 401.18 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 17739, Mar. 24, 2023]

**PART 404—LICENSING OF GOVERNMENT-OWNED INVENTIONS**

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AUTHORITY: 35 U.S.C. 207–209, DOO 30–2A.

SOURCE: 50 FR 9802, Mar. 12, 1985, unless otherwise noted.

**§ 404.1 Scope of part.**

(a) This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed. This part does not affect licenses which:

(1) Were in effect prior to April 7, 2006;

(2) May exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts;

(3) Are the result of an authorized exchange of rights in the settlement of patent disputes, including interferences; or

(4) Are otherwise authorized by law or treaty, including 35 U.S.C. 202(e), 35 U.S.C. 207(a)(3) and 15 U.S.C. 3710a, which also may authorize the assignment of inventions. Although licenses

on inventions made under a cooperative research and development agreement (CRADA) are not subject to this regulation, agencies are encouraged to apply the same policies and use similar terms when appropriate. Similarly, this should be done for licenses granted under inventions where the agency has acquired rights pursuant to 35 U.S.C. 207(a)(3).

(b) Royalties collected pursuant to this part, and used in accordance with 15 U.S.C. 3710c(a)(1)(B), are not intended as an alternative to appropriated funding or as an alternative funding mechanism.

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**§ 404.2 Policy and objective.**

It is the policy and objective of this subpart to promote the results of federally funded research and development through the patenting and licensing process. In negotiating licenses, the Government may consider payments under a licensing agreement as a means for encouraging the licensee to develop an invention in order to advance practical application and promote commercialization by the licensee.

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**§ 404.3 Definitions.**

(a) *Government owned invention* means an invention, whether or not covered by a patent or patent application, or discovery which is or may be patentable or otherwise protectable under Title 35, the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*) or foreign patent law, owned in whole or in part by the United States Government.

(b) *Federal agency* means an executive department, military department, Government corporation, or independent establishment, except the Tennessee Valley Authority, which has custody of a federally owned invention.

(c) *Small business firm* means a small business concern as defined in section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(d) *Practical application* means to manufacture in the case of a composition or product, to practice in the case

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of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(e) *United States* means the United States of America, its territories and possessions, the District of Columbia, and the Commonwealth of Puerto Rico.

[50 FR 9802, Mar. 12, 1985, as amended at 71 FR 11512, Mar. 8, 2006]

#### § 404.4 Authority to grant licenses.

Federally owned inventions shall be made available for licensing as deemed appropriate in the public interest and each agency shall notify the public of these available inventions. The agencies having custody of these inventions may grant nonexclusive, co-exclusive, partially exclusive, or exclusive licenses thereto under this part. Licenses may be royalty-free or for royalties or other consideration. They may be for all or less than all fields of use or in specified geographic areas and may include a release for past infringement. Any license shall not confer on any person immunity from the anti-trust laws or from a charge of patent misuse, and the exercise of such rights pursuant to this part shall not be immunized from the operation of state or federal law by reason of the source of the grant.

[71 FR 11512, Mar. 8, 2006]

#### § 404.5 Restrictions and conditions on all licenses granted under this part.

(a)(1) A license may be granted only if the applicant has supplied the Federal agency with a satisfactory plan for development or marketing of the invention, or both, and with information about the applicant's capability to fulfill the plan. The plan for a non-exclusive research license may be limited to describing the research phase of development.

(2) A license granting rights to use or sell under a Government owned invention in the United States shall normally be granted only to a licensee who agrees that any products embodying the invention or produced through

the use of the invention will be manufactured substantially in the United States. However, this condition may be waived or modified if reasonable but unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States or if domestic manufacture is not commercially feasible.

(b) Licenses shall contain such terms and conditions as the Federal agency determines are appropriate for the protection of the interests of the Federal Government and the public and are not in conflict with law or this part. The following terms and conditions apply to any license:

(1) The duration of the license shall be for a period specified in the license agreement, unless sooner terminated in accordance with this part.

(2) Any patent license may grant the licensee the right of enforcement of the licensed patent without joining the Federal agency as a party as determined appropriate in the public interest.

(3) The license may extend to subsidiaries of the licensee or other parties if provided for in the license but shall be nonassignable without approval of the Federal agency, except to the successor of that part of the licensee's business to which the invention pertains.

(4) The license may provide the licensee the right to grant sublicenses under the license, subject to the approval of the Federal agency. Each sublicense shall make reference to the license, including the rights retained by the Government, and a copy of such sublicense with any modifications thereto, shall be promptly furnished to the Federal agency.

(5) The license shall require the licensee to carry out the plan for development or marketing of the invention, or both, to bring the invention to practical application within a reasonable time as specified in the license, and continue to make the benefits of the invention reasonably accessible to the public.

(6) The license shall require the licensee to report periodically on the utilization or efforts at obtaining utilization that are being made by the licensee, with particular reference to the

plan submitted but only to the extent necessary to enable the agency to determine compliance with the terms of the license.

(7) Where an agreement is obtained pursuant to § 404.5(a)(2) that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States, the license shall recite such an agreement.

(8) The license shall provide for the right of the Federal agency to terminate the license, in whole or in part, if the agency determines that:

(i) The licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(ii) Termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee;

(iii) The licensee has willfully made a false statement of or willfully omitted a material fact in the license application or in any report required by the license agreement;

(iv) The licensee commits a substantial breach of a covenant or provision contained in the license agreement, including the requirement in § 35 U.S.C. 209(b); or

(v) The licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(9) The license may be modified or terminated, consistent with this part, upon mutual agreement of the Federal agency and the licensee.

(10) The license may be modified or terminated, consistent with this part, upon mutual agreement of the Federal agency and the licensee.

(11) Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person

any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this part shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

[50 FR 9802, Mar. 12, 1985, as amended at 71 FR 11512, Mar. 8, 2006; 88 FR 17739, Mar. 24, 2023]

#### § 404.6 Nonexclusive licenses.

Nonexclusive licenses may be granted under Government owned inventions without a public notice of a prospective license.

[71 FR 11513, Mar. 8, 2006]

#### § 404.7 Exclusive, co-exclusive, and partially exclusive licenses.

(a) Exclusive, co-exclusive or partially exclusive licenses may be granted on Government owned inventions, only if:

(1) Notice of a prospective license identifying the invention and the prospective licensee has been published and responses, if any, reviewed in accordance with 35 U.S.C. 209(e). The agency, in its discretion, may include other information as appropriate;

(2) After expiration of the public notice period and consideration of any written objections received in accordance with 35 U.S.C. 209(e), the Federal agency has determined that:

(i) The public will be served by the granting of the license, as indicated by the applicant's intentions, plans and ability to bring the invention to the point of practical application or otherwise promote the invention's utilization by the public;

(ii) The proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public; and

(iii) Exclusive, co-exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public;

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(3) The Federal agency has determined that the grant of such a license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws;

(4) The Federal agency has given first preference to any small business firms submitting plans that are determined by the agency to be within the capability of the firms and as having equal or greater likelihood as those from other applicants to bring the invention to practical application within a reasonable time; and

(5) In the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

(b) In addition to the provisions of § 404.5, the following terms and conditions apply to exclusive, co-exclusive and partially exclusive licenses:

(1) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice or have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

(2) The license shall reserve to the Federal agency the right to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety needs.

(3) The license shall be subject to any licenses in force at the time of the grant of the exclusive, co-exclusive or partially exclusive license.

(4) The license may grant the licensee the right to take any suitable and necessary actions to protect the licensed property, on behalf of the Federal Government.

(c) Federal agencies shall maintain a record of determinations to grant exclusive, co-exclusive or partially exclusive licenses.

[88 FR 17739, Mar. 24, 2023]

**§ 404.8 Application for a license.**

(a) An application for a license should be addressed to the Federal agency having custody of the invention and shall normally include:

(1) Identification of the invention for which the license is desired including the patent application serial number or patent number, title, and date, if known;

(2) Identification of the type of license for which the application is submitted;

(3) Name and address of the person, company, or organization applying for the license and the citizenship or place of incorporation of the applicant;

(4) Name, address, and telephone number of the representative of the applicant to whom correspondence should be sent;

(5) Nature and type of applicant's business, identifying products or services which the applicant has successfully commercialized, and approximate number of applicant's employees;

(6) Source of information concerning the availability of a license on the invention;

(7) A statement indicating whether the applicant is a small business firm as defined in § 404.3(c);

(8) A detailed description of applicant's plan for development or marketing of the invention, or both, which should include:

(i) A statement of the time, nature and amount of anticipated investment of capital and other resources which applicant believes will be required to bring the invention to practical application;

(ii) A statement as to applicant's capability and intention to fulfill the plan, including information regarding manufacturing, marketing, financial, and technical resources;

(iii) A statement of the fields of use for which applicant intends to practice the invention; and

(iv) A statement of the geographic areas in which applicant intends to manufacture any products embodying the invention and geographic areas where applicant intends to use or sell the invention, or both;

(9) Identification of licenses previously granted to applicant under federally owned inventions;

(10) A statement containing applicant's best knowledge of the extent to which the invention is being practiced by private industry or Government, or

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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