

(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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