

§ 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**Sec.**

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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.

[88 FR 17739, Mar. 24, 2023]

§ 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.

[88 FR 17739, Mar. 24, 2023]

§ 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

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