CHAPTER 18—PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

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§ 200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

§ 201. Definitions

As used in this chapter—

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, United States Code, and the military departments as defined by section 102 of title 5, United States Code.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title.

or any novel variety of plant which is or be protectable under the Plant Variety Protection Act (7 U 2321 et seq.)

(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.

: *Provided*, That in the case of a variety o plant, the date of determination (as defined in section 41(d) o the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance

(f) The term "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.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

§ 202. Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however*, That a funding agreement may provide otherwise (i) ~~when the funding agreement is for the operation of a Government-owned research or production facility~~,

when the contractor is not located in the United State does not have a place of business located in the United State is subject to the control of a foreign government,"

(ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter ~~or~~ (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject

invention is necessary to protect the security of such activities.

or, iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy."

The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

~~(b)(1) Any determination under (ii) of paragraph (a) of this section shall be in writing and accompanied by a written statement of facts justifying the determination. A copy of each such determination and justification shall be sent to the Comptroller General of the United States within thirty days after the award of the applicable funding agreement. In the case of determinations applicable to funding agreements with small business firms copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration.~~

~~(2) If the Comptroller General believes that any pattern of determinations by a Federal agency is contrary to the policy and objectives of this chapter or that an agency's policies or practices are otherwise not in conformance with this chapter, the Comptroller General shall so advise the head of the agency. The head of the agency shall advise the Comptroller General in writing within one hundred and twenty days of what action, if any, the agency has taken or plans to take with respect to the matters raised by the Comptroller General.~~

(b)(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iii) of subsection (a) exists. Except in the case of subsection (a)(ii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

"(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter, the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses."

(3) At least once each year, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the last paragraph of section 203(2)."

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) A requirement that the contractor disclose each subject invention to the Federal agency within a reasonable time after it is made and that the Federal Government may receive title to any subject invention not reported to it within such time.

(2) A requirement that the contractor make an election to retain title to any subject invention within a reasonable time after disclosure and that the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such time.

(3) A requirement that a contractor electing rights file patent applications within reasonable times and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world, and may, if provided in the funding agreement, have additional rights to sublicense any foreign government or international organization pursuant to any existing or future treaty or agreement.

"(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

"(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory

period: *And provided further*, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

"(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

"(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights; including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.".

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information ~~may~~

as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall

be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions ~~and which is not, itself, engaged in or does not hold a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention~~ (provided that such assignee shall be subject to the same provisions as the contractor); ~~(B) a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for a period in excess of the earlier of five years from first commercial sale or use of the invention or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance unless, on a case by case basis, the Federal agency approves a longer exclusive license. If exclusive field of use licenses are granted, commercial sale or use in one field of use shall not be deemed commercial sale or use as to other fields of use, and a first commercial sale or use with respect to a product of the invention shall not be deemed to end the exclusive period to different subsequent products covered by the invention;~~ ~~(C)~~ (B) a requirement that the contractor share royalties with the inventor; ~~and (D) a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education.~~

(C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility."

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(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employee to the contractor subject to the conditions set forth in this chapter.

(f)(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically, identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§ 203. March-in rights

(1) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(c) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(d) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

(2) A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. §601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, ", as appropriate, the determination of the Federal agency. In cases described in paragraphs (a) and (c), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence."

§ 204. Preference for United States industry

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

§ 205. Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

§ 206. Uniform clauses and regulations

~~The Office of Federal Procurement Policy, after receiving recommendations of the Office of Science and Technology Policy, may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and the Office of Federal Procurement Policy shall establish standard funding agreement provisions required under this chapter.~~

The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

§ 207. Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to—

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to—

"(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

"(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

"(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

§ 208. Regulations governing Federal licensing

The ~~Administrator of General Services~~ Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

§ 209. Restrictions on licensing of federally owned inventions

(a) No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

(b) A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c)(1) Each Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a federally owned domestic patent or patent application only if, after public notice and opportunity for filing written objections, it is determined that—

(A) the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;

(B) the desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;

(C) exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(D) the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public.

(2) A Federal agency shall not grant such exclusive or partially exclusive license under paragraph (1) of this subsection if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws.

(3) First preference in the exclusive or partially exclusive licensing of federally owned inventions shall go to small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

(d) After consideration of whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced, any Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a foreign patent application or patent, after public notice and opportunity for filing written objections, except that a Federal agency shall not grant such exclusive or partially exclusive license if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

(e) The Federal agency shall maintain a record of determinations to grant exclusive or partially exclusive licenses.'

(f) Any grant of a license shall contain such terms and conditions as the Federal agency determines appropriate for the protection of the interests of the Federal Government and the public, including provisions for the following:

(1) periodic reporting on the utilization or efforts at obtaining utilization that are being made by the licensee with particular reference to the plan submitted: *Provided*, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

(2) the right of the Federal agency to terminate such license in whole or in part if it determines that the licensee is not executing the plan submitted with 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;

(3) the right of the Federal agency to terminate such license in whole or in part if the licensee is in breach of an agreement obtained pursuant to paragraph (b) of this section; and

(4) the right of the Federal agency to terminate the license in whole or in part if the agency determines that such action 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.

§ 210. Precedence of chapter

(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with