

Calendar No. 668

105TH CONGRESS }
2d Session }

SENATE

{ REPORT
105-358 }

**TECHNOLOGY TRANSFER
COMMERCIALIZATION ACT OF 1998**

R E P O R T

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND
TRANSPORTATION

ON

S. 2120



SEPTEMBER 30, 1998.—Ordered to be printed

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

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TECHNOLOGY TRANSFER COMMERCIALIZATION ACT OF 1998

SEPTEMBER 30, 1998.—Ordered to be printed

Mr. MCCAIN, from the Committee on Commerce, Science, and
Transportation, submitted the following

REPORT

[To accompany S. 2120]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 2120), “A Bill to improve the ability of Federal agencies to license federally-owned inventions”, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

PURPOSE OF THE BILL

S. 2120, as reported, would improve the ability of the Federal agencies and laboratories to transfer technologies to the private sector for commercialization purposes.

BACKGROUND AND NEEDS

Technology transfer is the generic term used to describe procedures for private sector companies to get the information and intellectual property needed to transform federally owned inventions and technologies into commercial products and processes. The Federal involvement in technology transfer arises from an interest in promoting the economic growth that is vital to the nation’s welfare and security. It is through further development, refinement and marketing by private industry that results of research become dif-fused throughout the economy and generate growth.

Federal laboratories employ one-sixth of the nation’s scientists and have one-fifth of the country’s laboratory and equipment capabilities. Consequently, they are considered one of the nation’s most important research and development resources. Beginning in 1980

with the Stevenson-Wydler Technology Innovation Act, Congress has grappled with crafting an effective policy to transfer technologies discovered in federal laboratories to the private sector for commercialization.

The Stevenson-Wydler Act makes clear that Congress expects cooperation on research among universities, government agencies, and companies and sets up a variety of programs to encourage that cooperation. In 1986, a number of amendments were made to the Stevenson-Wydler Act including the establishment of the cooperative research and development agreement (CRADA) as a means for Federal laboratories to do cooperative research with others. The CRADA has now become the most significant legal mechanism for cooperation with Federal laboratories.

Another key statute with respect to the transfer and commercialization of new technologies is the University and Small Business Patent Procedures Act, commonly known as the Bayh-Dole Act. The Bayh-Dole Act is an attempt to establish a uniform policy for the patenting and ownership of federally funded inventions. The original 1980 law allowed universities, non-profit organizations, and small businesses to obtain title to inventions arising from federally funded research that they carried out. A 1982 Executive Order extended that authority to large businesses to the extent permitted by law, and the 1984 amendments extended it to entities that run government-owned and contractor-operated laboratories. The Bayh-Dole Act has not been amended since 1984.

While the Stevenson-Wydler Act and the Bayh-Dole Act have encouraged commercialization through CRADAs and licensing agreements, the approval process for such agreements can be cumbersome. Delays and uncertainty are characteristic of the process and increase transaction costs. In addition, much has changed since the 1984 changes to the Bayh-Dole Act and since the creation of CRADAs in 1986. These technology transfer programs would benefit from the streamlining and improvements in the process called for in S. 2120.

The reported bill incorporates ideas from Federal agencies which conduct significant research programs and makes further adjustments to existing law to compensate for advances in technology and changed circumstances. For instance, public notice requirements are encouraged to take advantage of current means of communication like electronic mail, and the deadlines for such notices would be shortened to reflect the more rapid pace at which business occurs today. The bill also makes adjustments to recognize ways in which CRADAs are now being used which were not contemplated in 1986. In 1986, the CRADA was designed as a way to make laboratories more accessible to small businesses and there were few restrictions on CRADA approval. However, in recent years some CRADAs have involved cutting edge technologies for entire industries and interagency concerns such as international competitiveness, national security, and domestic competitiveness have been raised.

SUMMARY OF MAJOR PROVISIONS

As reported, S. 2120, the Technology Transfer Commercialization Act of 1998 would improve the ability of Federal agencies to license federally owned inventions.

Sections 2 and 6 would amend the Stevenson-Wydler Act: (1) to allow for the licensing of a federally-owned invention that is made prior to the signing of a CRADA and is directly related to the scope of work under the agreement; and (2) to make changes to provisions relating to distribution of royalties received by Federal agencies.

Sections 3 and 5 would make several amendments to the Bayh-Dole Act. These amendments would: (1) clarify Federal authority with respect to a small business or nonprofit organization to permit the consolidation of intellectual property rights; (2) require 30 days' notice to be given prior to granting an exclusive or partially exclusive license; (3) require license applicants to submit a basic business plan with development or commercialization milestones, and provide for consistent small business exemption criteria with respect to non-exclusive licenses; (4) exempt the applicant's proprietary detailed plan for the development (or marketing) of the invention from disclosure under the Freedom of Information Act; and (5) clarify conditions under which the government may terminate a license for a federally-owned invention.

Section 4 would require the Office of Science and Technology Policy (OSTP) to review agency procedures for the approval or disapproval of CRADAs for national security or domestic/international competitiveness reasons. Within one year of enactment, OSTP would be required to establish and distribute to the agencies written criteria and procedures for interagency reviews of CRADAs.

LEGISLATIVE HISTORY

S. 2120, the Technology Transfer Commercialization Act of 1998, was introduced by Senator Rockefeller on May 22, 1998. The bill is cosponsored by Senator Frist. On April 28, 1998 the Subcommittee on Science, Technology and Space of the Commerce Committee held a hearing on federal research and development funding, including technology transfer, at which time testimony was heard from Senator Gramm; Senator Lieberman; Senator Domenici; Senator Bingaman; Dr. Kerri-Ann Jones, Acting Director, OSTP, the White House; Dr. Albert Teich, Director of Science and Policy Programs, American Association for the Advancement of Science; Dr. Judith Rodin, President, University of Pennsylvania; and Mr. Dan Peterson, President, DAP and Associates and former Lockheed Martin Corporation executive.

On July 29, 1998 the Committee met in open executive session and, by a voice vote, ordered the bill to be reported with an amendment.

ESTIMATED COSTS

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 403 of the Congressional Budget Act of 1974, the Committee provides the following cost estimate, prepared by the Congressional Budget Office:

U.S. CONGRESS,
 CONGRESSIONAL BUDGET OFFICE,
 Washington, DC, August 17, 1998.

Hon. JOHN MCCAIN,
 Chairman, Committee on Commerce, Science, and Transportation,
 U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 2120, the Technology Transfer Commercialization Act of 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Kathleen Gramp.

Sincerely,

JUNE E. O'NEILL, *Director*.

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

S. 2120—Technology Transfer Commercialization Act of 1998

S. 2120 would amend existing law regarding the licensing of technologies developed with federal resources. This bill would change the terms and procedures governing such licenses and would expand the scope of inventions that could be included in a license. Royalties collected by federal agencies would be available for obligation for two years after they are received rather than the one year allowed under current law. The bill also would direct the Office of Science and Technology Policy (OSTP) to analyze and recommend policies regarding major cooperative research and development agreements (CRADAs) within one year after enactment.

CBO estimates that implementing S. 2120 would have no significant effect on the federal budget over the 1999–2003 period. Based on information from OSTP, we expect that preparing the report on CRADAs would involve little additional cost because most of the analyses required by the bill are being done under current law. Provisions affecting the collection and spending of royalties by federal agencies would affect direct spending, so pay-as-you-go procedures would apply to this bill, but CBO estimates that the effects would not be significant. Although receipts from royalties could increase if more licenses are issued as a result of this legislation, any additional collections would be offset by an increase in direct spending by agencies for payments to inventors or for related agency programs. Likewise, giving agencies an additional year to obligate royalty income would have little effect on direct spending, because agencies obligate virtually all of the receipts within the one-year limit specified in current law.

S. 2120 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would have no impact on the budgets of state, local, or tribal governments.

On May 21, 1998, CBO transmitted a cost estimate for H.R. 2544, the Technology Transfer Commercialization Act of 1998, as ordered reported by the House Committee on Science on May 13, 1998. The provisions of that bill are similar to those of S. 2120, and the estimated costs are identical.

The CBO staff contact for this estimate is Kathleen Gramp. This estimate was approved by Paul N. Van de Water, Assistant Director for Budget Analysis.

REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following evaluation of the regulatory impact of the legislation, as reported:

Because S. 2120 does not create any new programs, the legislation will have no additional regulatory impact, and will result in no additional reporting requirements. The legislation will have no further effect on the number or types of individuals and businesses regulated, the economic impact of such regulation, the personal privacy of affected individuals, or the paperwork required from such individuals and businesses.

NUMBER OF PERSONS COVERED

The Committee believes that the bill will not subject any individuals or businesses affected by the bill to any additional regulation.

ECONOMIC IMPACT

This legislation will not have an adverse impact on the Nation and should increase the rate of transfer of technologies from Federal agencies and laboratories, thereby generating new business opportunities and revenues.

PRIVACY

This legislation will not have an adverse impact on the privacy of individuals.

PAPERWORK

This legislation will not increase the paperwork requirements for private individuals or businesses. Consistent with existing law, it would require businesses to submit a basic business plan as part of their application for a license.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

This section permits the bill to be cited as the “Technology Transfer Commercialization Act of 1998.”

Section 2. Cooperative Research and Development Agreements

This section would amend section 12 of the Stevenson-Wydler Act to allow the licensing of a federally-owned invention made before a CRADA is signed. The provision applies only when the invention is directly related to the scope of work under the CRADA.

Section 3. Licensing federally owned inventions

Subsection (a) of this section of the reported bill would amend and replace existing section 209 of the Bayh-Dole Act, which deals with licensing federally owned inventions.

Subsection (a) of the revised section 209 would allow a Federal agency to grant an exclusive or partially exclusive license on a federally-owned invention only if:

(1) granting the license is a reasonable and necessary incentive, as determined by the agency's head, to get investment capital and expenditures needed to bring the invention to practical application, or to otherwise promote the invention's public use;

(2) the Federal agency finds that 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 a practical application or otherwise promote the invention's public use, and that the proposed scope of exclusivity is not greater than is reasonably necessary, as defined by the agency's head, to provide the incentive for bringing the invention to practical utilization, as proposed by the applicant, or to otherwise promote public utilization;

(3) the applicant makes a commitment to achieve practical use of the invention within a reasonable time;

(4) granting the license will not tend to substantially reduce competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal government or U.S. industry in foreign commerce will be enhanced.

Amended section 209(b) of the Bayh-Dole Act would require that Federal agencies normally grant licenses to use or to sell any federally-owned invention in the United States only to those applicants who agree that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

Amended section 209(c) of the Bayh-Dole Act would give preference for the granting of any exclusive or partially exclusive license to small businesses having greater or equal likelihood as other applicants to bring the invention to practical application within a reasonable time. The meaning of the term "reasonable time" should be determined by the agency's head through a comparison of similar efforts.

Amended section 209(d) of the Bayh-Dole Act would require any license granted under section 207 of the Bayh-Dole Act to contain such terms and conditions as the granting agency considers appropriate. These terms and conditions include provisions that:

(1) retain a nontransferable, irrevocable, paid-up license for the Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the U.S. government;

(2) require periodic reporting, by the licensee, on the use of the invention, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with;

(3) empower the Federal agency to terminate the license in whole or in part if the agency determines that:

(A) the licensee is not working to achieve practical utilization of the invention, including commitments contained

in any plan submitted in support of its request for a license, and the licensee cannot 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 utilization of the invention;

(B) the licensee is in breach of an agreement described in subsection (b);

(C) termination is necessary to meet requirements for public use specified by Federal regulations after the date of issue of the license, and such requirements are not reasonably satisfied by the licensee; or

(D) the licensee has been found by a competent authority to have violated the Federal antitrust laws in connection with its performance under the license agreement.

Amended section 209(e) of the Bayh-Dole Act would require that no exclusive or partially exclusive license be issued unless a public notice of intent to grant such a license is published 30 days in advance. The Federal agency issuing the license would be required to consider all comments received in response to that public notice.

Amended section 209(f) of the Bayh-Dole Act would require all persons requesting a license of a federally-owned invention to submit a basic business plan with development or commercialization milestones. Each Federal agency, in consultation with the Small Business Administration, would be required to develop consistent standards for exempting small businesses from these requirements for non-exclusive licenses.

Amended section 209(g) of the Bayh-Dole Act would require that an application for a license include, as an independent subdocument, a detailed description of the applicant's plan for development or marketing (or both) of the invention. This subdocument would be exempt from disclosure under section 552 of title 5, United States Code. The subdocument would be required to state the following:

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

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

(3) the fields of use for which the applicant intends to practice the invention; and

(4) the geographic areas in which the applicant intends to manufacture any product embodying the invention, where the applicant intends to use or sell the invention, or both.

Section 4. Review of Cooperative Research and Development Agreement procedures

This section of the reported bill requires a review of CRADA procedures. Subsection (a) would require the Director of the OSTP, in consultation with the Office of Management and Budget, relevant Federal agencies, national laboratories, and any other person the Director considers appropriate, to review the procedures used by Federal agencies to gather and consider the views of other agencies before final approval or disapproval of:

(1) a joint work statement under section 12(c)(5) (C) or (D) of the Stevenson-Wydler Act of 1980; or

(2) in the case of a laboratory described in section 12(d)(2)(A) of the Stevenson-Wydler Act of 1980, a CRADA under section 12, that involves national security, or relates to a project which may have a significant impact on domestic or international competitiveness.

Subsection (b) requires the Director of OSTP, in consultation with relevant Federal agencies and laboratories and within one year after enactment of the bill, to evaluate the adequacy of existing procedures and methods for interagency coordination and awareness, and to establish and distribute to appropriate Federal agencies criteria and procedures for determining when interagency coordination and review procedures are necessary. To the extent practical, the procedures established under subsection (b) would be required to use or modify existing procedures, to minimize burdens on Federal agencies, and to minimize delay in the approval or disapproval of the joint work statement or CRADA under interagency review.

Section 5. Technical amendments to Bayh-Dole Act

This section of the reported bill would amend the Bayh-Dole Act to allow the government to consolidate intellectual property. Section 202(e) of the Bayh-Dole Act would be amended to clarify that the Federal agency employing a coinventor of any invention made under a funding agreement with a non-profit organization or small business firm may, for purposes of consolidating rights in the invention:

(1) license or assign any rights it may have under the funding agreement to the non-profit organization or small business firm; or

(2) acquire any rights in the invention from the non-profit organization or small business firm, but only if the non-profit organization or small business firm voluntarily enters into the transaction.

This section of the reported bill would also amend section 207(a) of the Bayh-Dole Act to allow Federal agencies to grant a license for “federally-owned inventions” instead of “federally-owned patent applications, patents, or other forms of protection obtained”. Section 207(a) would be amended to clarify that Federal agencies may undertake all suitable and necessary steps to protect and administer rights to federally-owned inventions on behalf of the Federal government either directly or through contract, including acquiring rights for the Federal government, but only to the extent the party from whom rights are being acquired voluntarily enters into the transaction.

Section 6. Technical amendments to the Stevenson-Wydler Technology Innovation Act of 1980

This section of the reported bill would make two technical amendments to section 14 of the Stevenson-Wydler Act. First, section 14 of the Act would be amended to allow the head of an agency or laboratory to pay royalties or other payments to the inventors or coinventors if the inventor’s or coinventor’s rights are assigned

to the United States. Second, section 14 would be amended to establish a two-year period for using or obligating any royalties or other payments transferred to a laboratory.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new material is printed in italic, existing law in which no change is proposed is shown in roman):

TITLE 15—COMMERCE AND TRADE

CHAPTER 63—TECHNOLOGY INNOVATION

§ 3710a. Cooperative research and development agreements

(a) GENERAL AUTHORITY.—Each Federal agency may permit the director of any of its Government-operated Federal laboratories, and, to the extent provided in an agency-approved joint work statement, the director of any of its Government-owned, contractor-operated laboratories—

(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and

(2) to negotiate licensing agreements under section 207 of title 35, United States Code, or under other authorities (in the case of a Government-owned, contractor-operated laboratory, subject to subsection (c) of this section) for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that may be voluntarily assigned to the Government.

(b) ENUMERATED AUTHORITY.—

(1) Under an agreement entered into pursuant to subsection (a)(1), the laboratory may grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, *or, subject to section 209 of title 35, United States Code, may grant a license to an invention which is federally owned, made before the signing of the agreement, and directly related to the scope of the work under the agreement,* for reasonable compensation when appropriate. The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement or, if there is more than one collaborating party, that the collaborating parties are offered the option to hold licensing rights that collectively encompass the rights that would be held under such an exclusive license by

one party. In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions:

(A) A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of section 552(b)(4) of title 5, United States Code, or which would be considered as such if it had been obtained from a non-Federal party.

(B) If a laboratory assigns title or grants an exclusive license to such an invention, the Government shall retain the right—

(i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention in the applicant's licensed field of use, on terms that are reasonable under the circumstances; or

(ii) if the collaborating party fails to grant such a license, to grant the license itself.

(C) The Government may exercise its right retained under subparagraph (B) only in exceptional circumstances and only if the Government determines that—

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the collaborating party;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the collaborating party; or

(iii) the collaborating party has failed to comply with an agreement containing provisions described in subsection (c)(4)(B).

This determination is subject to administrative appeal and judicial review under section 203(2) of title 35, United States Code.

(2) Under agreements entered into pursuant to subsection (a)(1), the laboratory shall ensure that a collaborating party may retain title to any invention made solely by its employee in exchange for normally granting the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

(3) Under an agreement entered into pursuant to subsection (a)(1), a laboratory may—

(A) accept, retain, and use funds, personnel, services, and property from a collaborating party and provide personnel, services, and property to a collaborating party;

(B) use funds received from a collaborating party in accordance with subparagraph (A) to hire personnel to carry

out the agreement who will not be subject to full-time-equivalent restrictions of the agency;

(C) to the extent consistent with any applicable agency requirements or standards of conduct, permit an employee or former employee of the laboratory to participate in an effort to commercialize an invention made by the employee or former employee while in the employment or service of the Government; and

(D) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party.

(4) A collaborating party in an exclusive license in any invention made under an agreement entered into pursuant to subsection (a)(1) shall have the right of enforcement under chapter 29 of title 35, United States Code.

(5) A Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement pursuant to subsection (a)(1) may use or obligate royalties or other income accruing to the laboratory under such agreement with respect to any invention only—

(A) for payments to inventors;

(B) for purposes described in clauses (i), (ii), (iii), and (iv) of section 14(a)(1)(B); and

(C) for scientific research and development consistent with the research and development missions and objectives of the laboratory.

(c) CONTRACT CONSIDERATIONS.—

(1) A Federal agency may issue regulations on suitable procedures for implementing the provisions of this section; however, implementation of this section shall not be delayed until issuance of such regulations.

(2) The agency in permitting a Federal laboratory to enter into agreements under this section shall be guided by the purposes of this Act.

(3)(A) Any agency using the authority given it under subsection (a) shall review standards of conduct for its employees for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority, including but not limited to cases where present or former employees or their partners negotiate licenses or assignments of titles to inventions or negotiate cooperative research and development agreements with Federal agencies (including the agency with which the employee involved is or was formerly employed).

(B) If, in implementing subparagraph (A), an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

(4) The laboratory director in deciding what cooperative research and development agreements to enter into shall—

(A) give special consideration to small business firms, and consortia involving small business firms; and

(B) give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, take into consideration whether or not such foreign government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements.

(5)(A) If the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement presented by the director of a Government-operated laboratory, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

(B) In any case in which the head of an agency or his designee disapproves or requires the modification of an agreement presented by the director of a Government-operated laboratory under this section, the head of the agency or such designee shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

(C)(i) Except as provided in subparagraph (D), any agency which has contracted with a non-Federal entity to operate a laboratory shall review and approve, request specific modifications to, or disapprove a joint work statement that is submitted by the director of such laboratory within 90 days after such submission. In any case where an agency has requested specific modifications to a joint work statement, the agency shall approve or disapprove any resubmission of such joint work statement within 30 days after such resubmission, or 90 days after the original submission, whichever occurs later. No agreement may be entered into by a Government-owned, contractor-operated laboratory under this section before both approval of the agreement under clause (iv) and approval under this clause of a joint work statement.

(ii) In any case in which an agency which has contracted with a non-Federal entity to operate a laboratory disapproves or requests the modification of a joint work statement submitted under this section, the agency shall promptly transmit a written explanation of such disapproval or modification to the director of the laboratory concerned.

(iii) Any agency which has contracted with a non-Federal entity to operate a laboratory or laboratories shall develop and provide to such laboratory or laboratories one or more model cooperative research and development agreements, for the purposes of standardizing practices and procedures, resolving com-

mon legal issues, and enabling review of cooperative research and development agreements to be carried out in a routine and prompt manner.

(iv) An agency which has contracted with a non-Federal entity to operate a laboratory shall review each agreement under this section. Within 30 days after the presentation, by the director of the laboratory, of such agreement, the agency shall, on the basis of such review, approve or request specific modification to such agreement. Such agreement shall not take effect before approval under this clause.

(v) If an agency fails to complete a review under clause (iv) within the 30-day period specified therein, the agency shall submit to the Congress, within 10 days after the end of that 30-day period, a report on the reasons for such failure. The agency shall, at the end of each successive 30-day period thereafter during which such failure continues, submit to the Congress another report on the reasons for the continuing failure. Nothing in this clause relieves the agency of the requirement to complete a review under clause (iv).

(vi) In any case in which an agency which has contracted with a non-Federal entity to operate a laboratory requests the modification of an agreement presented under this section, the agency shall promptly transmit a written explanation of such modification to the director of the laboratory concerned.

(D)(i) Any non-Federal entity that operates a laboratory pursuant to a contract with a Federal agency shall submit to the agency any cooperative research and development agreement that the entity proposes to enter into with a small business firm and the joint work statement required with respect to that agreement.

(ii) A Federal agency that receives a proposed agreement and joint work statement under clause (i) shall review and approve, request specific modifications to, or disapprove the proposed agreement and joint work statement within 30 days after such submission. No agreement may be entered into by a Government-owned, contractor-operated laboratory under this section before both approval of the agreement and approval of a joint work statement under this clause.

(iii) In any case in which an agency which has contracted with an entity referred to in clause (i) disapproves or requests the modification of a cooperative research and development agreement or joint work statement submitted under that clause, the agency shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

(6) Each agency shall maintain a record of all agreements entered into under this section.

(7)(A) No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of title 5, United States Code, which is obtained in the conduct of research or as a result of activities under this Act from a non-Federal party participating in a cooperative research and development agreement shall be disclosed.

(B) The director, or in the case of a contractor-operated laboratory, the agency, for a period of up to 5 years after development of information that results from research and development activities conducted under this Act and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement, may provide appropriate protections against the dissemination of such information, including exemption from subchapter II of chapter 5 of title 5, United States Code.

(d) DEFINITIONS.—As used in this section—

(1) the term “cooperative research and development agreement” means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31, United States Code;

(2) the term “laboratory” means—

(A) a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government;

(B) a group of Government-owned, contractor-operated facilities (including a weapon production facility of the Department of Energy) under a common contract, when a substantial purpose of the contract is the performance of research and development, or the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, for the Federal Government; and

(C) a Government-owned, contractor-operated facility (including a weapon production facility of the Department of Energy) that is not under a common contract described in subparagraph (B), and the primary purpose of which is the performance of research and development, or the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, for the Federal Government,

but such term does not include any facility covered by Executive Order No. 12344, dated February 1, 1982, pertaining to the naval nuclear propulsion program;

(3) the term “joint work statement” means a proposal prepared for a Federal agency by the director of a Government-owned, contractor-operated laboratory describing the purpose and scope of a proposed cooperative research and development agreement, and assigning rights and responsibilities among the

agency, the laboratory, and any other party or parties to the proposed agreement; and

(4) the term “weapon production facility of the Department of Energy” means a facility under the control or jurisdiction of the Secretary of Energy that is operated for national security purposes and is engaged in the production, maintenance, testing, or dismantlement of a nuclear weapon or its components.

(e) DETERMINATION OF LABORATORY MISSIONS.—For purposes of this section, an agency shall make separate determinations of the mission or missions of each of its laboratories.

(f) RELATIONSHIP TO OTHER LAWS.—Nothing in this section is intended to limit or diminish existing authorities of any agency.

(g) PRINCIPLES.—In implementing this section, each agency which has contracted with a non-Federal entity to operate a laboratory shall be guided by the following principles:

(1) The implementation shall advance program missions at the laboratory, including any national security mission.

(2) Classified information and unclassified sensitive information protected by law, regulation, or Executive order shall be appropriately safeguarded.

§ 3710c. Distribution of royalties received by Federal agencies

(a) IN GENERAL.—

(1) Except as provided in paragraphs (2) and (4), any royalties or other payments received by a Federal agency from the licensing and assignment of inventions under agreements entered into by Federal laboratories under section 12, and from the licensing of inventions of Federal laboratories under section 207 of title 35, United States Code, or under any other provision of law, shall be retained by the laboratory which produced the invention and shall be disposed of as follows:

(A)(i) The head of the agency or laboratory, or such individual’s designee, shall pay each year the first \$2,000, and thereafter at least 15 percent, of the royalties or other payments to the inventor or **coinventors.** *coinventors, if the inventor’s or coinventor’s rights are assigned to the United States.*

(ii) An agency or laboratory may provide appropriate incentives, from royalties, or other payments, to laboratory employees who are not an inventor of such inventions but who substantially increased the technical value of such inventions.

(iii) The agency or laboratory shall retain the royalties and other payments received from an invention until the agency or laboratory makes payments to employees of a laboratory under clause (i) or (ii).

(B) The balance of the royalties or other payments shall be transferred by the agency to its laboratories, with the majority share of the royalties or other payments from any invention going to the laboratory where the invention occurred. The royalties or other payments so transferred to any laboratory may be used or obligated by that laboratory during the fiscal year in which they are received or during

the ~~【succeeding fiscal year—】~~ *the 2 succeeding fiscal years—*

(i) to reward scientific, engineering, and technical employees of the laboratory, including developers of sensitive or classified technology, regardless of whether the technology has commercial applications;

(ii) to further scientific exchange among the laboratories of the agency;

(iii) for education and training of employees consistent with the research and development missions and objectives of the agency or laboratory, and for other activities that increase the potential for transfer of the technology of the laboratories of the agency;

(iv) for payment of expenses incidental to the administration and licensing of intellectual property by the agency or laboratory with respect to inventions made at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual property management and licensing services; or

(v) for scientific research and development consistent with the research and development missions and objectives of the laboratory.

(C) All royalties or other payments retained by the agency or laboratory after payments have been made pursuant to subparagraphs (A) and (B) that is unobligated and unexpended at the end of the second fiscal year succeeding the fiscal year in which the royalties and other payments were received shall be paid into the Treasury.

(2) If, after payments to inventors under paragraph (1), the royalties or other payments received by an agency in any fiscal year exceed 5 percent of the budget of the Government-operated laboratories of the agency for that year, 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent may be used or obligated under paragraph (1)(B). Any funds not so used or obligated shall be paid into the Treasury of the United States.

(3) Any payment made to an employee under this section shall be in addition to the regular pay of the employee and to any other awards made to the employee, and shall not affect the entitlement of the employee to any regular pay, annuity, or award to which he is otherwise entitled or for which he is otherwise eligible or limit the amount thereof. Any payment made to an inventor as such shall continue after the inventor leaves the laboratory or agency. Payments made under this section shall not exceed \$150,000 per year to any one person, unless the President approves a larger award (with the excess over \$150,000 being treated as a Presidential award under section 4504 of title 5, United States Code).

(4) A Federal agency receiving royalties or other payments as a result of invention management services performed for another Federal agency or laboratory under section 207 of title 35, United States Code, may retain such royalties or payments to the extent required to offset payments to inventors under

clause (i) of paragraph (1)(A), costs and expenses incurred under clause (iv) of paragraph (1)(B), and the cost of foreign patenting and maintenance for any invention of the other agency. All royalties and other payments remaining after offsetting the payments to inventors, costs, and expenses described in the preceding sentence shall be transferred to the agency for which the services were performed, for distribution in accordance with paragraph (1)(B).

(b) CERTAIN ASSIGNMENTS.—If the invention involved was one assigned to the Federal agency—

(1) by a contractor, grantee, or participant, or an employee of a contractor, grantee, or participant, in an agreement or other arrangement with the agency, or

(2) by an employee of the agency who was not working in the laboratory at the time the invention was made,
the agency unit that was involved in such assignment shall be considered to be a laboratory for purposes of this section.

(c) REPORTS.—

(1) In making their annual budget submissions Federal agencies shall submit, to the appropriate authorization and appropriation committees of both Houses of the Congress, summaries of the amount of royalties or other income received and expenditures made (including inventor awards) under this section.

(2) The Comptroller General, five years after the date of the enactment of this section, shall review the effectiveness of the various royalty-sharing programs established under this section and report to the appropriate committees of the House of Representatives and the Senate, in a timely manner, his findings, conclusions, and recommendations for improvements in such programs.

TITLE 35—PATENTS

PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

CHAPTER 18—PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

§ 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 contractor is not located in the United States or does not have a place of business located in the United States or 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, (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) 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 (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), 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 every five years, 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) 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 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 (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (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.

(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.]

(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 may, for the purpose of consolidating rights in the invention—

(1) *license or assign whatever rights it may acquire in the subject invention to the nonprofit organization or small business firm; or*

(2) *acquire any rights in the subject invention from the nonprofit organization or small business firm, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction.*

(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.

§ 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,**]** *inventions* 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;**]** *contract, including acquiring rights for the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally-owned invention;* 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.

§ 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 non-exclusive 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.]

§209. Licensing federally-owned inventions

(a) *AUTHORITY.*—A Federal agency may grant an exclusive or partially exclusive license on a federally-owned invention only if—

(1) *granting the license is a reasonable and necessary incentive to—*

(A) *call forth the investment capital and expenditures needed to bring the invention to practical application; or*

(B) *otherwise promote the invention's utilization by the public;*

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

(3) *the applicant makes a commitment to achieve practical utilization of the invention within a reasonable time;*

(4) *granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; 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) **MANUFACTURE IN UNITED STATES.**—*A Federal agency shall normally grant any license to use or sell any federally-owned invention in the United States 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.*

(c) **SMALL BUSINESS.**—*First preference for the granting of any exclusively or partially exclusive licenses under this section shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.*

(d) **TERMS AND CONDITIONS.**—*Any licenses granted under section 207 shall contain such terms and conditions as the granting agency considers appropriate. Such terms and conditions—*

(1) *shall include provisions—*

(A) *retaining a nontransferable, irrevocable, paid-up license for the Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;*

(B) *requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with; and*

(C) *empowering 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 utilization 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 utilization of the invention;

(ii) the licensee is in breach of an agreement described in subsection (b);

(iii) 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; or

(iv) the licensee has been found by a competent authority to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(e) *PUBLIC NOTICE.*—No exclusive or partially exclusive license may be granted under this section unless public notice of the intent to grant such a license has been provided at least 30 days before the license is granted, and the Federal agency has considered all comments received in response to that public notice.

(f) *DEVELOPMENT PLAN.*—A Federal agency may grant a license on a federally-owned invention only if the person requesting the license has supplied to the agency a basic business plan with development or commercialization milestones. Each Federal agency, in consultation with the Small Business Administration, shall develop consistent standards for exempting small business firms from the requirements of this subsection for non-exclusive licenses.

(g) *NONDISCLOSURE OF CERTAIN INFORMATION.*—An application shall include, as an independent subdocument a detailed description of the applicant's plan for development or marketing (or both) of the invention. The subdocument, which is exempt from disclosure under section 552 of title 5, United States Code, shall include only a statement—

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

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

(3) of the fields of use for which the applicant intends to practice the invention; and

(4) of the geographic areas—

(A) in which the applicant intends to manufacture any product embodying the invention;

(B) where the applicant intends to use or sell the invention; or

(C) both.