

\_\_\_\_ CONGRESS

\_\_\_\_ SESSION

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(NOTE.—Fill in all blank lines except those provided for the date, number, and reference of bill.)

IN THE SENATE OF THE UNITED STATES

Mr. Dole, for himself and Mr. Bayh

introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

**A BILL**

To amend Title 35 of the United States Code; to establish a uniform Federal patent procedure for small businesses and nonprofit organizations; to create a consistent policy and procedure concerning patentability of inventions made with federal assistance; and for other related purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Small Business Nonprofit Organization Patent Procedures Act."*

Sec. 2 Amendment of Title 35, United States Code, Patents. Title 35 of the United States Code is amended by adding after Chapter 17, a new chapter as follows:

CHAPTER 18 - PATENTABILITY OF INVENTIONS MADE WITH FEDERAL ASSISTANCE

- Sec.
- 200. Policy and Objective
- 201. Definitions.
- 202. Disposition of Rights.
- 203. March-in Rights.
- 204. Return of Government Investment.
- 205. Preference for United States Industry.
- 206. Confidentiality.
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- 208. Relationship to Anti-trust Laws.
- 209. Uniform Clauses.
- 210. Foreign Patent Protection and Federally Owned Patents.
- 211. Regulations Governing Federal Licensing and Small Business Preference
- 212. Coordination of Federal Licensing Practices.
- 213. Restrictions on Exclusive and Partially Exclusive Licenses of Federally Owned Patents.
- 214. Precedence of Chapter.
- 215. Effective Date.

Section 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 by nonprofit organizations and small business firms; 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.

Section 201. Definitions. As used in this Chapter--

(a) The term "Federal agency" means any "executive agency" as defined in 5 USC 105, and the military department, as defined by 5 USC 102,

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency and any person 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 "subject inventor" means any person that is a party to funding agreement.

(d) The term "subject invention" means any invention of the subject inventor conceived or first actually reduced to practice in the performance of work under a contract.

(e) 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 from the subject inventor or licensee or assignee of the subject inventor.

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

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

(h) The term "nonprofit organization" means universities and other institutions of higher education and organizations 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 USC 501(a)).

#### Section 202. Disposition of Rights.

(a) Each nonprofit organization or small business firm may, within a reasonable time, elect to retain title to any subject invention; provided, however, that each Federal agency may promulgate regulations otherwise (i) when the subject invention is made under a contract for the operation of a Government-owned research or production facility, (ii) when such election to retain title might cause disclosure of classified information or otherwise impair national security; or (iii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title will better promote the policy and objective of this Chapter. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (b) of this section and the other provisions of this Chapter.

(b) The subject inventor shall disclose to each Federal agency which is a party to a funding agreement under which the subject invention was made within a reasonable time after the making of a subject invention, and in any event at least 6 months before public disclosure thereof, the subject matter of the subject invention and whether the subject inventor intends to retain title to the subject invention or to relinquish title to the Government. The subject inventor shall file United States patent applications where appropriate within a reasonable time from making such disclosure and not later than six months after filing such United States applications shall inform the Federal agency as to the foreign countries in which the subject inventor intends to file patent applications.

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

(1) The right of the Federal Government, upon request, to receive title to any subject invention not reported to the Federal agency within such times as are prescribed in Section 4(b) hereof and in the regulations promulgated hereunder.

(2) The right of the Federal Government, upon request, to receive title to any subject inventions in the United States or other countries in which the subject inventor has not filed patent applications on a subject invention within such times as are prescribed in Section 4 (b) and in the regulations promulgated hereunder.

(3) The right of the Federal Government, upon request, to receive title to any subject invention in which the subject inventor does not elect to retain rights or fails to elect rights within such times as are prescribed in Section 4 (b) and in the regulations promulgated hereunder.

(4) With respect to any invention in which the subject inventor elects rights, the Federal agency shall have a nonexclusive, non-transferable, 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 pursuant to foreign policy considerations or any existing or future treaty or agreement.

(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 subject inventor or his licensees or assignees; 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 the Freedom of Information Act.

(6) An obligation on the part of the subject inventor, in the event a United States patent application is filed by or on its behalf or by any assignee of the subject inventor, 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 having prior approval of the Federal agency which has as one of its primary functions the management of inventions and which is not, itself, engaged in the manufacture or sale of products or processes that might utilize the invention or be in competition with embodiments of the invention and provided that such assignment is made subject to regulations promulgated hereunder governing rights in inventions and assignments of subject inventions; (b) a prohibition against the granting of exclusive licenses under United States Letters Patent in a subject invention by the Contractor or by a person deriving rights directly or indirectly from the Contractor 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. Exclusive field of use licenses may be granted and commercial sale or use in one field of use shall not be deemed to end the exclusive period as to unrelated fields of use.

(c) a requirement that the balance of any royalties or income earned by the subject inventor with respect to subject inventions, after payment of expenses (including any payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education.

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

(9) In any case when a Federal employee is a co-inventor of any subject invention under this Chapter, the Federal agency employing such co-inventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employee to a subject inventor electing to acquire rights hereunder subject to the conditions set forth in this Chapter.

Section 203. March-in Rights. 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 subject inventor, 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 either --

(a) That such action is necessary because the subject inventor 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; or

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

(c) That such 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.

Section 204. Return of Government Investment.

(a) If a nonprofit organization or small business firm receives \$250,000 in after tax profits from the licensing of any subject invention, in a period of ten years following reporting of the invention the United States shall be entitled to a share, to be negotiated, of up to 50% of all net income during said period from licensing received by the contractor above \$250,000; provided, however, that in no event shall the United States be entitled to an amount greater than that portion of the Federal funding under the funding agreement under which the subject invention was made which was expended on activities related to the making of the invention.

(b) In addition, if a nonprofit organization or small business firm receives after tax profits in excess of \$2,000,000 on sales of products embodying or manufactured by a process employing a subject invention, during a period of ten years commencing with commercial exploitation of the subject invention, the Government shall be entitled to a share, to be negotiated, of all additional income accruing from such sales up to the amount of the portion of the Government funding under



the contract under which the invention was made which was expended on activities related to the making of the invention less any amounts received by the Government in accordance with paragraph (a) of this section 7.

(c) The Director of the Office of Federal Procurement Policy is authorized and directed to revise the figures of \$250,000 and \$2,000,000 in paragraphs (a) and (b) of this section at least every three years in light of changes to the consumer price index or other indices which he considers reasonable to use.

Section 205. Preference for United States Industry.

(a) Notwithstanding any other provision of this Chapter, no small business firm or nonprofit organization which receives title to any subject invention and no person which receives an assignment of the subject invention shall assign the right to practice such invention in the United States or grant an exclusive license to practice the invention in the United States to any foreign corporation or any other organization substantially owned or controlled by foreign interests. However, in individual cases, this restriction may be waived by the Federal agency under whose funding agreement the invention was made.

(b) Notwithstanding any other provision of this Chapter, no small business firm or nonprofit organization which receives title to a subject invention and no person which receives an assignment of the subject invention from them shall assign the right to practice the invention outside the United States or grant an exclusive license to practice the invention outside the United States to any foreign corporation or any other organization substantially owned or controlled by foreign interests unless it shall have first undertaken reasonable efforts, as defined by regulations promulgated pursuant to this Chapter, to interest domestic, United States organizations or corporations in such foreign rights.

Section 206. Confidentiality. Any report of a subject invention under this Chapter may be treated by the Federal agency as a record exempt from disclosure pursuant to 5 USC 552 (b) (4) unless (i) a United States patent application describing the invention has been filed (provided that copies of the actual patent



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application may be treated by the Federal agency as records exempt from disclosure pursuant to 5 USC 552 (b) (4)), (ii) a description of the invention has been published elsewhere by the inventor, (iii) the subject inventor has not elected to retain title and/or a subject inventor or inventor has not requested the retention of title or other commercial rights, or (iv) the subject inventor has not elected to retain title and/or the Federal agency has denied the request of the subject inventor or inventor to retain title or other commercial rights.

Section 207. Background Rights. Nothing in this Chapter shall be deemed to preclude a Federal agency from obtaining rights in any background invention of a subject inventor or other contractor.

Section 208. Relationship to Anti-trust Laws. Nothing in this Chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.

Section 209. Uniform Clauses. 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 establishing standard funding agreement provisions required under this Chapter.

Section 210. Foreign Patent Protection and Federally Owned Patents. 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) promote the licensing of inventions covered by federally owned patent applications, patents, or other forms of protection obtained with the objective of maximizing utilization by the public of the inventions covered thereby;

(3) 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 28 of title 35, United States Code, as determined appropriate in the public interests;

(4) make market surveys and other investigations for determining the potential of inventions for domestic and foreign licensing and other forms of utilization, acquire technical information, and engage in negotiations and other activities for promoting the licensing and for the purpose of enhancing their marketability and public utilization;

(5) withhold publication or release to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest for a reasonable time in order for a patent application to be filed;

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

(7) transfer custody and administration, in whole or in part, to the Department of Commerce or to another Federal agency, of the right, title, or interest in any invention for the purpose of carrying out the provisions of paragraphs (1) through (4), without regard to the provisions of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 471); and

(8) designate the Department of Commerce as recipient of any or all funds received from fees, royalties, or other management of federally owned inventions authorized under this Act.

Section 211. Regulations Governing Federal Licensing and Small Business Preference. The Administrator of General Services is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention may be licensed on a nonexclusive, partially exclusive, or exclusive basis. First preference in licensing federally owned inventions shall go to small business firms.

Section 212. Coordination of Federal Licensing Practices. The Secretary of Commerce is authorized in cooperation with other Federal agencies to--

(1) coordinate a program for assisting all Federal agencies in carrying out the authority set forth in section 401;

(2) publish notification of all federally owned inventions that are available for licensing;

(3) evaluate inventions referred by Federal agencies, and patent applications filed thereon, in order to identify those inventions with the greatest commercial potential and to insure promotion and utilization by the public of inventions so identified;

(4) assist the Federal agencies in seeking and maintaining protection on inventions in the United States and in foreign countries, including the payment of fees and costs connected therewith;

(5) accept custody and administration, in whole or in part, of the right, title, and interest in any invention for the purposes set forth in paragraphs (1) through (4) of section 210, with the approval of the Federal agency concerned and without regard to the provisions of the Federal Property and Administrative Service Act of 1949 (40 U.S.C. 471);

(6) receive funds from fees, royalties, or other management of federally owned inventions authorized under this Chapter, but such funds shall be used only for the purposes of this Chapter; and

(7) undertake such other functions directly or through such contracts as are necessary and appropriate to accomplish the purposes of this title.

Section 213. Restrictions on Exclusive and Partially Exclusive Licenses of Federally Owned Patents. (a) (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.

(b) 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 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.

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

(d) Any grant of an exclusive or partially exclusive 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 written reports at reasonable intervals including, when specifically requested by the Federal agency, the extent of the commercial or other use by the public that is being made or is intended to be made of the invention;

(2) a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for the Federal Government the licensed invention throughout the world by or on behalf of the Federal Government (including any Federal agency), and the additional right to sublicense any State or domestic local government or to sublicense any foreign government pursuant to foreign policy considerations, or any treaty or agreement if the Federal agency determines it would be in the national interest to retain such additional rights;

(3) the right of the Federal agency to terminate such license in whole or in part unless the licensee demonstrates to the satisfaction of the Federal agency that the licensee has taken effective steps, or within a reasonable time is expected to take such steps, to accomplish substantial commercial or other use of the invention by the public; and

(4) the right of the Federal agency, commencing three years after the grant of a license, to require the licensee to grant a nonexclusive or partially exclusive license to a responsible applicant, upon terms reasonable under the circumstances to terminate the license in whole or in part, after

public notice and opportunity for a hearing, upon a petition by an interested person justifying such hearing, if the Federal agency determines, upon review of such material as it determines relevant and after the licensee or other interested person has had the opportunity to provide such relevant and material information as the Federal agency may require, that such license has tended substantially to lessen competition or to result in undue concentration in any section of the country in any line of commerce to which the technology relates, or to create or maintain other situations inconsistent with the anti-trust laws.

Section 214. Precedence of Act. This Chapter shall take precedence over any other act which would require a disposition of rights in subject inventions in a manner that is inconsistent with this Chapter, including but not necessarily limited to the following:

- (1) Section 10(a) of the Act of June 29, 1935, as added by Title 1 of the Act of August 14, 1946, (7 USC 427i(a); 60 Stat. 1085);
- (2) Section 205(a) of the Act of August 14, 1946 (7 USC 1624(a); 60 Stat. 1090);
- (3) Section 501(c) of the Federal Coal Mine Health and Safety Act of 1969 (30 USC 951(c); 83 Stat. 742);
- (4) Section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 USC 1935(c); 80 Stat. 721);
- (5) Section 12 of the National Science Foundation Act of 1950 (42 USC 1871(a); 82 Stat. 360);
- (6) Section 152 of the Atomic Energy Act of 1954 (42 USC 2182, 68 Stat. 943);
- (7) Section 305 of the National Aeronautics and Space Act of 1958 (42 USC 2457);
- (8) Section 6 of the Coal Research Development Act of 1960 (30 USC 666; 74 Stat. 337);
- (9) Section 4 of the Helium Act Amendments of 1960 (50 USC 167b; 74 Stat. 920);
- (10) Section 32 of the Arms Control and Disarmament Act of 1961 (22 USC 2572; 75 Stat. 634);

- (11) Subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 USC App. 302(e); 79 Stat. 5);
- (12) Subsection (a)(2) of section 216 of title 38, United States Code;
- (13) Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 USC 5901; 88 Stat. 1878);
- (14) Section 3 of the Act of June 22, 1976 (42 USC 1959d, note; 90 Stat. 694);
- (15) Subsection (d) of section 6 of The Saline Water Conversion Act of 1971 (42 USC 1959(d); 85 Stat. 161);
- (16) Section 303 of the Water Resources Research Act of 1964 (42 USE 1961c-3; 78 Stat. 332);
- (17) Section 5(d) of the Consumer Product Safety Act (15 USC 2054 (d); 88 Stat. 1211);
- (18) Section 3 of the Act of April 5, 1944 (30 USC 323; 58 Stat. 191); and
- (19) Section 8001 of the Solid Waste Disposal Act (42 USC 6981; 90 Stat. 2829).

The Act creating this Chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

Section 215. Effective Date. This Chapter shall take effect 180 days after the date of enactment of this Chapter, except that the regulations referred to in Section 12, or other implementing regulations, may be issued prior to that time.



## SECTION-BY-SECTION ANALYSIS

Outlined below are a number of important features of the bill:

Section 202 provides that each nonprofit organization (defined in the bill to include universities) and small business shall have a reasonable amount of time to elect to retain title to subject inventions. The federal agency may retain title if the invention is made under a contract for operation of a government owned research or production facility, might cause the disclosure of classified information or imperil national security, or if granting patents would not be in the public interest in terms of the purpose to be served by this legislation.

Section 202(c) provides that each funding agreement shall contain provisions to: (1) insure the right of the federal government to receive title to any subject invention not reported to it within the prescribed times of the contract; (2) insure the government's right to receive title to inventions when the inventor does not intend to file for patent rights; and (3) provide that the agency shall have a nonexclusive, nontransferable, paid-up license to use the invention.

Section 202 (c) (7) prohibits nonprofit institutions from assigning rights without the approval of the federal agency; prohibits granting such rights in excess of the earlier of 5 years from the date of first commercial use or 8 years from the date of invention, whichever comes first; and provides that all proceeds shall be used to support scientific research or education.

Section 203 gives the federal agency the right to require the subject inventor or his assignee to grant additional licenses if the agency feels that sufficient steps are not being taken to achieve commercialization. Additional licensing may also be required to alleviate health and safety needs, or under provisions for public use as specified by federal regulations.

Section 204 provides that if the patent holder receives \$250,000 in after tax profits from licensing any subject invention during a ten-year period, or receives in excess of \$2,000,000 on the sales of products embodying or manufactured by a process employing the subject invention within the ten-year period, that the government shall be entitled to collect up to 50% of all net income above these figures until such time as the amount of government research money has been repaid.

Section 205 specifies that no foreign owned or controlled firm shall be eligible to receive patent rights under this Act unless the federal agency determines that this is the only available means of achieving commercialization; a similar provision covers licensing the invention outside the U.S.

Section 210 will allow federal agencies to grant exclusive, partially exclusive, or non-exclusive licenses on government owned patents to achieve commercialization; the Department of Commerce is authorized to receive patents held by other agencies and to make the necessary steps to determine the market potential of the patent and to receive any fees or royalties due to the government.

Section 211 authorizes the Administrator of GSA to issue regulations regarding such licenses and gives first preference in licensing federal patents to small businesses.

Section 213 specifies that federal licenses be issued only after public notification and opportunity for filing objections and that exclusive or partially exclusive licenses not be granted if the result would be a lessening of competition; the agency has the right to require more licensing if it feels that this is necessary after three years and to require periodic written reports on progress toward commercialization.

A COPY OF THE BILL IS INCLUDED IN THE PRESS PACKET.