SECTIONAL ANALYSIS

OF THE

UNIVERSITY AND SMALL BUSINESS RESEARCH UTILIZATION ACT OF 1978

Section 1

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The official title of the Act is given in section 1 as the "University and Small Business Research Utilization Act of 1978." The Act deals with Government patent policy with respect to (1) universities and nonprofit organizations and (2) small business firms performing research with Government support, but does not establish policy with respect to contracts with larger, commercial concerns. Thus the Act focuses on two distinct classes of performers of Government R & D. It is believed that the principles that should be applied to these performers are clear and noncontroversial. Arguments raised against leaving rights in inventions to larger Government contractors, to the extent they are valid, clearly have no relevance when applied either to small business firms or to universities and nonprofit organizations that are not engaged in commerce. Indeed, if such arguments were accepted and applied with respect to these two groups, it is clear that a result opposite to that desired would occur.

Section 2

Section 2 sets forth the relevant findings that support the operative sections of the Act. The significant role of small business firms, universities, and nonprofit organizations in the performance of Government sponsored research is recognized. The need for additional private investment in inventions made by such organizations is also recognized as necessary for commercialization of such inventions. The fourth finding recognizes that Government patent policy can play an important role in promoting the commercial use of such inventions, and that patent policy should also be designed to meet the equities of the parties and to promote other goals. Among the latter are listed the promotion of universityindustry collaboration, small business participation in Government R & D programs, and the growth and competitive position of small business firms. Finally, it is recognized that Government patent policy must also meet the needs of the Government.

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Section 3

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Section 3 provides the basic framework for the allocation of rights to inventions made by universities and nonprofit organizations with Government support. It is designed to provide the minimal but critical rights needed to bring about commercialization of these inventions. At the same time sufficient safeguards are required to allow the Government the means to promote effective commercialization when a university or nonprofit organization either fails to elect rights in an invention or fails to achieve commercialization of an invention to which it elects rights. Section 3(a) provides that as a normal rule university and nonprofit organization grants and contracts are to contain a provision allowing the organization to elect to retain title to inventions subject to various terms and conditions as set forth in section 3(c) and 3(d). It also contemplates that the standard clause would include other administrative conditions dealing with such things as reporting time periods and patent application filing time periods.

Section 3(b) sets forth three situations in which Federal agencies may use different patent provisions. Section 3(b)(l) recognizes that in so-called "GOCO" situations, the contractor may have little equity, and the situation may be more suitable for direct Government licensing efforts. Or agencies might wish to use deferred determination clauses in such situations and decide the best way to promote identified inventions on a case-by-case basis. Section 3(b)(2) recognizes that classified work relating to the national security may require different patent provisions. Section 3(b)(3) recognizes that in isolated cases there may be reason for the Government to take title or defer determinations of rights. Possibly this might be the case in some projects where the Government plans to carry the research through full development and marketing.

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Section 3(c) is designed to ensure that the needs of the Federal Government and the public are fully protected. It requires provisions in the standard contract provisions to allow the Government to obtain title to inventions in which the university does not elect title or which were not reported to the Government within the times prescribed in the standard clause. It also allows the Government to take title in instances when the university fails to have a foreign or U. S. patent application filed, as the case may be. And though every detail is not spelled out, it is, of course, expected that the standard clause would have other provisions allowing the Government to take title in cases where patent applications are filed but not prosecuted or where patents are not maintained.

In cases where the contractor elects rights, the Government would obtain a royalty-free license for Governmental use. To ensure that the rights obtained by the university are not simply sold to the highest bidder, assignments are barred expect to patent management organizations unless the Federal agency approves of the assignment. Limits are placed on the period of exclusive license of U. S. rights.

Universities and nonprofit organizations would also be required to provide periodic reports on their licensing activities. And the Government is given the right to require licensing in fields of use where the contractor or its licensees are failing to take reasonable steps to bring the invention to the point of practical application. This could mean either non-use or commercialization on a scale insufficient to satisfy market demand or on terms that are unreasonable.

Section 3(c) also provides that in cases where a univeristy makes sizable royalty income a portion of the net income will be returned to the Government. Royalty sharing is required where the returns are substantial (above \$250,000) so as to prevent the destruction of the incentive for universities to engage in licensing activity. In no event is the Government to receive more than it actually contributed to the making of the invention under the applicable contract or grant. In most cases this will be less than the total amount of the contract under which the invention was made. For example, it is likely that the contract will have involved activities subsequent to the making of an invention. It may also have funded activities of various investigators who were not inventors and who were working on aspects of the project unrelated to the invention. It is expected that the agency and the university will negotiate the agreed-to amount as well as a formula for royalty sharing above the \$250,000 figure. The Office of Federal Procurement Policy is given authority to revise the threshold figure in light of general price changes.

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Finally, section 3(c) requires that any net income from inventions be used to promote education or scientific research.

Section 3(d) requires the use of a subcontract provision that is designed to prevent any subcontractors that are not themselves universities or nonprofit organizations from automatically getting title to their inventions. Case-by-case agency approval either at the time of subcontracting or after an invention is identified would be required for title to be left in commercial subcontractors.

The following is envisioned as the type of standard contract provision that would meet the requirements of sections 3(a), (c), and (d). With appropriate modification a similar clause could be used to implement section 4:

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PATENT RIGHTS - UNIVERSITIES AND NONPROFIT ORGANIZATIONS

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(a) Definitions

(1) "Invention" means any invention or discovery and includes any art, method, process, machine, manufacture, design or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable or otherwise protectable under the laws of the United States.

(2) "Subject invention" means any invention of the awardee conceived or first actually reduced to practice in the course of or under an award.

(3) "Award" means any contract, grant, or cooperative agreement entered into between the agency and any person for the performance of experimental, developmental, or research work substantially funded by the agency, and includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under an award.

(4) "Awardee" means the recipient of an award.

(5) "Agency" means the "executive agency" as defined at 5 U.S.C. 105 or the "military department" as defined at 5 U.S.C.
 102 that has made the award.

(6) "To bring to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine or system and, in any case, under such conditions as to establish that the invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements.

(7) "Made" when used in relation to any invention or discovery means the conception or first actual reduction to practice of such invention in the course of or under an award.

(b) Allocation of Principal Rights

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(1) (A) The awardee shall have the right to elect to retain the entire right, title, and interest throughout the world or in any countries thereof in and to each subject invention of the awardee submitted in an invention disclosure pursuant to (e) below, subject to the provisions of this clause. The awardee shall include with each invention disclosure an election as to whether or not it is exercising this right; provided that when the awardee desires additional time to determine the commercial potential of the invention, the awardee may request an extension of the election period. In such cases, the election must be made within such time as directed by the Agency. In the event a request for additional time is made and granted, the awardees shall (i) promptly advise

the of any decision not to elect rights and (ii) shall promptly notify the Agency of any on sale, public use, or publication of the invention of which it becomes aware after the time of its initial invention disclosure.

(B) At any time within 30 days from the date an awardee elects not to retain rights in a subject invention, any inventor of that invention may submit a request to the agency that he or she be allowed to retain title and principal rights in the invention. Such a request shall be subject to procedures set forth in applicable agency or other Government regulations.

(2) The awardee agrees to convey to the Government, upon request, the entire domestic right, title, and interest in any subject invention when the awardee:

(i) does not elect under paragraph (b)(1) to retain such rights; or

(ii) fails to have a United States Patent application filed on the invention in accordance with paragraph (e), or decides not to continue prosecution of such application; or
 (iii) at any time, no longer desires to retain title.

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(3) The awardee agrees to convey to the Government, upon request, the entire right, title, and interest in any subject invention in any foreign country when the awardee:

(i) does not elect under paragraph (b)(1) to retain such rights in the country; or

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(ii) fails to have a patent application filed in the country on the invention in accordance with paragraph (f), except that if an application has been filed in a foreign country after the time specified in paragraph (f) but prior to such request by the Government, the awardee shall retain the entire right, title, and interest in the Subject Invention in the country involved; or decides not to continue prosecution of such application or to pay any maintenance fees covering the invention. The awardee shall provide the agency with the earliest possible notice of any decision or contemplated decision to abandon a patent application or discontinue the payment of maintenance fees.

(4) A conveyance, requested pursuant to paragraph (b) (2) or (3), shall be made by delivering to the agency duly executed instruments (prepared by the agency) and such other papers as are deemed necessary to vest in the Government the entire right, title, and interest to enable the Government to apply for and prosecute patent applications covering the invention in this or the foreign country, respectively, or otherwise establish its ownership of such invention.

(c) Minimum Rights Acquired by the Government

(1) With respect to each subject invention to which the awardee retains principal or exclusive rights, the awardee:

(A) Hereby grants to the Government of the

United States a nonexclusive, nontransferable, paid-up license to make, use, and sell each subject invention throughout the world by or on behalf of the Government of the United States (including any Government agency).

(B) Hereby agrees to grant, upon the request of the agency, a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants in any field of use to an invention, upon terms reasonalbe under the circumstances; and further grants to the agency the right to issue such licenses itself if the awardee refuses to grant such licenses if the agency determines such action is necessary because the awardee has not taken, or is not expected to take within a reasonable time, effective steps to bring to the point of practical application the subject invention in such field of use. Any requests made pursuant to this paragraph shall be by the head of the agency or a duly authorized agent, and the awardee shall be given written notice of any proposed request not less than thirty days prior to the issuance of a formal request and, if the awardee so requests, a hearing shall be held before the request is issued and otherwise made effective.

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> (2) Nothing contained in this section shall be deemed to grant to the Government any rights with respect to any invention other than a subject invention.

> > (d) Invention Identification, Disclosure and Reports

The awardee shall furnish the agency a complete (1)technical disclosure for each subject invention promptly after the awardee has completed such technical evaluations and market studies that it finds necessary to determine whether an election to retain rights should be made; provided that in no event shall such disclosure be made later than two years after the subject invention is first known to awardee officials responsible for administering invention matters; and provided, further, the disclosure shall be made immediately in any case where publication or use has initiated the one-year statutory bar period for patenting. The disclosure shall identify the award and inventor(s) and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological, or

electrical characteristics of the invention. The disclosure shall include a statement as to whether or not the awardee is aware of any on sale, public use, or publication of the invention, and, if so, details shall be provided.

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(2) It is agreed and understood that each technical disclosure furnished under paragraph (d)(l) is submitted in confidence and is not to be disclosed outside the Government until after either a United States or foreign patent application has been filed by or on behalf of the awardee or until a description of the invention has been published elsewhere by the inventor or awardee, provided that the agency may duplicate and disclose any disclosure to which the awardee does not elect to retain rights beginning any time after 30 days from such non-election. However, if an inventor, in such a case, has made a timely request for rights, then the agency shall continue to hold the disclosure in confidence until such time as the agency determines that the inventor will not be allowed to retain rights.

(3) The awardee shall obtain patent agreements to effectuate the provisions of this clause from all persons in its employ who perform any part of the work under the award except nontechnical personnel, such as clerical employees and manual laborers.

(e) Filing of Domestic Patent Applications

(1) With respect to each subject invention in which the awardee elects to retain domestic rights pursuant to paragraph
(b) (1) of this clause, the awardee shall have a domestic patent application filed within six months after the election or such longer period as may be approved in writing by the agency.

(2) For each subject invention on which a U.S. patent application is filed by or on behalf of the awardee, the awardee shall: (A) within six months after the filing, or within six months after submission of the invention disclosure if the patent application was filed prior to the contract, deliver to the agency a duly executed and approved confirmation instrument on the form specified in paragraph (1).

(B) within six months after the filing, or within six months after submission of the invention disclosure if the patent application was filed prior to the award, notify the agency of the filing date and serial number of the application and deliver to the agency (a) a copy of that portion of the application as filed, which contains the statement required by paragraph (e)(2)(C), and (b) a copy of an assignment from the inventor or inventors to the institution of all right, title, and interest in the invention properly recorded in the United States Patent and Trademark Office;

(C)

include the following statement, appro-

(D) not less than thirty days before the expiration of the response period for any action required by the United States Patent and Trademark Office, notify the Agency of any decision not to continue the agency of the application and deliver to the agency executed instruments granting the Government a power of attorney;

(E) upon request, fully advise the agency concerning all actions taken during the prosecution of any patent application and furnish copies of any relevant documents as requested; and

 (F) provide the agency with a copy of the patent
 within six months after a patent issues on the application.

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(f) Filing of Foreign Patent Applications

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(a) With respect to each subject invention in which the awardee elects to retain principal rights in a foreign country pursuant to paragraph (b)(1) of this clause, the awardee shall have a patent application filed on the invention in that country, in accordance with applicable statutes and regulations, and within one of the following periods:

(i) eight months from the date of a corresponding United States application filed by or on behalf of the awardee, or if such an application is not filed, six months from the date an election is made pursuant to paragraph (b)(1) of this clause;

(ii) six months from the date a license is granted by the Commissioner of Patents and Trademarks to file foreign applications when such filing has been prohibited by security reasons; or

(iii) such longer period as may be approved by the agency.

(b) The awardee shall notify the agency of foreign applications filed and, upon request, shall furnish an English version of such application without additional compensation.

(g) Subcontracts

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(1) Except as provided in (2) below, the awardee shall include in any subcontract where a purpose of that subcontract is the conduct of experimental, developmental, or research work the following clause:

Patent Rights

(a) The Contractor hereby agrees to furnish a complete technical disclosure to the (Awardee) within six months after any invention is conceived or first actually reduced to practice in the course of or under this contract (hereinafter referred to as "subject inventions(s)") and, subject to (b), below, to assign all right, title, and interest in and to such invention to awardee or its designee.

(b) At the time the Contractor reports any "subject invention" to (Awardee) the Contractor, at its option, may also report the invention to the agency with which the institution holds the prime contract, and request that the agency make a determination whether and on what terms the contractor may retain principal rights in the invention in lieu of assigning it to Such determinations by the (Awardee) agency shall be in accordance with the policies and procedures of applicable agency or other Government regulations. Such determination shall be final on both the Contractor and (Awardee) provided that the Contractor may elect not to accept the agency's determination and instead assign all right title, and interest in the invention to or its de-(Awardee) signee.

(c) In addition, the Contractor agrees to furnish the following materials, disclosures and reports:

(ii) Prior to final settlement of this contract, upon request a final report listing all subject inventions or certifying that no inventions were conceived or first actually reduced to practice under the contract.

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(d) The Contractor shall include in any subcontract a clause identical to this clause, if a purpose of the subcontract is experimental, developmental, or research work. If a subcontractor refuses to accept this cluase or if, in the opinion of the Contractor, this clause is inconsistent with the policy set forth in 41 CFR 1-9. 107-3 and/or applicable agency regulations, the Contractor (i) shall promptly notify the Institution and (ii) shall not proceed with the subcontract without the written authorization of the Institution. It is understood that the Institution will seek direction from the appropriate federal agency.

(e) The Contractor shall not be obligated to enforce the agreements of any Subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to subject inventions.

(End of Subcontract Clause)

(2) In the event of a refusal by a subcontractor to accept the clause specified in (1), or if, in the opinion of the awardee, this clause is inconsistent with the policy set forth in agency regulations or 41 CFR 1-9 107-3, the awardee (i) shall promptly submit a written notice to the agency setting forth reasons for the Subcontractor's refusal and other pertinent information which may expedite disposition of the matter; and (ii) shall not proceed with the subcontract without the written authorization of the agency.

(3) It is understood that the Government is a third party beneficiary of any subcontract clause granting rights to the Government in subject inventions, and the awardee hereby assigns to the Government all rights that it would have to enforce the Subcontractor's obligations for the benefit of the Government with respect to subject inventions. The awardee shall not be obligated to enforce the agreement of any subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to subject invention.

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(4) Nothing in this Agreement is intended to preclude the awardee from granting a subcontractor rights or an option to rights in any inventions made by the subcontractor to the extent such rights are consistent with the provisions of this clause.

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(h) Administration of Inventions in which the Institution Elects to Retain Rights

(1) The awardee shall administer those subject inventions to which it elects to retain title in the public interest and shall, except as provided in subsection (2) below, make them available through licensing on a nonexclusive or exclusive, royaltyfree or reasonable royalty basis.

(2) Any exclusive license issued by the awardee under a U. S. patent or patent application shall be for a limited period of time and such period shall not, unless otherwise approved by the agency, exceed five years from the date of the first commercial sale or use in the United States of America of a product or process embodying the invention, or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance, whichever occurs first. However, commercial sale or use in one field of use of a subject invention shall not be deemed to end the exclusive period as to other fields of use. Such license shall also provide that the licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to approval of the agency. Upon expiration of the period of exclusivity or any extension thereof, licenses shall be offered to all qualified applicants at a reasonable royalty rate.

(3) The balance of the royalty income after payment of expenses *r*-including payments to inventors, incidental to the administration of all inventions assigned to it pursuant to the provisions of this clause shall be utilized for the support of education or scientific research. (4) All licenses issued by the awardee to other than the Government of the United States under any patent applicationor patent on a subject invention shall be made expressly subject to the conditions of this clause. The awardee shall, upon request, promptly furnish copies of any license agreements to the agency, provided that such licenses shall be considered privileged or confidential and the agency will not disclose such licenses to persons outside the Government.

(i) Patent Management Organizations

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Except with the specific approval of the agency, the awardee shall not assign any subject invention to any person or organization other than the Government of the United States or an organization which has as one of its primary functions the management of inventions and patents 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, provided that any assignment to a patent management organization shall specifically be made subject to all the terms and conditions of this clause.

(j) Reports on Development and Commercial Use

The awardee shall provide a written annual report to the agency on or before December 31st of each year covering the preceding year ending September 30th, regarding the status of development and commercial use that is being made or intended to be made of each subject invention left for administration to the awardee and the steps that have been taken by the awardee to bring the invention to the point of practical application. Such reports shall include information regarding status of development, the date of first commercial sale or use, gross royalties received by the awardee and such other data and information as the awardee may reasonably specify. To the extent data or information supplied to this section is considered by a licensee to be privileged or confidential and is so marked, the agency agrees that it will not disclose such information to persons outside the Government.

(k) Return of Government Support

If the awardee receives \$250,000 in net income from the licensing of a subject invention, it shall advise the agency. In such event the parties shall enter into negotiations to establish the amount of funds provided under this award which were expended on activities related to the making of the invention. The Government shall be entitled to receive up to this amount out of any additional net income about \$250,000 which is received by the The parties shall negotiate a reasonable share (not in awardee. excess of 50%) which the Government shall receive from net income above \$250,000 until the amount agreed upon has been reached. Equitable adjustments to any agreements entered into pursuant to this paragraph (k), including the return of income by the Government as appropriate, shall be made in the event that future costs of the awardee in connection with the invention such as litigation costs, have the effect of substantially reducing its net income before payment to the Government.

(1) Communications

Requests for Foundation approvals, extensions, or similar actions and other correspondence required by the Agreement should be addressed to the _____(To Be Inserted by the Agency).

(m) <u>Confirmation Instrument</u>

The following is the format for the confirmatory instrument required by paragraph (e)(2)(A) of this clause.

CONFIRMATORY INSTRUMENT

Application for:	(Title of Invention)
Inventor(s)	
Serial No.	Contract (Grant) No.
Filing Date:	Institution
The invention	identified above is a "Subject Invention'
under Award No.	with (Name of Agency)
This document	is confirmatory of the paid-up license
granted to the Governme	nt under this award in this invention,

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patent application and any resulting patent, and of all other rights acquired by the Government by the referenced award.

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It is understood and agreed that this document does not preclude the Government from asserting rights under the provisions of said Agreement or of any other agreement between the Government and the Awardee, or any other rights of the Government with respect to the above identified invention.

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The Government is hereby granted an irrevocable power to inspect and make copies of the above-identified patent application.

Signed this _____day of _____, 19_.

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(Print or type name)

(Official title)

CERTIFICATE

I,______, certify that I am the ______ of the Institution named as licensor herein; that _______, who signed this License on behalf of the Institution is _______ of said Institution; and that said License was duly signed for and in behalf of said Institution by authority of its governing body, and is within the scope of its corporate power.

(Signature)

~{END OF SAMPLE CLAUSE)

Section 4

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Section 4 provides the basic framework for the allocation of rights to small business firms. It is substantially identical to section 3 except that the assignment, licensing, and use of income limitations found at section 3(c)(6),(7), and (9) are not made applicable to small business firms. It is considered necessary to give small business firms greater flexibility in the use of their rights in order to maximize the growth and profitability of such firms. Income sharing with the Government is also provided in the case of substantial sales of products embodying subject inventions as well as royalty sharing where a small business contractor licenses a subject invention. The provisions and philosophy are similar to that discussed in connection with section 3(c)(10).

Section 5 is intended to make clear that agencies may consider requests by individual inventors for retention of rights in cases where the contractor or subcontractor does not elect or seek rights. It is, of course, expected that the standard clause will require that persons performing research functions under a contract or grant will be required to assign rights to subject inventions either to their employer or the sponsoring Federal agency upon request.

Section_6

Section 5

Section 6 is intended to allow agencies to withhold disclosure of invention reports up until the time that this is no longer needed to prevent the commencement of a statutory bar to patenting on account of the publication of the invention. Provision is also made for nondisclosure of copies of any patent applications in the possession of the Federal agency in order to prevent disruption of normal patent office procedures including the possibility that a party to an interference proceeding could obtain an unfair advantage through premature access under the Freedom of Information Act.

Section 7

Section 7 is intended to make clear that Federal agencies may negotiate for rights in background patents as part of the award process. It is expected that the need for this will be relatively rare.

Section 8

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Section 8 is a definitional section.

The definitions of "invention", "subject invention", and "made" are substantially similar to the definitions now given these terms in standard Government patent clauses. They represent terms of art that have been in use for many years.

The definitions of the terms "contract", "contractor", and "person" cover all forms of contracts, grants, and cooperative agreements now in use to support Federal research. Of special note is the fact that subcontractors are covered by the definition of "contractor". Thus the terms of this Act are applicable to small business subcontractors even if the prime contractor is a large business concern that is subject to more restrictive patent provisions.

The term "practical application" is based upon the definition of the same term found in the Presidential Memorandum and Statement of Government Patent Policy and current Government patent clauses.

The terms "Federal agency", "small business firm", and "nonprofit organization" are self-explanatory. Section 9

Section 9 makes clear that the fact that a person obtains rights in an invention in accordance with this act does not give him the right to use that invention in a manner that is violative of the anti-trust laws.

Section 10

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Section 10 provides the Office of Federal Procurement Policy and the Office of Science and Technology Policy authority to jointly issue regulations establishing a standard contract provision. Since OFPP has authority over contracts but not grants and because OSTP has cognizance over interagency patent policy activities, it is considered desirable to have a joint drafting effort. In turn, it is expected that additional regulations will be issued through normal OFPP, OMB, or agency channels implementing other aspects of the Act or otherwise amending existing regulations to take account of the Act and the standard OFPP/OSTP clause. Section 11

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Section 11 provides that the Act shall govern Federal patent policies and practices as they relate to universities and nonprofit organizations and small business firms. Section 11(a) lists nineteen statutory provisions that could arguably or clearly be interpreted as requiring a disposition of rights in a manner contrary to this Act. This Act will take precedence over these Acts and any other Acts that may have been overlooked that are inconsistent. Similarly, this Act is intended to take precedence over any future Acts dealing with the subject of patent policy vis-a-vis Government supported research unless such Act clearly states otherwise.

Section 12

Section 12 provides that the Act will take effect 180 days after its enactment. This is to enable the issuance of the necessary OFPP/OSTP joint regulations and other regulatory changes which are authorized to be issued prior to the 181st day.