The attached papers relate to the July 1, 1981, implementation of Patent Act (P.L. 96-517)

Tab 1 Decision paper:

One decision made (government-wide regulations)

One decision pending (lead agency monitor) June 30 Commerce per interpretation of Don of page 5 of decision memo. Rand P

Tab 2 Response to question about key issues of patent regulations.

Tab 3 OSTP memo agreeing to issue bulletin and acquire public comments

Tab 4 OMB Bulletin to be signed

Tab 5 Letter to Acting Comptroller General to be signed

FRED DIETRICH
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81-706

OFFICE OF MANAGEMENT AND BUDGET
ABSTRACT OF CORRESPONDENCE

TO: David A. Stockman

FROM: Donald E. Sowle

OUTGOING TO:

SUBJECT: Implementing the Patent and Trademark Act Amendments of 1980

The last Congress enacted P.L. 96-517, "The Patent and Trademark Amendments of 1980." This Act gives universities, nonprofit organizations and small businesses a first right of refusal of title in invention patents made in performance of government grants and contracts with some limited exceptions.

A decision needs to be made on the role OMB shall play in issuing patent regulations called for under the Act. A determination must be made expeditiously if regulations are to be in place prior to the July 1, 1981, effective date of the Act.

Issues for Decision

ISSUE #1: Should uniform, government-wide regulations implementing the Act be issued by OMB for both procurement and grant transactions?

Decision Options

X OMB issue uniform government-wide regulations to implement P.L. 96-517, Sections 202 thru 204 and 206 for both assistance and procurement transactions. (OFPP and AD/M recommends)

_____ Leave issuance of assistance regulations to individual agencies and procurement regulations to OFPP.

ISSUE #2: Should OMB assign to a lead agency government-wide responsibility for oversight and evaluation of the effectiveness of the Act and its implementing regulations?

Decision Options

_____ Assign a government-wide responsibility for oversight and evaluation of the Act to a single lead agency (a subsequent memo to the Director will address choice of a lead agency). (OFPP/AD/M recommends)

_____ No focus for responsibility assigned. Each agency shall monitor its own activities, and Inspectors General and GAO will review progress.

CONTROL NO. 477-8 7848

Mathis OFPP 5/28/81

	PREPARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY
SURNAME AND DIVISION (Typed)	Dietrich/OFPP HADD/IGA	Kelly IGA	Steinberg AD/M	Miller IRA	Sowle Admin/OFPP	Horowitz DO	Harper Dep. Dir.
INITIALS AND DATE	5/27	5/27	5/28	5/28/81	6/2/81	6/3/81	6/6

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OFFICE OF FEDERAL
PROCUREMENT POLICY

MEMORANDUM FOR: David A. Stockman
Director

FROM: Donald E. Sowle
Administrator-Designate

SUBJECT: Implementing the Patent and Trademark Act Amendment of 1980

Issues Requiring Decision

A decision needs to be made on the role OMB should play in the issuing of patent regulations. A determination must be made expeditiously if regulations are to be in place prior to the July 1, 1981, effective date of the Act. Therefore, we believe, the following issues need your decision.

- Should uniform governmentwide regulations implementing the Act be issued by OMB for both procurement and grant transactions?

- Should OMB assign to a lead agency governmentwide responsibility for oversight and evaluation of the effectiveness of the Act and its implementing regulations?

Background

After many years of public debate on means to enhance the utilization of the results of government funded research, the last Congress enacted P.L. 96-517, "The Patent and Trademark Amendments of 1980." (Copy of the Act is attached as Tab A.) Sections 202 through 204 of the Act give universities, nonprofit organizations and small businesses a first right of refusal to title in inventions, made in performance of government grants and contracts with some exceptions and conditions. In creating this right to ownership, the Act abolishes approximately 26 conflicting statutory and administrative policies. It should be noted, however, that the Act explicitly retains the status quo for contractors, other than small business, universities and nonprofit organizations. The status quo varies by agency and ranges from title in the Government to title in the contractor. We expect a continuing move in the Congress to give all businesses the first right of refusal to invention patent rights.

The Act covers the disposition of inventions resulting from approximately 1.2 billion dollars of grant and contract awards to small business and approximately 5 billion dollars to universities and nonprofit organizations. The incentive of invention ownership should initiate a significant increase in commercialization with all the resultant benefits and implications for advancing national goals of productivity and innovation.

In addition to the above, sections 207 and 209 of the Act authorize each Federal agency to grant nonexclusive or exclusive licenses under Federally owned patents or patent applications as determined appropriate in the public interest. The Act will become effective on July 1, 1981. To provide appropriate opportunity for public comment and timely guidance to agencies, publication of interim regulations in the Federal Register is necessary as soon as practicable.

A Patent Subcommittee of the Interagency Procurement Policy Committee (IPPC) has been established by GSA, under Title II of the Federal Property Act, to prepare Federal property management regulations governing agency licensing of Federally owned patents. Section 208 of the Act authorized GSA to issue these regulations. In addition, the subcommittee has begun drafting regulations governing agency disposition of inventions made by universities, nonprofit organizations and small businesses in performance of agency grants and contracts. Section 206 of the Act authorizes OFPP to issue this set of regulations. It is these regulations that are the subject of this memo.

The Patent Subcommittee is made up of representatives from 21 agencies. OMB is represented on an ex-officio basis by representatives from AD/M and OFPP. IGA has sent a letter to 14 of the agencies having grant programs, asking them to assure appropriate representation for assistance as well as procurement activities during the drafting of the regulations governing disposition of university, nonprofit organization and small business inventions

The Patent Subcommittee of the IPPC and the GSA Chairman of the IPPC have agreed to procedures prescribed by OMB/OFPP to ensure full consideration of public comment before final issuance of these regulations by OMB/OFPP. This will include subcommittee review of suggestions from the private sector during drafting. OMB/OFPP will reserve authority to analyze comments solicited on drafts through announcement in Federal Register and known private sector interest groups prior to issuing final regulations under section 206.

Section 206 of the Act requires recommendations from the Office of Science and Technology Policy (OSTP) before OFPP establishes regulations and standard funding agreement provisions. Since OSTP is not in a posture to make recommendations on implementing the law, we in OFPP have agreed to acquire OSTP's coordination prior to issuing regulations or standard funding agreement provisions.

Issue #1: Should uniform government-wide regulations implementing the Act for both procurement and grant transactions be issued by OMB?

Arguments in support

(a) Section 206 of the Act indicates that,

"The OFPP, after receiving recommendations of the OSTP, may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and the OFPP shall establish standard funding agreement provisions required under this chapter."

Page 26 of Senate Report No. 96-480 indicates that,

> "The bill . . . requires the OFPP to develop uniform regulations and clauses in order to ensure that there is not a new proliferation of inconsistent implementing clauses and regulations."

(b) Since the Act covers disposition of inventions made under grants, cooperative agreements and contracts, the assistance policy function of OMB is supporting OFPP to assure consistent application of the law across the spectrum of assistance and procurement relationships, and to avoid problems common to other crosscutting laws tied to assistance programs. While it is possible to draft and issue separate government-wide regulations for procurement and assistance, AD/M and OFPP have agreed that a single regulation would serve as a precedent setting model for future regulations which implement crosscutting statutes tied to procurement and assistance.

(c) The university and small business communities affected by this Act have already expressed a strong concern that OFPP may waive the authority intended by P.L. 96-517 to issue implementing regulations. They desire the use of uniform forms, procedures, and principles which would end the need to respond to the differing regulatory procedural requirements of each agency.

(d) There are indications that two agencies are planning to proceed with their own implementing regulations if a common set is not available to meet the July 1, 1981, effective date of the Act.

Arguments in Opposition

(a) Some agencies may argue that allowing each to issue its own regulations covering assistance and procurement programs may better represent their differences and thereby facilitate implementation.

(b) Traditionally, OMB has not promulgated policy guidance that has the force and effect of law enforceable in the courts.

Decision Options

__X__ OMB issue uniform government-wide regulations to implement P.L. 96-517, Sections 202 thru 204 and 206, for both assistance and procurement transactions. (OFPP and AD/M recommends)

_____ Leave issuance of assistance regulations to individual agencies and procurement regulations to OFPP.

_____ See me.

Issue #2: Should OMB assign to a lead agency government-wide responsibility for oversight and evaluation of the effectiveness of the Act and its implementing regulations?

Arguments in Support

(a) P.L. 96-517 abolishes 26 agency statutes and administrative patent regulations and establishes a single set of statutory guidelines which cover all assistance and procurement R&D programs. The Act is silent on a number of issues which are critical to consistent implementation. OMB would be burdened with day-to-day patent issues as well as being required to exercise oversight and evaluation the Act's effectiveness.

(b) The Act does not assign oversight and evaluation to any single agency, although five agencies and the Comptroller General are assigned some duties under the Act. (See Tab B.) A lead agency with government-wide responsibility would be able to:

(1) Coordinate, exchange and report information including the analysis of the results and benefits of the legislation;

(2) Evaluate effectiveness of the Act and OMB's implementing regulations and whether legislative or regulatory improvements need to be made;

(3) Provide consistent technical advice and assistance to agencies and recipients in situations where precise definitions beyond statutory language cannot be provided without operating experience;

(4) Review implementation of the Act and advise when and where government economies and efficiencies may be realized;

(5) Aid in the development of a national policy on innovation; and

(6) Convene conferences/workshops to assist agencies, universities and small businesses in implementing the Act.

Arguments in Opposition

(a) An assignment to a single agency for government-wide responsibility for oversight and evaluation of the Act may constrain operating agency flexibility in applying the Act to meet the special needs of its missions.

(b) An assignment to a single agency for government-wide oversight and evaluation may create a disincentive on the part of the agencies to fully cooperate in implementing the purposes of the Act.

Decision Options

_____ Assign a government-wide responsibility for oversight and evaluation of the Act to a single lead agency (a subsequent memo to the Director will address choice of a lead agency). (AD/M and OFPP recommends)

_____ No focus for responsibility assigned. Each agency shall monitor its own activities, and Inspectors General and GAO will review progress.

_____ See me.

What are the choices? Commerce

Tab B

Analysis of Statutory and Administrative Roles of Agencies

Section 6 of P.L. 96-517 is composed of 35 U.S.C. 200 through 211. Sections 202 through 204 cover disposition of inventions to universities, small business and non-profit organizations. Sections 207 through 209 cover the licensing of government-owned inventions.

OFPP is designated under 35 U.S.C. 206 as the office responsible for establishing standard funding agreement provisions called for by 35 U.S.C. 202 through 204. OFPP is also designated under 35 U.S.C. 206 as the office responsible for determining the need to issue regulations implementing 35 U.S.C. 202 through 204 after receiving recommendations from OSTP. While it is unclear from 35 U.S.C. 206 whether OFPP needs to obtain the advice of OSTP in drafting the standard funding agreement provision, it is presumed they do since the conditions of the provision are set out in 35 U.S.C. 202 through 204.

GSA is designated under 35 U.S.C. 208 as the office responsible for promulgating regulations for the licensing of government owned inventions under 35 U.S.C. 207 through 209. OSTP and OFPP are not given a role by 35 U.S.C. 208 in advising on these regulations.

OSTP, as noted, serves in an advisory capacity in drafting the standard funding agreement and regulations provided for in 35 U.S.C. 202 through 204. No input is required of OSTP in the drafting of regulations to implement 35 U.S.C. 207 through 209, the sections of the Act pertaining to licensing of government-owned inventions.

OMB has assistance policy development and coordination responsibilities but is not designated a specific role in the Act. However, clearly basic science assistance policies, productivity and innovation, the absence of an ongoing focal point for assuring implementation, and no provision for OSTP to be involved in advice on the licensing agreement provisions suggests at least an initial coordination responsibility and advice to the President on the implications of this Act in promoting a national policy on innovation. Also see Sec. 102(c)4 of P.L.94-282.

GAO is designated under 35 U.S.C. 202(b)(1)-3 to receive agency determinations involving exceptional circumstances which require the use of provisions other than the standard funding agreement provision; to advise agencies of patterns of determinations contrary to the policy and objectives of chapter 38 or that an agency's policies or practices are otherwise not in conformance with the Chapter; and at least once each year, transmit a report to the Committee on the Judiciary of the Senate and House on the manner in which Chapter 38 is being implemented and on such other aspects of government patent policies deemed appropriate.

SBA is designated under 35 U.S.C. 202(b)(1) to receive agency determinations involving exceptional circumstances which require the use of a provision other than the standard funding provision in funding agreements with small business firms.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OFFICE OF FEDERAL PROCUREMENT POLICY

JUN 19 1981

MEMORANDUM FOR DAVID STOCKMAN
EDWIN HARPER

FROM: Donald E. Sowle

SUBJECT: OFPP Weekly Activity Report

1. Significant Events

A. I participated in a seminar this week sponsored by the National Security Industrial Association to discuss Federal procurement issues and programs. About 75 top company executives attended. I was pleased to note that Dick Delauer of DOD and I were in general agreement on a whole range of procurement issues - including the validity of the Circular A-109 approach to major systems acquisition. Delauer agrees with me that the problems associated with A-109 are not due to its concept but due to inadequate implementation by the military services.

B. Implementation of P.L. 96-517, "Patent Reform Act" has generated diametrically opposed positions in various interested agencies on several key issues. As a result of another meeting this morning, we arrived at a consensus position that will permit us to release a draft OMB Bulletin for public comment and interim application by July 1, 1981 - as required by the law.

what are the key issues?

June 25

Key Issues

The issues which follow were key to those with opposing views --- (All of these issues, according to independent views of two patent attorneys from industry, are minor and would make little overall difference in implementation of the law).

1. March in provisions - establishing uniform criteria in regulation vs each agency establishing their own.
Resolution: Broad criteria included

2. Application of patent clause to foreign based contractors - applicable vs not applicable
Resolution: Not applicable

3. Disclosure of invention - disclosure prior to submittal of manuscript to publisher vs disclosure prior to publication
Resolution: Disclosure prior to publication with optional alternative permitting agencies with foreign patent filing programs to require disclosure prior to submittal of manuscript (DOE & NASA insistence)

Problem

4. Federally Funded R&D Centers - excluded vs included
Resolution: Excluded

5. Data Collection for GAO - maintain a count of all financial agreements with clause and without clause vs only count exceptions
Resolution: Allow 1 year to implement GAO request which will give agencies time to evaluate burden of collection information.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

June 26, 1981

MEMORANDUM

TO: Donald Sowle
Administrator-Designate, OFPP

FROM: G. A. Keyworth
Director-Designate

SUBJECT: Interim Patent Regulations

My staff and I have just reviewed the proposed Interim Policy Guidance to Executive Agencies on implementation of the patent provisions of P.L. 96-517, "The Patent and Trademark Amendments of 1980". That Act requires that OSTP be consulted prior to the issuance of such guidance.

In general, we feel that the interim regulations are a positive approach to uniform implementation of P.L. 96-517 by Federal agencies. An exception is section 5b(i)(vi) which permits agencies interested in retaining foreign patent rights to require, of contractors, prior notification of intent to disclose (e.g., by publication) information about a patentable discovery. We understand the rationale for this provision from the government's viewpoint, but are concerned that it will have the effect of allowing, once again, non-uniform patent policies among Federal agencies, and may have the effect of impeding the filing of patents by small businesses and universities.

In spite of this reservation, we are willing for these proposed regulations to be published on an interim basis allowing adequate time for comments by all concerned parties. Consistent with the requirements of P.L. 96-517, we ask that you include this Office in the process of reviewing the comments received and reaching a decision on the content of the final regulations.

p.54

OFFICE OF MANAGEMENT AND BUDGET
ABSTRACT OF CORRESPONDENCE

TO: THE DIRECTOR

FROM: Donald E. Sowle, Administrator-Designate, OFPP

OUTGOING TO: Heads of Executive Departments and Establishments

SUBJECT: Patents -- Small Business Firms and Non-Profit Organizations

See copy attached L Smith

The proposed Bulletin provides interim policy guidance to Executive Agencies for implementation of the patent provisions of P.L. 96-517, "The Patent and Trademark Amendments of 1980." The Act, which becomes effective July 1, 1981, gives universities, non-profit organizations and small businesses a first right of refusal to title in inventions they have made under Government funding agreements. Public comments willbe accepted until September 1, 1981. The final policy coverage will be issued in an OMB Circular on or before December 31, 1981. This policy covers both direct procurements and grants and cooperative agreements.

Compliance with E.O. 12291:

a. Procurement regulations have been exempted pursuant to the Director's memorandum of April 8, 1981. (see copy attached & Ed Springers note on to status) L Smith

b. The provisions of the Bulletin, which impact grants and cooperative assistance, are not considered to come within the requirements of a "Major Rule," as defined in E.O. 12291; however, a regulatory analysis is provided herewith for information purposes.

Cleared By	Cleared By
Harper Dep Dir	Schleede EAD
6/30/81	6/29/81 6/30

CONTROL NO. _____

	PREPARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY
SURNAME AND DIVISION (Typed)	Coleman OFPP	Dietrich OFPP	Sowle OFPP	Kelly IGA	Miller IRA	Horowitz GC	Smith OA ADA
INITIALS AND DATE	WSC 6/16/81	6/22/81	6/24/81	for Kelly 6/24	6/23/81	MH 6/23	L Smith 6/29

REGULATORY IMPACT ANALYSIS

1. Potential Benefits

The proposed rule implements 35 U.S.C. 200-206. That Act authorizes OFPP is issue implementing regulations and requires that OFPP issue a standard patent provision for all grants, contracts, and cooperative agreements (funding agreements) with small businesses and universities by July 1, 1981. The benefits that the Act and these regulations are intended to achieve are not readily quantifiable, but are discussed in Senate Report 96-480. They include:

(1) Increased commercialization and utilization of government supported inventions by the private sector.

(2) The increased participation of small business firms in government research programs.

(3) The elimination of numerous different and often conflicting individual agency clauses and policies governing the patent rights of non-profit and small business contractors.

2. Potential Costs.

This regulation should not increase any costs as compared to the current regulatory and administrative framework. It is intended to reduce substantially the administrative burdens on recipients, particularly those that deal with more than one government agency. It should reduce the administrative costs in agencies by eliminating the need to process requests for waivers of individual inventions or requests for the issuance of Institutional Patent Agreements in agencies such as NSF and HHS.

Depending on decisions made on the activities of the lead agency, this may involve a modest cost. However, a professional staff of between 1-3 FTE would only be required to perform the lead agency functions related to the implementation of the Act, and the Circular. Moreover, these functions should eliminate the need for similiar work to be performed in multiple agencies

3. Potential Net Benefits

As the above discussion indicates the benefits substantially outweigh any costs and indeed there should be net cost saving.

4. Alternative Approaches

Keeping in mind that the statute established the basic thrust of this or any other implementing regulations, the alternatives are somewhat limited.

One alternative would be to limit the regulation to the prescription of a standard clause while leaving all procedural details to the agenices. Such an approach, however, would frustrate the objective of achieving uniformity and minimizing administrative burdens on recipients. Thus, it is deemed more effective to issue govenmentwide standards in various areas.

For example, this regulation establishes uniform and fair standards for the exercise of march-in rights. The Senate report recommended that this be included in the central regulation. The Circular also contemplates that a lead agency will work with the agencies to develop a standard format for the reporting by contractors of utilization efforts. The statute requires that the standard clause provide for the right of agencies to receive utilization reports. The draft circular is designed to provide a mechanism for limiting the number and formats recipients will have to prepare.

Certain issues were raised during the drafting stage concerning particularly the requirements for reporting of inventions electing title and filing of patent application by contractors. Early drafts contained certain requirements not included in existing clauses that were objected to by university representatives as impractical and likely to frustrate the purposes of the Act. These provisions are revised in this draft, and it is believed that these requirements now represent an appropriate balance between the rights of the recipients and the need for agencies to protect their interests in inventions.

Since these regulations are to be issued on an interim basis, until public comments are received, it is difficult to determine whether further changes may be required. We expect that the interim regulation will be carefully reviewed by affected recipients and that based on these comments needed improvements, if any can be made.

Attention of those commenting on the regulations is specifically invited to issues related to Section B (vi) of the regulations. As now written, this provision allows agencies to ~~add~~ insert a ~~clause~~ provision to reporting requirements that would require prenotification to the agency of potentially patentable findings before taking certain actions, including submission of a manuscript for publication. Agencies favoring this requirement indicate it is necessary to assure protection of foreign patent rights, particularly when national security interest are involved. Others indicate that a prenotification requirement would be a disincentive to the filing of patents intended by the Act and to timely reporting of research results. Comments are encouraged on these and other considerations raised by this provision.

NOTE: To be inserted on the bottom of page 1 of bulletin. Refers to page 4 (vi)

OFFICE OF MANAGEMENT AND BUDGET

ABSTRACT OF CORRESPONDENCE

TO: THE DIRECTOR

FROM: Donald E. Sowle, Administrator-Designate, OFPP

OUTGOING TO: Heads of Executive Departments and Establishments

SUBJECT: Patents -- Small Business Firms and Non-Profit Organizations

The proposed Bulletin provides interim policy guidance to Executive Agencies for implementation of the patent provisions of P.L. 96-517, "The Patent and Trademark Amendments of 1980." The Act, which becomes effective July 1, 1981, gives universities, non-profit organizations and small businesses a first right of refusal to title in inventions they have made under Government funding agreements. Public comments willbe accepted until September 1, 1981. The final policy coverage will be issued in an OMB Circular on or before December 31, 1981. This policy covers both direct procurements and grants and cooperative agreements.

Compliance with E.O. 12291:

a. Procurement regulations have been exempted pursuant to the Director's memorandum of April 8, 1981.

b. The provisions of the Bulletin, which impact grants and cooperative assistance, are not considered to come within the requirements of a "Major Rule," as defined in E.O. 12291; however, a regulatory analysis is provided herewith for information purposes.

Cleared By	Cleared By
Harper Dep Dir	Schleede EAD

CONTROL NO. _____

	PREPARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY
SURNAME AND DIVISION (Typed)	Coleman OFPP	Dietrich OFPP	Sowle OFPP	Kelly IGA	Miller IRA	Horowitz GC	Smith OA
INITIALS AND DATE	WSC 6/16/81	SD 6/22/81	✓	✓	✓	✓	

REGULATORY IMPACT ANALYSIS

1. Potential Benefits

The proposed rule implements 35 U.S.C. 200-206. That Act authorizes OFPP is issue implementing regulations and requires that OFPP issue a standard patent provision for all grants, contracts, and cooperative agreements (funding agreements) with small businesses and universities by July 1, 1981. The benefits that the Act and these regulations are intended to achieve are not readily quantifiable, but are discussed in Senate Report 96-480. They include:

(1) Increased commercialization and utilization of government supported inventions by the private sector.

(2) The increased participation of small business firms in government research programs.

(3) The elimination of numerous different and often conflicting individual agency clauses and policies governing the patent rights of non-profit and small business contractors.

2. Potential Costs.

This regulation should not increase any costs as compared to the current regulatory and administrative framework. It is intended to reduce substantially the administrative burdens on recipients, particularly those that deal with more than one government agency. It should reduce the administrative costs in agencies by eliminating the need to process requests for waivers of individual inventions or requests for the issuance of Institutional Patent Agreements in agencies such as NSF and HHS.

Depending on decisions made on the activities of the lead agency, this may involve a modest cost. However, a professional staff of between 1-3 FTE would only be required to perform the lead agency functions related to the implementation of the Act, and the Circular. Moreover, these functions should eliminate the need for similiar work to be performed in multiple agencies

3. Potential Net Benefits

As the above discussion indicates the benefits substantially outweigh any costs and indeed there should be net cost saving.

4. Alternative Approaches

Keeping in mind that the statute established the basic thrust of this or any other implementing regulations, the alternatives are somewhat limited.

One alternative would be to limit the regulation to the prescription of a standard clause while leaving all procedural details to the agenices. Such an approach, however, would frustrate the objective of achieving uniformity and minimizing administrative burdens on recipients. Thus, it is deemed more effective to issue govenmentwide standards in various areas.

For example, this regulation establishes uniform and fair standards for the exercise of march-in rights. The Senate report recommended that this be included in the central regulation. The Circular also contemplates that a lead agency will work with the agencies to develop a standard format for the reporting by contractors of utilization efforts. The statute requires that the standard clause provide for the right of agencies to receive utilization reports. The draft circular is designed to provide a mechanism for limiting the number and formats recipients will have to prepare.

Certain issues were raised during the drafting stage concerning particularly the requirements for reporting of inventions electing title and filing of patent application by contractors. Early drafts contained certain requirements not included in existing clauses that were objected to by university representatives as impractical and likely to frustrate the purposes of the Act. These provisions are revised in this draft, and it is believed that these requirements now represent an appropriate balance between the rights of the recipients and the need for agencies to protect their interests in inventions.

Since these regulations are to be issued on an interim basis, until public comments are received, it is difficult to determine whether further changes may be required. We expect that the interim regulation will be carefully reviewed by affected recipients and that based on these comments needed improvements, if any can be made.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

Mr. John E. Byrne
Director, Office of the Federal Register
National Archives and Records Service
General Services Administration
Washington, D. C. 20408

Dear Mr. Byrne:

In accordance with 1 C.F.R. 5.2 37 FR 23604, enclosed for publication in the Federal Register is interim final OMB ~~Circular~~ Bulletin ___, entitled, "Patents -- Small Business Firms and Non-Profit Organizations."

Sincerely,

Daniel S. Mann
Budget and Management Officer

Enclosure

Letter replaced in orig. package

Requesting Emergency Treatment by 1 July to comply with PL 96-517.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OFFICE OF FEDERAL
PROCUREMENT POLICY

OFFICE OF MANAGEMENT AND BUDGET
Office of Federal Procurement Policy

Bulletin 81-__, Patents -- Small Firms and Non-Profit Organizations

Agency: Office of Federal Procurement Policy, Office of Management and Budget

Action: OMB Bulletin on patents affecting small business firms and non-profit organizations is being published as interim final policy coverage effective July 1, 1981, and for public comment. A final OMB Circular will be issued on or before December 31, 1981.

Summary: This Bulletin, issued pursuant to the authority contained in P.L. 96-517, sets forth policies procedures and a standard clause for Executive Branch agency use with regard to inventions made by small business firms and non-profit organizations and universities under funding agreements (contracts, grants and cooperative agreements) with Federal agencies where a purpose is to perform experimental, developmental and research work.

On December 12, 1980, Congress passed Public Law 96-517 governing the distribution of rights in inventions made by small business firms and non-profit organizations under funding agreements with Federal agencies.

Congress provided that this Act takes precedence over any other Acts which would require a disposition of rights in subject inventions of small business firms or non-profit organizations in a manner inconsistent with the new Act. Additionally, the new Act will take precedence over any future Act unless the future Act cites the new Act and provides that it will take precedence. This Bulletin takes effect on July 1, 1981, and will be applicable to all funding agreements with small business firms and non-profit organizations executed on or after that date. The provisions of this Bulletin may also be made applicable by mutual agreement to any subject inventions which are "made" on or after July 1, 1981, in the performance of funding agreements which were awarded prior to July 1, 1981, to small business firms or non-profit organizations, unless prohibited by law.

Commenters' views are encouraged. Where possible, revised language suggesting improvements and the rationale for proposed changes is invited. Comments are due by September 1, 1981.

Addresses: Send comments to Mr. Fred H. Dietrich, Associate Administrator, Office of Federal Procurement Policy, 726 Jackson Place, N. W., Washington, D. C. 20503.

For Further Information Contact: (Contracts) Mr. Fred H. Dietrich, (202) 395-6810. (Grants and Cooperative Agreements) Mr. Gerald A. Fill, (202) 395-3070.

Donald E. Sowle
Administrator
Office of Federal Procurement Policy

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

BULLETIN NO. 81-

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

SUBJECT: Patents - Small Business Firms and Non-Profit Organizations

1. Purpose. This Bulletin provides interim policies, procedures and guidelines with respect to inventions made by small business firms, non-profit organizations and universities under funding agreements (contracts, grants or cooperative agreements) with Federal agencies where a purpose is to perform experimental, developmental, or research work.

2. Authority. This Bulletin is issued pursuant to authority contained in P.L. 96-517, "The Patent and Trademark Amendments of 1980."

3. Background. After many years of public debate on means to enhance the utilization of the results of Government funded research, the last Congress enacted P.L. 96-517, "The Patent and Trademark Amendments of 1980." Sections 202-204 of the Act give universities, non-profit organizations and small businesses a first right of refusal to title in inventions they have made in performance of Government grants and contracts subject to some limited exceptions. In creating this right to ownership, the Act abolishes approximately 26 conflicting statutory and administrative policies.

Some understanding of the relative importance of the Act can be determined from the amount of research and development funding impacted. Based on fiscal year 1980's rate of Government R&D funding of small business, universities, and non-profit organizations, the Act covers the disposition of the invention results from approximately 1.2 billion dollars of grant and contract awards to small business and approximately 5 billion dollars to universities and non-profit organizations. The 5 billion dollars utilized by universities and non-profits covers approximately 65% of the toal cost of all the basic research conducted in the U.S. This large investment, coupled for the first time with the incentive of invention ownership in small businesses, non-profits and universities across all Government research and development programs, could initiate a significant increase in the commercialization of inventions resulting from these programs.

Under the Act, The Office of Federal Procurement Policy (OFPP) is responsible for issuance of the regulations implementing sections 202-204 after consultation with the Office of Science and Technology Policy (OSTP). In order to expedite the drafting of these regulations and obtain the advice of agency personnel familiar with patent matters, OFPP relied on an interagency committee for a preliminary draft of the implementing regulations for sections 202-204. This committee was formed through an invitation to all departments and agencies affected by the Act to participate in the drafting of regulations for both the Government patent policy and licensing provisions of the Act.

Regulations implementing the licensing provisions under the Act are available from the Office of Acquisition Policy, General Services Administration, Washington, D. C. 20405. This Bulletin and the funding agreement clauses of Part 5c represent a reflection of many of the views expressed by the Council on Government Regulations (COGR) and other interested groups.

4. Policy. This Bulletin takes effect on July 1, 1981, and will be applicable to all funding agreements with small business firms and non-profit organizations executed on or after that date which are to be performed within the United States. This Bulletin may also be made applicable by mutual agreement to any subject inventions which are "made" on or after July 1, 1981, in the performance of funding agreements which were awarded prior to July 1, 1981, to small business firms or non-profit organizations, unless prohibited by law.

5. Implementation of Policy

a. Definitions. As used in this Bulletin --

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

(2) The term "contractor" means any small business firm or non-profit organization that is a party to a funding agreement.

(3) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of the United States Code (USC).

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

(5) 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.

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

(7) The term "small business firm" means a small business concern, as defined as section 2 of Public Law 85-536 (15 USC 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this Bulletin, the size standard for small business concerns involved in Government procurement, contained in 13 CFR 121.3-8, and in subcontracting, contained in 13 CFR 121.3-12, will be used.

(8) The term "non-profit organization" means universities and other institutions of higher education or an organization of the type describes in section 501(c)(3) of the Internal Revenue Code of 1954 (26 USC 501a) or any non-profit scientific or educational organization qualified under a state non-profit organization statute.

b. Procedures

(1) Use of the Patent Rights (Small Business Firm or Non-profit Organization) (July 1981) Clause

(i) Each funding agreement awarded to a small business firm or non-profit organization which is to be performed in the United States, its possessions, or Puerto Rico and has as a purpose the performance of experimental, developmental or research work, shall contain the Patent Rights (Small Business Firm or Non-profit Organization), (July 1981) clause set forth in part 5(c), except that the funding agreement may provide otherwise.

(A) when the funding agreement is for the operation of a Federally Funded Research and Development Center or a Government-owned production facility.

(B) 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 chapter 38 of title 35 of the USC, or

(C) when it is determined by a Government authority which is authorized by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to porotect the security of such activities.

(ii) Any determination under subparagraph (b)(1)(i)(B) of this section will be in writing and accompanied by a written statement of facts justifying the determination. The statement of facts will contain such information as the funding Federal agencies deems relevant and, at minimum, will (1) identify the small business firm or non-profit organization involved, (2) describe the extent to which agency action restricted or eliminated the right to retain title to a subject invention, (3) state the facts and rationale supporting the agency action, (4) provide supporting documentation for those facts and rationale, and (5) indicate the nature of any objections to the agency action and provide any documentation in which those objections appear. A copy of each such determination and written statement of facts will be sent to the Comptroller General of the United States within thirty days after the award of the applicable funding agreement. In cases of determinations applicable to funding agreements with small business firms, copies will also be sent to the Chief Counsel for Advocacy of the Small Business Administration.

(iii) To assist the Comptroller General to accomplish his responsibilities under 35 USC 202, each Federal agency shall accumulate and, at the request of the Comptroller General, provide the Comptroller General or his duly authorized representative the total number of funding agreements entered into it with small businesses or non-profit organizations that contain the Patent Rights clause of section 5c of this Bulletin during each period of July 1 through June 30, beginning July 1, 1982.

(iv) To qualify for the Patent Rights in Inventions (Small Business Firm or Non-Profit Organization) (1981) clause, the small business firm or non-profit organization may be required by an agency to certify that it qualifies as a small business firm or non-profit organization as defined in subparagraphs (a)(7) and (a)(8). If the contracting officer has reason to question the status of the small business firm or non-profit organization under the definitions in subparagraph (a)(7) and (a)(8). he may file a request in accordance with 13 CFR 121.3-5 in regard to the status of the small business firm or he may require the non-profit organization to furnish evidence to establish that it satisfies the requirements of the definition in subparagraph (a)(8).

(v) Right to sublicense foreign governments and international organizations. When the agecy head or duly authorized designee determines at the time of contracting with a small business firm or non-profit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing or future treaty or agreement, a sentence will be added at the end of paragraph (b) of the Patent Rights clause in part 5c as follows:

> "This license will include the right of the Government to sublicense foreign governments and international organizations pursuant to any existing or future treaty or agreement with such foreign governments or international organizations."

However, this language may be modified by agencies to be limited to specific treaties or agreements or otherwise specify a time when the Government's right to sublicense ends.

(vi) Where agencies determine that, due to the need to support their programs to protect Government-owned inventions in foreign countries, additional procedural safeguards are necessary to prevent the defeat of foreign rights due to statutory bars, the following language may be added to paragraph (c)(1)(ii) of the clause of Part 5c:

> "but in any event, at least three months (unless shortened by the contracting officer) before (a) a public use or on sale of the invention occurs, (b) a manuscript describing the invention is submitted for publication without assurances of confidentiality, or (c) the invention is otherwise made available to the public."

When the above addition has been made to the clause of Part 5c, paragraph (c)(2) should be deleted.

(2) Minimum rights to contractor

(i) Paragraph (e) of the Patent Rights clause of Part 5c specifies the minimum rights retained by the contractor in subject inventions. When the Federal Government acquires title to a reported subject invention, the contractor will retain a revocable, nonexclusive. royalty-free license throughout the world in the subject invention. The contractor's license extends to its domestic subsidiaries and affiliates, if

any, within the corporate structure of which the contractor is a party and includes the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded. The license is transferable only with the approval of the funding Federal agency except when transferred to the successor of that party of the contractor's business to which the invention pertains.

(ii) The contractor's domestic license may be revoked or modified by the funding Federal agencies to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with (cite application portion of the new licensing regulations). This license will not be revoked in that field or use or the geographical areas in which the contractor has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding Federal agency to the extent the contractor, its licensees, or its domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(iii) Before revocation or modification of the license, the funding Federal agency will furnish the contractor a written notice of its intention to revoke or modify the license, and the contractor will be allowed thirty days (or such other time as may be authorized by the funding Federal agency for good cause shown by the contractor) after the notice to show cause why the license should not be revoked or modified. The contractor has the right to appeal, in accordance with (cite applicable portion of the new licensing regulations), any decision concerning the revocation or modification of its license.

(3) Subcontracts

(i) Paragraph (g) of the Patent Rights clause of Part 5c of this Bulletin requires that the Patent Rights clause, suitably modified to identify the parties, be included in all subcontracts with small business firms and non-profit organizations for experimental, developmental, or research work to be performed in the United States. For subcontracts, regardless of tier, with other than a small business firm or non-profit organization, paragraph (g) provides a blank space to be completed by agencies with their own or applicable Government-wide regulations such as the FPR or DAR identifying the appropriate clause for such subcontracts.

(ii) Contractors will not use their ability to award subcontracts as economic leverage to acquire rights for themselves in the inventions resulting from subcontracts.

(4) Publication or release of invention disclosures

(i) The publication of information disclosing an invention by any party before the filing of a patent application may create a bar to a valid patent. Where the contractor intends to file patent applications, the agency will use reasonable efforts to comply with any written request to restrict its publication of information disclosing the invention

for a reasonable period of time, in order to protect the patent rights in the invention. The contractor, must specify the reports and documents to be restricted and the period within which the patent application will be filed.

(ii) As provided in 35 USC 205, Federal agencies are authorized to withhold from disclosure to the public information disclosing any subject invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for patent application to be filed. Furthermore, Federal agencies are not required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

(5) Reporting on Utilization of Subject Inventions. Paragraph h of the Patent Rights clause in Part 5c of this Bulletin provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies shall obtain such information from their contractors. However, to ensure uniformity in the nature of the periodic reporting required by the various agencies, agencies shall work with the lead agency to establish standard utilization reporting requirements. To the extent such data or information supplied by the contractor is considered by the contractor, or its licensee or assignee, to be privileged and confidential and is so marked. agencies should not, to the extent permitted by 35 USC 202(c)(5), disclose such information to persons outside the Government.

(6) Additional Administrative Requirements. To the extent not required by other provisions of the funding agreement, agencies may add additional subparagraphs to paragraph (f) of the Patent Rights clause in Part 5c to require the contractor to do one or more of the following:

(i) Provide periodic (but no more frequently than annually) listings of all subject inventions required to be disclosed during the period covered by the report;

(ii) Provide a report prior to the close-out of a funding agreement listing all subject inventions;

(iii) Provide notification of all subcontracts for experimental, developmental or research work; and

(iv) Provide, upon request, the filing date, serial number, and title; a copy of the patent application; and patent number and issue date for any subject invention in any county in which the contractor has applied for patents.

c. Clause for Funding Agreements (Small Business Firms and Non-Profit Organizations)

(1) Patent Rights (Small Business Firms or Non-profit Organizations). (July 1981). The following clause with such modifications and tailoring as are authorized elsewhere in this Bulletin will be used in all funding agreements with small business firms and non-profit organizations unless the funding agreement falls within one of the exceptions described in part 5b(1)(ii).

PATENT RIGHTS

(Small Business Firms or Non-profit Organizations) (July 1981)

a. Definitions

(1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code (USC).

(2) "Subject Invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract.

(3) "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.

(4) "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) "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. For the purpose of this clause, the size standard for small business concerns involved in Government procurement, contained in 13 CFR 121.3-8, and in subcontracting, contained in 13 CFR 121.3-12, will be used.

(6) "Non-profit Organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 USC 501a) or any non-profit scientific or educational organization qualified under a state non-profit organization statute.

b. Allocation of Principal Rights

The contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause. With respect to any subject invention in which the contractor retains title, the Federal Government shall have a non-exclusive, 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 for which the contractor has elected to retain title.

c. Invention Disclosure, Election of Title and Filing of Patent Applications by Contractor

(1) After a subject invention has been disclosed in writing by the inventor(s) to contractor personnel responsible for the administration of patent matters, the contractor will:

(i) Disclose such invention to the Federal agency within six months;

(ii) Elect whether or not to retain title to any such invention by notifying the Federal agency within twelve months of disclosure to the contractor;

(iii) File its initial patent application on an elected invention within two years after election; and

(iv) File patent applications in additional countries within either ten months of the corresponding initial patent application, or six months from the date a license is granted by the Commissioner of Patents and Trademarks to file foreign patent applications when such filing was prohibited for security reasons.

(2) Notwithstanding the requirements of subparagraph c(1) above:

(i) Disclosure to the agency shall be made immediately after contractor personnel responsible for the administration of patent matters become aware of any manuscript describing the invention accepted for publication, or any publication, on sale or public use of such invention; and

(ii) In any case where publication, or sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title and filing of a United States patent application may be shortened by the agency to a date that is no more than 45 days prior to the end of the statutory period.

(3) Requests for extention of the time for disclosure to the agency, election and filing, where reasonable, will normally be granted.

(4) The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological or electrical characteristics of the invention. The report shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and accepted at the time of disclosure.

d. Forfeiture of Title

(1) The contractor will convey to the Federal agency, upon written request, title to any subject invention:

(i) If the contractor fails to disclose or elect the subject invention within the times specified in c above, or elects not to retain title.

(ii) In those countries in which the contractor fails to file patent applications within the times specified in c above; provided,

however, that if the contractor has filed a patent application in a country after the times specified in c above but prior to its receipt of the written request of the Federal agency, the contractor shall continue to retain title in that country; or

(iii) In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in a reexamination or opposition proceeding on, a patent on a subject invention.

e. Minumum Rights to Contractor

The contractor will retain a non-exclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title except if the contractor fails to disclose the subject invention within the times specified in c above. This license extends to, and is revocable and transferable, as specified in Part 5b(2) of this Bulletin.

f. Contractor Action to Protect Government's Interest

(1) The contractor agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to:

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions for which the contractor retains title, and

(ii) Convey title to the Federal agency when requested under (d) above and to enable the Government to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under this contract in order that the contractor can comply with the disclosure provisions of c above and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information requested by subparagraph c(4) above. The contractor shall instruct such employees through the employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The contractor will notify the Federal agency of any decision not to continue prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The contractor agrees to include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with

Government support under (identify the contract) awarded by the Federal agency. The Government has certain rights in this invention."

g. Subcontracts

(1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed in the United States by a small business firm or a non-profit organization. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The contractor will include in all other subcontracts, regardless of tier, for experimental, developmental or research work the patent rights clause required by (cite section of agency implementing regulations, FPR, or DAR).

h. Reporting on Utilization of Subject Inventions

The contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph j of this clause. To the extent data or information supplied under this section is considered by the contractor, its licensee or assignee to be privileged and confidential and is so marked, the agency agrees that, to the extent permitted by 35 USC 202(c)(5), it will not disclose such information to persons outside the Government.

i. Preference for United States Industry

Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have bee made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

j. March-in Rights

The contractor agrees that with respect to any subject invention in which it has acquired title, the Federal agency has the right in accordance with the procedures in OMB Bulletin ___ (and agency regulations at _____) to require the contractor, an assignee or exclusive licensee of a subject invention to grant a non-exclusive, 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 a request, the Federal agency has the right to grant such a license itself if the Federal agency determines that:

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

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

(3) 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; or

(4) Such action is necessary because the agreement required by paragraph i of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

k. Special Provisions for Contracts with Non-profit Organizations

If the contractor is a non-profit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned withhout the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions and which is not, itself, engaged in or does not hold a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention (provided that such assignee will be subject to the same provisions as the contractor);

(2) The contractor may not grant exclusive licenses under United States patents or patent applications in subject inventions to persons other than small business firms for a period in excess of the earlier of:

(i) five years from first commercial sale or use of the invention; or

(ii) eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance, unless on a case-by-case basis, the Federal agency approves a longer exclusive license. If exclusive field of use licenses are granted, commercial sale or use in one field of use will not be deemed commercial sale or use as to other fields of use, and a first commercial sale or use with respect to a product of the invention will not be deemed to end the exclusive period to different subsequent products covered by the invention.

(3) The contractor will share any royalties collected on a subject invention with the inventor; and

(4) 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, will be utilized for the support of scientific research or education.

END OF CLAUSE

(2) Tailoring the clause. When using this clause, agencies should replace the italicized (underlined) words and phrases with those appropriate to the particular funding agreement. For example, contract should be replaced by "grant" or "cooperative agreement" when those forms of funding agreements are used. In grant, contractor would become "grantee" and contracting officer might become "grants officer." Depending on its use, the Federal agency can be replaced either by the identification of the agency which is party to the funding agreement or by the specification of a particular office or official within that agency. Where the clause requires the contractor to communicate with the agency (as in section (h)),the agency should specify to whom the communication should be made and cite any regulations establishing a preferred form for that communication.

d. Retention of rights by inventor

In contracts with small business firms or non-profit organizations, if the contractor does not elect to retain title to a subject invention, the funding Federal agency may consider and, after consultation with the contractor, may grant requests for retention of rights by the inventor subject to the provisions of 35 U.S.C. 202-204.

e. Government Assignment to Contractor of Rights in Invention of Government Employee

In any case when a Federal employee is a coinventor of any invention made under the funding agreement with small business firm or non-profit organization, the Federal agency employing such coinventor may transfer or reassign whatever right it may acquire in the subject invention from its employee to the contractor subject to the conditions of this Bulletin.

f. Exercise of March-in Rights

The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 USC 203 and the clause at Part 5c of this Bulletin:

(1) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor in notice of the facts upon which the action is based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this Bulletin and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his delegee.

(2) Within 30 days after receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit, in person, in writing, or through a representative, information and argument in opposition of the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or his delegee shall refer the matter to another official of the agency for fact-finding.

(3) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures shall afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency.

(4) The agency official conducting fact-finding shall prepare written findings of fact and transmit them to the head of the agency or his delegee promptly after the conclusion of the fact-finding proceeding. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail.

(5) In cases in which fact-finding has been conducted, the head of the agency or his delegee shall base his determination on the facts found, together with any other information and argument submitted by the contractor (assignee or exclusive licensee) and any other information in the administrative record. In cases referred for fact-finding, the head of the agency or his delegee may reject only those facts that have been found that are clearly erroneous. Prompt written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or his delegee and sent to the contractor (assignee or exclusive licensee) by certified or registered mail.

(6) Agencies are authorized to issue additional supplemental procedures, not inconsistent herewith, for the conduct of march-in proceedings.

g. Appeals

In accordance with procedures prescribed by the funding Federal agency, any party to the funding agreement, licensee, or assignee may appeal to the agency or designee any decision or determination concerning the denial, interpretation, modification, or termination of a right to a subject invention under paragraphs (i), (k)(1), or (k)(2) of the clause in Part 5c. In addition, the contractor may appeal any decision of an agency head's delegee that there is no genuine dispute over a material fact provided for in section f(2).

h. Licensing of Background Patent Rights to Third Parties

(1) A funding agreement with a small business firm or non-profit organization will not 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 agency head and a written justification has been signed by the agency head. Any such provision will 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 agency head may not delegate the authority to approve such provisions or to sign justifications required for such provisions.

(2) A Federal agency will not require the licensing of third parties under any such provision unless the agency head 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 will be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination will be brought within sixty days after notification to the contractor of such determination.

i. Administration of Patent Rights Clause

(1) It is important that the Government and the contractor know and exercise their rights in subject inventions in order to ensure their expeditious availability to the public, to enable the Government, the contractor, and the public to avoid unnecessary payment of royalties, and to defend themselves against claims and suits for patent infringement. To attain these ends, contracts Patent Rights clauses should be so administered that:

(i) Inventions are identified, disclosed, and an election is made as required by the contract clause.

(ii) The rights of the Government in such inventions are established;

(iii) When appropriate, patent applications are timely filed and prosecuted by contractors or by the Government;

(iv) The filing of patent applications is documented by formal instruments such as licenses or assignments; and

(v) Expeditious commercial utilization of such inventions is achieved.

(2) With respect to the conveyance of licenses or assignments to which the Government may be entitled under the Patent Rights clause in section 5 of this Bulletin, agencies should follow the guidance provided in 41 CFR 1-9.109-5 or 32 CFR 9-109.5

j. Modification of Existing Agency Regulations

(1) Agency existing patent regulations or other published policies concerning inventions made under funding agreements shall be modified as necessary by December 31, 1981, to make them consistent with this Bulletin and 35 USC 200-206.

(2) After July 1, 1981, this Bulletin and 35 USC 200-206 shall take precedence over any conflicting agency regulations or policies.

6. Proposed Lead Agency Designation. As an option for assurance of coordinated and consistent implementation of 35 USC 200-206 and this Bulletin, consideration is being given to establishing a lead agency to carry out collaboration of the following functions with all affected agencies:

a. Coordinate, exchange and report information;

b. Evaluate the effectiveness of the Act and this OMB Bulletin and whether legislative or regulatory improvements need to be made;

c. Review implementation of the Act and advise when and where Government economies and efficiencies may be realized;

d. Aid in the development and coordination of a national policy on innovation;

e. Convene, as necessary, conferences/workshops to assist agencies, universities and small business in implementing 35 USC 200-206; and

f. Perform such other duties and responsibilities to carry out the goals and objectives of 35 USC 200-206.

Agency comments are encouraged regarding the lead agency concept.

7. Action Requirements. Each Executive Branch agency shall revise its regulations concerning patents in compliance with the policy and procedure set forth in this Bulletin. Such revisions shall not be more restrictive or burdensome than the provisions of this Bulletin.

8. Agency Comments. Comments from each Executive agency affected by the policy and procedure contained in this Bulletin will be accepted until September 1, 1981. Send comments to Mr. Fred H. Dietrich, 726 Jackson Place, N. W., Washington, D. C. 20503.

9. Information Contact: (Contracts) Mr. Fred H. Dietrich, (202) 395-6810. (Grants and Cooperative Agreements) Mr. Gerald A. Fill, (202) 395-3070.

10. Sunset Date. This Bulletin will expire on December 31, 1981, unless replaced by an OMB Circular on an earlier date.

Donald E. Sowle
Administrator

David A. Stockman
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