

OFFICE OF FEDERAL PROCUREMENT POLICY

#### OFFICE OF MANAGEMENT AND BUDGET OFFICE OF FEDERAL PROCUREMENT POLICY

## Circular No. A-124, Patents -- Small Firms And Non-Profit Organizations

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

#### Action: Final Rule.

Summary: This Circular, 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. This supersedes OMB Bulletin No. 81-22 and reflects public comments received on OMB Bulletin No. 81-22.

#### Effective Date: March 1, 1982.

For Further Information Contact: Mr. Fred H. Dietrich, Associate Administrator, Office of Federal Procurement Policy, 726 Jackson Place, N.W., Washington, D.C. 20503, (202) 395-6810.

Supplementary Information: This Circular is a revision of OMB Bulletin No. 81-22 which was issued on July 1, 1981, accompanied by a request for comments from the public and Federal agencies. Approximately 138 comments were received from individuals, universities, nonprofit organizations, industrial concerns, and Federal agencies.

Copies of all the comments are available on record at 0FPP. A compilation of summaries of the comments organized by Bulletin section along with a rationale for their disposition can be obtained by writing to: Fred Dietrich, address as above.

The Bulletin has been reformated for easier reading and simplified reference to its provisions. For example, the standard clause has been moved from the body of the Circular to Attachment A. Instructions and policies on the use of the standard clause have been consolidated in Part 7. Instructions for modification or tailoring of the clause have been consolidated in Part 8. Other general policies relating to the clause or the Act have been treated in separate parts.

simplified reference to its provisions. For example, the standard clause has been moved from the body of the Circular to Attachment A. Instructions and policies on the use of the standard clause have been consolidated in Part 7. Instructions for modification or tailoring of the clause have been consolidated in Part 8. Other general policies relating to the clause or the Act have been treated in separate parts. Some of the more significant changes that were made as a result of the comments are discussed below. Explanations are also given as to why certain comments were not adopted.

### I. Comments Relating to Policy and Scope Sections

## A. <u>Subcontracts</u>

A number of comments indicated that more clarification on the application of the Circular to subcontracts was needed. Revisions were made in Part 5 and Part 7c. to address this concern.

# B. Limitation to Funding Agreements Performed in the United States

There were also a large number of comments questioning the limitation of the Bulletin to funding agreements performed in the United States. The Circular has been revised to eliminate any distinctions based on where the funding agreement is performed. However, the definition of "nonprofit performed. However, the definition of "nonprofit organization" at 35 USC 201 has been interpreted to cover only <u>domestic</u> nonprofit organizations. The definition of "small business" in SBA regulations which are referenced in the Act excludes foreign business. A strong argument can be made that the Congress did not include foreign nonprofits. For example, part of that the statutory definition referencing organizations "qualified under a State nonprofit organization statute" clearly is limited to U.S. organizations. Similarly, that part of the definition referencing Section 501 of the Tax Code manifest an intention to cover U.S. based organizations, since foreign corporations are not subject to U.S. tax except if they are doing business in the United States.

#### C. Inventions Made Prior to July 1, 1981

Part 5 of the Circular was revised, as suggested by commentors, to encourage agencies to treat inventions made under funding agreements predating the Act in a manner similar to inventions under the Act, if such action is consistent with the Congress did not include foreign nonprofits. For example, that part of the statutory definition referencing organizations "qualified under a State nonprofit organization statute" clearly is limited to U.S. organizations. Similarly, that part of the definition referencing Section 501 of the Tax Code manifest an intention to cover U.S. based organizations, since foreign corporations are not subject to U.S. tax except if they are doing business in the United States.

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#### D. Collaborative Research and "De minimus" Recommendations

Act which does not define subject invention in terms of the size of the government financial contribution in making the invention.

These comments appear to be based on a concern that the Circular does not provide adequate guidance on the obligations of a recipient of government research funds when such research is closely related to other research sponsored by an industrial concern. Since one of the primary purposes of P.L. 96-517 is to foster cooperative research arrangements among government, universities and industry in order to more effectively utilize the productive resources of the nation in the creation and commercialization of new technology, it is important to remove any doubt as to the propriety of such cooperative arrangements and the proper application of the Circular to them.

Traditionally there have been no conditions imposed on research performers by the government which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Such complex funding arrangements are a necessity given the limited financial resources of individual sponsors, the unpredictable nature and continual expansion of research, the sharing of expensive resources, and the dynamic interactions among scientists at research institutions.

Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the Act would remain applicable to any invention "conceived or first actually reduced to practice in performance" of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

To the extent that a non-government sponsor establishes a project which, although closely related, falls outside the planned and committed activities of a government funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the nongovernment sponsored project would not be subject to the conditions of the Act. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field with a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in

having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a "subject invention", the challenge is appealable as described in Part 14.c.

An invention which is made outside of the research activities of a government funded project but which in its making otherwise benefits from such project without adding to its cost, is not viewed as a "subject invention" since it cannot be shown to have been "conceived or first actually reduced to practice" in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government funded project, in making an invention all expenses of which involve only non-government funds.

#### E. Reports to the General Accounting Office

In response to the comment of one agency, Part 7.b.(2) was amended to avoid the necessity of agencies that do not enter into research grants or contracts with nonprofit organizations or small businesses from having to make reports to the Comptroller General.

#### F. Right to Sublicense Foreign Governments

Several commentators expressed concern that the optional language authorized for addition to the standard clause to permit sublicensing in accordance to treaties or international agreements was too open-ended. In response to this Part 8.d. now requires that existing treaties and international agreements be identified when the optional language is used. However, in view of the broad wording of the statute, agencies may continue to use the optional language for "future" treaties at their discretion. However, specific language has into research grants or contracts with nonprofit organizations or small businesses from having to make reports to the Comptroller General.

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# G. Publication or Release of Invention Disclosures

Some agencies expressed the concern that the language in Part 5.b.(4) of the Bulletin required agencies to delay publication for excessive periods. Careful review of the language of Part 5.b (4) indicated that it needed to be restructured to more clearly distinguish between situations where the publication of technical reports was involved and situations where the release or publication of invention disclosures provided as required under the standard clause was involved. Part 9 has been revised to distinguish between the two and to clarify the policies in the two situations.

### H. Reporting on Utilization of Subject Inventions

In response to the comments of one agency and to minimize the burden on contractors, Part 10 provides that agencies shall not implement their rights to obtain utilization reports under the standard clause until a Government-wide reporting format is established. This will be one of the first tasks of the Department of Commerce as lead agency.

Also adopted was the recommendation of one commentor that utilization reports be afforded maximum protection from disclosure as authorized by P.L. 96-517. Accordingly, language was revised to provide that such reports "shall not" be disclosed under FOIA to the extent permitted by 35 USC 202(c.) (5).

## I. Procedures for Exercise of March-in Rights

35 USC 203 requires that march-in rights be exercised in accordance with OFPP regulations. There were extensive comments on the procedures included in the Bulletin and a number of changes have been made as a result of the comments.

Several agencies felt the procedures were too formal and cumbersome. Some universities were also concerned that there did not appear to be a way for an agency to reject a march-in without going into a full-blown procedure. To address these concerns part 13.b. was added to provide for an informal and rapid agency decision making process as to whether or not to begin a more formal proceeding. Part 13.h. was also added to make clear that an agency could discontinue a proceeding at any time it is satisfied that march-in is not warranted. This emphasizes that march-in is strictly a matter for agency discretion. Even though an agency may begin march-in because of the complaints of a third-party, that third party does not have standing and cannot insist on either the initiation or continuation of a march-in proceeding.

discretion. Even though an agency may begin march-in because of the complaints of a third-party, that third party does not have standing and cannot insist on either the initiation or continuation of a march-in proceeding. A number of universities asked that time limits be placed on the duration of a march-in proceeding. It is not believed to be practical to place an overall time limit on a march-in proceeding, particularly since delays in fact-finding might be the result of contractor requests for delays. However, Part 13.b. includes a procedure for informal agency decisionmaking, as noted above, with specified time restraints. In addition, Part 13.g. places a 90 day time limit on the issuance of a determination after fact-finding is completed.

Several universities also recommended that march-in determinations be appealable to the lead agency. However, this recommendation was not adopted. It is believed the procedures established will ensure that march-ins are only exercised after careful consideration. Contractors may also appeal any arbitrary decisions or those not conducted in accordance with proper procedures to the courts.

Part 13.j. was added to clarify the relationship of the procedures of the Contract Disputes Act to the march-in procedures of Part 13 c. -g. to the extent a determination to march-in is considered a contract dispute.

Several universities also recommended that march-in proceedings be closed to the public where confidential information might be disclosed. Language has been included in Part 13.e. to require this. The information on utilization obtained as part of a march-in is considered within the scope of the utilization information which agencies are required to obtain the right to under 35 USC 202(c)(5), and the same statutory exclusion from disclosure is applicable to it. It can also be expected that the same information would be tradesecret information exempt from public disclosure.

#### J. Appeals

As a result of a number of comments, it was determined that the appeals provisions of Part 5.g. of the Bulletin did not address the full scope of appealable decisions and that particularly in forfeiture cases more detailed procedures abauld\_be-fallynete area and this. The information on utilization obtained as part of a march-in is considered within the scope of the utilization information which agencies are required to obtain the right to under 35 USC 202(c)(5), and the same statutory exclusion from disclosure is applicable to it. It can also be expected that the same information would be tradesecret information exempt from public disclosure.

#### J. Appeals

As a result of a number of comments, it was determined that the appeals provisions of Part 5.g. of the Bulletin did not address the full scope of appealable decisions and that particularly in forfeiture cases more detailed procedures should be followed. Part 14 has been revised accordingly. However, other recommendations to allow appeal to the lead agency were not adopted since a number of agencies were concerned that this would interfere with their prerogatives.

## K. Multiple Sources of Agency Support

One university suggested that there was a need for additional guidance in cases when a subject invention can be attributed to more than one agency funding agreement. To address this concern Part 16c. was added to require agencies to select one agency to administer a given subject invention when there have been multiple agencies providing support. It is intended that only that agency could then exercise march-in or take other actions under the clause. It would be a matter between the agencies as to how any actions of the selected agency would be coordinated with the others.

### L. Lead Agency

Bulletin 81-22 noted that the lead agency concept was under discussion and solicited comments on this matter. The Department of Commerce has been selected as the new lead agency based on its prior experience and wide ranging interest in technology transfer, productivity, innovation and Government patent policy. The lead agency will, among other assignments, review agency implementing regulations; disseminate and collect information; monitor administrative or compliance measures; evaluate the P.L. 96-517's implementation; and recommend appropriate changes to OMB/OFPP.

# M. Optional Clause Language at Section 5b.(1)(Vi) of the Bulletin

The most commented upon aspect of the Bulletin was the optional reporting language authorized by Part 5.b.(l)(vi). Approximately 70 comments were received from universities and nonprofit organizations objecting to its use. The premises underlying the rationale for the optional language was brought in question by a number of commentors. Many others made the point that the use of the clause would undermine their licensing efforts, result in nonreporting of inventions by inventors, and would generally be counterproductive. By way of contrast no agency provided any rationale for the need for these provisions.

In view of the comments and lack of any established need for the optional language, part 5.b.(l)(vi) of the Bulletin has been eliminated from the final Circular. As will be discussed, below, some changes have been made to paragraph c. of the standard clause of Attachment A of the Circular that relate to the issues raised by the optional language.

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# II. Comments on Standard Patent Rights Clause

#### A. Paragraph b. - License to State and Local Governments

One agency suggested that the right to license state and local governments be made part of the standard rights of the Government. This, however, has not been done since the granting of licenses to state and local governments is not consistent with P.L. 96-517. That statute defines the Government's license rights, and any expansion of these rights, would have to be justified under the "exceptional circumstances" language of 35 USC 202 on a case-by-case basis. It is not anticipated that the taking of such rights would ordinarily be consistent with the policy and objectives of the Act since such licenses have acted as a disincentive to general commercialization. Thus, while appearing to be useful to state and local governments such licenses have actually acted to their disadvantage to the extent they have precluded private development of inventions useful to state and local governments.

## B. Paragraph c. - Reporting, Election, and Disclosure

There were a number of comments on various aspects of paragraph c. As a result some changes have been made. In general, these changes were designed to provide a reasonable accommodation to the interests of several agencies in obtaining early knowledge of inventions and to minimize the possibility of statutory bars being created in situations where the agency might wish to seek patents if the contractor does not elect rights. Thus, the reporting period was lowered from six months to two months after contractor personnel become aware of the invention. Paragraph (c)(1) also contains revised language to ensure that contractors keep the agency informed as to initiation of the one year statutory period within which a patent application must be filed in order to obtain a valid patent in the United States. The period in which an agency may require an election of rights has also been increased from 45 days prior to a U.S. statutory bar to 60 days. However, the requirements that a contractor also general, these changes were designed to provide a reasonable accommodation to the interests of several agencies in obtaining early knowledge of inventions and to minimize the possibility of statutory bars being created in situations where the agency might wish to seek patents if the contractor does not elect rights. Thus, the reporting period was lowered from six months to two months after contractor personnel become aware of the invention. Paragraph (c)(1) also contains revised language to ensure that contractors keep the agency informed as to initiation of the one year statutory period within which a patent application must be filed in order to obtain a valid patent in the United States. The period in which an agency may require an election of rights has also been increased from 45 days prior to a U.S. statutory bar to 60 days. However, the requirements that a contractor also file 45 days prior to the bar date has been eliminated, but paragraph (c)(3) has been revised to require the contractor to file before the U.S. bar date in all cases. It is believed that it would be rare for a contractor to elect and not file

given to tightening up the clause provisions to cover cases when a contractor elects but makes no progress towards the timely preparation for filing.

One commentor expressed the concern that the clause requires a contractor to file foreign patents if it elects rights. It should be clear that while there is an implicit obligation to file an initial patent application when an election is made, the language is not intended to require the filing of foreign applications. Instead, it is intended to establish a cut-off point so that the sponsoring agency can file foreign applications if the contractor decides not to.

In short, the clause provisions have been written to ensure that agencies are able to make U.S. filings in cases when contractors have received reports from their inventors in time to allow this but are not themselves interested. Where such initial filings have been made, the clause is designed to protect the opportunity for the filing of foreign patents in cases when a bar was not created prior to the initial filing. However, it has been determined to be unreasonable to require contractors to forfeit domestic rights because publication creates an immediate bar to valid patent protection in some foreign countries.

# C. <u>Paragraph k</u>

There were several comments on paragraph k. Some commentators were apparently unaware that these restrictions are required by P.L. 96-517. One commentator incorrectly interpreted paragraph k. (2) as requiring agency approval of exclusive licenses to large firms, whereas the language only requires approval of licenses to such firms which would exceed the five and eight year periods in the statute.

Probably the most significant comments in this area were related to the use of the word "any" in paragraph k. (3). It was pointed out that the use of the word "any" could be interpreted as requiring sharing of gross royalties, whereas many universities have sharing formulas based on net royalties. In response to these comments, the word "any" has been dropped since it is not in the statutory language. The intent is that nonprofit organizations share either on a net or gross basis in accordance with their usual policies.

There were also a few comments that some minimum sharing formula be established. However, this suggestion was rejected as being inconsistent with the legislative intent as manifest on p. 33 of Senate Report 96-480.

formula be established. However, this suggestion was rejected as being inconsistent with the legislative intent as manifest on p. 33 of Senate Report 96-480.

# Paragraph 1 -- Communications

A new paragraph has been added at the end of the clause in which agencies are instructed to designate a central point of contact for administration of the clause. This paragraph was added as a result of a number of comments suggesting this in lieu of the provision in the bulletin that contact points be indentified throughout the clause whenever notices or communications to the agency were required.

OMB Circular No.A-124 follows.

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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 <u>contractor</u>, 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 <u>contractor</u>, 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. <u>Special Provisions for Contracts with Non-profit</u> Organizations

If the <u>contractor</u> is a non-profit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions and which is not, itself, engaged in or does not hold a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention provided that such assignee will be subject to the same provisions as the contractor);

(2) The <u>contractor</u> 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

(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 <u>contractor</u> will share royalties collected on a subject invention with the inventor; and

(4) The balance of any royalties or income earned by the <u>contractor</u> 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.

1. <u>Communications</u>. (Complete According to Instructions at Part 8.b. of this Circular).

END OF CLAUSE