

UNIVERSITY TECHNOLOGY CORPORATION

South Square Corporate Centre Suite 210 3710 University Drive Durham, North Carolina 27707 (919) 493-0101

TECHNOLOGY LIAISON OFFICE

TRAINING MANUAL

AUGUST 1987

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TECHNOLOGY LIAISON OFFICE TRAINING MANUAL

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The following press release is indicative of the background of why UTC was formed and indicates in general terms the purposes and marketing strategy of the company. Following the press release are a series of short paragraphs giving the major features of UTC's business, its officers, and its procedures.

** Press Release **

Corporation Formed To Help Transfer Of Technology From Universities Of Industry

Durham, NC - September 3, 1986

University Technology Corporation (UTC) has been formed to solve the problems of getting the intellectual innovations of U. S. universities to the appropriate U. S. companies. UTC is starting with financing of \$3.5 million and exclusive signed licensing contracts with The Georgia Institute of Technology, and the Universities of Maryland and Connecticut.

"American university researchers are making some of the most exciting advances in the world, but getting those inventions out of the labs and into production is often a secondary concern," says Carl B. Wootten, President of UTC.

UTC, as the exclusive agent for licensing most forms of technology from these universities, will identify the innovations, find the most likely potential users, and negotiate the licensing terms on behalf of the universities. Where it is appropriate, UTC will obtain venture capital to develop and market the invention.

Says Wootten, "UTC is already playing the essential role of making sure that advances that could benefit the national economy do not languish in an isolated laboratory. We intend to play the facilitating role similar to that often played by government departments in Japan, only we will do so as a private sector company."

Wootten co-founded UTC after seeing the problems and opportunities while the Director of the patents program at the University of Virginia and then Duke University. He was responsible for technology transfer programs at both institutions.

UTC's approach of having a full time specialist on campus and a separate group of licensing specialists is unique in the U. S.

The other co-founder of UTC is Stanley P. Fisher, a noted patent attorney.

While Georgia Institute of Technology, Atlanta Georgia; the University of Maryland, College Park; and the University of Connecticut, Storrs, Connecticut have already made UTC their exclusive agent, negotiations continue with a number of other universities.

Contracts with these universities provide for a 50/50 sharing of compensation or income that results from a license. UTC's income will come only as a result of successful licensing arrangements, a strong incentive.

Collectively, the three signed universities undertake relevant research of over \$150 million per year.

Says Wootten, "Companies can approach UTC to tap into all this valuable research. To them, we are like one-stop shopping. One enquiry with us will tell them what is available at several universities and provide a business-like organization with which to negotiate. Our unique approach simplifies the approach of technology transfer."

The \$3.5 million financing was just raised in conjunction with the Atlanta based investment banking firm of Robinson-Humphrey, Inc., a subsidiary of American-Express. Among the investors are a number of prominent business leaders in the Southeast, Robinson-Humphrey and several Japanese business persons.

UTC has started with seven employees and is located in Durham, North Carolina near the Research Triangle Park.

As part of its early growth, UTC is assisting in establishing a similar company (UTC-Japan) to facilitate world awareness of its client's research and is working to establish UTC-Europe.

BUSINESS CONCEPT

- Exclusive licensing agent for selected major universities.
- Screen all university research
- Identify inventions with commercial applications.
- Protect the inventions with patents
- Locate companies needing the technology.
- Negotiate licenses to use the technology
- Share royalties on a 50/50 basis.

TYPICAL UNIVERSITY PROBLEMS WITH TECHNOLOGY TRANSFER

- Law requires active licensing program
- Usually assigned as a part time job to an inexperienced and overworked staff member
- Difficult to obtain adequate funding specifically for technology transfer activities
- Many inventions presently lost
- Faculty upset if not pursued

VALUE ADDED BY UTC

- Support provided for a full time, experienced on-campus staff
- Supervision and support of the on-campus staff
- Special computer system for university patents
- Highly trained, industry-specific licensing executives
- Proprietary data base with technology interests of hundreds of companies worldwide

UTC STAFF

Carl B. Wootten - President, Chairman of the Board, Chief Executive Officer and Treasurer, age 53. From 1979 to mid 1986, Director of Patent Administration at Duke University. Held a similar position at the University of Virginia prior to Duke. From 1964 to 1975, Mr. Wootten was an Officer and a Board Member of several corporations dealing primarily with the Nuclear field. He was responsible for the formation of Iradaco, Inc., a new type of irradiation sterilization facility. Prior to this he served for eight years in management and administrative positions with the U. S. Navy. Mr. Wootten obtained his Bachelor of Science degree from the U. S. Naval Academy in 1956.

John A. Fraser - Executive Vice President, age 40. From 1984 to mid 1986 Mr. Fraser was a private consultant in Toronto, Canada in the area of business development of technology products. From 1980 to 1984 he was Vice President of a \$15 million Toronto based venture capital company. From 1973 to 1980 he was a senior officer at the Natural Sciences and Engineering Research Council (the Canadian equivalent of the U. S. National Science Foundation). Mr. Fraser received a Masters Degree in Biochemistry from the University of California at Berkeley.

David W. Strevel, Ph.D. - Licensing Executive, age 39. David was most recently Manager for Technology Assessment in the computer area at RJR Nabisco headquarters. In this job he evaluated many different lines of computer hardware and new software products. David has managed several software development projects in the dental and medical fields and was Assistant Professor at Bowman Gray School of Medicine for seven years. He has a Bachelor's and Master's degree in electrical and computer design engineering from the University of Michigan and a Ph.D. in Decision Science from the Wharton School of Business.

Jacob W. Maczuga - Licensing Executive, age 38. Mr. Maczuga will join the Company on August 1, 1987, rounding out UTC's technical capabilities in the areas of chemicals and chemical engineering. From 1984 to present he served as Engineer/Scientest at Western New York Technology Development Center and from 1980 to 1984 as Development Engineer for Allied Chemical. Mr. Maczuga has a Bachelor's degree in Biochemistry and a Master's in Chemical Engineering. He has been responsible for licensing and development of start-up companies for the New York University system for the last several years, and is experienced in the licensing of university technology to industry.

Edward F. Horne - Associate Licensing Executive, age 30. From 1984 to 1986, Marketing Specialist - Analyst for Gregory Poole Equipment Company in Raleigh, North Carolina. His duties included development of procedures for making five year sales forecasts and annual updates to the forecast, preparation of five year economic forecasts and monthly sales analysis for the sales department. In 1983 he served with E. Boyd and Associates with responsibility for coordinating the flow of frozen poultry from the plant to overseas customers. Mr. Horne has a Masters of International Management from the American Graduate School of International Management in Arizona awarded in 1982.

The licensing professionals are supported by an Administrative Staff of four excellent people who handle the financial and administrative functions of the company.

UTC BOARD OF DIRECTORS

- Carl B. Wootten, Chairman, Chief Executive Officer and President.
- Charles B. Heustis. From 1966-1986 was Senior Vice President of Finance for Duke University. Previously (1958-1966) was Director of Finance for Hughes Aircraft Company.
- Norman A. Jacobs, President and CEO, Biotechnica, International, Inc. Mr. Jacobs was past President of Amicon Division, W.R. Grace from (1982-1985) and was President of Amicon, Inc.. Was a founder of the company in 1962.
- Edward S. Croft, III, Managing Director and Director of Corporate Finance, Robinson-Humphrey, Inc.,
- Stanley P. Fisher, Director, Secretary and co-founder of UTC.
 Mr. Fisher is "of Counsel" at the law firm of Oblon, Fisher,
 Spivak, McClelland & Maier, P. C. and was a founder of the firm.
 Mr. Fisher was previously a technical writer for the Navy Department
 and served as Patent Examiner in the U. S. Patent Office for four years.
- Additional two from investors

UTC BOARD OF ADVISORS

- Dr. William T. Davis, Director of Licensing, Pfizer, Inc. (1973-Present). He has held prior positions in licensing and science with Squibb, Inc. Ciba-Geigy, Inc. and Abbott Laboratories, Inc.
- Roger F. Drake, Director of Advanced Technology, American Technology and Ventures Division, American Hospital Supply Corp. (Now part of Baxter-American). Mr. Drake has sixteen years experience in licensing and science with AHSC. Organized the centralization of research for AHSC, and directed the Corporate Technology Center for nine years.
- Robert Goldscheider, Esq., Chairman, International Licensing Network, Limited. Past Vice President, Licensing Executive Society. He is an International lecturer and consultant on technology transfer and licensing.
- Preston W. Grounds, Manager, University-Industry Liaison Program and Associate Director for Research, The Proctor and Gamble Company, Inc. He has held several research and business management areas for Proctor and Gamble for the last twenty years.
- Shozo Saotome, President and Chairman, DIA Research Corporation, Tokyo. He set up by Mitsubishi as an advanced technology and business forecasting company for the Mitsubishi Group. He was previously Chief Patent Counsel, Mitsubishi Chemicals and Past President of LES Japan. Mr. Saotome has received the "Blue Medal" twice from Emperor top honor in Japan for industry and the only one twice so honored.
- Robin J. Skelton, Esq., Senior partner in March, Pearson, & Skelton, Manchester, Eng. Mr. Skelton in a Past president, LES U.K. and Chairman, LES University-Industry Committee. He is the Director of several companies in the U.K. and founder of the Manchester Science Park, a joint venture with universities.
- Mr. W. Bjorn Eriksen, President of Danish Technology Transfer, which is a new company he formed this past summer. Previously Mr. Eriksen was the Director of the Danish Invention Center where he handled all of the technology from Denmark as part of the Danish Government.
- Dr. Joseph J. Curry, Vice President, Hambrecht & Quist Technology Partners, Inc. Dr. Curry has been involved in semiconductor manufacturing technology since he joined Bell Labs in 1969. Since then he has served as V.P., and General Manager of Storage Technology, Microtechnology Corporation, Senior Director of semiconductor manufacturing at Four-Phase Systems and has operated his own consulting company, Semiconductor Microelectronics International.

UNIVERSITY TECHNOLOGY LIAISON OFFICER

In order to assist the University in locating and hiring appropriate candidates for the position of Technology Liaison Officer at the University, UTC has prepared the following outline of the type of person we feel best suited to filling this role and maximizing the University's disclosure rate. Obviously, these guidelines are not "cast in stone", but experience has shown that a person who meets these general requirements has the best chance of performing the required functions in an outstanding manner to the benefit of both the University and UTC.

Education

The candidate should have a University degree in the Sciences or in Engineering, with advanced degrees helpful.

Preferred Experience

Prior working history should include familiarity with a range of technologies and/or sciences.

A history of practical working experience with product development of a technology based product in a research management role would be of particular help.

Must have enough work history to be credible to the faculty, but should not be at the retirement age, which many times tends to result in a lower energy level than is needed for this position.

Must have a proven organizational ability and the desire to create this new campus office.

Other Attributes

Must have good verbal and writing skills, with an outgoing type of personality. Must show demonstrated administrative ability, follow through and completion of assignments with particular attention to detail.

Must be flexible and have the ability to respond promptly and favorably to work pressures.

Must be a "shirt sleeves" manager, who will not be adverse to meeting the faculty in their laboratory and will respond promptly to faculty requests.

Must have an appreciation of the important factors in the University environment, and be sensitive to the politics of University interaction between faculty and staff.

Must be willing and able to serve as a staff arm to the faculty to assist them in the administrative details of invention management.

As previously stated, these guidelines are for review and comment by the University, and are presented in the hope that they will provide a useful working tool to assist the University in finding the <u>right</u> Technology Liaison Officer.

ROLE OF THE TECHNOLOGY LIAISON OFFICER

The role of the TLO in the overall operation is a critical one, both from the University's and UTC's standpoint.

without the TLO, the faculty does not have anyone to consult who is versed in patenting procedures and rules, and consequently many inventions are lost via publication or inadvertent disclosure. Without the TLO, the faculty does not have anyone to translate the technical jargon of the invention to something meaningful in the eyes of the businessman who must review it and make the decision to invest corporate funds in its development. Most importantly, without the TLO, UTC does not have the flow of solid disclosures to take to industry.

Thus, the TLO is one of the most critical elements in the entire technology transfer process. Without the TLO's continuous supply of disclosures, the financial base upon which both UTC and the TLO's position at the University are based cannot be maintained.

The following pages contain the description of the TLO's position and the advertisement describing the position sent to the University, as well as copies of the contract clauses pertinent to the position.

By way of guidance, the TLO is expected to build the disclosure of inventions to a rate equal to at <u>least</u> one disclosure per \$1 million in hard science research.

This rate should be attained by the end of the first year.

ADVERTISEMENT FOR TECHNOLOGY LIAISON OFFICER POSITION

UNIVERSITY TECHNOLOGY LIAISON OFFICER

University Technology Corporation is a company in the business of identifying university research with commercial potential and managing the transfer of the research to an interested industrial corporation.

UTC is seeking three unique individuals with industrial technical and management experience to take leadership of its program at three universities to enhance and increase activities in the areas of university technology identification and development on the selected university campus.

These universities are the University of Connecticut at Storrs, Connecticut, the Georgia Institute of Technology at Atlanta, Georgia, and the University of Maryland at College Park, Maryland.

Duties include:

- Maintain liaison with university researchers, administration and UTC;
- Review research underway at the university and actively seek out research with commercial potential;
- Coordinate with faculty and UTC the review and processing of each potential invention;
- Provide support to faculty members in the administrative details of invention management.

Attractive candidates will have a substantial background in at least one science or engineering discipline, approximately five years of practical working experience with product development of a technology based product in a research management role, have acquired familiarity with a broad range of technologies and have a proven ability to recognize the commercial possibilities of research work. The individuals must have the technical expertise necessary to elicit the confidence of individual researchers. They must also have excellent written communication skills necessary to document and communicate technological information to diverse audiences. They must have a proven organizational ability and the desire to create this new campus activity. They must be a shirt sleeves manager with entrepreneurial drive. Attractive candidates will have a knowledge of, and be local to each university.

Each individual will be located at and employed through the university to assist faculty to prepare documentation for UTC to seek commercial interest.

The salary will be in the \$35-50K range depending on qualifications with unique performance incentives. The universities and UTC are seeking multitalented, high energy level individuals to spearhead this increasingly important university activity.

Please send resume and name of three references within four weeks to UTC, 5012 Butternut Road, Durham, North Carolina 27707.

This is an equal employment opportunity.

EXTRACT FROM UTC/UMCP AGREEMENT

"UMCP agrees to implement under the authority of a senior UMCP officer, a full-time Technology Transfer Office as described in Article IV. A. of this Agreement, and to promptly disclose to UTC all technology subject to this Agreement. The full-time Technology Transfer Officer, who shall be a UMCP employee or employees of its designee, shall be identified and trained by UMCP, assisted by UTC, and shall have duties including he following:

- A. Maintain close contact with the research faculty to insure and encourage maximum disclosure rate and patent awareness of faculty.
- B. Based on advise of patent counsel, advise UMCP and UTC as to the patentability of identified technology which UMCP desires to be patented and actively pursue patenting of such technology.
- C. Assist faculty inventors and provide in-laboratory consultation in preparation of disclosures and marketing documents, etc.
- D. Prepare and submit monthly reports to UTC as called for in the UTC technology tracking program, and such other reports as required by UMCP.
- E. On behalf of both UTC and UMCP, monitor additional research funded by grants from licensees who have taken licenses through the efforts of UTC.
- F. Prepare marketing documentation for all inventions in consultation with UTC, such as Executive Summaries, Technical Packages, etc.
- G. Operate said Technology Transfer Office in conjunction with the automated technology tracking program provided by UTC.
- H. Conduct faculty awareness workshops/seminars regarding technology transfer opportunities and UMCP policy/employee obligations regarding inventions.
 - I. Arrange on-campus corporate visits for potential licensees.
- J. Acquire, prepare or arrange for and submit all necessary documentation to protect the interests of the inventor, UMCP and UTC, including patent opinions and technical packages and appropriate government reports.

VII

It is understood between the parties that the performance of the UMCP's Technology Transfer Office is critical to the intent of this Agreement, and that UTC may, from time to time, convey written recommendations to UMCP for setting the procedures of the Technology Transfer Office."

OF THE

TECHNOLOGY LIAISON OFFICE

ORGANIZATION

PROPOSED CHARTER AND PROGRAM DESCRIPTION

FOR THE

OFFICE OF TECHNOLOGY LIAISON

2.4 PROMOTE COLLABORATIVE AGREEMENTS WITH INDUSTRY

If an invention is not developed to a stage where it is ready for transfer to an industrial client, the Office of Technology Liaison will with the assistance of UTC where applicable, identify and encourage collaborative agreements with industry to facilitate technology development and utilize commercially feasible scientific discoveries. The Office will:

- *act as liaison with the Office of Sponsored Programs
- *if needed, aid in the preparation of proposals
- *track progress of the work to help assure client/researcher interaction and project success
- *interact with State and local Economic Development Agencies as necessary

2.5 FULFILL CONTRACT OBLIGATIONS

The Office will assist in the fulfillment of the terms of research grants and contracts so as to

- *comply with federal laws and regulations regarding inventions when federal research funds are involved
- *comply with obligations of collaborative "technology development and utilization agreements" with industry
- *where applicable, draft or review University/Industry agreements before signature by University officials

3.0 SIX-MONTH TIMETABLE FOR INITIATING THE PROGRAMS (STATUS AND PLANS)

The following five sections list the plans and example of specific actions designed to initiate Charter Programs within the first six months of operation.

3.1 PROMOTE INTELLECTUAL PROPERTY PROTECTION

-Publicize the Office, achieve positive publicity for the University and UTC

Campus Paper

Month One

Business Section of local paper and major area paper

Month Two

-Make presentations to campus groups concerning Office Services

At least one per month

Ongoing

-Distribute new and Comprehensive Invention Disclosure Forms

Month Three

-Coordinate seminar by Legal Counsel to faculty and interested administration	Month Five
-Distribute an educational Brochure to faculty	Month Six
3.2 ENCOURAGE RESEARCH	
-Present Invention Disclosure Incentive Plan and have approved by University	Month Two
-Publicize Incentive Program (campus papers)	Month Three
3.3 TRANSFER TECHNOLOGY	
-Complete initial action items for all prior disclosures and recommend action to UTC	Month Four
3.4 INTERACTION WITH SPONSORED PROGRAMS ON NEW	GRANTS
-Design a system, with the Office of Sponsored Programs for entering and assigning keywords to new contract and grant awards	Month Four
-Debug and test UTC database system	Month Five
-Finalize system and begin operations	Month Six
3.5 FULFILL CONTRACT OBLIGATION	
-Design a system, with the Office of	
Sponsored Programs, for making interim and final government reports	Month Four
Debug system	Month Five
Finalize System	Month Six
-Review various agreements and Memoranda of Understanding for University researchers involved in industrial client relationships involving patent agreements	
Complete review of prior agreements	Month Two
Review new agreements	Ongoing

OFFICE OF TECHNOLOGY LIAISON

1.0 CHARTER

Provide expert guidance, support and assistance to: safeguard intellectual property, encourage research, facilitate technology transfer, promote collaborative R & D agreements with industrial sponsors, and assist in fulfilling terms of research grants and contracts in order to provide maximum benefit to the public and the University.

2.0 PROGRAMS

2.1 PROMOTE INTELLECTUAL PROPERTY PROTECTION

In order to safeguard the intellectual property of the University, the Office of Technology Liaison will provide materials and educational services to researchers in the following areas:

- *patentability (requirements for obtaining a patent)
- *the invention disclosure process
- *guidelines for technical records and documentation of inventions

2.2 ENCOURAGE RESEARCH

The Office will provide individual incentives to inventors in the form of:

- *professional recognition and
- *financial compensation

2.3 TRANSFER TECHNOLOGY

The Office will act as a technology liaison to link the goals of the University to opportunities in the industrial sector through interactions with University Technology Corporation (UTC). The Office will:

- *review University Policy in the areas of research, technology development and intellectual property protection;
- *recommend modifications of policy to include new incentives which are consistent with the spirit of the University;
- *seek out and identify opportunities for technology transfer and serve as a liaison between University researchers and University Technology Corporation;
- *develop and nurture interactions with industry for technology transfer;
- *maintain an awareness of technical expertise and individual accomplishments of University staff to promote research and technology development at the University.

UTC COMPUTER PROGRAM FLOW CHART

The following pages describe, in flow chart format, the functions of the Technology Liaison Office. The charts are divided into five main areas and show how each section is interconnected.

-Grants and Contracts: The liaison with Office of Sponsored Programs to identify new research and introduce the TLO to individual researchers.

-Receipt of Invention Disclosures: Tracks a new disclosure to the decision point of proceeding with marketing or obtaining a patent opinion.

-Marketing: Delineates TLO action required to provide UTC with documentation for marketing.

-Patent Opinion: Shows TLO action needed when patent opinion required to bring the invention to the marketing step, reject it or put it in abeyance.

-Government Reports: Tracks invention reports required on government sponsored research.

FLOW CHART

Technology Liaison Office

Legend:

CE = Computer Entry Required

DL = Disclosure Log

ES = Executive Summary

FL = Form Letter

FU = Follow Up Action Required

GC = General Correspondence

GF = Grants File

GR = Government Report

IA = Immediate Action

IDS = Invention Data Sheet

1&1 = Inventor & Invention

KW = Keywords

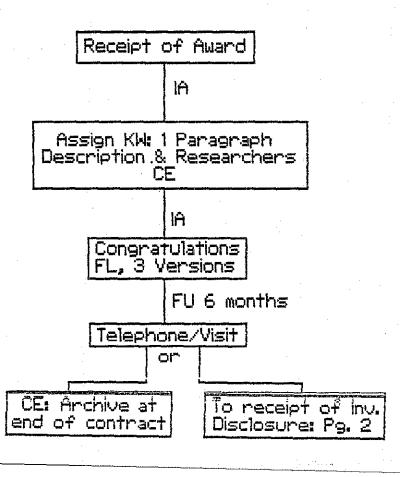
MDS = Monoclonal Data Sheet

TP = Technical Package

VX = Volkswriter

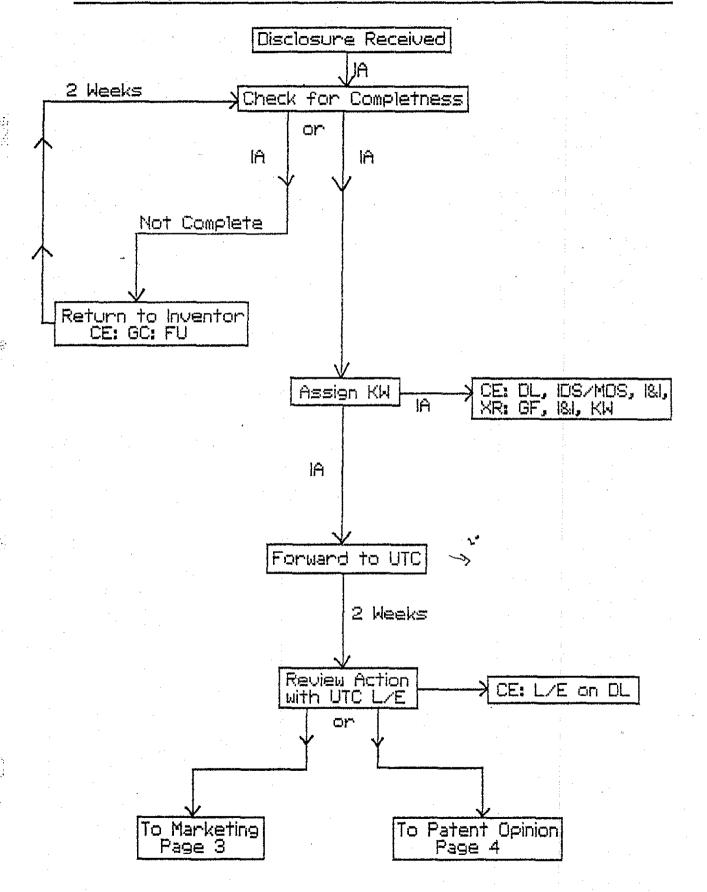
XR = Cross Reference File

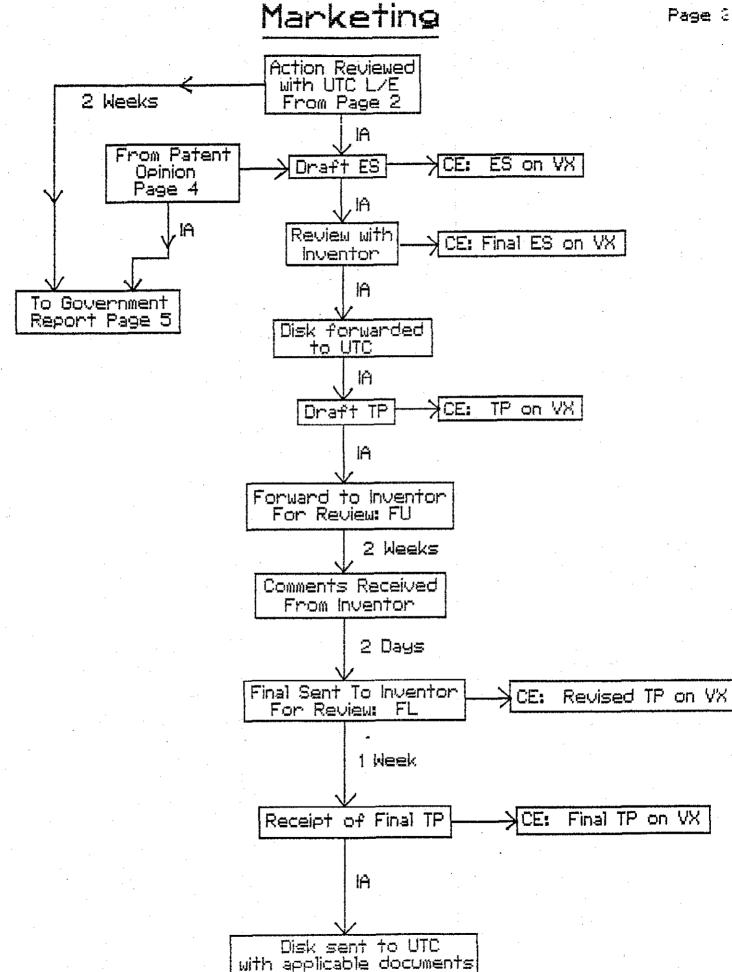
Grants & Contracts

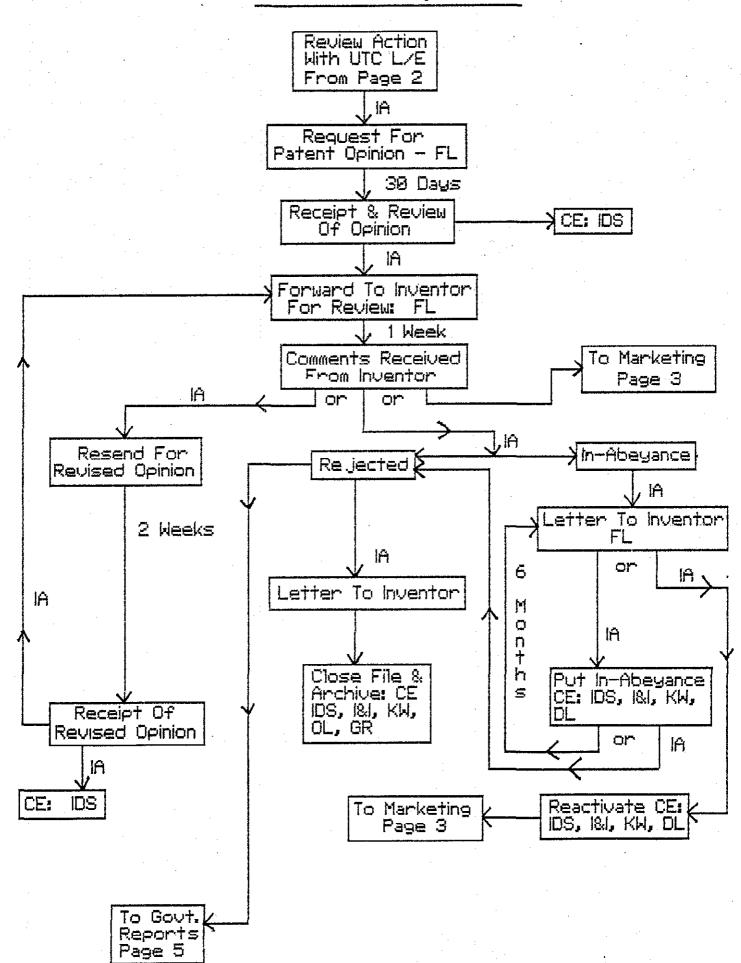


Receipt of Invention Disclosure

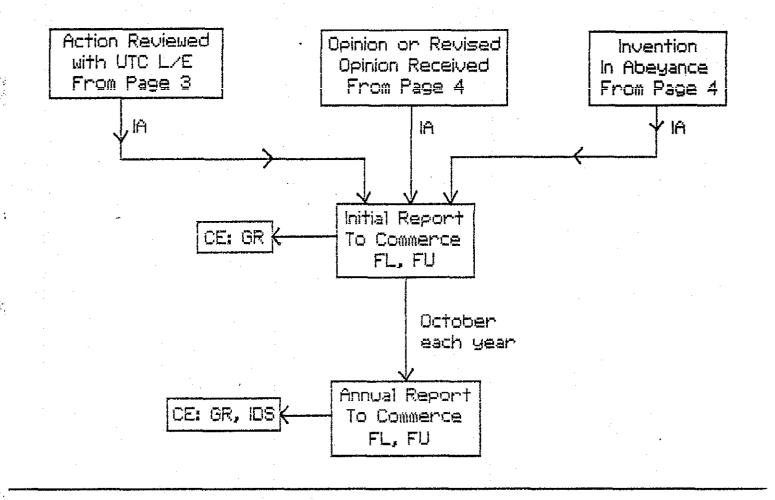
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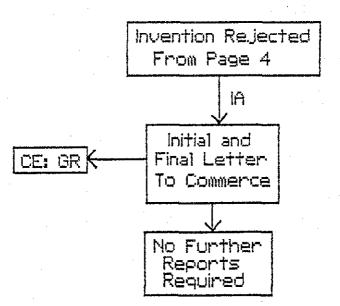






Government Reports





TECHNOLOGY LIAISON OFFICE SECRETARY'S HANDBOOK

I. Secretarial Office Procedures

A. Telephone

- Incoming Calls Maintain pleasant and courteous telephone manner at all times.
 - a. On each incoming call obtain person's name, who they are associated with and what the call is in reference to. This is done so that the TLO can access the appropriate file from the computer system for the telephone discussion.
- 2. Outgoing Calls Long distance calls associated with invention management should be made on the office telephone. All other long distance calls must be charged to a separate account.

B. Mail

- Incoming Mail All correspondence should be date and file stamped and logged in on the computer by the Secretary, and given to the TLO for review. This system has proven to be very efficient and allows immediate response on a daily basis to most correspondence.
- 2. Outgoing Mail To be sent out at least once a day, unless it is urgent, in which case arrangements will be made for immediate mailing, e.g. Emory, Federal Express, Telefax, etc.
- C. Office Supplies An inventory of supplies is to be made at least monthly. A list of supplies is maintained in the office and should be kept up-to-date. See Appendix A for basic requirements.
- D. Filing All filing should be maintained on a daily basis due to the constant need for referral to the files.

II. Outgoing Correspondence

A. Two copies of all outgoing correspondence associated with inventions will be made, with one copy filed in the appropriate invention file and one copy filed in a chronological file.

III. Procedures For Invention Disclosures

- A. Make sure all signatures have been obtained and sponsor section is complete. If not fully executed, return to the Inventor(s) with appropriate instructions. These must be signed completely by all parties, including the witness and inventor(s) signatures inside the disclosure document. Do not stamp, log in or assign an ID # until complete.
- B. Date and File Stamp each Invention Disclosure Form as received, but only when it is complete.
 - 1. Assign the calendar year, sequential number to the invention, e.g., 02-86-002 (This is the invention ID number).
 - 2. Complete the following computer entries:
 - a. Invention Data Sheet
 - b. Record appropriate follow-up dates for government sponsorship, if applicable, check of publication status, etc.
 - c. Invention Status Sheet.
- C. Review by TLO with Inventor(s) for initial decision on acceptance/in-abeyance/rejected and verification of keywords.
 - 1. If rejected, forward only the Invention Status Sheet to UTC for concurrence. If UTC concurs, prepare appropriate government report (if applicable) and file in Rejected files.
 - If "in-abeyance", forward entire disclosure to UTC for concurrence. If UTC concurs, file government report accepting invention for government purposes, and place in appropriate follow-up with the inventor(s).
 - 3. If accepted, forward entire disclosure to UTC for review and assignment to responsible LE. Prepare government report, if applicable, and put on appropriate follow-up.
- D. The TLO, in conjunction with the inventor, prepares an Executive Summary and Technical Package. These then need to be typed into the computer for future use along with sending the Executive Summary and Technical Package to UTC on a floppy disk for review by the responsible LE.

IV. File Set-Up And Maintenance

- A. Set-up the Invention files in the following manner:
 - 1. Technical & Patent Files:
 - a. White, long tab on 8-1/2 x 14" manila folder with the label on the left hand side. There will ultimately be several technical and patent files for each invention for such items as Continuations-in-Part (CIP's), Divisional Applications (DIV's), and a variety of foreign filings, such as individual countries and/or Patent Community Treaty (PCT). These files contain the Invention Disclosure Form and all technical and patent (legal) information and correspondence associated with the invention.
 - b. Green, long tab on $8-1/2 \times 11$ " manila folder with the label in the center. This file will contain government reports and all government correspondence associated with the invention.
 - c. Blue, long tab on 8-1/2 x 11" manila folder with the label on the right hand side. This file contains correspondence with the inventor(s) concerning internal matters only. Correspondence with the inventor(s) concerning technical aspects belong in the Technical & Patent files.
 - d. Red. long tab on 8-1/2 x 14" manila folder with the label on the left hand side. This file should be made only when and Option/License/Research agreement is concluded. This file contains the original legal document of the Option/ License/Research agreement.
 - 2. Labels on each file should contain the following:
 - a. Technical & Patent file I.D.#, Title of Invention, and identification of the file, e.g., U.S. Patent, PCT, CIP, etc.
 - Government Reports I.D.#, Title of Invention, Government Agency involved.
 - c. Inventor Correspondence I.D.#, Title Of Invention, Primary Inventors Name.
 - d. Option/License/Research I.D.#, Title Of Invention and Company Name.
 - 3. Hanging files are to be set-up with corresponding colors and tab locations for each invention.
 - 4. Other files General correspondence and General information files are to be set-up as desired by the individual TLO.

V. Future Improvements

A. As the system is refined, Executive Summaries and Technical Packages, including additional technical information requested by UTC (addendums to the Technical Package) will be sent by modem directly to UTC's computers.

APPENDIX A

Basic Supplies Needed

Date Stamp - See attached

File Stamp - See attached

High Density Floppy Disks

8 1/2 x 14' Manila Folders

8 1/2 x 11" Manila Folders

Hanging File Folders

Labels:

White - Long

Green - Short

Blue - Short

Red - Long

Hanging Folder Tabs:

White - Long

Green - Short

Blue - Short

Red - Long

Other various office supplies

The following stamp should be procured to serve as the log in of inventions and separation to the appropriate files

	Jul 15 1987	Date 9	Stamp
	University Name		
File .	T/P		Technical & Patent
ightarrow Stamp	Inv.Corr.		Inventor Correspondence
	Gov.Rpt		Government Report
·	0/L		Option/License
	Visits		Visits
	Gen.Info		General Information
	Other		Other
	Logged In		Logged In Date
	L.E		UTC Licensing Executive
		1	

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UNIVERSITY TECHNOLOGY CORPORATION

(University Name)

I.D.No.

INVENTION DATA SHEET

	Discl. Date					
TECHNICAL TITLE:						
LAYMAN TITLE:	Discl	.Date				
Inventor (1)	Dept.	Royalty %				
Inventor (2)	Dept.	Royalty %				
Inventor (3)	Dept	Royalty %				
Inventor (4)	Dept.	Royalty %				
Attorney:	Docket Number	· · · · · · · · · · · · · · · · · · ·				
Govn't Sponsored: Y N	C/G Number_	:				
<u>s</u>	TATUS INFORMATION	•				
Initial Patent Opinion: Re	eceived:					
Comments:	<u> </u>					
Revised Patent Opinion: Re	eceived:					
Comments:	·					
Initial Report Sent To Sponsoring	ng Agency:	<u></u>				
Annual Report 19_;: 1	9;: 19;	: 19;				
Patent Application & Assignment	Filed:	· · · · · · · · · · · · · · · · · · ·				
Declaration Executed:						
Small Entity Status Filed: Y	<u>N</u>					
Rejected/In-Abeyance:	Archived? Y	N N				

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JAP.					CIP_DIV_	I.D.#
CAN.					CIP DIV	I.D.#
						
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UNIVERSITY TECHNOLOGY CORPORATION

(University Name)

MONOCLONAL DATA SHEET

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TITLE:					
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Inventor (2)		Dept		· · · · · · · · · · · · · · · · · · ·	Royalty %
Inventor (3)		Dept.		·	Royalty %
Inventor (4)		Dept	<u></u>	· · · · · · · · · · · · · · · · · · ·	Royalty %
Government Sponsored YN	1	C/G No			
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(University Name)

	DISC	C. NO	
	I.D.	.No	 -
RE: REPORT OF INVENTION DEVELOR	PED UNDER FEDERALLY	FUNDED RESEARCH	
1. Type of report: Initial	Annual as	of	
2. Agency			
3. Contract: Grant	Start Date:		
4. Title:			
5. Inventor(s):			
6. Date of disclosure to Univers	sity:		
7. Description of invention:			
8. Status of U.S. Application:			
9. Recorded assignment to Univer	csity:		
10. Publication status:			
<u>Journal</u>	Accepted	Published	
	<u> </u>		
Copies of published paper	rs enclosed: Yes	No	
11. Publications ban by agency	requested: Yes	No	
12. Elections of title to be made	de by:		
13. U.S. Application to be filed	d by:		
14. Foreign filing election to k	oe made by:		
15. Utilization of invention:			

Page 2	•			I.D.
Date:			-	

RE: REPORT OF INVENTION DEVELOPED UNDER FEDERALLY FUNDED RESEARCH

Number

- 16. Status of development
- 17. Date of first commercial sale or use:
- 18. Licensees and Intended Commercial Use:
- 19 Copy of Application:
- 20 Copy of Licenses:
- 21. Government license status:
- 22. Copy of patent:

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INVENTION DISCLOSURE INCENTIVE PLAN

FOR

(UNIVERSITY NAME)

Prepared by

TICE OF TECHNOLOGY LIAISON

Date

(University Name)

TECHNOLOGY LIAISON OFFICE

CAMPUS PROMOTION PROGRAM

The following pages are recommended programs for the Inventor Incentive Plan to be put in place on the campus and to outline the initial promotional activities when the Technology Liaison Office is first started.

Once approved by the appropriate University administrative officials, they should be widely publicized.

1.0 Description of the Plan and Potential Benefits

1.1 Description

This plan outlines the mechanism to recognize and award inventiveness at the University. The awards will take the form of cash payments from the TLO Office and funded by UTC. Although the amounts are small when compared to the inventor's share of revenue from a licensed invention, an early incentive is provided to inventors to disclose and follow-up on their inventions. Three types of cash awards will be provided.

First, the author(s) of each invention disclosure, accepted by the TLO and approved for marketing by UTC, will be awarded a small cash payment of \$50. This will give inventors the incentive to complete and submit disclosures.

Second, a \$100 cash payment will be made to the inventor(s) for any filed U.S. Patent application. This payment will offer an incentive to work with the TLO and the patent attorney in the time preceding filing of the application. It also serves as payment for the assignment of rights to the University.

Third, an annual Outstanding Invention Award will be presented to the inventor (s) for the best overall invention, as determined by an inventor ballot. Presentation of the award will be made at an annual "Inventors Luncheon (Dinner)". All inventors, listed on disclosures for the calendar year, and selected University administrators will be invited to the presentation ceremonies and luncheon. The program will include the recognition of all disclosures submitted during the year and a cash award of \$1000 will be made by UTC to the inventor, along with a plaque commemorating the occasion.

1.2 Other Benefits

In addition to the benefits described in Section 1.1, other benefits accrue to the University, such as:

- *the awards will serve as an avenue for publicity for the Office of Technology Liaison
- *the luncheon (dinner) and award ceremony for the Outstanding Invention Award for the year will provide a forum to remind researchers of the services available through the Technology Liaison Office.
- *the award ceremony will provide professional recognition for the inventors, their disclosures and the inventors' accomplishments.

2.0 Description of the Awards

2.1 Individual Disclosure Awards

Each invention disclosure submitted to the Office of Technology Liaison will be reviewed by the TLO and UTC for acceptability. Upon acceptance, a total cash award of \$50 will be made to the inventor(s). Each inventor will receive an equal share of the award.

2.2 Assignment Awards

An assignment payment will be made to the inventor(s) of each invention disclosure which results in a United States Patent Application. A total cash payment of \$100 will be made to the inventor(s) upon assignment of the invention. Each inventor will receive an equal share of the award.

2.3 Outstanding Invention Award

An annual award will be given to the inventor(s) of the most outstanding invention. A \$500 cash award will be presented at the annual inventors luncheon (dinner) along with a plaque. The cash award will be presented and funded by UTC, and the plaque presented by the University. The University will host the luncheon (dinner).

TECHNOLOGY LIAISON OFFICE

PROMOTION PROGRAMS

- 1. On opening the office, arrange for a press release on-campus and in the local newspapers.
- Arrange a time for UTC to give an open seminar on Inventions/Patents/ Commercialization (see attached for agenda).
- 3. Arrange to meet the Principal Investigators of major contracts to review their technologies and make them aware of the new office.
- 4. Arrange to meet key University Administrative Deans and Department Heads.

MEETING KEY PERSONS

It is important to identify and meet key decision makers on campus.

Review the disclosures and identify these people. In your review of their cases, determine if it is beneficial to meet them. Ask who the "inventive people" are on campus.

Meet Department Heads and request an invitation to address a departmental meeting.

Meet key Deans and Vice Presidents to inform them of the program. Learn of expectations and anticipated problems. Win their support.

Meet key faculty members who have been successful in acquiring company contracts.

UTC SEMINAR

INVENTIONS/PATENTS/COMMERCIALIZATION

- l. University Host Introduction.
- 2. UTC Who/Why/Structure
- 3. University:
 - Slide of Contract/Grant \$ and recent number of disclosures
 - UTC Incentive Plan
 - UTC Goal
- 4. University TLO Who and Why
- 5. UTC Disclosure Forms What and Why
- 6. Patenting Why and When
- 7. TLO Process:
 - Visit To Inventor
 - Disclosure Form
 - UTC Executive Summary
 - UTC Technical Package
- 8. UTC Marketing:
 - Database
 - Inventor Suggestions
 - Others
 - Visits To University Inventor
 - Deal Option & Research & Development
 - Closing A Deal
- 9. Expectations:
 - Per project 6 months
 - Per university Disclosures/\$1 Million
 - Compensation
- 10. Getting Started

TLO LETTER TO UNIVERSITY CONTRACT HOLDER Date:

Name/Address			
Re: Contract Number	-		
Dear Dr. X:			
I note that you	received the above con	tract starting in	•
I am interested one week's time.	to learn more about yo	ur research program an	d will call you in
action to commercial	rom the enclosed news ize research that has and hard work on my par	excellent potential.	
	o talking with you nex 't hesitate to give me		ny questions in the
	: :	Sincerely,	
	÷ .		
		TLO Title	<u>.</u>
		; ;	

DISCLOSURE FORMS

ITEMS FOR DISCUSSION DURING FACULTY INTERVIEW

- 1. Background of TLO/UTC
- 2. Describe TLO/UTC Interaction
- 3. Review the disclosure in detail; following the Invention Disclosure Form with the Inventor
- 4. Discuss marketing strategy as seen by the Inventor
- 5. Construct a positive course from disclosure and define follow-up items needed and time frames/milestones to completion
- 6. Explain the procedures from disclosure to marketing by UTC, and how UTC approaches the marketing
- 7. Review "Patent Information" with the Inventor to insure that he is aware of the procedures
- 8. Give the Inventor TLO's initial reaction to the Invention. Be sure to include negative items, but don't emphasize.

Summary:

Be Enthusiastic

Leave With Positive Ending

PREPARATION OF EXECUTIVE SUMMARY

THE EXECUTIVE SUMMARY

The Executive Summary is designed for the busy executive. It should briefly describe, in layman's terms, what the invention does, but not how it does it.

The following are guidelines for the preparation of the Executive Summary:

- 1) One page maximum
- 2) Point to cover:
 - a) A summary of the problem being addressed.
 - b) A summary of how the invention solves or addresses the problem.
 - c) A paragraph on current results and future work planned.
 - d) A paragraph on potential market and applications as seen from our perspective.
 - e) Patent situation and licensing statement.



UNIVERSITY TECHNOLOGY CORPORATION

South Square Corporate Centre Suite 210 3710 University Drive Durham, North Carolina 27707 (919) 493-0101

CATHETER DEVICE TO TEMPORARILY SEAL VENTRICULAR SEPTAL DEFECTS POST MYOCARDIAL INFARCTION

Executive Summary

Approximately 600,000 Americans are hospitalized each year after having heart attacks. In 2% - 3% of these cases, ventricular septal defects (VSDs - holes between chambers of the heart) occur leading to stresses such as right ventricular volume overload, congestive heart failure, and diminished cardiac output. Such defects have an 85% early mortality rate.

The Emory University School of Medicine has recently initiated a joint research program with the Georgia Institute of Technology to perfect a device to temporarily close such defects when the infarct patient is admitted to the hospital. This catheter-based, non-surgical technique allows the physicians to stabilize the patient's condition before surgical closure is attempted. The intent is to allow sufficient time (10-14 days) for healing of the tissue adjacent to the VSD to occur so that the defect can be closed successfully and permanently by surgery. This device is a radical departure from what is clinically available in the management of ventricular septal defects post myocardial infarction.

The internationally known Cardiology expertise of the Emory University School of Medicine will be combined with the mechanical design and manufacturing expertise of the Georgia Institute of Technology in the development and testing of this device.

Preliminary designs of this device have been created and prototypes constructed. In the next several months, studies will be undertaken in vitro in a bench-top heart model, with in vivo canine studies to follow.

The inventors are targeting the first market as heart attack victims with VSDs requiring emergency open heart surgery. Given the current high mortality associated with alternative therapeutic procedures, it is felt that the risk-benefit ratio for this technique is more than acceptable.

Other possible markets for this device include the temporary closure of the rupture of the free wall of the left ventricle into the pericardium, as well as the closure of acquired aorto-venocaval fistulae.

Patent protection is under evaluation. The inventors are currently seeking governmental and private foundation funds to finance further research and development.

UTC, as exclusive agent for the Georgia Tech. Research Corporation and the Emory University School of Medicine for this project, is seeking a corporate partner to guide, finance and, if successful, to introduce the device commercially.

PREPARATION OF THE TECHNICAL PACKAGE

If a patent application has <u>not</u> been filed, <u>and</u> the inventor has not published, this document will contain confidential information, and should be marked CONFIDENTIAL on the cover.

The document is drafted by the TLO using the invention disclosure and any additional test results available from the inventor. Once drafted, it is reviewed with the inventor for accuracy and completeness. The Technical Package should be arranged in the following general format:

- Abstract (usually the Executive Summary)
- Introduction to the problem addressed
- Full technical description of the invention
- Apparatus and procedures used for achieving the test results
- Test results to date
- Technical advantages and disadvantages of invention (Do not try to hide any technical disadvantages, but don't highlight them, either)
- Further work required, including what portion is being accomplished by the inventor and what the inventor is unable to do because of funding, equipment or staff limitations
- References (including copies of publications, if any)

Once completed and forwarded to UTC, a follow-up should be scheduled for six months to review and update the Technical Package based upon any new results obtained by the inventor.

INTERACTING WITH YOUR PATENT ATTORNEY:
PATENT OPINIONS AND FILING APPLICATIONS

SELECTING A PATENT ATTORNEY

In order for the TLO to build up an inventory of firms that have the patent expertise to handle university technologies, the following is suggested:

- 1. Obtain qualifications brochure or other documentation outlining specific areas of technical expertise in firm. This should not be too general if possible.
- 2. Interview a partner with a specific Invention in hand. Quiz partner in regards to actual experience of specific attorney he would assign.
- 3. Select one attorney based on experience. You may find specific attorneys, in different firms, for different types of technology.
- 4. Obtain specific information re billing rates, types of expenses; control of interaction by TLO.

INTERACTION WITH PATENT ATTORNEY

- 1. Ask inventor for all background documentation and send this, plus Invention, to patent attorney.
- 2. Patent attorney reviews documentation and provides cost quote to TLO.
- 3. TLO approves quote and gets attorney to talk with inventors to ask specific questions on invention, obtain background information, and even ask blue sky questions to smoke out undisclosed aspects.
- Attorney prepares first draft, sends it to TLO (not inventor). TLO forwards it to inventor and requests review by certain date. TLO follows up.
- 5. Drafts go back and forth through TLO.
- 6. Attorney can get together with inventor on an "as needed" basis. Preferably by phone.
- 7. Billings to TLO are to be done monthly, specifying action done, person involved and billing rate and costs.
- 8. Typical letters requesting opinions and requesting the filing of an application are attached.

PATENT INFORMATION

The business of a university is the gathering and dissemination of knowledge. Making an invention and putting it to use in the service of the public is a thoroughly valid mode of accomplishing this objective.

The following paragraphs outline in a very general sense the relationships between patents and university research., It explains why, in a university setting, it is best to wait as long as possible before filing patent applications.

The idea that a patent should be filed at the completion of the research program is a common misconception. The research program and patents should proceed as a cooperative effort from the time an invention is first conceived. The information provided at an early stage of the invention will necessarily be somewhat tentative and any proposed patent may need to be modified as data accumulates.

A research project often suggests a number of different solutions to a problem. These different solutions may each be patentably distinct inventions which form the subject of separate patent applications. Some will be fully developed commercially, others that are less attractive may only be explored to a limited extent. It is useful at the early stage to explore the level of commercial interest to ensure that the patent will have later commercial appeal as opposed to those proposed ideas which may be of technical interest only.

Thus, delaying the actual filing of the application until all of the data is available is important. Additionally, the company to which the invention is licensed should review the application to insure that the application reflects items of importance in the commercial marketplace and that the resulting patent would not be directed solely at the "lab model". Furthermore, filing of the U. S. Patent Application starts the time clock ticking on filing foreign patents, which the University cannot afford without assistance from a commercial partner. See the paragraph below concerning patent law requirements for a further explanation of this problem.

Formulating and writing a patent application is done with the assistance of an outside patent attorney. Normally, the work involved is done by the attorney, selecting information from the disclosure document, reprints, preprints and research notes. However, it must be carefully reviewed by the inventor and requires as much careful consideration as a peer reviewed publication.

It is important to understand the relationship between publication and the requirements of the patent laws of the various countries. If a public disclosure (such as a publication, poster board talk at a technical meeting, reprint of a talk at such a meeting, etc.) is made prior to filing of the U. S. Patent Application, you have one year from the date of such publication to file the U. S. Application, but essentially all foreign patents would be forfeited. On the other hand, if the U. S. Patent Application is filed prior to such publication, the date of filing in the U. S. protects the opportunity of filing for foreign applications.

EXCERPTED CONTENTS OF PATENT SEARCH REPORTS

The purpose of this document is to define what the TLO and the inventor should receive from a patent search firm as the results of a patent search. It is presumed that the submission to the firm included a paper and /or the disclosure form describing the invention and an opinion as to how broad the search should be (what topics, in what countries to search). It would have specified the time limit within which you expect the reply and the approximate expense you expect to pay for the search.

In reply, you should receive a multi-page letter containing:

- 1. A summary of the invention in the reviewer's own words to show his understanding of the invention.
- 2. A review of the scientific literature on the subject, with a summary of its implications for the patent claim and full citations on the most relevant articles.
 - 3. Copies of the most relevant articles and abstracts should be attached.
- 4. A documented conversation with a named Patent Examiner to aid in orienting the search.
 - 5. A list by number and name of all classes and subclasses selected for search.
 - 6. A description of prior patents found.
 - 7. Copies of the most relevant previous patent documents should be attached.
- 8. The reviewer's detailed and thoughtful outline of all features that could likely be claimed as advances over the prior art.
- 9. A list of questions and issues for the inventor to consider to aid in clarifying and strengthening his claim.

If any of the nine parts mentioned above could be consider optional, it would be numbers 2 and 3.

The purpose of item 1 is to check on the understanding of the invention developed by the attorney so all of us who read his product know we share that understanding.

Item 4 helps assure that the search was properly directed.

Item 5 lets us check up on the searcher's judgement and if there is ever a question as to the quality of the work, it gives us a basis for discussion with the firm.

Items 1, 4, and 5 take very little time to do or to report, yet they add a lot of assurance that the patent search has been well done.

All nine items from a competent firm should be received in 30 days at a cost in the \$500 - \$700 range.

TYPICAL STANDARD PATENTABILITY OPINION REQUEST

Date:

Stanley P. Fisher, Esquire Oblon, Fisher, Spivak, McClelland & Maier Crystal Square Five - Suite 400 1755 South Jefferson Davis Highway Arlington, Virginia 22202

Re: 02-86-001; Invention Title

Dear Stan,

Enclosed herewith is a recent disclosure on the referenced subject.

Would you please conduct a patent search on the referenced invention within the standard thirty day time frame and send your opinion as to it's patentability to me at your earliest convenience? Please search all prior patents, both domestic and foreign, to determine whether the invention is patentable. I understand the cost will be approximately \$_____.

Sincerely,

TIO Title

TLO:

Enclosure

cc: To Inventor(s)

TYPICAL STANDARD REQUEST TO FILE AN APPLICATION

Date:

Stanley P. Fisher, Esquire Oblon, Fisher, Spivak, McClellar Crystal Square Five - Suite 400 1755 South Jefferson Davis High Arlington, Virginia 22202			
Re: 02-86-001; Invention Title	; Your File #	· · · · · · · · · · · · · · · · · · ·	
Dear Stan,		. •	
Please prepare a patent app	lication on the above ref	erenced applic	ation.
[The technical material was ion, and subsequent information		ou for a paten	ntability opin-
[The filing deadline for this for review at least 30 days price		_, and we must	have the draft
*[Since the invention was deve appropriate credit is given in			insure that the
I understand the cost of prosperior prosperi			imately
	Ci		* *

Sincerely,

TLO Title

TLO:

*Enclosure

cc: Inventor(s)

*[To be added as applicable].

OBLON, FISHER, SPIVAK, McCLELLAND & MAIER, P.C.

"Recent developments with respect to patent filings in accordance with the PCT (Patent Cooperation Treaty) format have occurred. PCT became effective in January of 1978 and was designed as an alternative to the conventional approach to international filing. However, PCT was not widely used because the only advantage it provided was an additional eight-month period during which foreign filing could be delayed. PCT filings were thus used in a few instances as emergency techniques of buying an additional eights months time.

The scope of PCT has now been extended since the U.S. has now agreed to Chapter 2 of the Treaty. Chapter 2 provides a total of 30 months from the priority date of an international application before an applicant must decide whether to proceed with national patent prosecution. Thirty months is a long period of time, and could be well suited to your program.

A PCT filing for your organization would proceed as follows. Your original application would be prepared, as a normal U.S. application. However, it would be filed as a PCT application rather than a standard U.S. application. The only difference between a PCT and a conventional U.S. application are the forms filed with the application and the fee. The PCT fee is about twice the normal U.S. filing fee.

After the PCT application is filed, you basically do nothing for nineteen months. At that time you file a "demand" for a preliminary examination and pay a government fee. Within twenty-eight months from the PCT filing date, you receive a non-binding opinion from the examining authority as to whether the invention is patentable. You then have two months, for a total of thirty months, in which to decide whether or not to proceed further with the application. Proceeding further means entering the national stage (i.e. normal prosecution) in the U.S. as well as other designated foreign countries. Normally this would mean entering prosecution in the U.S., the European Patent Office, and the Japanese Patent Office.

Disadvantages of this system appear to be relatively minor. The first is that Canada is not a member of PCT. Thus a separate Canadian application would have to be filed. This is not a major problem since Canadian filings are relatively inexpensive. The second disadvantage is that the government fees for PCT applications are higher than those for national applications. However, we are talking in terms of only about \$1,000. You may consider this additional fee the price of deferring foreign filing expenses for an additional eighteen months.

In summary, the PCT approach provides a technique of preserving world-wide rights in an invention for about the same costs as the preparation of a U.S. application. Furthermore, it will delay prosecution and issuance of the U.S. patent for approximately eighteen months. Thus, if you want to put international patent rights "on ice" for about a year and a half, the PCT route appears to be the way to go."

THE MARKETING PROCESS

UTC PROCEDURES

The following paragraphs summarize the steps taken in the marketing process of an invention, including the TLO's role in this process.

ACCEPTANCE

UTC will <u>not</u> accept a disclosure and will <u>not</u> begin marketing until the <u>complete</u> disclosure is received together with keywords and an Executive Summary. Only at that time will UTC officially accept a disclosure.

UTC Procedure

Based on the industrial experience of its staff and a computerized keyword database of commercial interests, UTC will contact target companies, qualify their interest and negotiate a technology transfer agreement.

On-Campus Visits

- 1. After receiving an indication of corporate interest, UTC will arrange for the corporate technical and corporate licensing people to visit the university inventor and TLO.
- 2. The TLO will organize the logistics of the on-campus visits to arrange for a suitable conference room with blackboard and coffee available.
- 3. Prior to the visit, UTC will work with the TIO (and through him with the inventor) to get an initial estimate of the work required and its associated budget. This information will be passed to the company, along with the basic terms of the option/license prior to the visit. The TIO also prepares and forwards the Agenda to UTC for forwarding to the company after discussion and concurrence.

PREPARATION BY TLO FOR CORPORATE VISIT

- 1. Arrange for suitable rooms for meetings.
- 2. Arrange for refreshments.
- 3. Arrange for availability of necessary university people.
- 4. Throughly discuss situation with Inventor(s).
 - Review and practice Inventor(s) presentation.
 - Ensure necessary documentation is available (Executive Summary, Technical Package, etc.)
- 5. Sensitive Issues
 - Other companies Do not volunteer that there have been discussion with other companies.
 - If asked if there have been discussions with other companies, state YES or NO. If YES, say that since we would not inform other companies of your name, we cannot inform you of the name of the other companies
- 6. Information Needed Prior To Meeting (as applicable in each case):
 - Executive Summary
 - Technical Package, prepared by TLO and Inventor and sent to UTC. UTC must get it to Potential Licensee prior to visit.
 - Agreement (Option or License) prepared by UTC and sent to potential licensee prior to visit
 - R & D Proposal Outlining:
 - Further development and associated costs

This can be presented, discussed and finalized during the visit.

THE MARKETING PROCESS

THE ON-CAMPUS VISIT

- 1. Suitable room arranged for presentation.
 - 2. Meeting agenda
 - Welcome by TLO
 - Presentation by Potential Licensee of their general activities, sales, specific activities in the area of "invention"
 - Presentation by Inventor (1-1/2 hours (wide ranging questions and answers)
- 3. After Q & A presentation: Inventor, corporate technical people and TLO adjourn to finalize technical discussion and agree on R&D contract and timetables. Discussion of costs should be only in "ball-park" terms, with specific costs forwarded later with the proposal.
 - UTC and corporate business people adjourn to finalize business discussion and discuss Agreement (Option, License, R&D contracts)
- 4. Reconvene to finalize arrangements, have a meal and disperse.

THE MARKETING PROCESS

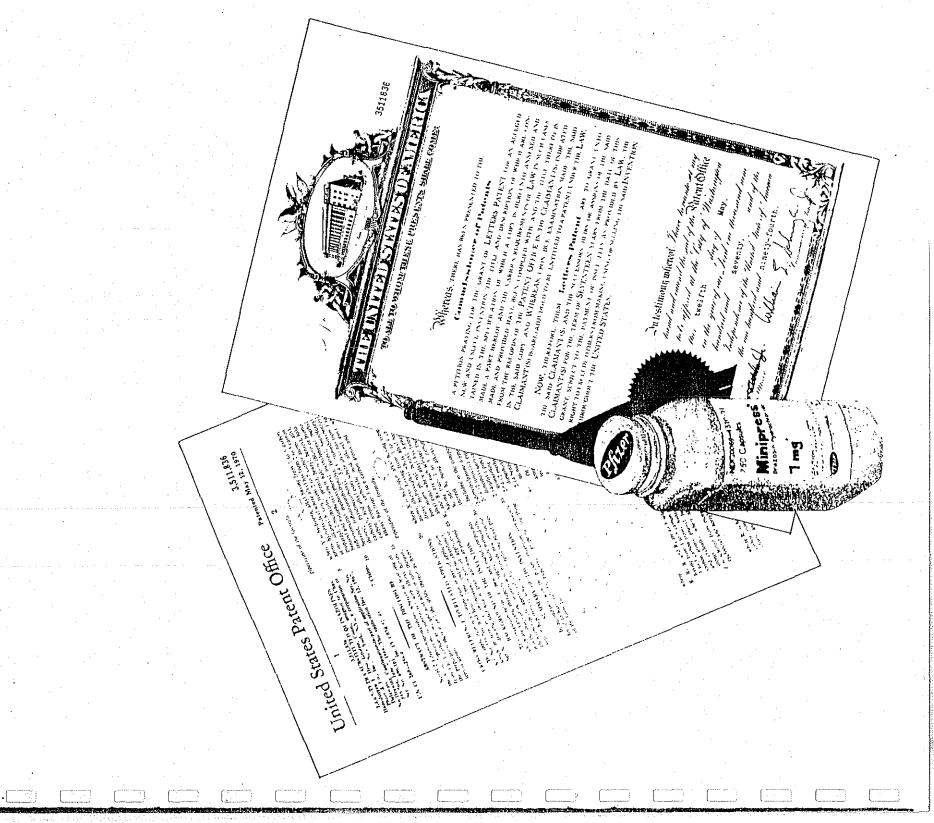
Licensing: The TLO's Role

- 1. It is important that the TLO not let himself or the inventor get caught in a situation where the potential licensee can play them against UTC in the licensing negotiations. Accordingly, all licensing questions and/or licensing contacts from the potential licensee should be referred to UTC. Do not attempt to answer even what seem to be basic licensing questions.
- 2. Conversely, the TTO should get intimately involved with preparation of the research proposal and the tracking of the proposal through the appropriate University approvals. Once approved, this proposal will form a part of the option/license agreement negotiated by UTC.

TLO Follow-up On R&D Contracts

- 1. Continuing goodwill between the researcher and the corporate technical respresentative is what will move initial option agreements to license agreements and the production of a product.
- 2. The TLO needs to review timing of deliverables and, in conjunction with the Contracts office, check that these deliverables are met.
- 3. The TLO must check on the research progress and address and solve problems as they arise in concert with the Contracts Office.
- 4. The TLO must establish rapport with the corporate technical liaison person so that problems are addressed and solved.
- 5. The most common cause of an option failing to turn into a long term license is a lack of communication between the researcher and the company that results in unfulfilled expectations on the part of each. The TLO must solve these problems before they reach either the corporate or university management.





Pfizer and Patents

Although many people believe that they have a firm grasp of patent fundamentals, there are in fact few subjects which give rise to so many misconceptions. This booklet is provided to you by the Patent Section of the Pfizer Legal Division in an effort to dispel some of those misconceptions and to promote full cooperation between the research and patent functions; such cooperation is essential to preserving the property rights resulting from research.

What is a Patent?

By grant of a patent, the United States Patent and Trademark Office gives the inventor or his assignee the right to exclude others for a limited term from practicing his invention for other than experimental purposes. In return, the public acquires the information contained in the patent for the advancement of research and, upon expiration of the patent term, for commercial exploitation. The patent system thus fulfills the aim stated in the Constitution "to promote the progress of . . . useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries."

Note that the grant of a patent does not confer on the inventor the right to make, use or sell his invention; rather it permits him to exclude others from such acts. The inventor's freedom to exploit his own invention commercially will be determined by the unexpired patents of others. A homely example may clarify the point. Assume that, at the dawn of technology, A obtains a patent on the pail, and B subsequently patents the improvement of a pail with a handle. B cannot sell pails with handles without infringing A's dominating patent on the pail. Conversely, A cannot sell pails with handles without infringing B's patent. Until the dominating patent expires, neither party can market the improvement without a license from the other.

The patent right represents in effect a legal monopoly and, as such, is subject to misunderstanding and even hostility. Some legislators and courts pay inadequate attention to the distinction between legal and illegal monopolies, believing that all restrictions on patent grant and enforcement are in the public interest. In fact, however, patents provide the public with newly created knowledge which would not exist if it were not for the efforts of the inventor—knowledge which would otherwise be kept secret. Indeed, secrecy represents the only alternative to patent protection of a new discovery, an alternative which seldom assures the degree of exclusivity afforded by the patent system.

What is Patentable?

In the United States, patents are granted for processes, machines, articles of manufacture and compositions of matter, and improvements thereof, provided that they are new, useful and unobvious. (In some foreign countries, specific subject matter restrictions apply.)

The novelty requirement will not be met if any of the following conditions exists:

- (a) The subject matter was publicly known, used, or on sale in this country before you made your invention, or more than a year before your patent application was filed.
- (b) The subject matter was published anywhere in the world before you made your invention, or more than a year before your patent application was filed.
- (c) Someone else, who did not abandon, suppress or conceal it, made the invention before you did.

From paragraphs (a) and (b) above, you will appreciate how important it is to file your U.S. patent application within 12 months after commercial operation commences or publication occurs. (Unrestricted disclosure of your invention to even a single outside party can constitute publication for purposes of triggering the 12-month period.) However, if patent protection abroad is desired, even more strict criteria apply. Most foreign countries do not give the inventor the year's grace which is provided by U.S. law. Any commercial use or publication even one day before filing the patent application will bar a valid patent in most foreign countries.

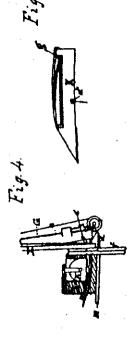
However, as discussed later, most industrial nations will recognize the U.S. filing date as the effective date abroad (the "Convention priority") if certain conditions are met. The important fact to remember is that, to preserve patent rights overseas, the patent application ought to be filed in the United States before any publication or commercial use of the invention.

Paragraph (c) above prevents the grant of a patent if someone else made the invention first. This forms the basis for interference practice, in which the Patent Office decides who will get the patent when two or more rival applicants have filed for protection on the same invention. In such a proceeding, the burden of proof falls on the inventor who files last. Therefore, prompt filing of Pfizer patent applications gives us the best chance of having the advantageous "senior party" status in any interference which may be declared.

Simple usefulness will meet the U.S. utility requirement, which does not necessarily connote commercially competitive properties. In the case of pharmaceutical inventions for use in humans, in vitro and animal test results are often acceptable to demonstrate utility, provided that a good correlation of the test with effectiveness in humans can be shown.

The unobviousness requirement is the most difficult to define. The question asked is whether the subject matter would have been obvious at the date of invention to a hypothetical person of "ordinary skill" in the art to which the invention pertains. In chemical patent practice, while homologs, analogs and isomers of known compounds are presumed to be obvious, this presumption is rebuttable by submission to the Patent Office of evidence that the new compounds possess unexpected properties in comparison with their closest relatives in the prior art.

E. Howe, Ir. Sewing Machine. Patented L



The Patent Claims

Every patent application includes one or more claims. The claims represent the most important part of the application and require most careful preparation. They must define the invention broadly enough to cover all aspects, but not so broadly as to include anything in the prior art. In this respect, the claims are expected to define the scope of the invention as accurately as a survey defines the extent of a piece of real estate: to cover the full expanse of the property without encroaching on the neighboring property of others.

Claims of broad, intermediate and narrow scope are usually asserted, and the validity of each claim is considered separately in patent litigation. The broadest or "generic" claims provide the broadest protection, but they also present the broadest target for attack. If only broad claims were filed, they might later prove unpatentable or invalid in the light of previously undetected prior art. (In addition, there is a risk that the claims could be so broad as to include inoperable subject matter, another source of patent invalidity.) On the other hand, if only very narrow claims ("species claims" directed to the "preferred embodiments") were filed, inadequate protection would result. Claims of intermediate scope ("subgeneric claims") provide some insurance that the protection obtained will be adequate.

On occasion, the information needed to define the preferred embodiments and subgenera may not be fully developed until after the patent application has been filed. Such later refinements should always be brought to the attention of the Patent Section, since it will often be possible to protect them in a continuation-in-part ("CIP") application, which can be filed to replace or supplement the original application. A CIP may also be filed to eliminate inaccuracies brought to light by later research. For priority purposes, the CIP is entitled to the parent filing date with respect to subject matter brought forward unchanged. New subject matter added in the CIP is entitled only to the filing date of the CIP.

Record Keeping

It is important that you promptly and carefully record any invention which you conceive, together with its utility and a method for carrying it out. This "conception record" should contain as much detail as possible. It should be signed and dated by you, and read, understood, countersigned and dated by at least one and preferably two individuals who are familiar with the subject, but who are unlikely to be deemed coinventors with you. Such entries should be made in ink in your laboratory notebook.

As your research progresses, your findings should also be recorded in the notebook, without erasure or double transfer from slips of paper, and promptly signed, dated and witnessed. A senior laboratory technican familiar with the work may serve as a witness. Keep in mind that the recording of premature unfavorable conclusions may destroy the value of your record or be construed as abandonment of the invention. For example, it would be unwarranted to conclude your notebook entry with the statement "Another failure" merely because the yield is low. Such statements in your notebook, or in your periodic reports, can and will be distorted to your disadvantage by defendants in a future infringement suit. Remember that your records may constitute important evidence in litigation and in interference contests with rival outside inventors.

When you have conducted a highly significant experiment, the results of which appear to be of substantial importance, it is advisable to arrange for someone else, not a coinventor, to repeat it with authenticated starting materials. He should also identify the product and confirm its utility, so that he may serve as a corroborative witness to such "reduction to practice" in any interference proceeding. In such contests between rival applicants the inventor's own evidence of priority activity requires corroboration by an independent witness having first-hand knowledge of the work.

When you have successfully carried out the invention and demonstrated its utility, i.e., reduced it to practice, you have completed the process which, with the prior conception, constitutes the inventive act. Even where actual reduction to practice is absent, the filing of a patent application is construed as a "constructive reduction to practice" which completes the invention.

Filing the Patent Application*

Your invention should be brought to the attention of your supervisor to detemine whether it is of sufficient interest to warrant filing an application. If he and your Division Manager approve, a Patent Application Request Form (#8400-14) should be completed and forwarded to the Patent Section in New York for processing.

You will be contacted by a member of the Section and asked to provide all available information, including any prior developments in the field which may have a bearing on patentability. Should it appear that the discovery is unpatentable, you and your supervisor will be so advised, and the reasons for this conclusion will be explained. This, of course, represents no reflection on the merit of your work: many developments of great commercial value do not happen to match the particular criteria of patent practice.

The preparation of your patent application will be undertaken by one of the members of the Patent Section, and you will then be provided with a draft for review. It will contain a detailed description of the invention, illustrative examples and a series of claims. Every effort is made to provide a full disclosure in support of the claims.

The final selection of inventors will then be made on the basis of all available facts, and the application will be placed in final form. After you have signed the required formal papers, including an assignment of the worldwide patent rights to Pfizer, the application will be filed in the Patent Office.

^{*}A summary of these procedures appears in Corporate Procedure No. 1150.

Obtaining Protection Abroad

As noted earlier, most industrial nations including the United States adhere to the International Convention for the Protection of Industrial Property (the "Paris Convention"). This agreement provides that an applicant for a patent in any member country is entitled to the priority of his original filing date in the other member countries, provided he files his application in such other countries within 12 months of the original filing date. The purpose of preserving the original priority date is, of course, to insure that the patent rights will not be impaired by intervening publications or use, or by intervening applications of rival inventors.

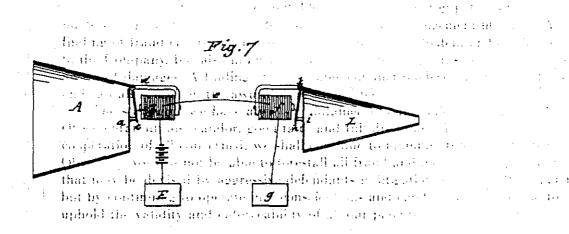
The usual procedure for protecting inventions made within the Pfizer organization involves filing first in the country where the invention was made. About six months later the subject matter is again reviewed, to assess the advisability of filing conterpart applications in one or more additional countries. This evaluation is conducted in consultation with the appropriate Pfizer Research and International Development personnel. Corresponding applications are then filed within the Convention year in the additional countries in which patent protection appears warranted. In certain instances, the application will be filed in the European Patent Office, which affords an opportunity to seek patent protection in many European countries through a single filing and examination.

The requirements for obtaining grant of a patent vary considerably from country to country. At one extreme are the so-called registration countries, where there is no examination for patentability. In such countries, grant follows automatically when formalities are completed; the enforceability of the patent is left to the determination of the courts in any subsequent infringement litigation. At the other extreme are the strict examination countries, where the application undergoes a very close scrutiny for patentability, and where the claims may require modification before acceptance. In a number of countries, third parties may intervene to oppose grant of the patent after it has been found acceptable by the Patent Office.

During prosecution in the United States and in foreign patent offices, you may be asked to supply additional information or assistance in meeting questions raised by the various patent examiners. Should you leave the Company, you have a continuing obligation to cooperate in protecting inventions made during your employment at Pfizer.

Your Duty of Candon:

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Your Duty of Candor

You should carefully read the Declaration you are asked to sign when your application is ready for filing in the United States Patent Office. In it, you affirm your belief that you are the original and sole (or joint) inventor of the subject matter of the claims, and that you do not believe that it was ever known or used in the United States or published anywhere before your invention or more than a year before your filing.

In signing, you also acknowledge your obligation to disclose any information of which you are aware which is material to the examination of your application. This duty continues throughout the period of prosecution. If any information comes to your attention which is material to your right to claim the invention, this should promptly be brought to the attention of a member of the Patent Section, in order to satisfy your obligation. Such information could include, for example, newly discovered prior art, adverse test results, or any information which reasonably could be construed as inconsistent with your good faith belief in the novelty, operability or unobviousness of your invention, or with arguments being made to the Patent Office in support of patentability. Even after grant of a patent, discovery that it is defective could necessitate reissue or disclaimer. In addition, you are required to disclose in your application the "best mode" known to you for carrying out the invention. In a chemical product invention this could include, for example, the best compound and the best method of making and using it.

The term "material" as used above connotes information having more than a trivial relationship to your invention, i.e. where there is substantial likelihood that a reasonable patent examiner would consider it important in deciding whether to grant your patent.

The rules provide that a patent application shall be stricken from the files if clear and convincing evidence shows that there has been any violation of the duty of disclosure through bad faith (i.e., with intent to deceive) or gross negligence.

Charges that fraud and inequitable conduct occurred in patent prosecution are made with great frequency by defendants in patent infringement litigation. A finding of fraud can result, not only in invalidation of a patent and embarassment to the Company, but also in award of attorneys' fees and, in some circumstances, award of damages. A finding of inequitable conduct renders a patent unenforceable and can also result in the award of attorneys' fees.

The standards we have always maintained in our dealings with the Patent Office entail utmost candor, good faith and full disclosure, and, with the cooperation of all concerned, we shall continue to maintain those standards. Obviously, we will not be able to forestall all fraud and inequitable conduct charges that may be devised by aggressive defendants in litigation involving Pfizer patents, but by continuing to operate in a conscientious and careful manner, we aim to uphold the validity and enforceability of all our patents.

Planning the Patent Program

The idea that the patent program is to be launched at the completion of the research program is a common misconception which may result in the loss of important patent rights. Implementation of the patent program cannot wait until all the questions have been answered; by that time, competitors may have preempted the patent scene. Instead, the research program and the patent program should proceed cooperatively from the outset. The information provided to the Patent Section at an early stage of the research will necessarily be somewhat tentative, and the patent program may require modification as the data accumulate. Such modification can take the form of CIP applications if weaknesses in the original filings are disclosed by the advancing research program. If such weaknesses are not corrected, a future infringer intent on neutralizing the patent can be depended on to unearth them.

A research project often suggests a number of different solutions to a problem, e.g. alternate processes for preparing a compound, or alternate substituents on a chemical nucleus. These may be patentably distinct inventions which should form the subject of separate patent applications. Some will be fully developed to the optimum; others, less attractive, may be explored to only a limited extent but will still require patent protection. Further developments may make such secondary approaches preferable from a commercial standpoint.

The alternatives of lower priority are understandably relegated to the bottom of the research timetable, but this can create problems with the patent program. The approaches of highest priority, maturing early, give rise to patent applications which will be published in early publication countries about 18 months after their initial filing. These published applications will alert competitors, who may explore and patent the lower priority approaches before these are tested in house. To block such "pursuit research," it may be necessary to divert part of the early research effort to preliminary testing of the deferred approaches, to permit formulation and filing of appropriate patent applications early in the patent program.

The Patent Search

From time to time in the course of your work you may have occasion to request a search by the Patent Section. Request forms (#8400-13) are available for this purpose, which are to be signed by your supervisor and Division Manager to authorize the work. It is important that you understand the various kinds of searches and their aims and limitations.

An infringement search is conducted to determine whether a product can be marketed or a process operated without infringing the patents of others. Such a search requires an examination of the claims of all unexpired patents in the field of interest. Where worldwide activity is contemplated, it will often be necessary to extend the search to include patents in key foreign countries.

A state-of-the-art search is undertaken at the outset of a research program in order to collect the major patents in the field of interest. It can play a useful role in identifying existing patent infringement bars to some research paths and in recognizing other paths which remain available. In addition, it can give a preliminary indication of patentability problems: unless the research paths selected lend themselves to potential patent protection, they may not be worth pursuing.

A patentability search is the most ambitious type of search. It is designed to determine whether any prior patents or publications exist which would bar issuance of a valid patent on an invention. Sometimes a search of this nature is undertaken to evaluate the enforceability of the patents of others—in this case it is called a validity search, but the principles involved are the same.

Since patentability may be barred by any publication anywhere in the world, the potential scope of a patentability search is almost limitless, and a truly exhaustive validity search is seldom undertaken except in contemplation of litigation. Although the computerized Chemical Abstract and Derwent data bases have substantially facilitated searching of the most recent technical and patent literature, you may have access to the major technical journals in your area of specialization and should bring relevant prior literature to the attention of the Patent Section when requesting a patent application or a patentability search.

Even when patentability searches are limited to the patent literature, they can be time-consuming and expensive. Not only must expired as well as unexpired patents be examined, but the disclosures as well as the claims of the prior patents must be studied. Prior patent disclosures often contain speculative broadening statements or vague generalizations which are difficult to retrieve but which may be cited in hindsight by the Patent Office or the courts against the patentability of later inventions.

Security

In your employment with Pfizer you have access to a substantial amount of confidential information of considerable value to the Company. Such information may include technical data, process conditions, future plans with respect to new products or processes, sources of raw materials, customer lists and the like. You have a definite obligation to safeguard that information during your employment and at all times thereafter. Confidential information which you may have acquired in the service of a prior employer should be treated with the same respect.

Machine. Speaking A. EDISON. Phonograph

Patented Feb. 19, 1878. No. 200,521

Twonter Fromas A. Edison.

federal Tegister

Federal Register / Vol. 47, No. 34 / Friday, February 19, 1982 / Notices

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, OMB.

ACTION: Notice.

7556

SUMMARY: This Circular, issued pursuant to the authority contained in Pub. 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 (46 FR 34776, July 2, 1981).

PFFECTIVE DATE: March 1, 1982.

POR FURTHER INFORMATION CONTACT:

Mr. Pred H. Dietrich, Associate

Administrator, Offics of Federal

Procurement Policy, 726 Jackson Place,

NW., Washington, D.C. 20503, (202) 395–

110.

SUPPLEMENTARY SUPPRIMATION: 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 128 comments were received from individuals, universities, nonprofit organizations, industrial concerns, and Federal agencies.

Copies of all the comments are available on record at OFPP. 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. 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.

L Comments Relating to Policy and Scope Sections

A. Subcontracts

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 organization" at 35 U.S.C. 201 has been interpreted to cover only domestic 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, 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.

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 law.

D. Collaborative Research and "de minimus" Recommendations

There were several comments that some "de minimus" standard be established to define a threshold contribution of government funding to the making of a jointly funded invention below which the Circular regulations should not apply. These recommendations were rejected as being inconsistent with the 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 Pub. 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 somprehensively 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 . non-government 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 expend scientific understanding in 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 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 nongovernment 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 S.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 been added to encourage agencies to drop the reference to future treaties unless shown to be in the national interest.

One agency also expressed the concern that the language in the Bulletin was too limited and implied only a right to sublicense, whereas some international agreements call for more extensive rights. Section 8.d. has been revised to make clear that more than the right to sublicense can be taken.

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 Pub. L. 96-517. Accordingly, language was revised to provide that such reports "shall not" be disclosed under FOIA to the extent permitted by 35 U.S.C. 202(c.) (6).

I. Procedures for Exercise of March-in Rights

25 U.S.C. 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 marchin 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.

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 decision-making, 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 he 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 consitered within the scope of the utilization information which agencies are required to obtain the right to under 35 U.S.C. 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 trade-secret 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 prerogratives.

Since it is anticipated that in contract situations a number of these actions would be subject to the Contract Disputes Act, language was added to Part 14 to expressly acknowledge that procedures under that Act would fully comply with the requirements established in Part 14.

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 Pub. 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 communied upon aspect of the Bulletin was the optional reporting language authorized by Part 5.b.(1)(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 5b(1)(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.

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 Pub. 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 U.S.C. 202 on a case-bycase 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 patient 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 within this time. It is also expected that an interested agency should be able to discuss with a contractor its plans for filing. If the contractor has subsequently changed its mind, the agency should be able to either convince the contractor to rescind its election or to take title under paragraph (d) on the grounds that the contractor has, in effect, abandoned its application. Should any real problems in this area develop in the future, consideration would be 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 notcreated 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. Paragraph k

There were several comments on paragraph k. Some Commentators were apparently unware that these restrictions are required by Pub. 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.

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. Donald E. Sowie. Administrator.

Circular No. A-124

February 10, 1982.

To the Heads of Executive Departments and Establishments.

Subject: Patents—Small Business Firms and Nonprofit Organizations.

- 1. Purpose. This Circular provides policies, procedures, and guidelines with respect to inventions made by small business firms and nonprofit organizations, including universities, under funding agreements with Federal agencies where a purpose is to perform experimental, developmental, or research work.
- 2. Rescissions. This Circular supersedes OMB Bulletin 81–22 effective March 1, 1982.

3. Authority. This Circular is issued pursuant to the authority contained in 35 U.S.C. 206 (Section 6 of Pub. L. 96–517, "The Patent and Trademark Amendments of 1980").

4. Background. After many years of public debate on means to enhance the utilization of the results of Government funded research, Pub. L. 96–517 was enacted. This Act gives nonprofit organizations and small businesses, with limited exceptions, a first right of refusal to title in inventions they have made in performance of Government grants and contracts. The Act takes precedence over approximately 26 conflicting statutory and administrative policies.

Under the Act, the Office of Federal Procurement Policy (OFPP) is responsible for the issuance of the regulations implementing 35 U.S.C. 202–204 after consultation with the Office of Science and Technology Policy (OSTP). On July 2, 1981, OMB Bulletin 81–22 was issued to provide interim regulations while agency and public comments were sought. Based on a review of these comments, this Circular is issued to establish permanent implementing regulations and a standard patent rights clause.

5. Policy and Scope. This Circular takes effect on March 1, 1982, and will be applicable to all funding agreements with small business firms and domestic nonprofit organizations executed on or after that date. This includes subcontracts at any tier made after March 1, 1982, with small business firms and nonprofit organizations even if the prime funding agreement was made prior to March 1, 1982. Unless prohibited by law, agencies are encouraged to treat subject inventions made under funding agreements made prior to July 1, 1981, in substantially the same manner as contemplated by Pub. L. 96-517 and this Circular for inventions made under funding agreements entered into subsequent to July 1, 1981. This can be accomplished through the granting of waivers of title on terms and conditions substantially similar to those set forth in the standard clause of Attachment A.

Agencies should be alert to determining whether amendments made after March 1, 1982, to funding agreements entered into prior to July 1, 1981, result in new funding agreements subjects to this Circular and the Act. Renewals and continuations after March 1, 1982, of funding agreements entered into prior to July 1, 1981, should be normally treated as new funding agreements.

This Circular is intended to establish uniform and coordinated

implementation of 35 U.S.C. 200-206 so as to foster the policy and objectives set forth in 35 U.S.C. 200.

Definitions. As used in this Circular—

a. 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,

a funding agreement, as herein defined.

b. The term "contractor" means any person, small business firm or nonprofit organization that is a party to a funding

developmental, or research work under

agreement.

c. 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.

d. The term "subject invention" means any invention of a contractor conceived or first actually reduced to practice in be performance of work under a

unding agreement.

e. The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system: and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable

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

practice of such invention.

g. The term "small business firm"
means a small business concern as
defined at section 2 of Pub. L. 35-536 (15
U.S.C. 632) and implementing
regulations of the Administrator of the
Small Business Administration. For the
purpose of this Circular, the size
standards for small business concerns
involved in Government procurement
and subcontracting at 13 CFR 121.3-8
and 121.3-12, respectively, will be used.

h. The term "nonprofit organization" means universities and other institutions of higher education or an organization of he type described in section 501(c) (3)

the Internal Revenue Code of 1954 (28 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational

organization qualified under a state nonprofit organization statute.

7. Use of the Patent Rights (Small Business Firm or Nopprofit

Organization) (March 1982) Clause.

a. Each funding agreement awarded to a small business firm or domestic nonprofit organization which has as a purpose the performance of experimental, development or research work shall contain the "Patent Rights (Small Business Firm or Nonprofit Organization) (March 1982)" clause set forth in Attachment A with such modifications and tailoring as may be authorized in Part 8, except that the funding agreement may contain alternative provisions—

(1) When the funding agreement is for the operation of a Government-owned research or production facility; or

(2) 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 United States Code; or

(3) 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 protect the security of such-

activities.

b. (1) Any determination under Part 7.a.(2) of this Circular 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 agency deems relevant. and, at minimum, will (i) identify the small business firm or nonprofit organization involved, (ii) describe the extent to which agency action restricted or eliminated the right to retain title to a subject invention, (iii) state the facts and rationale supporting the agency action, (iv) provide supporting documentation for those facts and rationale, and (v) indicate the nature of any objections to the agency action and provide any documentation in which those objections appear. A copy of the each such determination and written statement of facts will be sent to the Comptroller General of the United States within 30 days after the award of the applicable funding agreement. In cases of determinations application to small business firms, copies will also be sent to the Chief Counsel for Advocacy of the Small Business Administration.

(2) To assist the Comptroller General to accomplish his or her responsibilities under 35 U.S.C. 202, each Federal

agency that enters into any funding agreements with nonprofit organizations or small business firms during the applicable reporting period shall accumulate and, at the request of the Comptroller General, provide the Comptroller General provide the Comptroller General with or her daily authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause of Attachment A during each period of October 1 through September 30, beginning October 1, 1982.

c. (1) Agencies are advised that Part 7.a. applies to subcontracts at any tiar under prime funding agreements with contractors that are other than small business firms or nonprofit organizations. Accordingly, agencies should take appropriate action to ensure that this requirement is reflected in the patent clauses of such prime funding agreements awarded after March 1, 1982.

(2) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with either this Circular or OMB Bulletin 81-22 (if it was applicable at the time the funding agreement was awarded), the agency shall take appropriate action to ensure that small business firms or domestic nonprofit organization subcontractors under such prime funding agreements that received their subcontracts after July 1, 1981, will receive rights in their subject inventions that are consistent with Pub. L. 98-517 and this Circular. Appropriate actions might include (i) amendment of prises contracts and/or subcontracts; (ii) requiring the inclusion of the clause of Attachment A as a condition of agency approval of a subcontract; or (iii) the granting of title to the subcoutractor to identified subject inventions on terms substantially the same as contained in the clause of Attachment A is the event the subcontract contains a "deferred determination" or "acquisition by the Government" type of patent rights clause.

d. To qualify for the classes of
Attachment A. a prospective contractor
may be required by an agency to certify
that it is either a small business firm or
a domestic nospective contractor. If the
agency has reason in question the status
of the prospective contractor as a small
business firm or domestic nospectit
organization, it may file a protest in
accordance with 13 CFR 121.3-5 if small
business firm status is questioned or
require the prospective contractor to

furnish evidence to establish its status as a domestic nonprofit organization.

8. Instructions for Modification and Tailoring of the Clause of Attachment A.

a. Agencies should complete the blank in paragraph g.(2) of the clause of Attachment A in accordance with their own or applicable Government-wide regulations such as the FPR or DAR. The flow-down provisions of the clause cited by the agency should, of course, reflect the requirement of Part 7.c.(1).

b. Agencies should complete paragraph 1. "Communications" at the end of the clause of Attachment A by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in

paragraph 1.

c. Agencies may replace the italicized or underlined words and phrases with those appropriate to the particular funding agreement. For example "contract" could be replaced by "grant". "contractor" by "grantee", and "contracting officer" by "grants officer." Depending on its use, "Federal agency" can be replaced either by the identification of the agency or by the specification of the particular office or official within that agency.

d. When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or agreement, a sentence may be added at the end of paragraph b. of the clause of Attachment A as follows:

This license will include the right of the Government to sublicense foreign governments and international organizations pursuant to the following treaties or international agreements: ; or pursuant to any future treaties or agreements with foreign governments or international organizations.

The blank in the above should be completed with the names of applicable existing treaties or international agreements. The above language is not intended to apply to treaties or agreements that are in effect on the date of the award which are not listed. The above language may be modified by agencies by deleting the reference to future treaties or agreements or by otherwise more narrowly defining classes of future treaties or agreements. The language may also be modified to make clear that the rights granted to the foreign government or international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or

international agreement. For example, in some cases exclusive licenses or even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

e. 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 of Attachment A to require the contractor to do one or more of the following:

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

[2] Provide a report prior to the closeout of a funding agreement listing all subject inventions or stating that there were none:

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

(4) 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 country in which the contractor has applied for patents.

Part 9. Publication or Release of Invention Disclosures.

a. 35 U.S.C. 205 provides as follows:

Federal agencies are authorized to withhold from disclosure to the public information disclosing any 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 a patent application to be filed. Furthermore, Federal agencies shall not be 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

 b. To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph c. of the clause of Attachment A or such other clause that may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in

which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor an FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

c. As authorized by 35 U.S.C. 205. Federal agencies shall not release copies of any document which is part of an application for patent filed on a subject invention to which a small business firm or nonprofit organization elected to

retain title.

- d. A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in Government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention, could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs, copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph c. of the clause of Attachment A, except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under Part 9.b. above, agencies may publish such disclosures.
- e. Nothing in this Part is intended to preclude agencies from including in the publication activities described in the first sentence of Part 9.d., the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected or may elect title, the agency will use reasonable efforts to restrict its publication of the material for six months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

f. Nothing in this Part 9 is intended to limit the authority of agencies provided in 35 U.S.C. 206 in circumstances not specifically described in this Part 9. 10. Reporting on Utilization of Subject

Inventions.

a. Paragraph h. of the clause of Attachment A provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. In accordance with such instructions as may be issued by the Department of Commerce, agencies shall obtain such information from their contractors. Pending such instructions. agencies should not impose reporting requirements. The Department of Commerce and the agencies, in conjunction with representatives of small business and nonprofit organizations, shall work together to establish a uniform periodic reporting system.

b. To the extent any 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 shall not, to the extent permitted by 35 U.S.C. 202(c)(5), disclose such information to persons outside the

Government.

11. Retention of Rights by Inventor. Agencies which allow an inventor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs d. (ii) and (iii); f.(4); h.; i.; and j. of the clause of Attachment A.

12. 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 a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such coinventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as would apply to the contractor under the clause of Attachment A.

13. Exercise of March-in Rights. a. The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and the clause at Attachment

b. Whenever an agency receives 'nformation that it believes might arrant the exercise of merch-in rights, before initiating any march-in proceeding in accordance with the procedures of Part 13.c.-h. below, it shall

notify the contractor in writing of the information and request informal written or oral comments from the contractor. In the absence of any comments from the contractor within 39 days, the exency may, at its discretion, proceed with the procedures below. If a comment is received, whether or not within 30 days, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march in rights based on the information about which the contractor was notified

c. 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 on notice of the facts upon which the action would be 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 Circular and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or designee, except as provided in Part 13.j. below.

d. 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 or argument in opposition to the proposed merch-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 . designee shall undertake or refer the matter to another official for fact-

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e. 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 should 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. Any portion of a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining willington that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees.

L The official conducting the factfinding shall prepare written findings of fact and transmit them to the head of the agency or designee 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.

g. in cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her 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. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200-206 and this Circular shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found that are clearly erroneous. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee or exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

h. An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

i. The procedures of this Part shall also apply to the exercise of march-in rights against inventors receiving title to . subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term "contractor" as used in this Part shall be deemed to include the inventor.

j. Notwithstanding the last sentence of Part 13.c., a determination to exercise march-in in cases where the subject invention was made under a contract may be made initially by the contracting officer in accordance with the procedures of the Contract Disputes Act. In such cases, the procedures of the Contract Disputes Act will apply in lieu of those in Parts 13.d.-g. above (except that the last sentence of Part 13.e. shall continue to apply). However, when the procedures of this Part 13.j. are used, the contractor, assignee, er exclusive

licensee will not be required to grant a license and the Government will not grant any license until after either. (1) 90 days from the date of the contractor's receipt of the contracting officer's decision, if no appeal of the decision has been made to an agency board of contract appeals, or if no action has been brought under Section 10 of the Act within that time; or (2) the board or court, as the case may be, has made a final decision in cases when an appeal or action has been brought within 90 days of the contracting officer's decision.

k. Agencies are authorized to issue supplemental procedures, not inconsistent herewith, for the conduct of

march-in proceedings.

14. Appeals.

a. The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action:

(1) A refusal to grant an extension under paragraph c.(4) of the clause of

Attachment A.

(2) A request for a conveyance of title under paragraph d. of the clause of Attachment A.

(3) A refusal to grant a waiver under paragraph L of the clause of Attachment A.

(4) A refusal to approve an assignment under paragraph k.(1) of the clause of Attachment A.

(5) A refusal to approve an extension of the exclusive license period under paragraph k.(2) of the clause of Attachment A.

- b. Each agency shall establish and publish procedures under which any of the agency actions listed in Part 14.a. above may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the action and its consistency with the policy and objectives of 35 U.S.C. 200–206 and this Chruslar.
- c. Appeals procedures established under Part 14.b. above shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in Part 13.e.-g. of this Circular whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph d. of the clause of Attachment A, including any dispute as to whether or not an invention is a subject invention.

d. To the extent that any of the actions described in Part 14.a. are subject to appeal under the Contracts Dispute Act, the procedures under that Act will satisfy the requirements of Parts 14. b. and c. above.

15. Licensing of Background Patent Rights to Third Parties.

- a. A funding agreement with a small business firm or a domestic nonprofit 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 the justification required for auch provisions.
- b. Á 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 practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing, and the contractor shall be given prompt notification of the determination by certified or registered mail.

16. Administration of Patent Rights Clause.

s. 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 should be so administered that:

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

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

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

(4) The rights in patent applications are documented by formal instruments such as licenses or assignments;

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

b. With respect to the conveyance of license or assignments to which the Government may be entitled under the clause of Attachasent A. agencies should follow the guidance provided in 41 CFR 1-9.109-5 or 32 CFR 9-109.5.

c. In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative, the agencies shall designate one agency as responsible for administration of the rights of the Government in the invention.

17. Modification of Existing Agency

Regulations.

a. Existing agency patent regulations or other published policies concerning inventions made under funding agreements shall be modified as necessary to make them consistent with this Circular and 35 U.S.C. 200–206. Agency regulations shall not be more restrictive or burdensome than the provisions of this Circular.

b. After March 1, 1982, this Circular and 35 U.S.C. 200–206 shall take precedence over any conflicting agency

regulations or policies.

- 18. Lead Agency Designation. In order to assist the Office of Federal Procurement Policy to ensure that 35 U.S.C. 200-206 and this Circular are implemented in a uniform and consistent manner, the following responsibilities are assigned to the Department of Commerce (hereafter referred to as "The Department"). Other agencies shall fully cooperate and assist in the carrying out of these responsibilities:
- a. The Department will monitor agency regulations and procedures for consistency with the Act and this Circular, and it shall provide recommendations to OFPP and agencies whenever it finds inconsistencies.

b. The Department will consult with representatives of agencies and contractors to obtain advice on—

- (1) the development of the periodic reporting system required under Part 10 of this Circular, and
- (2) changes in this Circular which may be needed based on actual experience under the Circular.
- c. The Department will accumulate, maintain, and publish such statistics and analysis on utilization and activities under this Circular and under Government patent policies and practices generally, as may be agreed to between the Department and OFPP.

d. The Department will make recommendations to OFPP on changes that may be needed in this Circular.

19. Sunset Review Date. This Circular shall have a policy review no later than three years from the date of its issuance.

20. Inquiries. All questions or inquiries should be submitted to the Office of Management and Budget,

Office of Federal Procurement Policy, telephone number (202) 395–6810.

Donald E. Sowis.

Administrator.

David A. Stockman,

Director.

Attachment A-Circular A-124

The following is the standard patent rights claused to be used in funding agreements as provided in Part 7.

Patent Rights (Small Business Firms and Nonprofit Organizations) (March 1982)

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.

(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 Pub. L. 85.536 (15 U.S.C. 832) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.
- (6) "Nonprofit Organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (28 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (28 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit 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 and 35 U.S.C. 203. 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 on behalf of the United States the subject invention throughout the world.

- c. Invention Disclosure, Election of Title and Filing of Potent Applications by Contractor.
- (1) The contractor will disclose each subject invention to the Federal agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. 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, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the inventionhas been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(2) The contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within twelve months of disclosure to the contractor Provided. That in any case where publication, on 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 may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The contractor will file its initial patent application on an elected invention within two years after election or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The contractor will file patent applications in additional countries within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign

patent applications where such filing has been prohibited by a Secrecy Order.

- (4) Requests for extension of the time for disclosure to the agency, election, and filling may, at the discretion of the funding Federal agency, be granted.
- d. Conditions When the Government May Obtain 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.

(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 reexamination or opposition proceeding on, a patent on a subject invention.

e. Minimum Rights to Contractor

- [1] The contractor will retain a nonexclusive, 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. 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.
- (2) The contractor's domestic license may be revoked or modified by the funding Federal agency 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 applicable provisions in the Federal Property Management Regulations. This license will not be revoked in that field of 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 affliates have failed to achieve practical application in that foreign country.

(3) 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 applicable regulations in the Federal Property Management Regulations concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of its license.

f. Contractor Action to Protect the Governments 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 to which the contractor elects to retain title, and (ii) convey title to the Federal agency when requested under paragraph 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 nontechnical 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 contract in order that the contractor can comply with the disclosure provisions of paragraph 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. This disclosure format should require, as a minimum, the information required by c.(1) above. The contractor shall instruct such employees through 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 the 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 (identify 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 by a small business firm or domestic nonprofit 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 allother subcontracts, regardless of tier, for experimental, developmental or research work the patent rights clause required by (cite section of agency implementing regulations, FPR, or

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the agency, subcontractor, and the contractor agree that the natural obligations of the parties created by this clause constitute a contract between the subcontractor and the Faderal agency with respect to those matters covered by this clause.

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 U.S.C. 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 been 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 Circular A-124 (and agency regulations at 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 schieve practical application of the subject invention in such field of use.

[2] Such action is necessary to alleviate health or safety needs which

ire not reasonably satisfied by the contractor, assignee, or their licensees;

(3) Such action is necessary to meet equirements for public use specified by 'ederal regulations and such equirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) Such action is necessary because he 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 nvention 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 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 nanagement of inventions and which is not, itself, engaged in or does not hold a substantial interest in other organizations engaged in the nanufacture or sale of products or the ase of processes that might utilize the invention or be in competition with mbodiments of the invention provided at such assignee will be subject to the ame 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 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 yment 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. Communications

(Complete According to Instructions at Part 8.b. of this Circuiar).

FR Doc. 55-450 Filed 2-15-42; 8-45 em]
BALLING CODE 2116-61-M



Monday July 14, 1986

Part VI

Department of Commerce

37 CFR Part 401

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms; Interim Final Rule 37 CFR Part 401

[Docket No. 41278-6009]

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms

AGENCY: Assistant Secretary for Productivity. Technology and Innovation, Commerce.

ACTION: Interim final rule.

SUMMARY: Pub. L. 98-620 amended Chapter 18 of Title 35, United States Code, dealing with patent rights in inventions made with Federal funding by nonprofit organizations and small business firms. It also reassigned responsibility for the promulgation of regulations implementing 35 U.S.C. 202-204 and the establishment of standard funding agreement provisions from the Office of Management and Budget (OMB) to the Secretary of Commerce. This regulation, to appear at 37 CFR Part 401, establishes such implementing regulations and standard funding agreement provisions.

DATES: July 14, 1986. Comments by: September 12, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Norman Latker, Director, Federal Technology Management Policy Division, Office of Productivity, Technology and Innovation, U.S. Department of Commerce, Room 4837, Washington, DC 20230. Phone: 202–377–0659.

SUPPLEMENTARY INFORMATION:

Background

Pub. L. 98-620 amended Chapter 18 of Title 35, United States Code, and assigned regulatory authority to the Secretary of Commerce. The Secretary has delegated his authority under 35 U.S.C. 206 to the Assistant Secretary for Productivity, Technology and Innovation. Section 206 of Title 35 U.S.C. requires that the regulations and the standard funding agreement be subject to public comment before their issuance. Accordingly, on April 4, 1985, the Assistant Secretary published a notice of proposed rulemaking in the Federal Register (50 FR 13524) for public comment. As noted at that time, the regulation closely follows OMB Circular A-124 which the regulation will replace. Differences between the proposed rule and the Circular were highlighted in Supplementary Information accompanying the notice of proposed rulemaking.

Additionally, to comply fully with section 208 of Title 35 U.S.C., the

Department is requesting public comments on this Final Interim Rule. Comments should be sent to the address listed in the "FOR FURTHER INFORMATION CONTACT" section above. Comments received by September 12, 1986 will be considered in promulgating a final rule.

Copies of all comments received are available for public inspection in the Department's Central Reference Records Inspection Facility (CRRIF), room 6628 in the Hoover Building, Information about the availability of these records for inspection may be obtained from Mrs. Hedy Walters at (202) 377–3271.

Treatment of Substantative Comments on Regulation Provisions

Twenty-three comments from seventeen different sources were received on the proposed rule in response to the April 4 notice. The substantative issues raised in the twenty-three comments will first be discussed as they refer to the specific sections of the proposed regulation. General comments on issues not mentioned in the regulation will be discussed later in this Supplementary Information Section.

Section 401.1(a)—Two comments were received on this subject. One suggested adding a sentence alerting readers to the fact that the regulation also includes policy guidance concerning the administration of funding agreements that predate the effective date of the regulation. This was done.

The second comment suggested the reference to the statute implemented by this regulation should be to 35 U.S.C. 200–206 and 212 rather than just 202–204. This suggestion was rejected as authority granted the Secretary of Commerce by 35 U.S.C. 206 is limited to issuing regulations related only to sections 202–204.

Section 401.1(d)-Several comments from federal agencies suggested rewriting the first part of this section to better reflect the relationship of this regulation, agency regulations, and the FAR system. One agency suggested the regulation should permit agencyinitiated deviations without approval by the Secretary of Commerce. This was rejected as being inconsistent with the statute's requirement to develop a standard patent rights clause. However, the need to obtain approval by the Secretary of Commerce of certain deviations requested by contractors has been eliminated and it has been made clear that modification and tailoring of clauses, as authorized elsewhere in the regulation, are not considered "deviations."

The suggestion by two agencies that the FAR be used as the regulatory

implementation of Chapter 18 of Title 35. U.S.C. was not accepted because it would be inconsistent with the law and Congressional intent.

It was also suggested that limitations on deviations were too strict and that the more liberal deviation procedures of the FAR system should be adopted. This was not accepted.

As a result of one agency comment. § 401.1(d) has been revised to specify when regulations should be submitted to the Secretary for review.

One agency suggested that the opening sentence of § 401.1(d) be deleted or amended as it "may throw the validity of every other regulation implementing Pub. L. 98-620 into doubt since lack of coverage of a point by the Commerce regulations could suggest that no coverage is permitted." It is. in fact, the purpose of § 401.1(d) and the statute to override inconsistent regulations. That is also why it is directed that all regulations supplementing this part be submitted to the Secretary for review for consistency. The Department of Commerce will work with those responsible for Part 27 of the FAR system to ensure that it is consistent with this regulation.

Section 401.2(a)—A comment suggested that the definition of "funding agreement" include language removing 35 U.S.C. 212 from its coverage. This concern has been dealt with in §§ 401.1(a) and 401.3(a) which exclude 35 U.S.C. 212 awards.

Section 401.2(h)—A comment suggested that the word "possession" be added in the definition of "nonprofit organizations" after the word "state." This has not been done as the statutory definition does not include the word "possession." The need for seeking an amendment to the act is being studied.

Section 401.3(a)(2)—One agency comment raised the question of whother the exceptional circumstance provision of 35 U.S.C. 202(a)(ii) can be used to except from contractor ownership a class of research contracts and all their resulting inventions on the grounds that national security may require classification of some of the results of the research. Three responding agencies believed the general principle of contractor ownership should be preserved as it does not preclude the advanced classification of research contracts and their resulting inventions for national security reasons under provisions of law other than 35 U.S.C. 202(a)(ii). Agencies are encouraged to use established national security classification procedures set out in regulation and Executive Order to protect from public disclosure those

nventions which pose security risks. fhese procedures allow the contractor to elect to retain title to such inventions. Thus, if at some later date security classification is lifted the contractor can immediately commence commercialization. However, it is recognized that in some limited situations agencies may be able to use national security to justify an alternate ownership provision under the exceptional circumstance paragraph of 35 U.S.C. 202(a)(ii). In such cases provision must be made to permit the contractor to elect ownership if there is no security classification of a reported invention by the agency within six . months. Accordingly, § 401.3(b) provides that should an agency exercise an exceptional circumstance exception under § 401.3(a)(2) and include provisions to own inventions on the basis of national security, the contractor shall be entitled to own any invention if the agency does not classify the contractor's invention report within six months of the date it is reported to the agency, or within the same period the Department of Energy does not, as authorized by regulation, law, Executive Order or implementing regulations thereto, prohibit unauthorized 'semination of the invention.

from this paragraph. Section 401.3(b)-Two agency comments suggested that the requirement to use the standard clause with modifications, even when exceptions under subsection 202(a) are invoked, is too restrictive. The language of the Act, particularly the introduction to 35 U.S.C. 202(c), makes no distinction between funding agreements under which the contractor retains the right to lect title and those in which this right has been curtailed through one of the exceptions. A standard clause will romote maximum uniformity and ssurance that small business and nonprofit contractors understand their obligations.

.ntracts in support of DOE's naval

nuclear propulsion program are exempt

Section 401.3(e)—Comments were equested on whether determinations of class exceptions should be allowed. One comment stated that the law ontemplates case-by-case exceptions and felt that only rarely could a class exception be justified. On the other hand, one agency comment stated that lass determinations are needed to duce paperwork. That agency aggested the use of a single

mination be authorized for multiple cacts involving identical roumstances to facilitate contracting long as each contractor is accorded its right of appeal. This suggestion was accepted.

In response to one comment, language has been added requiring an agency to advise a contractor of its appeal rights when it notifies the contractor that one of the exceptions at 35 U.S.C. 202(a) are being invoked.

Section 401.3(g)—One agency comment expressed concern about this section's requirement to provide information to the Comptroller General. The requirement has been retained as it was developed during the drafting of OMB Circular A-124 at the request of and in consultation with the GAO.

Section 401.4(b)(3)—In response to one comment, the word "present" has been changed to "rely upon."

Section 401.4(b)(6)—In response to one comment, language has been added requiring the agency head to detail the basis for the rejection of facts found during the fact-finding process.

Section 401.5(a)—One agency comment pointed out that, particularly in grants or cooperative agreements where an agency has a policy of applying the standard clause in all subcontracts, paragraph (g)(3) is not needed and the standard clause could be simplified by eliminating paragraph (g)(2). This has been done by expanding \$401.5(a) to authorize such modification of the subcontract provisions of the standard clause at \$401.14.

Section 401.5(d)—At the suggestion of one agency, several minor changes to this section have been made. The most significant of these changes is the additional language that agencies are authorized to add to the standard clauses which allow agencies to identify international agreements that are "to be entered into." This change is needed to enable future agreements to be entered into during contract performance and is only to be applied to subject inventions made after the date of contract amendment.

In response to agency comments, the number of situations in which the language at the end of the subsection related to international agreements can be used has been increased to include all long-term contracts such as those frequently used for funding operation of Government-owned research facilities, and not just those involving a series of task orders.

Section 401.5(e)(2)—One comment suggested adding "or other form of protection of intellectual property" to this requirement. This has not been done because it goes beyond the scope of the

Section 401.5(e)(3)—In response to several agency comments, the option of

the agencies to obtain annual listings of reported subject inventions has been retained.

Section 401.5(f)—One university comment raised the question of whether a university licensing office on the same campus but organizationally separate from a university-operated, Government-owned facility would meet the "most effective technology transfer" standard in the last sentence of paragraph (k)(3) which is prescribed at § 401.5(f). The situation described meets the standard.

One agency comment suggested that language be added at the end of § 401.5(f) as follows: "However, in the case of facilities of the Department of Energy, the paragraph shall be used in contracts designated by the Department of Energy as management and operating contracts for such facilities in accordance with Subpart 17.6 of the Federal Acquisition Regulations as supplemented by the Department of Energy Acquisition Regulations." This suggestion has not been accepted because it is inappropriate to include language that is tied to other regulations that could change and which may contain definitions based on other objectives and purposes. However, DOE may designate such contracts, and to the extent it finds that the proposed language is consistent with 35 U.S.C 204(c)(7)(E) and § 401.5(f) it may prescribe such language in its supplementary regulations or instructions.

Several comments suggested the deletion of the words "at the facility" from the clause language prescribed by § 401.5[f]. The basis for this suggestion was that limiting the use of income to research at the facility will act as a deterrent to university investment in the promotion of inventions. This change has been made because it is more appropriate to leave the question of royalty sharing with the facility to negotiations among the interested parties.

Section 401.5(g)—For clarity, a paragraph has been added authorizing agencies to require that contractors operating Government-owned facilities furnish certain information concerning their invention reporting and disclosure procedures.

Section 401.8(c)—For clarity, a change has been made that agencies are expected to give notice only if they have actual knowledge of assignees or licensees.

Section 401.6(f)—For clarity, the words "or adopt" have been added to the subsection.

this paragraph to follow the statutory language most closely. Alternatively, the comment suggested that "without permission of the contractor" be inserted at the end of that sentence. The alternative suggestion has been adopted as disclosure with the permission of the contractor would appear consistent with the stautory intent and language.

4. Paragraph (i)—One comment noted that other countries have local manufacture regulations and that in some cases there could be conflicts with the domestic manufacturing requirement. The comment suggested that some provision should be made in this subsection that an agency will automatically ameliorate the U.S. manufacture requirement if there is a direct conflict with a similar clause in another country and a single commercial embodiment would involve inventions from both countries. This suggestion was not accepted as there is sufficient latitude under the existing language to allow an agency to waive its requirements under such circumstances and therefore explicit discussion in the regulation is not warranted.

Paragraph (k)(2)—Several agency comments have pointed out that by requiring royalty-sharing with agency employees, there may be situations in which the employee would be placed in a violation of the conflict-of-interest statutes. This change has been accepted by adding to the paragraph the words "where the agency deems it appropriate."

One university comment suggested "inventor" be changed to "inventors" and that "we would like to hold open the possibility of sharing royalities with close technical associates of the inventor(s)." For clarity the first change has been made. The second change has not been made as such payments can be made and considered as "expenses incidental to the administration of subject inventions."

Section 401.14(b)-For clarification, several changes have been made to the alternative language prescribed for use by DOE when the exception at § 401.3(a)(4) is invoked and title to inventions made under the Navy nuclear propulsion or nuclear weapons programs are retained by DOE. These changes included elimination of the exclusive license provided to the contractor in fields of use other than Navy nuclear propulsion or nuclear weapons. While the statute does not mandate this right to contractors, DOE s urged to take a liberal approach in providing such right on a case-by-case basis as being within the spirit of the statute.

One university comment suggested that the requirement to assign title to inventions under paragraph (c)(1)(B) as prescribed at 401.14(b)(2) be limited to subject inventions that are "nuclear weapons, naval propulsion systems, components thereof, or directly therein." This suggestion has been rejected because it is not consistent with the statute. DOE is urged to take a liberal approach to granting waivers to inventions that fall within paragraph (c)(1)(B) as it is written but which are not within the scope of this suggested language, since we believe that to be within the spirit and intent of the statute.

At the request of DOE, provision has been made for the use of an alternative clause. Provisions for record keeping and reporting requirements will be submitted to OMB for review under the Paperwork Reduction Act.

Section 401.15(a)—This section has been revised to allow the Department of Energy to use their existing waiver procedures in lieu of the procedures prescribed in this section.

Treatment of Comments on Issues Not Mentioned in the Regulation

Successor contracts—The notice of proposed rulemaking requested comments on the issue of transfer of patent rights to successor contractors in contracts for the operation of Government-owned facilities. One agency favored authorizing agencies to add provisions dealing with this. Several universities and nonprofit organizations opposed transfer of their ownership as not being authorized by law. The Department believes the best solution to this issue would be to allow the federal agency and each of the contractors involved to negotiate issues of allocation of royalties, continuation of commercialization efforts, and other related issues taking into account the equities of the parties.

Cooperative Research Arrangements and "de minimus" Support—Several commenters suggested that some "de minimus" standard be established to define a threshold contribution of Government funding to the making of a jointly funded invention below which the regulations should not apply. There is no authority to make this change because the Act does not define "subject invention" in terms of the size of the Government financial contributions in making the invention.

Plant Variety Protection—One university comment suggested that separate regulatory coverage was needed in this area and indicated an intent to discuss this with the Department of Agriculture and to submit

suggested changes later. A second comment expressed concern that, if literally read, the disclosure and election requirements could require substantial paperwork for plant varieties that were not found to be commercially viable. The Department of Agriculture indicates that they have no intent to require such paperwork. The Department of Commerce is working with the Department of Agriculture to determine whether changes in the clause may be appropriate for plant varieties.

Rulemaking Requirements

As stated in the proposed notice this regulation is not a major rule as defined in Executive Order 12291, and it adds no paperwork burdens. In fact, it reduces certain paperwork requirements of the regulations it replaces. And, as discussed in connection with the proposed rule, the General Counsel of the Department of Commerce has certified to the Small Business

Administration that this rule will not have a substantial economic impact on a substantial number of small entities.

List of Subjects in 37 CFR Part 401

Inventions and patents. Nonprofit organizations. Small businesses. Grant programs, Government contracts, Administrative practice and procedure.

Dated: July 9, 1986.

D. Bruce Merrifield,

Assistant Secretary for Productivity, Technology and Innovation.

Accordingly, Chapter IV of Title 37 of the Code of Federal Regulations is amended by the addition of a new Part 401, to read as follows:

PART 401—RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

Sec.

401.1 Scope.

401.2 Definitions.

401.3 Use of the Standard Clauses at 5 401.14

401.4 Contractor appeals of exceptions.
401.5 Modification and tailoring of clauses.

401.6 Exercise of match-in rights.

401.7 Small business preference.

401.8 Reporting on utilization of subject inventions.

401.9 Retention of rights by contractor employee inventor.

401.10 Government assignment to contractor of rights in invention of Government employee.

401.11 Appeals.

401.12 Licensing of background patent rights to third parties.

Administration of patent rights

4 14 Standard patent rights clauses. 401.15 Deferred determinations. 401.16 Submissions and Inquiries.

Authority: 35 U.S.C. 208 and the delegation withority by the Secretary of Commerce to Assistant Secretary for Productivity, Technology and Innovation at section 3(g) of DOO 10-1.

01.1 Scope.

(a) This part implements 35 U.S.C. 202-204 and is applicable to all Federal agencies. It applies to all funding

reements with small business firms d nonprofit organizations executed after the effective date of this part, except for a funding agreement made imarily for educational purposes.

tor the administration of funding agreements which predate the effective te of this part. In accordance with 35 S.C. 212, no scholarship, fellowship, aining grant, or other funding agreement made by a Federal agency

rimarily to an awardee for educational irposes will contain any provision ving the Federal agency any rights to inventions made by the awardee.

(b) The "march-in" and appeals

edures in §§ 401.6 and 401.11 shall
.y to any march-in or appeal
proceeding under a funding agreement
subject to Chapter 18 of Title 35, U.S.C.,
itiated after the effective date of this
art even if the funding agreement was

executed prior to that date.

(c) At the request of the contractor, a funding agreement for the operation of a lovernment-owned facility which is in iffect on the effective date of this part shall be promptly amended to include the provisions required by § 401.3(a) inless the agency determines that one of the exceptions at 35 U.S.C. 202(a) (i)-(iv) (section 401.3(a)(i)-(4) of this part) is applicable and will be applied. If the exception at § 401.3(a) (4) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by § 401.3(b).

(d) This regulation supersedes OMB— Circular A-124 and shall take preedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor

d not inconsistent with Chapter 18 of le 35. United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by § 401.5 or § 401.3, when alternative provisions are used under § 401.3(a) (i)–(4), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in § 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget for review under Executive Order 12291 or, if no submission is required to be made to OMB, before their submission to the Federal Register for publication.

(e) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier OFPP regulations (OMB Circular A-124 or OMB Bulletin 81-22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontractors after July 1, 1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.

(f) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use Governmentowned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the Government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered "funding agreements" as defined at 35 U.S.C. 201(b) and § 401.2(a) of this part.

§ 401.2 Definitions.

As used in this part-

(a) The term "funding agreement" means any contact, 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. This term also 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 defined in the first sentence of this paragraph.

(b) The term "contractor" means any person, small business firm or nonprofit organization which is a party to a

funding agreement.

(c) 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, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(d) The term "subject invention" means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(e) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

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

(g) The term "small business firm" means a small business concern as defined at section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this part, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.5 will be used.

(h) The term "nonprofit 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 (28 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (28 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(i) The term "Chapter 18" means Chapter 18 of Title 35 of the United States Code.

(j) The term "Secretary" means the Secretary of Commerce or his or her designee.

§ 401.3 Use of the Standard Clauses at § 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14(a) with such

modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions—

(1) When the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a

foreign government: or

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 18 of Title 35 of the United States Code; or

[3] 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 protect the security of such

activities: or

(4) When the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above

two programs.

(b) When an agency exercises the exceptions at § 401.3(a)(2) or (3), it shall use the standard clause at § 401.14(a) with only such modifications as are. necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the clause might be modified along lines similar to those described in § 401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at 401.15. When an agency justifies and exercises the exception at § 401.3(a)(2) and uses an alternative provision in the funding agreement on the basis of national security, the provision shall provide the contractor with the right to elect ownership to any invention made under such funding agreement as provided by the Standard Patent Rights Clause found at § 401.14(a) if the invention is not classified by the agency within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law or Executive Order or implementing regulations thereto. prohibit unauthorized dissemination of

the invention. Contracts in support of DOE's naval nuclear propulsion program are exempted from this paragraph.

(c) When the Department of Energy exercises the exception at § 401.3(a)(4), it shall use the clause prescribed at § 401.14(b) with such modification and tailoring as authorized or required elsewhere in this part.

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exceptions at § 401.3(a)(2) or (3) to individual task orders, and it may structure the contract so that modified patent rights provisions will apply to the task order even though the clauses at either § 401.14(a) or (b) are applicable to the remainder of the work. Agencies are authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

(e) Before utilizing any of the exceptions in paragraph 401.3(a) of this section, the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which an exception is applicable. In cases when § 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200. A copy of each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. 202(b)(4) and § 401.4 of this part.

(f) Except for determinations under § 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or

otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

(g) To assist the Comptroller General of the United States to accomplish his or her responsibilities under 35 U.S.C. 202, each Federal agency that enters into any funding agreements with nonprofit organizations or small business firms shall accumulate and, at the request of the Comptroller General, provide the Comptroller General or his or her duly authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause in this part or under OMB Circular A-124 for each fiscal year beginning with October 1, 1982.

(h) To qualify for the standard clause, a prospective contractor may be required by an agency to certify that it is either a small business firm or a nonprofit organization. If the agency has reason to question the status of the prospective contractor as a small business firm, it may file a protest in accordance with 13 CFR 121.9. If it questions nonprofit status, it may require the prospective contractor to furnish evidence to establish its status

as a nonprofit organization.

§ 401.4 Contractor appeals of exceptions.

(a) In accordance with 35 U.S.C. 202(b)(4) a contractor has the right to an administrative review of a determination to use one of the exceptions at § 401.3(a)[1]-[4] if the contractor believes that a determination is either (1) contrary to the policies and objectives of this chapter or (2) constitutes an abuse of discretion by the agency.

Paragraph (b) of this section specifies the procedures to be followed by contractors and agencies in such cases. The assertion of such a claim by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award. Pending final resolution of the claim the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended accordingly and the amendment made retroactive to the effective date of the funding agreement.

(b)(1) A contractor may appeal a determination by providing written notice to the agency within 30 working days from the time it receives a copy of

kency's determination, or within longer time as an agency may fy in its regulations. The intractor's notice should specifically lentify the basis for the appeal.

The appeal shall be decided by the of the agency or by his/her esignee who is at a level above the erson who made the determination. If otice raises a genuine dispute over haterial facts, the head of the gency or the designee shall undertake, r refer the matter for, fact-finding.

[21] Fact-finding shall be conducted in rdance with procedures established ie agency. Such procedures shall be is informal as practicable and be onsistent with principles of amental fairness. The procedures ild afford the contractor the prortunity to appear with counsel, ubmit documentary evidence, present lesses and confront such persons asagency may rely upon. A transcribed ord shall be made and shall be available at cost to the contractor upon Hest. The requirement for a scribed record may be waived by ual agreement of the contractor and the agency.

(4) The official conducting the factshall prepare or adopt written s of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding ceeding along with a recommended ision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or tified mail.

 Fact-finding should be completed whin 45 working days from the date

the agency receives the contractor's

written notice.

3) When fact-finding has been ducted, the head of the agency or designee shall base his or her decision on the facts found, together with any ument submitted by the contractor. ncy officials or any other information in the administrative record. In cases referred for fact-finding, the agency nd or the designee may reject only se facts that have been found to be arly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. The agency ad or the designee may hear oral uments after fact-finding provided that the contractor or contractor's attorney or representative is present and en an opportunity to make arguments d rebuttal. The decision of the agency or the designee shall be in writing f it is unfavorable to the contractor has include an explanation of the basis

the decision. The decision of the

30 working days after fact-finding or, if

ency or designee shall be made within

there was no fact-finding, within 45 working days from the date the agency received the contractor's written notice. A contractor adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claim Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate, the determination of the Federal agency.

§ 401.5 Modification and tailoring of clauses.

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable Government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause and delete the words to be performed by a small business firm or domestic nonprofit organization" from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) may be deleted. When either paragraph (g)(2) or paragraphs (g)(2) and (3) are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (l), "Communications", at the end of the clauses at § 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in

paragraph (l).

(c) Agencies may replace the underlined words and phrases in the clauses at § 401.14 with those appropriate to the particular funding agreement. For example, "contracts could be replaced by "grant." "contractor" by "grantee," and "contracting officer" by "grants officer." Depending on its use, "Federal agency" can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d)(1) When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or international agreement, a

sentence may be added at the end of paragraph (b) of the clauses at § 401.14 as follows:

This license will include the right of the Government to sublicense foreign governments, their nationals, and international organizations pursuant to the following treaties or international agreements:

The blank above should be completed with the names of applicable existing treaties or international agreements, agreements of cooperation, memoranda of understanding, or similar arrangements including military agreements relating to weapons development and production. The above language is not intended to apply to treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the Government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign Government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or international agreement. For example, in some cases exclusive licenses or even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

(2) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a Government-owned facility, the following language may also be added:

The agency reserves the right to unilaterally amend this funding agreement to identify specific treaties or international agreements entered into or to be entered into by the Government after the effective date of this funding agreement and effectuate those license or other rights which are necessary for the Government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(e) Agencies may add subparagraphs to paragraph (f) of the clauses at § 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the closeout of a funding agreement listing all subject inventions or stating that there were none.

(2) 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 country in which the contractor has applied for patents.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered

by the report.

(f) If the contract is with a nonprofit organization and is for the operation of a Government-owned contractor-operated facility, the following will be substituted for paragraph (k)(3) of the clause at §401.14(a):

- (3) After payment of patenting costs. licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalties or income earned and retained by the contractor during any fiscal year on subject inventions under this or any successor contract containing the same requirement, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the contractor only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.
- (g) If the contract is for the operation of a Government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at § 401.14(a):
- (5) The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the contracting officer so that the contracting officer may evaluate and determine their effectiveness.

§ 401.6 Exercise of march-in rights,

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (j) of the clause at § 401.14.

 (b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights.
 efore initiating any march-in

roceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(c) 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 and if known to the agency, 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 on notice of the facts upon which the action would be 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 section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(d) Within 30 days after the 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 or argument in opposition to 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 designee shall undertake or refer the matter to another official for fact-

finding.

(e) 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 should 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. Any portion of the march-in proceeding, including a fact-finding

hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the Government except when such release is authorized by the contractor (assignee or licensee).

- (f) The official conducting the factfinding shall prepare or adopt writtenfindings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.
- (g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives. and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee or ... exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated. may be exercised.
- (h) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

J The procedures of this Part shall so apply to the exercise of march-in ghts against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term contractor" as used in this section shall e deemed to include the inventor.

(j) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in beyance pending the exhaustion of ppeals or petitions filed under 35 U.S.C. 203(2).

(k) For purposes of this section the erm "exclusive licensee" includes a artially exclusive licensee.

(I) Agencies are authorized to issue supplémental procedures not inconsistent with this part for the onduct of march-in proceedings:

401.7 Small business preference.

(a) Paragraph (k)(4) of the clauses at 401.14 implements the small business. reference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the ircumstances to attract small business icensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for

nses. What constitutes reasonable orts to attract small business. licensees will vary with the circumstances and the nature, duration. and expense of efforts needed to bring the invention to the market. Paragraph (k)(4) is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies. Under such circumstances it would not be reasonable to seek and to give a preference to small business licensees.

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the Secretary. To the extent deemed appropriate, the Secretary will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All the above

'estigations, discussions, and gotiations of the Secretary will be in coordination with other interested agencies, including the Small Business Administration; and in the case of a

contract for the operation of a Government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

§ 401.8 Reporting on utilization of subject inventions.....

(a) Paragraph (h) of the clauses at § 401.14 and its counterpart in the clause at Attachment A to OMB Circular A-124 provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies exercising this right should accept such information, to the extent feasible, in the format that the contractor normally prepares it for its own internal purposes. The prescription of forms should be avoided. However, any forms or standard questionnaires that are adopted by an agency for this purpose must comply with the requirements of the Paperwork Reduction Act. Copies shall be sent to the Secretary. An had his entry of hadden

(b) In accordance with 35 U.S.C. 202(c)(5) and the terms of the clauses at § 401.14, agencies shall not disclose such information to persons outside the Government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the and the second of the second o agency.

§ 401.9 Retention of rights by contractor. employee inventor... 化重线 微抗动物

Agencies which allow an employee/ inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(i) and (iii); (f)(4); (h); (i); and (j) of the clause at section 401.14(a).

§ 401.10 Government assignment to contractor of rights in invention of government employee.

In any case when a Federal employeeis a co-inventor of any invention made under a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such co-inventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as apply to the contractor under the patent rights clause of its funding agreement. Agencies may add additional conditions

so long as they are consistent with 35 U.S.C. 201-206.

§ 401.11 Appeals.

(a) As used in this section, the term "standard clause" means the clause at § 401.14 of this part and the clauses previously prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period underparagraph k(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for factfinding at least comparable to those set forth in § 401.6(e)-(g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.

(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the Contracts Dispute Act, the procedures under that Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§ 401.12 Licensing of background patent rights to third parties.

(a) A funding agreement with a small business firm or a domestic nonprofit 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 the justification required for such provisions.

(b) 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 practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing. The contractor shall be given prompt notification of the determination by certified or registered mail. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§ 401.13 Administration of patent rights clauses.

(a) In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the Government in the invention.

(b) Agencies shall promptly grant, unless there is a significant reason not to, a request by a nonprofit organization under paragraph k(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 inasmuch as 35 U.S.C. 202(c)(7) has since been amended to eliminate the limitation on the duration of exclusive licenses. Similarly, unless there is a significant reason not to, agencies shall promptly approve an assignment by a nonprofit organization to an organization which has as one of its primary functions the management of inventions when a request for approval has been necessitated under paragraph k(1) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 because the patent management organization is engaged in or holds 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. As amended, 35 U.S.C. 202(c)(7) no longer contains this limitation. The policy of this subsection should also be followed in connection with similar approvals that may be required under Institutional Patent Agreements, other patent rights clauses, or waivers that predate Chapter 18 of Title 35, United States Code.

(c) The President's Patent Policy Memorandum of February 18, 1983, states that agencies should protect the confidentiality of invention disclosure, patent applications, and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws. The following requirements should be followed for funding agreements covered by and predating this Part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph c of the standard clause found at 401.14(a) or such other clause may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor an FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the application to third parties pursuant to requests under the Freedom of Information Act or otherwise copies of any document which the agency obtained under this clause which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (of its assignees, licensees, or employees) on a subject invention to

which the contractor has elected to retain title.

(3) A number of agencis have policies to encourage public dissemination of the results of work supported by the agency through publication in Government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph c of the standard clause found at 401:14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section. agencies may publish such disclosures.

(4) Nothing in this paragraph is intended to preclude agencies from including in the publication activities described in the first sentence of paragraph (c)(3) of this section, the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, the agency shall use reasonable efforts to restrict its publication of the material for six months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

(5) Nothing in this paragraph (c) is intended to limit the authority of agencies provided in 35 U.S.C. 205 in circumstances not specifically described in this paragraph (c).

§ 401.14 Standard patent rights clauses.

(a) The following is the standard patent rights clause to be used as specified in § 401.3(a).

Patent Rights (Small Business Firms and Nonprofit Organizations)

(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, or any noval variety of plant which is or may be protected under the

Variety Protection Act (7 U.S.C. 2321 et

(2) "Subject invention" means any invention of the contractor conceived or first actually reduced to practice in the

rformance of work under this contract, ovided that in the case of a variety of plant, e date of determination (as defined in section 41(d) of the Plant Variety Protection Act. 7 U.S.C. 2401(d)) must also occur during

e period of contract performance. (3) "Practical Application" means to anufacture 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 achine or system; and, in each case, under ch conditions as to establish that the vention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the ablic on reasonable terms.

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

(5) "Small Business Firm" means a small usiness concern as defined at Section 2 of ublic Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business dministration. For the purpose of this lause, the size standards for small business oncerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, he used.

"Nonprofit Organization" means a ... versity or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal tevenue Code of 1954 (26 U.S.C. 501(c) and xempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit

rganization statute.

(b) Allocation of Principal Rights. The contractor may retain the entire right, title, and interest throughout the world to ach subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the contractor retains title, the Federal Government shall have a nonexclusive. nontransferable, irrevocable, paid-up license o practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(c) Invention disclosure, Election of Title and Filing of Patent Application by

Contractor.

(1) The contractor will disclose each subject invention to the Federal agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. 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

irstanding to the extent known at the of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure 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, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(2) The contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valld patent protection can still be obtained in the United States, the period for ... election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.

(d) Conditions When the Government May Obtain Title

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 title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

(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.

(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 reexamination oropposition proceeding on, a patent on a subject invention.

(e) Minimum Rights to Contractor and Protection of the Contractor Right to File.

(1) The contractor will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the contractor fails to disclose the invention

within the times specified in (c), above. The contractor's license extends to its domestic subsidiary and affiliates, if any, within the cornorate 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 Federal agency except when transferred to the successor of that party of the contractor's business to which the invention pertains.

(2) The contractor's domestic license may be revoked or modified by the funding Federal agency 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 applicable provisions at 37 CFR Part 404 and agency licensing regulations (if any). This license will not be revoked in that field of 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 the domestic subsidiaries or affiliates have failed to

country. (3) 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 applicable regulations in 37 CFR Part 404 and agency regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

achieve practical application in that foreign

(f) Contractor Action to Protect the

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 to which the contractor elects to retain title, and (ii) convey title to the Federal agency when requested under paragraph (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 nontechnical 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 contract in order that the contractor can comply with the disclosure provisions of paragraph (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. This disclosure format should require, as a minimum, the information required by (c)(1), above. The contractor shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filling of patent applications prior to U.S. or foreign statutory bars.

: (3) The contractor will notify the Federal agency of any decisions not to continue the 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 applications 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 (identify the Federal agency). The Government has certain rights in the invention."

يَّا الْحَامِةِ (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 by a small business firm or domestic nonprofit 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 or FAR).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the agency, subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause: provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(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. As required by 35 U.S.C. 202(c)[5], the agency agrees it will not disclose such information to persons outside the Government without permission of the contractor.

(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 inventions 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 been 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 37 CFR 401.6 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such 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 of 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 Nonprofit Organizations.

If the contractor is a nonprofit

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, provided that such assignee will be subject to the same provisions as the contractor:

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee coinventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) 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; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

(1) Communications.

(Complete According to Instructions at 401.5(b)).

(b) When the Department of Energy (DOE) determines to use alternative provisions under § 401.3(a)(4), the standard clause at § 401.14(a), above, shall be used with the following modifications unless a substitute clause is drafted by DOE:

(1) The title of the clause shall be changed to read as follows:

Patent Rights to Nonprofit DOE Facility Operators

(2) Add an."(A)" after "(1)" in paragraph (c)(1) and add subparagraphs (B) and (C) to paragraph (c)(1) as follows:

(B) If the subject invention occurred under activities funded by the naval nuclear propulsion or weapons related programs of DOE, then the provisions of this subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). In such cases the contractor agrees to assign the Government the entire right, title, and interest thereto throughout the world in and to the subject invention except to the extent that rights are retained by the contractor through a greater rights determination or under paragraph (e),

nelow. The contractor, or an employee-inventor, with authorization of the contractor, may submit a request for greater rights at the time the invention is disclosed or within a reasonable time thereafter. DOE will process such a request in accordance with procedures at 37 CFR 401.15. Each determination of greater rights will be subject to paragraphs (h)-(k) of this clause and such additional conditions, if any, deemed to be appropriate by the Department of Energy.

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, or within 90 days thereafter, the contractor will submit a written statement as to whether or not the invention occurred under a naval nuclear propulsion or weapons-related program of the Department of Energy, If this statement is not filed within this time, subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). The contractor statement will be deemed conclusive unless, within 60 days thereafter. the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending resolution of the matter, the invention will be subject to . subparagraph (c)(1)(B).

(3) Paragraph (k)(3) of the clause will be modified as prescribed at § 401.5(f).

401.15 Deferred determinations.

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at § 401.3(a) was applied.

except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations of this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any event, if a bar to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under Government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances of concerns which originally led the agency to invoke an exception under § 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at § 401.14(a) had been used originally.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded Government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at § 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under

§ 401.11 of this part.

§ 401.16 Submissions and inquiries.

All submissions or inquiries should be directed to Federal Technology Management Policy Division, telephone number 202–377–0659, Room H4837, U.S. Department of Commerce, Washington, DC 20230.

[FR Doc. 86–15777 Filed 7–11–86; 8:45 am] BILLING CODE 3510-18-M

Public Law 96-517 96th Congress

An Act

To amend the patent and trademark laws.

Dec. 12, 1980 [H.R. 6933]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That title 35 of the United States Code, entitled "Patents", is amended by adding after chapter 29 the following new chapter 30:

Patent and trademark laws, amendment.

"CHAPTER 30—PRIOR ART CITATIONS TO OFFICE AND REEXAMINATION OF PATENTS

"301. Citation of prior art.
"302. Request for reexamination.

"303. Determination of issue by Commissioner.
"304. Reexamination order by Commissioner.
"305. Conduct of reexamination proceedings.

"306. Appeal.
"307. Certificate of patentability, unpatentability, and claim cancellation.

"\$301. Citation of prior art

35 USC 301.

"Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential.

"§ 302. Request for reexamination

35 USC 302.

"Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301 of this title. The request must be in writing and must be accompanied by payment of a reexamination fee established by the Commissioner of Patents pursuant to the provisions of section 41 of this title. The request must set forth the Post p. 3017. pertinency and manner of applying cited prior art to every claim for which reexamination is requested. Unless the requesting person is the owner of the patent, the Commissioner promptly will send a copy of the request to the owner of record of the patent.

"§ 303. Determination of issue by Commissioner

35 USC 303.

"(a) Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Commissioner will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and any time, the Commissioner may determine whether a substantial new question of patentability is

PUBLIC LAW 96-517-DEC. 12, 1980

raised by patents and publications discovered by him or cited under

the provisions of section 301 of this title. Record

"(b) A record of the Commissioner's determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent and to the person requesting reexamination, if any.

"(c) A determination by the Commissioner pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and nonappealable. Upon such a determination, the Commissioner may refund a portion of the reexamination fee required under section 302 of this title.

"§ 304. Reexamination order by Commissioner

"If, in a determination made under the provisions of subsection 303(a) of this title, the Commissioner finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question. The patent owner will be given a reasonable period, not less than two months from the date a copy of the determination is given or mailed to him, within which he may file a statement on such question, including any amendment to his patent and new claim or claims he may wish to propose, for consideration in the reexamination. If the patent owner files such a statement, he promptly will serve a copy of it on the person who has requested reexamination under the provisions of section 302 of this title. Within a period of two months from the date of service, that person may file and have considered in the reexamination a reply to any statement filed by the patent owner. That person promptly will serve on the patent owner a copy of any reply filed.

"§ 305. Conduct of reexamination proceedings

"After the times for filing the statement and reply provided for by section 304 of this title have expired, reexamination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133 of this title. In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter. All reexamination proceedings under this section, including any appeal to the Board of Appeals, will be conducted with special dispatch within the Office.

"§ 306. Appeal

"The patent owner involved in a reexamination proceeding under this chapter may appeal under the provisions of section 134 of this title, and may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the

"\$ 307. Certificate of patentability, unpatentability, and claim cancellation

"(a) In a reexamination proceeding under this chapter, when the time for appeal has expired or any appeal proceeding has terminated,

Refund:

35 USC 304.

Filing period.

35 USC 305.

35 USC 132, 133.

35 USC 306.

35 USC 134.

35 USC 141-145.

35 USC 307.

the Commissioner will issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to

be patentable.

"(b) Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.".

SEC. 2. Section 41 of title 35, United States Code, is amended to read as follows:

"§ 41. Patent fees

35 USC 41.

35 USC 252.

"(a) The Commissioner of Patents will establish fees for the processing of an application for a patent, from filing through disposition by issuance or abandonment, for maintaining a patent in force, and for providing all other services and materials related to patents.

No fee will be established for maintaining a design patent in force.

"(b) By the first day of the first fiscal year beginning on or after one calendar year after enactment of this Act, fees for the actual processing of an application for a patent, other than for a design patent, from filing through disposition by issuance or abandonment, will recover in aggregate 25 per centum of the estimated average cost to the Office of such processing. By the first day of the first fiscal year beginning on or after one calendar year after enactment, fees for the processing of an application for a design patent, from filing through disposition by issuance or abandonment, will recover in aggregate 50 per centum of the estimated average cost to the Office of such

(c) By the fifteenth fiscal year following the date of enactment of this Act, fees for maintaining patents in force will recover 25 per centum of the estimated cost to the Office, for the year in which such maintenance fees are received, of the actual processing all applications for patents, other than for design patents, from filing through disposition by issuance or abandonment. Fees for maintaining a patent in force will be due three years and six months, seven years and six months, and eleven years and six months after the grant of the patent. Unless payment of the applicable maintenance fee is received in the Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period. The Commissioner may require the payment of a surcharge as a condition of accepting within such six-month grace period the late payment of an applicable maintenance fee.

"(d) By the first day of the first fiscal year beginning on or after one calendar year after enactment, fees for all other services or materials related to patents will recover the estimated average cost to the Office of performing the service or furnishing the material. The yearly fee for providing a library specified in section 13 of this title 35 USC 13. with uncertified printed copies of the specifications and drawings for all patents issued in that year will be \$50.

(e) The Commissioner may waive the payment of any fee for any service or material related to patents in connection with an occasional or incidental request made by a department or agency of the

94 STAT, 3018

35 USC 132.

Government, or any officer thereof. The Commissioner may provide any applicant issued a notice under section 132 of this title with a copy of the specifications and drawings for all patents referred to in that notice without charge.

"(f) Fees will be adjusted by the Commissioner to achieve the levels of recovery specified in this section; however, no patent application processing fee or fee for maintaining a patent in force will be adjusted

more than once every three years.

"(g) No fee established by the Commissioner under this section will Notice. take effect prior to sixty days following notice in the Federal Register.

Sec. 3. Section 42 of title 35, United States Code, is amended to read

as follows:

35 USC 42.

"\$42. Patent and Trademark Office funding

"(a) All fees for services performed by or materials furnished by the Patent and Trademark Office will be payable to the Commissioner.

"(b) All fees paid to the Commissioner and all appropriations for defraying the costs of the activities of the Patent and Trademark Office will be credited to the Patent and Trademark Office Appropriation Account in the Treasury of the United States, the provisions of section 725e of title 31, United States Code, notwithstanding.

"(c) Revenues from fees will be available to the Commissioner of Patents to carry out, to the extent provided for in appropriation Acts,

the activities of the Patent and Trademark Office.

"(d) The Commissioner may refund any fee paid by mistake or any amount paid in excess of that required.'

Sec. 4. Section 154 of title 35, United States Code, is amended by deleting the word "issue".

Sec. 5. Section 31 of the Trademark Act of 1946, as amended (15)

U.S.C. 1113), is amended to read as follows:

"§ 31. Fees

"(a) The Commissioner of Patents will establish fees for the filing and processing of an application for the registration of a trademark or other mark and for all other services performed by and materials furnished by the Patent and Trademark Office related to trademarks and other marks. Fees will be set and adjusted by the Commissioner to recover in aggregate 50 per centum of the estimated average cost to the Office of such processing. Fees for all other services or materials related to trademarks and other marks will recover the estimated average cost to the Office of performing the service or furnishing the material. However, no fee for the filing or processing of an application for the registration of a trademark or other mark or for the renewal or assignment of a trademark or other mark will be adjusted more than once every three years. No fee established under this section will take effect prior to sixty days following notice in the Federal Register.

"(b) The Commissioner may waive the payment of any fee for any service or material related to trademarks or other marks in connection with an occasional request made by a department or agency of the Government, or any officer thereof. The Indian Arts and Crafts Board will not be charged any fee to register Government trademarks of genuineness and quality for Indian products or for products of particular Indian tribes and groups.".

SEC. 6. (a) Title 35 of the United States Code, entitled "Patents", is amended by adding after chapter 37 the following new chapter 38:

Refund.

Notice.

Waiver.

Indian products, exception.

"CHAPTER 38—PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

"Sec.
"200. Policy and objective.
"201. Definitions.
"202. Disposition of rights.
"203. March-in rights.
"204. Preference for United States industry.
"205. Confidentiality.
"206. Uniform clauses and regulations.
"207. Domestic and foreign protection of federally owned inventions.
"208. Regulations governing Federal licensing.
"209. Restrictions on licensing of federally owned inventions.
"210. Precedence of chapter.
"211. Relationship to antitrust laws.

"§ 200. Policy and objective

35 USC 200.

"It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

"§ 201. Definitions

35 USC 201.

"As used in this chapter-

"(a) The term 'Federal agency' means any executive agency as defined in section 105 of title 5, United States Code, and the military departments as defined by section 102 of title 5, United States Code.

"(b) 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.

"(c) The term 'contractor' means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

"(d) The term 'invention' means any invention or discovery which is or may be patentable or otherwise protectable under

'(e) 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.

"(f) 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.

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

invention.

"(h) The term 'small business firm' means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the

Small Business Administration.

"(i) The term 'nonprofit 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 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

35 USC 202.

"§ 202. Disposition of rights

"(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: Provided, however, That a funding agreement may provide otherwise (i) when the funding agreement is for the operation of a Governmentowned research or production facility, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter or (iii) 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 protect the security of such activities. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b)(1) Any determination under (ii) of paragraph (a) of this section shall be in writing and accompanied by a written statement of facts justifying the determination. A copy of each such determination and justification shall be sent to the Comptroller General of the United States within thirty days after the award of the applicable funding agreement. In the case of determinations applicable to funding agreements with small business firms copies shall also be sent to the

Chief Counsel for Advocacy of the Small Business Administration. "(2) If the Comptroller General believes that any pattern of determinations by a Federal agency is contrary to the policy and objectives of this chapter or that an agency's policies or practices are otherwise not in conformance with this chapter, the Comptroller General shall so advise the head of the agency. The head of the agency shall advise the Comptroller General in writing within one hundred and twenty days of what action, if any, the agency has taken or plans to take with respect to the matters raised by the Comptroller General.

"(3) At least once each year, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

Funding agreement.

Written determination.

Copy to Comptroller General.

Copy to SBA.

Contrary agency determinations.

Report to congressional committees.

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

requirements.

the following:

(1) A requirement that the contractor disclose each subject invention to the Federal agency within a reasonable time after it is made and that the Federal Government may receive title to any subject invention not reported to it within such time. (2) A requirement that the contractor make an election to

retain title to any subject invention within a reasonable time after disclosure and that the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such time.

"(3) A requirement that a contractor electing rights file patent applications within reasonable times and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such

"(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world, and may, if provided in the funding agreement, have additional rights to sublicense any foreign government or international organization pursuant to

any existing or future treaty or agreement.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

"(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the

"(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions 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 shall be subject to the same provisions as the contractor); (B) a prohibition against the granting of exclusive licenses under United States Patents or Patent Applications in a subject invention by the contractor to persons other than small business firms for a period in excess of the earlier of five years from first commercial sale or use of the invention or eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to

obtain premarket clearance unless, on a case-by-case basis, the Federal agency approves a longer exclusive license. If exclusive field of use licenses are granted, commercial sale or use in one field of use shall 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 shall not be deemed to end the exclusive period to different subsequent products covered by the invention; (C) a requirement that the contractor share royalties with the inventor; and (D) a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education. "(8) The requirements of sections 203 and 204 of this chapter.

"(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act

and regulations promulgated hereunder.

"(e) In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employee to the contractor

subject to the conditions set forth in this chapter.

"(f)(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications

required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of

such determination.

35 USC 203.

"§ 203. March-in rights

"With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to

Rights, retention.

Rights, transfer or assignment.

Third-party licensing, prohibition. grant such a license itself, if the Federal agency determines that

"(a) 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;

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

"(c) 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

"(d) action is necessary because the agreement required by section 204 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 its agreement obtained pursuant to section 204.

"§ 204. Preference for United States industry

35 USC 204.

"Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall 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 under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been 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.

"\$ 205. Confidentiality

35 USC 205

"Federal agencies are authorized to withhold from disclosure to the public information disclosing any 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 a patent application to be filed. Furthermore, Federal agencies shall not be 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.

"\$ 206. Uniform clauses and regulations

35 USC 206.

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

"§ 207. Domestic and foreign protection of federally owned inven- 35 USC 207. tions

"Each Federal agency is authorized to-

"(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title,

or interest:

"(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

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

"(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

35 USC 208.

35 USC 281 et

seq.

"§ 208. Regulations governing Federal licensing

"The Administrator of General Services is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

35 USC 209.

"\$ 209. Restrictions on licensing of federally owned inventions

Development or marketing plan.

"(a) No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

Manufacture in

"(b) A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

"(c)(1) Each Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a federally owned domestic patent or patent application only if, after public notice and opportunity for filing written objections, it is determined that-

'(A) the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public:

"(B) the desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;

"(C) exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

"(D) the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise

promote the invention's utilization by the public.

"(2) A Federal agency shall not grant such exclusive or partially exclusive license under paragraph (1) of this subsection if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent ith the antitrust laws.

"(3) First preference in the exclusive or partially exclusive licens- Small business ing of federally owned inventions shall go to small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and equally likely, if executed, to bring the invention to practical application as any plans submitted by appli-

cants that are not small business firms.

"(d) After consideration of whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced, any Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a foreign patent application or patent, after public notice and opportunity for filing written objections, except that a Federal agency shall not grant such exclusive or partially exclusive license if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

"(e) The Federal agency shall maintain a record of determinations Record.

to grant exclusive or partially exclusive licenses.

"(f) Any grant of a license shall contain such terms and conditions Terms and as the Federal agency determines appropriate for the protection of conditions. the interests of the Federal Government and the public, including

provisions for the following:

"(1) periodic reporting on the utilization or efforts at obtaining utilization that are being made by the licensee with particular reference to the plan submitted: Provided, That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

"(2) the right of the Federal agency to terminate such license in whole or in part if it determines that the licensee is not executing the plan submitted with its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

"(3) the right of the Federal agency to terminate such license in whole or in part if the licensee is in breach of an agreement obtained pursuant to paragraph (b) of this section; and

"(4) the right of the Federal agency to terminate the license in whole or in part if the agency determines that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee.

Antitrust

35 USC 210.

"\$210. Precedence of chapter

"(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

"(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085); "(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C.

1624(a); 60 Stat. 1090):

"(3) section 501(c) or the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); \$3 Stat. 742);
"(4) section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C 1395(c); 80 Stat. 721);

"(5) section 12 of the National Science Foundation Act of 1950

(42 U.S.C. 1871(a); 82 Stat. 360);

"(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

"(7) section 305 of the National Aeronautics and Space Act of.

1958 (42 U.S.C. 2457);
"(8) section 6 of the Coal Research Development Act of 1960 (30

U.S.C. 666; 74 Stat. 337);

"(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

"(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

"(11) subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5); "(12) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5901; 88 Stat. 1878);

"(13) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);
"(14) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat.

191);
"(15) section 8001(c)(3) of the Solid Waste Disposal Act (42)

"(16) section 219 of the Foreign Assistance Act of 1961 (22

U.S.C. 2179; 83 Stat. 806);
"(17) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);

"(18) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455);

"(19) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);

"(20) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);

"(21) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178(j); 92 Stat. 2533);

"(22) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and

provides that it shall take precedence over this Act.

"(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the perform-

91 Stat. 1320.

64 Stat. 154.

68 Stat. 944.

88 Stat. 1887.

42 USC 5908.

92 Stat. 1316.

7 USC 178i.

ance of funding agreements with persons other than nonprofit

organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of Rights, agencies to agree to the disposition of rights in inventions made in the disposition. performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on August 23, 1971 (36 Fed. Reg. 16887), agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

"(d) Nothing in this chapter shall be construed to require the Disclosure. disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or

methods.

"§ 211. Relationship to antitrust laws

35 USC 211.

"Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law."

(b) The table of chapters for title 35, United States Code, is amended by adding immediately after the item relating to chapter 37 the following:

"38. Patent rights in inventions made with Federal assistance.".

Sec. 7. Amendments to Other Acts.—The following Acts are amended as follows:

(a) Section 156 of the Atomic Energy Act of 1954 (42 U.S.C. 2186; 68 Stat. 947) is amended by deleting the words "held by the Commission ര=".

(b) The National Aeronautics and Space Act of 1958 is amended by repealing paragraph (g) of section 305 (42 U.S.C. 2457(g); 72 Stat. 436).

(c) The Federal Nonnuclear Energy Research and Development Act of 1974 is amended by repealing paragraphs (g), (h), and (i) of section 9 (42 U.S.C. 5908 (g), (h), and (i); 88 Stat. 1889–1891).

SEC. 8. (a) Sections 2, 4, and 5 of this Act will take effect upon Effective dates.

enactment.

(b) Section 1 of this Act will take effect on the first day of the seventh month beginning after its enactment and will apply to

patents in force as of that date or issued thereafter.

(c) Section 3 of this Act will take effect on the first day of the first fiscal year beginning on or after one calendar year after enactment. However, until section 3 takes effect, the Commissioner may credit the Patent and Trademark Office appropriation account in the Treasury of the United States with the revenues from collected reexamination fees, which will be available to pay the costs to the Office of reexamination proceedings.

(d) Any fee in effect as of the date of enactment of this Act will remain in effect until a corresponding fee established under section 41 of title 35, United States Code, or section 1113 of title 15, United

States Code, takes effect.

(e) Fees for maintaining a patent in force will not be applicable to patents applied for prior to the date of enactment of this Act.

35 USC 41 note.