TV's 'Quincy' Tells Hill About Rare Diseases

By Lois Dale
Washington Post Staff Writer

A highly unusual pitch on behalf of an unlikely TV spokesman will be underway shortly when [illegible] holding of public information meetings to have a dozen of their lobby staff [illegible] on the job.

Dozens of [illegible] whose [illegible] news [illegible] [illegible] [illegible] [illegible] because they are not enough patients to make [illegible] [illegible] [illegible] [illegible]

ERNE

C

ERNEST A. LADO, P.E.
5085 N.W. 66 Drive
Coral Springs, FL 33067
Phone: 305 755-0095

Mr. Norman J. Latker, Attorney at Law
Browdy and Neimark
419 Seventh Street NW
Washington, DC 20004

20004-2205 07

ERNEST A. LADO, P. E.

5065 NW 66 Drive
Coral Springs, Florida 33067
Phone (954) 755 0095
Fax (954) 340 2070
May 4, 1998

Mr. Norman J. Latker, Attorney at Law
Browdy and Neimark
419 Seventh Street NW
Washington, DC 20004

Re: NIST (30507/014827)

Dear Mr. Latker:

With reference to my letter of January 26 which I assume you did not find to be of immediate interest to you or to your firm, you should be aware of recent developments that are pertinent and may help in reevaluation of its potential.

I have continued the good fight and can report drastic changes in the NIST organization, for the evaluation role of NIST has been terminated by the Department of Energy whose Office of Industrial Technologies (OIT) will henceforth do their own evaluation under an "Inventions and Innovation Program for FY 1998" in which I expect to participate.

The new NIST table of organization eliminates the Office of Technology Innovation, and its Director as well as the Office of Congressional and Legislative Affairs.

As an agency of the Department of Commerce NIST remains liable for compensatory and punitive damages resulting from gross negligence, ineptitude, non-compliance with or possibly outright violation of Public Law 93 577.

I remain persuaded that NIST rejection of my technology was the work of a disgruntled past associate who was repeatedly by-passed for promotions by me and by others, and was more intent on avenging percieved past grievances than in the objective evaluation of my sludge incineration technology.

A formal FOIA inquiry from you representing me on a tentative basis might force NIST to identify an acknowledged consultant from the private sector who should not have been assigned to evaluation of my technology by virtue of a prior relationship deemed likely to affect the impartiality of his performance.

I am suggesting that an exploratory inquiry from you to NIST at this time may lead to disclosure of the identity of a NIST consultant that engineered rejection of my technology for reasons personal and unrelated to the merits of my technology, and I could then submit compelling evidence of his being repeatedly by-passed for promotion as the real reason for his opposition.

Sincerely,

Ernest A. Lado, P.E.

[illegible] my technology, and I could then submit compelling evidence of his being repeatedly by-passed for promotion as the real reason for his opposition.

Sincerely,

Ernest A. Lado, P.E.

Great Paper - baseline

Personal Observations?

Tough Area

~~What are~~ our goals?

Std Govt be in any better position to obtain full rights to proprietary data than a private sector purchaser? Most would probably say NO.

Raises Question of Prime/Sub

What is proprietary data?

Prime + Sub.

7

development of

Notwithstanding the source of funding for the ~~technical data~~ ~~[redacted]~~ any item ~~[redacted]~~ by the ~~Govt~~ Any party will negotiate a ~~[redacted]~~ only right to direct the contractor delivering the item to license others supplies for delivery of the item to the Govt.

~~[redacted]~~ only right to direct the contractor delivering the item to license others supplies for delivery of the item to the Govt.

We tend to forget the benefits that inventors and other creators bring to us on a daily basis. — If we stripped away all the invention that surrounds us in this room, we would no doubt be sitting on the cold ground with no clothes. In addition, there would be no art, music, literature or drama.

Fortunately, our founding fathers recognized the need to honor and support the works of these creators by providing to them in our constitution the exclusive rights to their respective writings and discoveries. In recent times the reward intended for our creative few has been diluted by the general requirement that a person's ideas be assigned to their employers as a condition of employment.

But an enlightened U. of Md. policy recognizes that the successful application of its technology must assume that the participants involved including the inventor must

a practical demonstration of
today in a this policy by making
this special presentation.

...from potential
of depletion of stratospheric
tocol was negotiated under
the United Nations Envi-
m, pursuant to the Vienna
the Protection of the Ozone
as ratified by the United
1986.

c agreement, the interna-
ty undertakes cooperative
tect a vital global resource.
es played a leading role in
of the Protocol. United
is necessary for entry into
ive implementation of the
ratification by the United
rge similar action by other
rticipation is also essential.
hat the Senate give early
sideration to the Protocol
e and consent to ratifica-

Ronald Reagan

7.

mbus Quincentenary
ion

xander P. Papamarkou
mber 22, 1987

lay announced his inten-
ander P. Papamarkou to

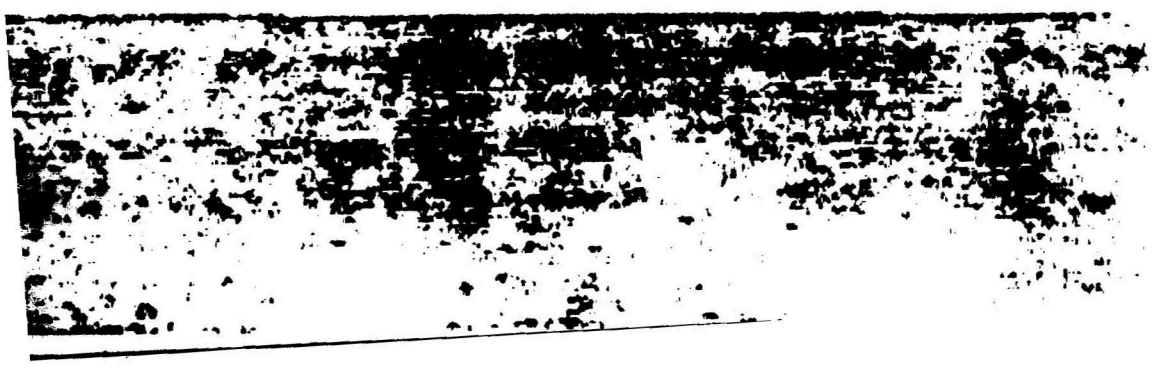
Uniform Treatment of Federally Funded Inventions

Executive Order 12618.
December 22, 1987

By the authority vested in me as President by the Constitution and laws of the United States of America, and having concluded that the ability of the United States to achieve the statutorily prescribed policy (35 U.S.C. 200) of using the patent system to promote the utilization of inventions arising from federally supported research or development requires that Federal agencies follow uniform policies in administering patents and licenses conceived or first reduced to practice during the course of federally funded research, Executive Order No. 12591 of April 10, 1987, is amended by redesignating Sections 1(b) 5 and (6) as 1(b) (6) and (7), respectively, and by adding a new Section 1(b)(5) as follows:

"(5) administer all patents and licenses to inventions made with federal assistance, which are owned by the non-profit contractor or grantee, in accordance with Section 202(c)(7) of Title 35 of the United States Code as amended by Public Law 98–620, without regard to limitations on licensing found in that section prior to amendment





FAX

DATE: April 23, 1998

TO: Norm Latker, Esq.
Browdy and Neimark, Attorneys at Law
Tel: 202-628-5197
Fax: 202-737-3528

From: Robert Kneller, J.D., M.D.
Abe Fellow on Leave from the Technology Transfer and Commercialization Branch of NCI, NIH and
Guest Researcher at the Research Center for Advanced Science and Technology
University of Tokyo
Tel. (office): 81-3-3481-4597
Fax (office): 81-3-3481-4092
Tel/Fax: (home): 81-3-3449-9681
Email: urwk@hongo.ecc.u-tokyo.ac.jp

RECEIVED
APR 23 1998
BROWDY & NEIMARK

Total no. of pages: 9

Dear Mr. Latker:

Thank you very much for the fax of your Congressional testimony from May, 1977 and also for the insights in our telephone conversation yesterday. It is interesting to know the antecedents of Bayh-Dole and to realize that important changes were being worked out even before 1980. If DHEW held only 400 patents (or applications) in 1977, I wonder what agencies were holding the other 20,000 plus patents--I suppose DOD, DOE and NASA. Japan is not yet at the stage of working out the equivalent of IPAs.

Thank you again for your time and thoughtful consideration in responding to my inquiry.

Sincerely,

Bob Kneller

YES NO

out the equivalent of IPAs.

Thank you again for your time and thoughtful consideration in responding to my inquiry.

Sincerely,

Bob Kneller

YES NO 4/30/98
Most having No commercial utility filed for defensive purposes

********** -JOURNAL- ********** DATE APR-30-1998 ***** TIME 16:23 **********

DATE/TIME = APR-30 16:22
JOURNAL NO. = 29
COMM.RESULT = OK
PAGES = 01
FILE NO. =
DURATION = 00:00'45
MODE = XMT
STATION NAME =
TELEPHONE NO. = T 01181334814092#
RECEIVED ID = 81334814092
RESOLUTION = STANDARD

-BROWDY AND NEIMARK -

********** - 2027373528- **********

PART II

RESEARCH AGREEMENT[1]

THIS AGREEMENT effective this ____ day of _____, 198___, by and between _____ (hereinafter referred to as "Sponsor") and the UNIVERSITY OF _____, a non-profit educational institution (or its agent) of the State of _____ (hereinafter referred to as "University").

WITNESSETH:

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to University and to sponsor, will further the instructional and research objectives of University in a manner consistent with its status as a non-profit, tax-exempt, educational institution, and may derive benefits for both Sponsor and University through inventions, improvements, and/or discoveries;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, the parties hereto agree to the following:

Article 1 - Definitions

As used herein, the following terms shall have the following meanings:

1.1 "Project" shall mean the description of the project as described in Appendix A hereof, under the direction of Dr. _____ as principal investigator.

1.2 "Contract Period" is _____, 198___ through _____, 198___.

1.3 "University Intellectual Property" shall mean individually and collectively all inventions, improvements and/or discoveries which are conceived and/or made (i) by one or more employees of University, or (ii) jointly by one or more employees of University and by one or more employees of

---

[1] Brackets ([]) have been placed in the text where appropriate to indicate variable time frames that can be used in an agreement. In some cases, ranges of time have been placed in the brackets to suggest reasonable lengths of time.

employees of University and by one or more employees of

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[1] Brackets ([]) have been placed in the text where appropriate to indicate variable time frames that can be used in an agreement. In some cases, ranges of time have been placed in the brackets to suggest reasonable lengths of time.

Sponsor in performance of Project.

Article 2 - Research Work

2.1 University shall commence the performance of Project promptly after the effective date of this Agreement, and shall use reasonable efforts to perform such Project substantially in accordance with the terms and conditions of this Agreement. Anything in this Agreement to the contrary notwithstanding, Sponsor and University may at any time amend Project by mutual written agreement.

2.2 In the event that the Principal Investigator becomes unable or unwilling to continue Project, and a mutually acceptable substitute is not available, University and/or Sponsor shall have the option to terminate said Project.

Article 3 - Reports and Conferences

3.1 Written program reports shall be provided by University to Sponsor every [_____] months and a final report shall be submitted by University within [forty-five (45) days] of the conclusion of the Contract Period, or early termination of this Agreement.

3.2 During the term of this Agreement, representatives of University will meet with representatives of Sponsor at times and places mutually agreed upon to discuss the progress and results, as well as ongoing plans, or changes therein, of Project to be performed hereunder.

Article 4 - Costs, Billings, and Other Support

4.1 It is agreed to and understood by the parties hereto that, subject to Article 2, total costs to Sponsor hereunder shall not exceed the sum of _____ Dollars ($_____). Payment shall be made by Sponsor according to the following schedule:
[_____].

4.2 Sponsor shall loan/donate the following equipment to University under the following conditions:
[_____
].
University shall retain title to any equipment purchased with funds provided by Sponsor under this Agreement.

4.3 Anything herein to the contrary notwithstanding, in the event of early termination of this Agreement by Sponsor pursuant to Article 9 hereof, Sponsor shall pay all costs accrued by University as of the date of termination, including non-cancellable obligations, which shall include all non-cancellable contracts and fellowships or postdoctoral associate appointments called for in Appendix A, incurred prior to the effective date of termination.

4.3 Anything herein to the contrary notwithstanding, in the event of early termination of this Agreement by Sponsor pursuant to Article 9 hereof, Sponsor shall pay all costs accrued by University as of the date of termination, including non-cancellable obligations, which shall include all non-cancellable contracts and fellowships or postdoctoral associate appointments called for in Appendix A, incurred prior to the effective date of termination.

After termination, any obligation of Sponsor for fellowships or postdoctoral associates shall end no later than the end of University's academic year following termination.

Article 5 - Publicity

5.1 Sponsor will not use the name of University, nor of any member of the University's Project staff, in any publicity, advertising, or news release without the prior written approval of an authorized representative of University. University will not use the name of Sponsor, nor any employee of Sponsor, in any publicity without the prior written approval of Sponsor.

Article 6 - Publications

6.1 Sponsor recognizes that under University policy, the results of University Project must be punishable and agrees that Researchers engaged in Project shall be permitted to present at symposia, national, or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of Project, provided, however, that Sponsor shall have been furnished copies of any proposed publication or presentation at least [_____] months in advance of the submission of such proposed publication or presentation to a journal, editor, or other third party. Sponsor shall have [_____] months, after receipt of said copies, to object to such proposed presentation or proposed publication because there is patentable subject matter which needs protection. In the event that Sponsor makes such objection, said Researcher(s) shall refrain from making such publication or presentation for a maximum of [_____] months from date of receipt of such objection in order for University to file patent application(s) with the United States Patent and Trademark Office and/or foreign patent office(s) directed to the patentable subject matter contained in the proposed publication or presentation.

Article 7 - Intellectual Property

7.1 All rights and title to University Intellectual Property under Project shall belong to University and shall be subject to the terms and conditions of this Agreement.

7.2 Rights to inventions, improvements and/or discoveries, whether patentable or copyrightable or not, relating to Project made solely by employees of Sponsor shall belong to Sponsor. Such inventions, improvements, and/or discoveries shall not be subject to the terms and conditions of this Agreement.

7.3 University will promptly notify Sponsor of any University Intellectual Property conceived and/or made during the

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7.3 University will promptly notify Sponsor of any University Intellectual Property conceived and/or made during the

Contract Period under Project. If Sponsor directs that a patent application or application for other intellectual property protection be filed, University shall promptly prepare, file, and prosecute such U.S. and foreign application in University's name. Sponsor shall bear all costs incurred in connection with such preparation, filing, prosecution, and maintenance of U.S. and foreign application(s) directed to said University Intellectual Property. Sponsor shall cooperate with University to assure that such application(s) will cover, to the best of Sponsor's knowledge, all items of commercial interest and importance. While University shall be responsible for making decisions regarding scope and content of application(s) to be filed and prosecution thereof, Sponsor shall be given an opportunity to review and provide input thereto. University shall keep sponsor advised as to all developments with respect to such application(s) and shall promptly supply to Sponsor copies of all papers received and filed in connection with the prosecution thereof in sufficient time for Sponsor to comment thereon.

7.4 If Sponsor elects not to exercise its option or decides to discontinue the financial support of the prosecution or maintenance of the protection, University shall be free to file or continue prosecution or maintain any such application(s) and to maintain any protection issuing thereon in the U.S. and in any foreign country at the University's sole expense.

Article 8 - Grant of Rights

8.1 Pursuant to Article 7.3, University grants Sponsor the first option, at Sponsor's sole selection, for either a non-exclusive, royalty-free license or, for consideration, an exclusive license with a right to sublicense on terms and conditions to be mutually agreed upon. The option shall extend for a time period of [_____] from the date of termination of the Agreement.

Article 9 - Term and Termination

9.1 This Agreement shall become effective upon the date first hereinabove written and shall continue in effect for the full duration of the Contract Period unless sooner terminated in accordance with the provisions of this Article. The parties hereto may, however, extend the term of this Agreement for additional periods as desired under mutually agreeable terms and conditions which the parties reduce to writing and sign. Either party may terminate this agreement upon ninety (90) days prior written notice to the other.

9.2 In the event that either party hereto shall commit any breach of or default in any of the terms or conditions of

Article. The parties hereto may, however, extend the term of this Agreement for additional periods as desired under mutually agreeable terms and conditions which the parties reduce to writing and sign. Either party may terminate this agreement upon ninety (90) days prior written notice to the other.

9.2 In the event that either party hereto shall commit any breach of or default in any of the terms or conditions of

this Agreement, and also shall fail to remedy such default or breach within ninety (90) days after receipt of written notice thereof from the other party hereto, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect, and such termination shall be effective as of the date of the receipt of such notice.

9.3 Subject to Article 8, termination of this Agreement by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. No termination of this Agreement, however effectuated, shall affect the Sponsor's rights and duties under Article 7 hereof, or release the parties hereto from their rights and obligations under Articles 4, 5, 6, 7, 8, and 10.

Article 10 - Independent Contractor

10.1 In the performance of all services hereunder:

10.1.1 University shall be deemed to be and shall be an independent contractor and, as such, University shall not be entitled to any benefits applicable to employees of Sponsor;

10.1.3 Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither shall be bound by the acts or conduct of the other.

Article 11 - Insurance

11.1 University warrants and represents that University has adequate liability insurance, such protection being applicable to officers, employees, and agents while acting within the scope of their employment by University, and University has no liability insurance policy as such that can extend protection to any other person.

11.2 Each party hereby assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees, and agents thereof.

Article 12 - Governing Law

12.1 This Agreement shall be governed and construed in accordance with the laws of the State of _____.

injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees, and agents thereof.

Article 12 - Governing Law

12.1 This Agreement shall be governed and construed in accordance with the laws of the State of _____.

Article 13 - Assignment

13.1 This Agreement shall not be assigned by either party without the prior written consent of the parties hereto.

13.2 This Agreement is assignable to any division of Sponsor, any majority stockholder of Sponsor, and/or any subsidiary of Sponsor in which [_____] percent of the outstanding stock is owned by Sponsor.

Article 14 - Agreement Modification

14.1 Any agreement to change in terms of this Agreement in any way shall be valid only if the change is made in writing and approved by mutual agreement of authorized representatives of the parties hereto.

Article 15 - Notices

15.1 Notices, invoices, communications, and payments hereunder shall be deemed made if given by registered or certified envelope, postage prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below, or such other address as may hereafter be designated by notice in writing:

If to Sponsor:
SPONSOR
ADDRESS
CITY, STATE, ZIP CODE

If to University:
UNIVERSITY
ADDRESS
CITY, STATE, ZIP CODE

If Technical Matter:
PRINCIPAL INVESTIGATOR
TITLE
UNIVERSITY ADDRESS
CITY, STATE, ZIP CODE

IN WITNESS WHEREOF, the parties have caused these presents to be executed in duplicate as of the day and year first above written.

(SPONSOR)	(UNIVERSITY)
_____	_____
By:	By:
Title:	Title:
_____	_____
Witness	Witness
_____	_____
By:	By:
Title:	Title:
_____	_____
Witness	Witness

PART II

RESEARCH AGREEMENT*

THIS AGREEMENT effective this __ day of _____, 198_, by and between _____ (hereinafter referred to as "Sponsor") and the UNIVERSITY OF _____, a non-profit educational institution (or its agent) of the State of_____ (hereinafter referred to as "University").

WITNESSETH:

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to University and to Sponsor, will further the instructional and research objectives of University in a manner consistent with its status as a non-profit, tax-exempt, educational institution, and may derive benefits for both Sponsor and University through inventions, improvements, and/or discoveries;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, the parties hereto agree to the following:

Article 1 - Definitions

As used herein, the following terms shall have the following meanings:

1.1 "Project" shall mean the description of the project as described in Appendix A hereof, under the direction of Dr._____ as principal investigator.

1.2 "Contract Period" is_____, 198_ through _____, 198_.

1.3 "University Intellectual Property" shall mean individually and collectively all inventions, improvements and/or discoveries which are conceived and/or made (i) by one or more employees of University, or (ii) jointly by one or more employees of Sponsor in performance of Project.

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- 2 -

Article 3 - Reports and Conferences

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9.2 In the event that either party hereto shall commit any breach of or default in any of the terms or conditions of this Agreement, and also shall fail to remedy such default or breach within ninety (90) days after receipt of written notice thereof from the other party hereto, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect, and such termination shall be effective as of the date of the receipt of such notice.

9.3 Subject to Article 8, termination of this Agreement by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. No termination of this Agreement, however effectuated, shall affect the Sponsor's rights and duties under Article 7 hereof, or release the parties hereto from their rights and obligations under Articles 4, 5, 6, 7, 8, and 10.

Article 10 - Independent Contractor

10.1 In the performance of all services hereunder:

10.1.1 University shall be deemed to be and shall be an independent contractor and, as such, University shall not be entitled to any benefits applicable to employees of Sponsor;

10.1.3 Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither shall be bound by the acts or conduct of the other.

Article 11 - Insurance

11.1 University warrants and represents that University has adequate liability insurance, such protection being applicable to officers, employees, and agents while acting within the scope of their employment by University, and University has no liability insurance policy as such that can extend protection to any other person.

11.2 Each party hereby assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees, and agents thereof.

Article 12 - Governing Law

12.1 This Agreement shall be governed and construed in accordance with the laws of the State of _____.

Article 13 - Assignment

13.1 This Agreement shall not be assigned by either party without the prior written consent of the parties hereto.

Article 12 - Governing Law

12.1 This Agreement shall be governed and construed in accordance with the laws of the State of _____.

Article 13 - Assignment

13.1 This Agreement shall not be assigned by either party without the prior written consent of the parties hereto.

- 5 -

13.2 This Agreement is assignable to any division of Sponsor, any majority stockholder of Sponsor, and/or any subsidiary of Sponsor in which [____] percent of the outstanding stock is owned by Sponsor.

Article 14 - Agreement Modification

14.1 Any agreement to change the terms of this Agreement in any way shall be valid only if the change is made in writing and approved by mutual agreement of authorized representatives of the parties hereto.

Article 15 - Notices

15.1 Notices, invoices, communications, and payments hereunder shall be deemed made if given by registered or certified envelope, postage prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below, or such other address as may hereafter be designated by notice in writing:

If to Sponsor:

SPONSOR
ADDRESS
CITY, STATE, ZIP CODE

If to University:

UNIVERSITY
ADDRESS
CITY, STATE, ZIP CODE

If Technical Matter:

PRINCIPAL INVESTIGATOR
TITLE
UNIVERSITY ADDRESS
CITY, STATE, ZIP CODE

IN WITNESS WHEREOF, the parties have caused these presents to be executed in duplicate as of the day and year first above written.

(SPONSOR)

By:
Title:

Witness

(UNIVERSITY)

By:
Title:

Witness

Witness

Witness

- 6 -

LAW OFFICES

LUCAS & JUST

205 EAST 42ND STREET

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January 31, 1989

sent by telecopier

COPY

Mr. Dana D. Downing
General Manager of Cyclodextrins
Corn Processing Division
American Maize-Products Company
1100 Indianapolis Boulevard
Hammond, Indiana 46320-1094

Dear Dana:

Attached is Dr. Merrifield's decision affirming NTIS' denial of Maize's application for non-exclusive license under U.S. Patent No. 4,727,064.

Sincerely yours,
LUCAS & JUST

By Donald C. Lucas

DCL:pd

Att. - Decision of NTIS

cc: Mr. Norman Latker w/att.

UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity, Technology and Innovation
Washington, D.C. 20230
(202) 377-1984

JAN 27 1989

RECEIVED
JAN 30 1989
LUCAS & JUST

Donald C. Lucas, Esq.
Lucas & Just
205 East 42d Street
New York, NY 10017

Re: Appeal - Pharmaceutical Preparations Containing Cyclodextrin Derivatives

Dear Mr. Lucas:

This letter is in response to your December 1, 1988 appeal of the National Technical Information Service (NTIS) determination denying your application for a license under the pharmaceutical preparation containing cyclodextrim derivatives invention disclosed and claimed in U.S. Patent 4,727,064.

I have examined the record in this case, and based thereon it is my opinion that NTIS in forming the denial in its October 31, 1988 letter to American Maize Products Company (AMAIZO) did so in a manner fully in compliance with 37 CFR Part 404. The September 10, 1987, notice of intent to grant a co-exclusive license to CYCLEX and PHARMATEC published in the Federal Register provided an opportunity for filing written objections within a 60-day period thereafter. No objections or competing applications were received by NTIS during this 60-day period which expired on November 9, 1987. AMAIZO's application for a nonexclusive license under U.S. Patent 4,727,064 was not received until September 16, 1988 over ten months from the November 9, 1987 expiration date for the submission of objections to the proposed license. The failure of AMAIZO or any other entity to submit objections of any type during this period permits NTIS to proceed with the grant of a co-exclusive license to CYCLEX and PHARMATEC. It is my considered opinion that NTIS, in reaching its decision to do so did not exceed the amount of discretion entrusted to it by the regulations.

Further review of the record of this case indicates there was ample opportunity for AMAIZO to file a timely objection to the grant of the co-exclusive license in order to be in compliance with 37 CFR 404.7. The filing of an application for a non-exclusive license, such as AMAIZO did on September 16, 1988, was properly considered by NTIS as being equivalent to an objection to the proposed grant of the co-exclusive license. I must therefore advise you that your September 16, 1988 application

ample opportunity for AMAIZO to file a timely objection to the grant of the co-exclusive license in order to be in compliance with 37 CFR 404.7. The filing of an application for a non-exclusive license, such as AMAIZO did on September 16, 1988, was properly considered by NTIS as being equivalent to an objection to the proposed grant of the co-exclusive license. I must therefore advise you that your September 16, 1988 application

constituted an untimely objection and that to allow such a nonexclusive license to issue would in effect negate the proposed co-exclusive license to be granted. To decide otherwise would establish a harmful precedent and exceed the authority and amount of discretion entrusted to the Department by statute and regulation.

I sincerely hope that AMAIZO will continue its interest in licensing other forms of technology as they become available through NTIS. I have been informed that NTIS will entertain an application for a license on the invention disclosed and claimed in U.S. Patent No. 4,727,064 after the period for co-exclusivity to CYCLEX and PHARMATEC expires.

The appeal is denied. This is a final decision of the Department of Commerce. Judicial review is available as the law permits.

Sincerely,

D. Bruce Merrifield
Assistant Secretary for
Productivity, Technology
and Innovation

401CHANG 6/20/86

Billing Code 3510-18

Department of Commerce

Office of the Assistant Secretary for Productivity, Technology and Innovation

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

ACTION: Interim Final Rule

SUMMARY: Public Law 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.

EFFECTIVE DATE: (Date of publication of this notice)

COMMENTS BY: (60 days from date of publication)

FOR FURTHER INFORMATION CONTACT: Mr. Norman Latker, Director, Federal Technology Management Policy Division, Office of Productivity, Technology and Innovation, U. S. Department of

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, D. C. 20230.

Phone: 202-377-0659.

SUPPLEMENTARY INFORMATION:

Background

Public Law 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 206 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 (60 days from date of publication) 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

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.

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.

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 agency-initiated deviations without approval by the Secretary of

relationship of this regulation, agency regulations, and the FAR system. One agency suggested the regulation should permit agency-initiated 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, section 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 section 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 section 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

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

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will work with those responsible for Part 27 of the FAR system to ensure that it is consistent with this regulation.

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 section 401.1(a) and section 401.3(a) which exclude 35 U.S.C. 212 awards.

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.

401.3(a)(ii) -- One agency comment raised the question of whether 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 inventions which pose security risks. These procedures allow the contractor to elect to retain title to such inventions. Thus, if

Executive Order to protect from public disclosure those inventions which pose security risks. These procedures allow the contractor to elect to retain title to such inventions. Thus, if

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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, section 401.3(b) provides that should an agency exercise an exceptional circumstance exception under 401.3(a)(ii) 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 time period the Department of Energy does not, as authorized by regulation, law, Executive Order or implementing regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempt from this paragraph.

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

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 elect title and those in which this right has been curtailed through one of the exceptions. A standard clause will promote maximum uniformity and assurance that small business and nonprofit contractors understand their obligations.

401.3(e) -- Comments were requested on whether determinations of class exceptions should be allowed. One comment stated that the law contemplates case-by-case exceptions and felt that only rarely could a class exception be justified. On the other hand, one agency comment stated that class determinations are needed to reduce paperwork. That agency suggested the use of a single determination be authorized for multiple contracts involving identical circumstances to facilitate contracting so 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.

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.

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

401.4(b)(6) -- In response to one comment, language has been

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

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.

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 section 401.5(a) to authorize such modification of the subcontract provisions of the standard clause at section 401.14.

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.

401.5(e)(ii) -- One comment suggested adding "or other form of protection of intellectual property" to this requirement. This

not just those involving a series of task orders.

401.5(e)(ii) -- 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 Act.

401.5(e)(iii) -- In response to several agency comments, the option of the agencies to obtain annual listings of reported subject inventions has been retained.

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 section 401.5(f). The situation described meets the standard.

One agency comment suggested that language be added at the end of section 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 section 401.5(f) it may prescribe such language in its supplementary regulations or instructions.

to the extent it finds that the proposed language is consistent with 35 U.S.C. 204(c)(7)(E) and section 401.5(f) it may prescribe such language in its supplementary regulations or instructions.

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Several comments suggested the deletion of the words "at the facility" from the clause language prescribed by section 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.

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.

401.6(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.

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

401.6(g) -- To conform with section 401.4(b)(6), language has been added requiring the agency head to detail the reasons for rejecting facts found during the fact-finding process.

401.6(k) -- For clarity, a paragraph has been added providing that exclusive licensees include "partially exclusive licensees" for purposes of march-in proceedings.

401.7 -- Several comments expressed concern that it should be made clear that the small business preference not be construed to prevent a university from providing a right of first refusal

401.7 -- Several comments expressed concern that it should be made clear that the small business preference not be construed to prevent a university from providing a right of first refusal

or other type of option to a larger business that is providing support under a long-term agreement for research related to the invention. This change has been made because small business preference is not intended to inhibit industrial support of university research.

One agency comment suggested that the Secretary's role may conflict with that of the agency in matters pertaining to the "domestic preference" in licensing agreements. Therefore, it was suggested that "matters in regard to the contractor's licensing practices would be better handled by the contractor agency." This comment was rejected because the role of the Secretary will not include involvement in an individual licensing decision.

One comment suggested that the regulations "need to reflect that no individual small business will have standing to attack any particular license agreement." This suggestion was not accepted because it is already reflected in the subsection and the clause.

401.8(a) -- One agency comment suggested relaxing the requirement that agencies receive periodic information on the utilization of inventions pending instructions by this Department. In response, a change has been made that agencies refrain, to the extent feasible, from specifying specific formats for the information and instead rely on information in the form in which it is customarily prepared by the contractor for its own internal reporting purposes. The Paperwork Reduction Act will apply to any information gathering efforts. If further

in which it is customarily prepared by the contractor for its own internal reporting purposes. The Paperwork Reduction Act will apply to any information gathering efforts. If further

11

experience under the regulations indicates that agencies' requests to contractors are developed on an uncoordinated basis or create undue burden, a uniform reporting system may be instituted.

401.8(b) -- In response to one agency comment, a provision has been added requiring contractor marking of utilization data which they wish to have protected.

401.10 -- Several agencies suggested revising this subsection so that agencies may apply additional conditions. This has been permitted, providing the additional conditions are consistent with sections 201-206 of the statute. In addition, the royalty-sharing requirement with Government employee/ inventors under paragraph (k)(2) of the clause at section 401.14(a) has been eliminated. Agencies may still require royalty-sharing with their employee/inventors on a case-by-case or other broader basis.

One university comment suggests that the coverage of this subsection be expanded so that disparate regulations do not develop among the various agencies. Agency activities will be monitored in order to attain consistency.

401.12 -- One university comment suggests adding language to section 401.12 requiring the payment of reasonable royalties when licensing of background inventions is required. This change was not accepted because such payments can be negotiated in connection with the use of such provisions.

401.13 -- One comment suggested that we add language

not accepted because such payments can be negotiated in connection with the use of such provisions.

401.13 -- One comment suggested that we add language

to section 401.13 to state that the duration of an exclusive license granted by a university can extend for the life of the patent plus an extension of the patent term granted under the Drug Price Competition and Patent Term Restoration Act of 1984. As the Act now contains no restrictions on licensing, no such language is required.

One comment also requested the inclusion of language in section 401.13 making clear that a long-term license granted by a university to a small business firm prior to the enactment of Pub. L. 98-620 can be transferred to a large business firm without agency approval as part of the acquisition of the smaller firm. This suggestion was not accepted because under the current law, such a transfer does not require agency approval. The approvals required under OMB Circular A-124 for long-term licenses to other than small business firms are not applicable when a small business firm assigns this as part of a transfer of the firm to a larger firm.

401.13(b) -- In response to suggestions, advice in subsection 401.13(b) has been expanded to cover contract clauses predating P. L. 96-517.

Two university comments suggested waiving any requirement for agency approvals under funding agreements predating Pub. L. 98-620. This comment was not accepted as there is no authority to apply the law retroactively.

401.13(c) One agency suggested that the requirement that agencies not disclose information, which is part of a patent

authority to apply the law retroactively.

401.13(c) One agency suggested that the requirement that agencies not disclose information, which is part of a patent

application, be limited to a period of no more than 18 months. This suggestion was accepted.

401.14(a) (Standard Clause) --

Paragraph (c)(1) -- One comment suggested that this subparagraph should specifically state that a proposed patent application would meet the disclosure requirements. This suggestion was not accepted as a proposed patent application, by definition, would meet the disclosure requirement.

Paragraph (c)(3) -- In response to one suggestion, language has been added to make clear that filing in supranational patent offices will satisfy the foreign filing requirements.

Several comments suggested:

a) The requirement to make foreign filings within ten months of the corresponding initial patent application forces a university to make a commitment to file foreign much earlier than such a decision would normally be made.

b) Amending the subsection to either "authorize the filing" or "make a commitment to file."

c) Adding "will file or authorize the preparation and filing."

One agency comment opposed the above changes noting that a contractor may withdraw its authorization to file at a time too late to permit the agency to protect its reversionary interests.

The issue raised by the above comments has been deferred pending a more comprehensive cost-benefit analysis. Contractors are reminded that paragraph (c)(4) of the standard clause (Sec.

The issue raised by the above comments has been deferred pending a more comprehensive cost-benefit analysis. Contractors are reminded that paragraph (c)(4) of the standard clause (Sec.

14

401.14(a)) allows contractors to request extensions of time to file patent applications.

Paragraph (d)(ii) -- One comment suggested that it is unreasonable to expect a contractor to file in every patent office in the world in order to protect its foreign rights. No change has been made because the statute clearly specifies the steps a contractor must take to secure title against reversion to the agency.

Paragraph (e)(4)-(6) -- One agency comment recommended that the content of these clauses be moved into the preamble to the standard clause in the same manner as OMB Circular A-124. This has been done.

Paragraph (f) -- One agency comment suggested adding language to paragraph (f) requiring contractors to submit, without agency request, a confirmatory license and a copy of any U. S. patent. This suggestion was not accepted as paragraph (f)(1) already requires a confirmatory license and the optional language at section 401.5(e) allows agencies to add language so they can obtain patent numbers.

Paragraph (h) -- One agency comment suggested altering the last sentence of this paragraph to follow the statutory language more 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 statutory intent and language.

sentence. The alternative suggestion has been adopted as disclosure with the permission of the contractor would appear consistent with the statutory intent and language.

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 royalties 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."

401.14(b) -- For clarification, several changes have been

considered as "expenses incidental to the administration of subject inventions."

401.14(b) -- For clarification, several changes have been

made to the alternative language prescribed for use by DOE when the exception at section 401.3(a)(iv) 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 is 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.

401.15(a) -- This section has been revised to allow the Department of Energy to use their existing waiver procedures in

the Paperwork Reduction Act.

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

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 Ch. IV

Inventions, Patents, Nonprofit Organizations, Small Business Firms.

Date:

D. Bruce Merrifield
Assistant Secretary for Prouctivity, 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:

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

Section

401.1 Scope.

401.2 Definitions.

401.3 Use of the Standard Clauses at section 401.14.

401.4 Contractor appeals of exceptions.

401.5 Modification and tailoring of clauses.

401.6 Exercise of march-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.

401.13 Administration of patent rights clauses.

401.14 Standard clauses.

401.15 Deferred determinations.

401.16 Submissions and Inquiries.

Authority - 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary for Productivity, Technology and Innovation at section 3(g) of DOO 10-1.

Section 401.1 Scope.

35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary for Productivity, Technology and Innovation at section 3(g) of DOO 10-1.

Section 401.1 Scope.

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(a) This part implements 35 U.S.C. 202-204 and is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations executed after the effective date of this part, except for a funding agreement made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(b) The "march-in" and appeals procedures in sections 401.6 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part 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 Government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by section 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i)-(iv) (section 401.3(a)(i)-(iv) of this part) is applicable and will be applied. If the exception at section 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by section 401.3(b).

is applicable and will be applied. If the exception at section 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by section 401.3(b).

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(d) This regulation supersedes OMB Circular A-124 and shall take precedence 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.~~ P.L. 98-620 Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. ~~Modifications or tailoring of clauses as authorized by section 401.5 or section 401.3, when alternative provisions are used under section 401.3(a)(i)-(iv), are not considered deviations requiring the Secretary's approval.~~ Three copies of proposed and final agency regulations supplementing ~~this part shall~~ the req. one requirement to be submitted to the Secretary at ~~the office~~ Department of Commerce set out in ~~section 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. (Read) (Typo) means of maintaining uniformity

(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 subcontracts after July 1, 1981, receive rights in their subject inventions that are

appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontracts 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 Government-owned 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 section 401.2(a) of this part.

Section 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

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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.

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 (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.

(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.

Section 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 section 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions--

(i) 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

(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 Chapter 18 of Title 35 of the United States Code; or

(iii) when it is determined by a Government authority

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

(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; or

(iv) 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 section 401.3(a)(ii) or (iii), it shall use the standard clause at section 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 section 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 section 401.3(a)(ii)~~ the exceptional circumstances exception 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

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 section 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 section 401.3(a)(iv), it shall use the clause prescribed at section 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 section 401.3(a)(ii) or (iii) 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 section 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

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 such an exception is applicable. In cases when section 401.3(a)(ii) 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 section 401.4 of this part.

(f) Except for determinations under section 401.3(a)(iii), 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

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.

Section 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 section 401.3(a)(i)-(iv) if the contractor believes that a determination is either (i) contrary to the policies and objectives of this chapter or (ii) 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

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 the agency's determination, or within such longer time as an agency may specify in its regulations. The contractor's notice should specifically identify the basis for the appeal.

(2) The appeal shall be decided by the head of the agency or by his/her designee who is at a level above the person who made the determination. If the notice raises a genuine dispute over the material facts, the head of the agency or the designee shall undertake, or refer the matter for, fact-finding.

(3) Fact-finding shall be conducted in accordance with 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 rely upon. A transcribed record shall be made and shall be available at cost to the contractor upon request.

contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may rely upon. A transcribed record shall be made and shall be available at cost to the contractor upon request.

The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency.

(4) The official conducting the fact-finding shall prepare or adopt written findings 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 decision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or certified mail.

(5) Fact-finding should be completed within 45 working days from the date the agency receives the contractor's written notice.

(6) When fact-finding has been conducted, the head of the agency or designee shall base his or her decision on the facts found, together with any argument submitted by the contractor, agency officials or any other information in the administrative record. In cases referred for fact-finding, the agency head or the 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. The agency head or the designee may hear oral arguments after fact-finding provided that the contractor or contractor's attorney or representative is present and given an opportunity to make arguments and rebuttal. The decision of the agency head or the designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made within 30 working days after fact-finding or, if there was no

designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made within 30 working days after fact-finding or, if 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 Claims 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.

Section 401.5 Modification and Tailoring of Clauses.

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at section 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 (1), "Communications", at the end of the clauses at section 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on

should be renumbered appropriately.

(b) Agencies should complete paragraph (1), "Communications", at the end of the clauses at section 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 (1).

(c) Agencies may replace the underlined words and phrases in the clauses at section 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) 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 section 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

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.

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 additional subparagraphs to paragraph

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 additional subparagraphs to paragraph

(f) of the clauses at section 401.14 to require the contractor to do one or more of the following:

(i) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(ii) 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.

(iii) 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 section 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 <u>contractor</u> during any fiscal year on subject inventions under this or any successor <u>contract</u> 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

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 section 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.

Section 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 section 401.14.

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as

believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, 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

(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 fact-finding shall prepare or adopt written findings 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.

(f) The official conducting the fact-finding shall prepare or adopt written findings 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.

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.

(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 section shall be deemed to include the inventor.

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

(k) For purposes of this section the term "exclusive licensee" includes a partially exclusive licensee.

(l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

Section 401.7 Small Business Preference.

(a) Paragraph (k)(4) of the clauses at section 401.14 implements the small business preference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the circumstances to attract small business licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts to attract small business licensees will vary with the circumstances and the nature, duration, and expense of efforts

licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts 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 investigations, discussions, and negotiations 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.

Section 401.8 Reporting on Utilization of Subject Inventions.

(a) ~~Paragraph (h) of the clauses~~ There reps. at section 401.14 and its counterpart in the clause at Attachment A to OMB Circular A-124 Read.

discussions or negotiations with the contractor.

Section 401.8 Reporting on Utilization of Subject Inventions.

(a) ~~Paragraph (h) of the clauses~~ There reps. at section 401.14 and its counterpart in the clause at Attachment A to OMB Circular A-124 Read.

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.

(b) In accordance with 35 U.S.C. 202(c)(5) and the terms of the clauses at section 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 agency.

Section 401.9 Retention of Rights by Contractor Employee Inventor.

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).

Section 401.10 Government Assignment to Contractor of Rights in Invention of Government Employee.

In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a small business

(f)(4); (h); (i); and (j) of the clause at section 401.14(a).

Section 401.10 Government Assignment to Contractor of Rights in Invention of Government Employee.

In any case when a Federal employee is 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.

Section 401.11 Appeals.

(a) As used in this section, the term "standard clause" means the clause at section 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

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 under paragraph 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. 200-206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in section 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.

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

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.

Section 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~~ to extend the period of exclusivity previously capped under P.L. 96-517.

Redd

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~~ to extend the period of exclusivity previously capped under P.L. 96-517.

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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

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 (or its assignees, licensees, or employees) on a

part of an application for patent with the U. S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a

subject invention to which the contractor has elected to retain title.

(3) 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 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 subparagraph (1) above, 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 subparagraph (3), 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

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 publicaton 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.

Section 401.14 Standard Patent Rights Clauses.

(a) The following is the standard patent rights clause to be used as specified in section 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 novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et. seg.).

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

(3) "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of

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.

(3) "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of

a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

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

(5) "Small Business Firm" means a small business concern as defined at Section 2 of Public Law 85-536 (15 U.S.C. 632) 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 (26 U.S.C. 501(c) and exempt 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 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 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 nonexclusive, nontransferable, irrevocable, paid-up license to 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 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 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

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 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 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

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 or opposition 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 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 Federal agency except when transferred to the successor of

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 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 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.

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.

(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 filing 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

the filing 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."

(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

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

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.

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

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

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

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

(k) Special Provisions for Contracts with 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 co-inventors (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;

subject invention with the inventor, including Federal employee co-inventors (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 contactor 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).

(l) Communications.

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

to implement more effectively the requirements of this paragraph (k)(4).

(l) Communications.

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

(b) When the Department of Energy (DOE) determines to use alternative provisions under section 401.3(a)(iv), the standard clause at section 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), below. 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

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

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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 section 401.5(f).

Section 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 section 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should

one of the exceptions at section 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or 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 or concerns which originally led the agency to invoke an exception under section 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 section 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

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 section 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 section 401.11 of this part.

Section 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, D. C. 20230.

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Attendance List for Federal Coordinating Council for Science, Engineering and Technology Committee on Intellectual Property for Innovation and Technology Transfer.

Name	Organization	Phone
Bruce Merrifield	Assistant Secretary, Productivity, Technology and Innovation Department of Commerce	377-1984
Egils Milbergs	Department of Commerce	377-1581
J. Lisle Reed	U. S. Department of Interior Room 6117 18th and C Street, N.W. Washington, DC 20240	343-5183
Ruth Greenstein	General Counsel National Science Foundation Room 501 Washington, DC 20550	357-9438
William A. Rosenkranz	U. S. Environmental Protection Agency Room 631 West Towers Mail Code RD 681 401 M. Street, S.W. Washington, DC 20460	382-2583
Richard J. Shane	Director, Small Business Research and Acquisition Policy Office of Innovation, Research and Technology Small Business Administration 1441 L. Street, N.W. Washington, DC 20416	653-7875
Robert D. Nutter	Research Analyst Office of Industry Policy (P-13) U. S. Department of Transportation Room 9222 400 7th Street, S.W. Washington, DC 20570	426-2916
Howard Deeley	Patent Counsel C-15 Department of Transportation 400 7th Street, S.W. Washington, DC 20570	426-2916
~~Charles F. (Rick) Rule~~	~~Department of Justice/Antitrust~~ ~~Room 3112~~ ~~Antitrust Division~~ Washington, DC 20530	633-1157

400 7th Street, S.W.
Washington, DC 20570

~~Charles F. (Rick) Rule~~	~~Department of Justice/Antitrust~~ ~~Room 3112~~ ~~Antitrust Division~~ Washington, DC 20530	633-1157

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Doug Pewitt	Office of Science and Technology Policy Room 5005 New Executive Office Building 1700 PA Avenue, N.W. Washington, DC 20506	395-3817
Tip Parker	Department of Commerce	377-8100
William B. Ferguson	General Services Administration Room 4018 18th and F Street, N.W. Washington, DC 20405	566-1043
W. J. Maraist	Office of Management and Budget/OFPP Room 9026 New Executive Office Building 1726 Jackson Place, N.W. Washington, DC 20503	395-3300
M. Howard Silverstein	U. S. Department of Agriculture Office of General Counsel Room 2328 South Building Washington, DC 20250	447-5474
John Chester	General Counsel National Science Foundation Room 501 Washington, DC 20550	357-9447
B. H. Bochenek	U. S. Environmental Protection Agency Room 513 East Towers 401 M. Street, S.W. Washington, DC 20460	382-5460
Donald A. Gardiner	Senior Attorney Branch of Procurement and Patents U. S. Department of Interior Room 6517 18th and C Street, N.W. Washington, DC 20240	343-4472
A. Pettifor	Office of Science and Technology Policy Room 5005 New Executive Office Building 1700 PA Avenue, N.W. Washington, DC 20506	557-3065

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AGENCY REPRESENTATIVES FOR THE FCCSET COMMITTEE ON INTELLECTUAL PROPERTY

AGENCY	NAME & ADDRESS	PHONE	COMMENTS
OMB	Mr. Hugh F. Loweth Deputy Associate Director for Energy and Science Office of Management & Budget Room 8001 NEOB Washington, D. C. 20503	395-3404	NSF Senior Staff notes that Mr. Loweth disagrees with DOE's position that government keep title to inventions resulting from Federal R&D.
DOD	Ms. Mary Ann Gilleece Deputy Under Secretary of Defense (Acquisition Management Room 3E144 Pentagon Washington, D. C. 20301	695-7145	Staff with House Committee on Armed Services, Ms. Gilleece only recently moved to DOD.
DOE	Mr. Theodore J. Garrish General Counsel Department of Energy 1000 Independence Ave., S.W. Room 6A245 Washington, D. C. 20585	252-5281	Unknown, but we are talking to new staff.
NASA	Mr. Robert F. Kempf Assistant General Counsel for Patent Matters NASA Mail Code GP-4 Room 7035 Washington, D. C. 20546	755-3932	Kempf, one of the FAR drafters is on vacation. He may be represented by his deputy, Garland McCoy. Kempf's staff tells us that he believes that the small business/nonprofit position of FAR must be changed to conform with the law. However, he has not agreed to extend small business treatment to other performers.
VA	Dr. Earl X. Freed Deputy Assistant Chief Medical Director for Research and Development VA Central Office Room 644 810 Vermont Avenue, S.W. Washington, D. C. 20420	389-2616	V. A. staff is supporting Commerce position on single clause.

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Education	Dr. Donald J. Senese Assistant Secretary Office of Educational Research and Improvement 400 Maryland Avenue, S.W. Brown Building Room 722 Washington, D. C. 20202	254-8224	No information.
SBA	Mr. Donald E. Templeman Assistant Administrator Office of Innovation, Research and Technology, SBA 1441 L. Street, N.W. Room 500 Washington, D. C. 20416	653-7875	Runs Small Business Innovation Research Program. Strong ally and supports Commerce single clause position.
NSF	Mr. Chuck H. Herz General Counsel National Science Foundation Room 501 Washington, D. C. 20550	357-9435	NSF staff is supporting Commerce position on a single clause. However, Mr. Herz is sometimes unpredictable.
USDA	Dr. Terry B. Kinney, Jr. Administrator Agricultural Research Service Room 302A U. S. Department of Agriculture Washington, D. C. 20250	447-3656	Agriculture staff is supporting Commerce position on single
HHS	Dr. Lowell T. Harmison Science Advisor Office of the Assistant Secretary for Health Parklawn Building Room 1395 5600 Fishers Lane Rockville, Md. 20857	443-2650	Strong ally. Supports single clause.
GSA	It is not clear who will represent GSA.		
DOT	Mr. Martin Convisser Director, Office of Industry Policy U. S. Department of Transportation Room 9222 Washington, D. C. 20590	426-4220	DOT staff supports Commerce position on single clause.
NRS	Mr. Gerald K. Tomlin Senior Research Program Coordinator Willste Building 7915 Eastern Avenue Silver Spring, Md. 20555	427-4159	Unknown.

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State	Mr. William Schneider, Jr. Under Secretary for Security Assistance, Science and Technology Department of State Room 7208 Washington, D. C. 20520	532-1410	A. I. D. staff is strong supporter of single clause.
EPA	Dr. Courtney Riordan Acting, Assistant Administrator for R&D U. S. Environmental Protection Agency 401 M. Street, S. W. Room 913 West Towers Washington, D. C. 20460	382-7676	EPA staff is strong supporter of single clause.
Interior	Mr. Donald A. Gardiner Senior Attorney Branch of Procurement and Patents U. S. Department of Interior Room 6517 18th and C Street, N. W. Washington, D. C. 20240	343-4471	Interior staff is strong supporter of single clause.

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