Dear Marvin

Thank you so much for the invitation to speak before the ___.

~~I thought the~~

~~In my view most of the speakers demonstrated~~

It seemed to me that the speakers in most part had no problem reaching the various goals they wanted within the bounds of Bayh-Dole.

~~without~~

~~I frankly do not believe~~

In light of this I don't believe there is any real necessity to ignore the law.

Re: FOI Case
No. 25880

Dear Ms. Williams,

At this time, my interest in grant U54 GM62114-01 is limited to the grant page wherein the grantee accepts as a condition of the grant to abide by the DHHS policies in effect on the ~~time~~ date of the grantee's executed ~~work~~ acceptance of the grant.

This should be the last page of the grant documents. If you are able to identify this page I would appreciate a fax copy at 202-737-3528.

(Not the grant application)

Further
My initial request was limited to the grant document which ~~has not been released~~ does not include any materials provided by the grantee in the grant application.

From: Norman Latker
To: williamy@nigms.nih.gov
Date: Thu, Oct 26, 2000 2:44 PM
Subject: FOI Case No. 25880

Dear. Ms. Williams,

At this time, my interest in grant U54 GM62114-01 is limited to the grant page where the grantee accepts as a condition of the grant to abide by the DHHS policies in effect on the date of the grantee's executed acceptance of the grant.

This should be the last page of the grant documents (not the grant application). If you are able to identify this page I would appreciate a fax copy at (202) 737-3528.

Further, my initial request was limited to the grant documents which does not include any materials provided by the grantee in the grant application.

Sincerely,

Norman J. Latker

NJL:dr

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200

http://www.nigms.nih.gov

RECEIVED
OCT 25 2000
BROWDY & NEIMARK

October 23, 2000

Norman Latker
Browdy and Neimark, P.L.L.C.
Attorneys at Law
Patent and Trademark Causes
624 Ninth Street, N.W.
Washington, D. C. 20001-5303

RE: FOI Case No. 25880

Dear Mr. Latker:

This acknowledges your September 15, 2000 Freedom of Information Act request. You requested a copy of grant, U54 GM62114-01, "Alliance for Cellular Signaling-Phase 11," awarded to Alfred G. Gilman, M.D. by the National Institute of General Medical Sciences of the National Institutes of Health.

We will send you all material consistent with the exemptions recognized by the Freedom of Information Act. It is Department of Health and Human Services policy to expunge social security numbers, EIN numbers, birth dates, percentage of effort, institutional base salary, source of private support, pending support, and any patenatable material wherever they appear throughout the grant material. The priority score, direct costs recommended, evaluation, opinion, and information pertaining to the budget recommendation are also expunged from the summary statements. If you feel that this information should not be excluded from the material, please advise me and I will consult with the NIH Freedom of Information Officer.

We are asking the grantee to advise this office if release of the material you requested will adversely affect any patent rights or reveal other confidential commercial or financial information. Subsequent to receipt of such advice this office will make a decision regarding releasability. We will do everything possible to comply with your request in a timely manner. Please feel free to call me on (301) 594-5135 for additional information or to inquire about the status of your request.

In accordance with the Freedom of Information Act and Department of Health and Human Services Regulations charges for duplication, search time, review time and edit will be made if applicable.

Williamy@nigms.nih.gov

Sincerely,

Yvonne Williams

Yvonne G. Williams
Freedom of Information Coordinator
The National Institute of General Medical Sciences

To: Joe Allen
From: Norm L.

WISCONSIN ALUMNI RESEARCH FOUNDATION

TELECOPY (FAX) TRANSMITTAL FORM

FACSIMILE (FAX) NUMBER (608)263-1064

DATE: 08 May 1998 TIME: _____

TO: Norm Hotken FROM: Howard Bremer

WISCONSIN ALUMNI RESEARCH FOUNDATION
614 Walnut Street, 13th floor
Madison, WI 53705

~~393-1012~~
~~202 737-3598~~
202
(Their Fax Number)

Pages being sent 3 (including this page)

Operator's Name: _____

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL (608)263-2500.

COMMENTS: Norm - per our discussion. Hope you don't have apoplexy over the commentary. Best regards -Howard.

RECEIVED
MAY -8 1998
BROWDY AND NEIMARK

esa:fax.frm

SCIENCE ONLINE AND BEYOND

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

150 YEARS · 1848-1998

THE RISE OF INTELLECTUAL PROPERTY PROTECTION IN THE AMERICAN UNIVERSITY



LITA NELSEN *is director of the Technology Licensing Office of the Massachusetts Institute of Technology, where she has been since 1986.*

Intellectual property scarcely existed in the vocabularies of U.S. academic researchers and administrators even 15 years ago. Now it is an ever-present part of discussions on research policies and directions. This new importance of intellectual property in academia reflects a changing view of the relationships of research universities to the surrounding society. Until recently, research at universities has been relatively isolated from demands of economic utility, and education of graduate students has emphasized a career in academic research as the final goal. The university's contentment with this relative isolation was affected by two major events of the late 1980s and early 1990s: the fall of the Berlin wall, leading to an expected decrease in military funding of research, and the emphasis on balancing the federal budget—both producing a fear of a decline in federal funding of university research. The reaction on the part of the university has been to emphasize the benefits of taxpayer funding of research and to seek increased research support from industry. Intellectual property plays an important part in both of these efforts.

The impact of the Bayh-Dole amendment. Economic development through exploitation of intellectual property is now widely touted as one of the major benefits of federally sponsored research. This effect was given a major boost by the passage of the Bayh-Dole Act (Public Law 96-517), implemented in 1980. The primary intent of this law was to foster the growth of technology-based small businesses by allowing them to own the patents that arose out of federally sponsored research.

Universities and other nonprofit recipients of federal funding were included in the definition of "small entities" benefiting from the Bayh-Dole Act, largely as an afterthought. Under the Bayh-Dole Act, the universities themselves would not develop the patented technologies, but would license the patents to industry. A provision of the law allowed the universities to retain royalties from such licensing and specified that a fraction of the royalties would be shared as personal income to the inventors. By law, the university's share of the royalties must be plowed back into its research and educational activities.

A key aspect of university licensing of their inventions under Bayh-Dole was the granting of exclusivity. How could the federal government justify allowing a single company to be given the advantage of intellectual property developed under taxpayer funding? The universities pointed out that exclusive licenses were imperative for the development of early-stage technology. The commercial licensee must devote substantial tim and money to attempt to develop the technol gy, with no guarantee that it will be successf Exclusive licenses are an inducement and rewa for a company willing to step forward and ta such a risk—knowing that if it succeeds in t development, the exclusive license will prote it from more risk-averse competitors.

Now almost all research universities in t United States have technology licensing oper tions. The number of U.S. patents granted American universities in a year rose from abo 300 in 1980 to almost 2000 in 1995. A survey university licensing activities documents 5396 censes granted by universities between 1991 a 1995.* More than 250 new companies we formed directly through university licenses 1996—and a total of more than 1900 compan since the inception of the Bayh-Dole Act 1980. Hundreds of products are already on t market that were developed under licenses—ranging from n vaccines to computer security systems, electronic music chi chemotherapeutic agents, and low-pollution industrial burners.

The direct economic impact of technology licensing on t universities themselves has been relatively small (a surprise many who believed that royalties could compensate for decl ing federal support of research). Although a very few, and hig ly visible, "blockbuster" inventions such as the Cohen-Boy gene-splicing patent from Stanford University and the Univer ty of California, the fax patent owned by Iowa State, and the c platin patents of Michigan State University have made tens millions for universities, most university licensing offices bar break even. In contrast, the impact of university technolo transfer on the local and national economies has been substa tial, and leads to the conclusion that the Bayh-Dole Act is o of the most successful pieces of economic development and jo creation legislation in recent history. It has been estimated† t more than 200,000 jobs have been created in the United Sta in product development and manufacturing of products fr university licenses, with the number increasing fairly rapidly the licenses mature.

These results of university licensing have been noted w great interest by local communities, state legislatures, the U Congress, and many policy-makers abroad. Locally, some u versities have noted a lessening (and even "sweetening") of "town/gown" conflict, as cities such as Cambridge see new co panies and jobs springing up out of the universities in their co munities. State governments are setting aside moneys specifi ly to fund technology transfer offices and new-company incu tors in their universities. The phrase "Bayh-Dole" is heard quently in Japan and Germany as their educational minist seek to emulate the U.S. university technology transfer syste

Industrial support of university research. Parallel with the de opment of the university infrastructure for protection and lic ing of intellectual property has come an increased interest in

The author is at the Massachusetts Institute of Technology, Five Cambridge Center, Kendall Square, Cambridge, MA 02142–1493, USA.

*D. E. Massing, Ed., *AUTM Licensing Survey, FY1991–1995. Five-Year Survey Summary* (Association of University Technology Managers, Norwalk, CT, 1996), p. 58. †L. Pressman, S. K. Guterman, I. Abrams, D. E. Geist, L. Nelsen, *J. Assoc. Technol. Managers* 7, 49 (1995).

search partnerships between industry and universities—from both partners. Universities see industrial support as potential replacement for funds cut by the federal government. Industry has many reasons for increased interest: Technology is developing too rapidly for in-house development to be sufficient; central research laboratories with cutting-edge scientists were closed down in the draconian down-sizing of the late 1980s and early 1990s, and companies are reluctant to rebuild them; universities have specialized facilities and staff that cannot readily be obtained elsewhere; and companies can experiment with new technologies and approaches at universities without committing to hiring permanently the expertise that will be needed to develop these technologies.

Intellectual property terms have become vitally important. The company wants to be assured that it can use the results of the research—and that these results will not be available to their competitors. But most universities insist that dissemination of research results is key to their identity and mission and will not agree to keep the project results secret. The key to resolving this dilemma is to grant patents: The university will publish the results, but will first agree to file patents that will protect the company's exclusivity in the commercial marketplace.

The critical factor in making this accommodation work is an efficient, knowledgeable technology transfer process at the university. The negotiators must be savvy about both technology and business, able to understand the industrial partner's needs and to craft reasonable intellectual property terms that meet those needs while preserving the rights, policies, and freedom of action of the university. These university technology transfer professionals are part of a new and surprisingly creative profession.

Impact on students. An unpredicted effect of the increasing interest in exploitation of university intellectual property has been that on students and the educational process. Contrary to expectations that patenting and technology transfer might somehow shut out students from full participation in the research process, the effect has instead been to motivate students and to increase their awareness of the potential commercial utility of their research findings.

Many engineering, design, and business development courses now include at least one session on patenting and technology transfer. Product development courses, previously unknown, are now popular in even the most science-based engineering schools. The biggest impact of university technology transfer on students comes from the success of start-up companies based on university licenses. The process tends to be very visible on campus, providing role models for many students. At the Massachusetts Institute of Technology, for example, the annual student business plan contest elicits 75 to 100 entries, a large fraction of which are based on plans that the students fully intend to turn into businesses. Of the six semifinalists each year, more than half achieve venture capital financing, and many who do not make the semifinals nevertheless go on to form successful companies.

Entrepreneurship courses and entrepreneurship tracks in MBA programs are now among the most popular offerings in business schools, and an increasingly large number of graduates are seeking employment in venture capital or in start-up companies. A relatively new trend is that of joint programs between engineering and business schools, many of which stress moving technology "from the laboratory to the production floor."

The future: trends and problems. University management of intellectual property is still young, and both policy-makers and technology transfer officers are learning by doing. Most policies have been formed ad hoc, with modifications made as problems arise. Yet the field is beginning to mature. Certain norms have arisen and some issues, such as taking of equity in start-up companies as a form of royalties, were initially highly controversial, but have become accepted as experience is gained and the predicted disasters have been largely averted through thoughtful formation and enforcement of policies. With maturity, however, are coming new problems and challenges, as there is an inherent conflict between free dissemination of knowledge (widely accepted as the university's primary mission), industry needs for confidentiality and control of intellectual property, and the university's obligation to protect and foster the development of its intellectual property in the cause of public economic development.

Although the past 10 years have shown that effective compromises can be wrought between these competing objectives, new situations show that these compromises may not be sufficient. Examples include:

- Restricted availability or delays in exchange of "research tools" (such as vectors or transgenic mice) in biological research.
- "Inappropriate" granting of exclusive licenses (such as the licensing of receptor "targets" for high-throughput drug screening) where wide availability might better foster development.
- New forms of collaboration with industry that do not lend themselves to the "sponsored research" model. For example, should the university insist on owning the intellectual property when a company sponsors a design competition in an undergraduate design class for ideas to improve the company's camera? Or how should the university treat collaborative projects where the student spends half of his or her time as an intern in the company's laboratory, and half in the university lab?
- Trading-off of benefits to the university may conflict with the expectations of the researchers. A recent suit against the University of California (Singer *v.* The Regents of the University of California), for example, alleged that the university gave overly favorable licensing terms to a company in return for sponsored research funds, depriving the inventors of substantial potential royalties.
- Tenure evaluations. Junior faculty members worry about whether participation in technology transfer is good or bad for their tenure prospects. Some are concerned that any such activities will lead to the assumption that their academic pursuits are not primary in their minds. Others assume that licenses are critical to the tenure committee deciding that the researcher's technology is "important."

Policy fiats, changes in the law, or even attempts to categorize types of intellectual property and the "appropriate" handling of them are very likely doomed to have overly broad effects with harmful, unintended consequences. The answer at the present time seems to be to handle situations on a case-by-case basis, but under a process of continual dedication within the university to "do the right thing"—and a continuing search to discover what the "right thing" is.

"THIS NEW IMPORTANCE OF INTELLECTUAL PROPERTY IN ACADEMIA REFLECTS A CHANGING VIEW OF THE RELATIONSHIPS OF RESEARCH UNIVERSITIES TO THE SURROUNDING SOCIETY."



ILLUSTRATION: TERESE WINSLOW

NIMH Technology Transfer Office Staff:
TTO Director (& TDC): Kathleen M. Conn
Technology Transfer Specialist: Suzanne L. Winfield
Technology Development Administrative Specialist: Joyce L. Williams

Phone: (301) 496-8828 FAX: (301) 480-1384
Mailing Address: Building 10, Room 4N222

NIMH Technology Transfer Office Web Site:
http://intramural.nimh.nih.gov/techtran
or you may access our website through the NIMH Home page (click on the Intramural Research Program)

You may also wish to review the information on the NIH Office of Technology Transfer Web Site: www.nih.gov/od/ott/

NIMH Version Revised 5/24/00
Approved by TTPB on 11/19/98
Update approved by OTT on 5/25/00

The primary mission of the NIH is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In pursuing this mission, NIH scientists often discover new technologies. The process of sharing these new technologies with other organizations and the public is called technology transfer. Although not all inclusive, the sharing of new research materials with colleagues, the pursuit of collaborative relationships with outside entities, and the awarding of intellectual property rights to commercial entities for development and commercialization, are all considered technology transfer activities.

Federal technology transfer is governed by a comprehensive set of laws, regulations, and policies. To ensure awareness and compliance with those requirements, every Institute/Center (IC) has designated a Technology Development Coordinator (TDC) who assists IC scientists with technology transfer issues. Your TDC is available to discuss any discovery, proposed collaborative working relationship or sharing of materials.

The following are highlights of some key activities and issues involved in technology transfer.

Material Transfer Agreements (MTAs) NIH uses this mechanism when there is an exchange of materials without an exchange of intellectual property rights. An MTA protects the scientist and the NIH against improper use of materials. ***Current NIH policy requires that MTAs be used whenever an NIH scientist sends out or receives materials, e.g. cDNAs, cell lines, antibodies, etc. These agreements must be signed by authorized IC personnel.***

The Simple Letter Agreement (SLA) is the MTA that NIH and a number of other **non-profit** institutions have agreed to use for the transfer of **most** materials. Care must be exercised, however, in using the SLA for proprietary materials that could be patentable, particularly when a patent application has not yet been filed. In this situation, the SLA can be modified by the institute to include a confidentiality clause (or, if you wish to have a more indepth discussion about the material, a separate confidentiality agreement can be signed). In situations where another institution has modified the SLA or has sent you its own MTA for signature, you must contact your IC technology transfer office for review of the agreement.

Cooperative Research and Development Agreements (CRADAs) CRADAs are a mechanism used by NIH scientists to collaborate with other organizations outside of NIH. CRADAs allow the exchange of resources including materials, personnel, and equipment among the parties and may confer intellectual property rights. Additionally, funds can be transferred to, but not from, the NIH laboratory/branch to assist in carrying out the project. Since CRADAs involve important legal and ethical constraints on the scientist and the research project, there is a formal clearance process for all NIH CRADAs. A scientist contemplating the use of a CRADA should contact their IC TDC.

Inventions Inventions arise from new discoveries including, but not limited to, vaccines, diagnostics, devices, compounds, research tools, compositions of matter, or any new and useful improvements on existing technologies. ***Inventions made by Federal employees***

Summary of Technology Transfer Responsibilities For the NIH Scientist

Attached is a Technology Transfer handout that will provide to you some basic information about the NIH scientist's responsibilities in the area of inventions, material transfers, Cooperative R&D Agreements (CRADAs) and other related topics. Also included is the NIMH Technology Transfer Office's web site address and information on how to directly contact the NIMH Technology Transfer Office.

I have received the handout on the technology transfer responsibilities of an NIH scientist and I am aware of who should be contacted for advice in these matters.

_____ _____

Signature Date

_____

Printed Name

TECHNOLOGY TRANSFER & YOU

and persons under certain other types of appointments belong to the Federal Government and, as required by 45 CFR 7.1, must be reported by using the PHS Employee Invention Report (EIR) Form PHS 6364.

Patents NIH may seek a patent on a reported invention when it is necessary to facilitate and attract investment by commercial partners for further research and commercial development of the technology.

Dates are critical in patent law because disclosures such as posters, abstracts, talks, public databases or published manuscripts made prior to filing a patent application with the appropriate patent offices may eliminate NIH's ability to obtain comprehensive patent protection on an invention. ***If you believe you have a new invention, it is important to contact your IC TDC who may suggest that you file an Employee Invention Report (EIR) as soon as possible. If an invention exists, there is no reason to wait until preparation of a scientific paper or scheduling of an oral/poster presentation before an EIR is filed.***

Licences A license is a mechanism used by NIH to award NIH intellectual property rights to a commercial entity. NIH may seek to license a new technology reported by an employee whether or not that technology is patented. NIH seeks to ensure the development of technologies and the availability of research tools to advance further scientific discovery through the use of various types of licenses.

Royalty Distribution NIH provides financial incentives to inventors from royalty income received under licenses to their inventions. NIH inventors share the first $2,000 of royalty income received under a license and a percentage thereafter up to a maximum of $150,000 in royalty income per inventor per year. The remaining income is returned to the IC for use as prescribed by law.

Confidentiality This is an important issue in technology transfer since these activities involve considerable interaction with the private sector. Collaborative agreements, patents, and licenses all require some degree of confidentiality, which must be carefully considered and balanced to ensure a thriving scientific enterprise. Confidential Disclosure Agreements (CDAs), signed by ICs and other organizations, are one mechanism which allows signatories to freely exchange information that could be beneficial to the scientific, and public health mission of the NIH yet insure that information is not made available to the public prior to official disclosure.

Ethics As stewards of the public trust, Federal employees must always be aware of practicing ethical behavior. This is particularly important for NIH scientists participating in technology transfer activities. NIH scientists must be vigilant in ensuring that they are not using public resources for private and personal gain. NIH scientists should consult their IC TDC and/or Ethics Officer when contemplating technology transfer activities.

To learn more about your rights and responsibilities regarding technology transfer, consult your Institute's Technology Transfer Office:

NORMAN J. LATKER

5112 Edgemoor Lane
Bethesda, MD 20814

Home: (301) 951-0375
Office: (202) 628-5197

TITLE:

Managing Attorney
Browdy and Neimark

EDUCATION:

B.S. Civil Engineering, 1953 from the University of Illinois
J.D., 1956 from the University of Illinois (U. of I.)
L.L.D., Honorary Doctor of Laws, 1985 from the U. of I.

Post graduate courses in electronics, advanced chemistry, biochemistry, and medicinal chemistry.

Judge Advocate General's Procurement Law School, University of Virginia, 1961.

EXPERIENCE:

BROWDY AND NEIMARK 1990 to Present

Managing Attorney

Responsible for the management of **BROWDY AND NEIMARK,** a 35 person law firm specializing since 1952 in intellectual property law including patents, trademarks, trade secrets, copyrights, unfair competition, and related licensing and litigation.

BROWDY AND NEIMARK is particularly noted for its involvement with the life sciences, including molecular biology, microbiology, immunology, pharmacology, and biomedical engineering. In addition to managing the firm, also pursues the prosecution of patent applications and license agreements for the firm.

MAXWELL COMMUNICATIONS CORPORATION, 1987 to 1989

Vice President, Legal and Technology Affairs, University Sciences and Engineering Technology (USET)

Responsible for identification of acquisition candidates for new Maxwell technology management corporation (USET) and design and development of an on-line technology database for commercial sale.

DEPARTMENT OF COMMERCE, 1982 to 1988

Director, Office of Federal Technology Management, Office of Productivity, Technology and Innovation

Responsible for the identification of problems that would affect the licensing and utilization of technology resulting from Federally-funded research. Government-wide administrative, legislative or regulatory positions developed and implemented.

SMALL BUSINESS ADMINISTRATION, 1980 to 1982

Assistant Chief Counsel for Patents and Research and Development

Responsible for the resolution of intellectual property, and research and development problems that affect small business through administrative, legislative or regulatory recommendations. (On loan to Office of Federal Procurement Policy, OMB to develop OMB Circular A-124.)

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Department Patent Counsel, Office of General Counsel
1965 - 1980

Responsible for administration of the Department's technology licensing and patent program including legal and administrative services relating to patents, inventions, copyrights and licensing of intellectual property resulting from the Department's multi-billion dollar research program.

National Institutes of Health, 1963 - 1965

Patent Counsel, Office of the Director

BEFORE 1963

Patent Examiner, U.S. Patent and Trademark Office.

Responsible for examining patent applications for inventions in the building arts.

Civil Engineer, Illinois State Highway Department

Responsible for inspection of bridges and highways for code compliance.

MAJOR PROFESSIONAL ACCOMPLISHMENTS:

- 1969 to 1975-Developed and implemented the Institutional Patent Agreement Policy and Regulations for Department of Health, Education and Welfare (DHEW). These served as precursor to the Bayh-Dole Act which established university technology management programs.
- Aided universities and other DHEW contractors in the delivery of over 75 health-related inventions to the marketplace and the licensing of many other inventions.
- 1963 to 1978-Managed the DHEW patent portfolio and technology licensing program.
- Architect of the Bayh-Dole Act, the University and Small Business Patent Act of 1980 (P.L. 96-517), which built on DHEW experience and established a national policy of small business and university ownership of technology resulting from federal research.
- 1980 to 1982-Developed the implementing regulations for the Bayh-Dole Act (OMB Circular A-124).
- 1982-Assisted the Senate Small Business Committee in the conception of the Small Business Innovation Development Act of 1982 (P.L. 97-207).
- Developed the President's Patent Policy Memorandum of 1983 which expanded contractor ownership policies to those not covered by the Bayh-Dole Act.
- 1984-Architect of P.L. 98-620, which extends and improves the concept of the Bayh-Dole Act.
- 1984 to 1987-Developed the implementing regulations for P.L. 98-620 (37 C.F.R. 401).

- 1982 to 1987-Designed and assisted in creating the "Office of Federal Technology Management" in the Department of Commerce.

- Architect of the Federal Laboratory Technology Transfer Act of 1986 P.L. 99-502, which extends the concepts of decentralized technology management of the Bayh-Dole Act to inventions made at Federally managed laboratories.

- 1987-Assisted in development of Executive Order 12591 "Facilitating Access to Science and Technology."

SPECIAL AWARDS:

Presidential Citation

For development of patent section of the Nonnuclear Energy Research and Development Act, 1974.

Small Business Administration

Outstanding Performance Citation, 1980

Department of Commerce

Secretarial Citation for development of President Reagan's February 18, 1983 memorandum on Government Patent Policy

Outstanding Performance Citations, 1984, 1985, 1986 and 1987

1983 Department Silver Medal for "contribution leading to new products, industries and jobs through the commercialization of Federally funded technologies."

1987 Department Bronze Medal for "passage of the Federal Technology Transfer Act of 1986."

University of Illinois

Chi Epsilon, National Civil Engineering Society for high Scholastic Achievement

Honorary Doctor of Laws, 1985 for "commitment and dedication to improving the national environment for research (which has) led to a national technology alliance involving the Federal government, universities, and private industry." (Copy Attached)

Association of University Technology Adminstrators (AUTM)

1983, "The Birch Award" for "unselfish commitment to establish and preserve the values of the technology transfer process."

The Association of Federal Technology Transfer Executives (AFT^2E)

July 13, 1994, "Vannevar Bush Award" for "outstanding contribution to the United States of America for creating the model for successful public and private technology partnership."

OTHER:

Guest Lecturer, 1980 to 1987, George Washington University Procurement Law - "Technology Transfer and Government Intellectual Property Policy"

INTERAGENCY EXECUTIVE AND LEGISLATIVE COMMITTEE AND COMMISSION SERVICE:

Chairman, Department of Commerce Interagency Committee to Implement the Federal Technology Transfer Act of 1986.

Chairman, Subcommittee on University Patent Policy of the Federal Council for Science, Engineering and Technology, 1971 to 1978.

Vice-Chairman, Subcommittee on Intellectual Property of the Federal Council for Science, Engineering and Technology, 1974 to 1978.

Technical Advisor on Intellectual Property and Research and Development to Subcommittee on the Constitution of Senate Judiciary, 1976 to 1980.

House Committee on Science and Technology's Workshop on Aid to the Handicapped, 1980 (recommendations resulted in Orphan Drug Act).

DHEW Interagency Committee on Significant Drugs with Little Commercial Value, 1978 (Recommendations lead to Orphan Drug Act).

Draftsman for the Patent Task Force for the Commission on Government Procurement, 1971.

Interagency Drafting Committee for Development of the Federal Property Management Regulations on Licensing of Government-Owned Inventions, 1980 to 1982.

Interagency Drafting Committee for Development of Standard Patent Rights Clauses for use in the Federal Procurement Regulations, 1971 to 1986.

PROFESSIONAL SOCIETIES:

American Bar Association
Federal Bar Association
American Intellectual Property Law Association
Licensing Executive Society
Association of University Technology Managers (AUTM)
Maryland Patent Law Association

BAR MEMBERSHIP:

Illinois, District of Columbia, U.S. Patent Office and United States Supreme Court

PUBLICATIONS, PRESENTATIONS, AND TESTIMONY:

"Washington in Review", Presentation to Society of University Patent Administrators, February, 1988.

"Commercializing the Results of Federal Research and Development", Testimony before the Senate Judiciary Committee, February, 1987.

"Public Law 98-620 Regulations", Presentation to Society of University Patent Administrators, June, 1986.

"Transfer of Technology Resulting from Government Funded Research", Presentation to Licensing Executive Society, May, 1986.

"Small Business Innovation Research Program", Testimony before U.S. House of Representatives Committee on Small Business, May, 1986.

"Federal Initiatives for Innovation," Presentation to American Intellectual Property Law Association, May, 1984.

"Technology Management", Presentation to Aerospace Industries Association of America, April, 1983.

"Current Status of Legislation Affecting the Licensing of Technology", Presentation to Licensing Executive society, October, 1980.

"The Philosophy of Different Policies on Disposing of Government Funded Inventions", Presentation to Government Patent Lawyers Association, April, 1979.

"The Ramifications of the Small Business and University Patent Procedures Act", Presentation to the 2nd Annual TechEx World Fair, March, 1979.

"The Impact of Laws and Regulations on the Innovation Process", Presentation to Society of University Patent Administrators, February, 1977.

"Current Government Patent Policy as Applicable to Universities and Nonprofit Organization", Presentation to American Patent Law Association, January, 1976.

"The Protection of Intellectual Property Under the Fourth Exemption of the Freedom of Information Act", Presentation to Academy of Pharmaceutical Sciences, November, 1975.

"Current Trends in Technology Transfer", Presentation to Third Annual University/Industry Forum Technology Exchange, February, 1975.

"Universities Opportunities and Responsibilities", Presentation to Conference on Technology Transfer, Case Western University, October, 1974.

"Science Policy Implications of DNA Recombinant Molecule Research", Testimony before U.S. House of Representatives committee on Science and Technology, May, 1977.

"Government Patent Policy", Testimony before U.S. House of Representatives Committee on Science and Technology, September, 1976.

"Utilization of Government-Owned Health and Welfare Inventions", Journal of the Patent Office Society, November, 1965.

PERSONAL:

Married to Carole H. Latker, Ph.D., Health Scientist Administrator, National Institutes of Health

Two Children:

Miriam E. Sell, M.D.

Richard E. Latker, Business Editor, Healthcare Publication, The Economist, Intelligence Unit, London, England

Citation of

UNIVERSITY OF ILLINOIS, MAY 19, 1985

NORMAN J. LATKER

for the

HONORARY DEGREE OF DOCTOR OF LAWS

Norman J. Latker, Director of the Office of Federal Technology Management Policy, U.S. Department of Commerce. Government administrator and public servant, your commitment and dedication to improving the national environment for research has led to a national technology alliance involving the federal government, universities, and private industry. You have worked tirelessly in various capacities as a respected public servant to institute change and improvement in U.S. patent laws. You prudently recognized the need for a better system of administration to enhance transfer of important inventions and research from universities to the private sector for commercial development. Your efforts for significant change in national policy for the betterment of the nation have earned you the widespread respect of your colleagues in the legal and academic communities. The University of Illinois is glad to join research institutions throughout the world which have recognized you as a leader in patent law and technology transfer. On recommendation of the Senate of the Urbana-Champaign campus, I present you to the President of the University for the honorary degree of Doctor of Laws.

Presentation by: Peter H. Hay, Dean of the College of Law, University of Illinois at Urbana-Champaign

federal register

Wednesday
March 18, 1987

Part II

Department of Commerce

Office of the Assistant Secretary for Productivity, Technology and Innovation

37 CFR Part 401

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms; Final Rule

DEPARTMENT OF COMMERCE

Office of the Assistant Secretary for Productivity, Technology and Innovation

37 CFR Part 401

[Docket No. 41278-7006]

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms

AGENCY: Assistant Secretary for Productivity, Technology and Innovation.

ACTION: 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 through 204 and the establishment of standard funding agreement provisions from the Office of Mangement and Budget (OMB) to the Secretary of Commerce. This rule makes final the interim final rule published in the Federal Register on July 14, 1986, and incorporates minor changes as a result of comments received on the interim final rule.

EFFECTIVE DATE: April 17, 1987.

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

SUPPLEMENTARY INFORMATION:

Background

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 replaced. 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 published in the Federal Register (51 FR 25508) on July 14, 1986, a final interim rule and requested comments by September 12, 1986.

Copies of all comments received were made 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 Interim Final Rule.

A number of comments from eight (8) different sources were received on the interim final rule in response to the July 14, 1986 notice.

The Department of Energy (DOE) submitted five comments on the interim final rule. All of the comments were found to have merit and have been incorporated in the final rule as follows:

DOE's first comment relates to a suggested clarification in the discussion portion of the interim final rule relating to § 401.3(a) (2). DOE's concern is that the discussion suggests that the right of the government to declare exceptional circumstance for national security reasons is limited to "some limited situations" and that application of this section is therefore limited to situations where the invention report is classified. DOE correctly points out that this is not consistent with the actual language of the regulation. We agree that the words "some limited situations" should not have been included in the discussion portion of the July 14, 1986 notice.

DOE's second comment states that the reference in the discussion portion of the interim final rule, in § 401.14(b) to nuclear weapons programs is inaccurate. We agree that the word nuclear should not have been included in the discussion of § 401.14(b).

DOE's third comment suggests that § 401.3(c) be revised to be consistent with § 401.14(b), which permits DOE to draft a substitute clause. We agree and have included the words, "or substitute thereto" after the reference to § 401.14(b) in § 401.3(c).

Another DOE comment suggests that § 401.13(c) (2) goes beyond the similar provision of OMB Circular A-124 by appearing to preclude confidential disclosure of patent applications or information which is part of a patent application obtained under the clause to other agencies or contractors of government agencies. We have clarified this by adding the following additional language to the end of § 401.13(c) (2):

> This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

DOE also suggests that § 401.13(c)(3) is unnecessary in view of § 401.13(c)(1). However, DOE suggests that if it is retained, § 401.13(c)(3) should be limited to the same time period as § 401.13(c)(1). We agree but have made no change because the language of § 401.13 (c) (3) already refers back to and incorporates the § 401.13(c)(3) already refers back to and incorporates the § 401.13(b)(1) limitation.

DOE also states that in § 401.15, first sentence, third word from the last word, "of" should be "or". We agree and have made this change.

Finally, DOE suggests that § 401.15(b) should have the following five words added at the end: "Unless it has been licensed." We agree and have included these five words at the end of § 401.15(b).

Another person submitted six comments which have been treated as follows:

The first comment suggests that a statement be added to § 401.3(c) as follows: "the Department of Energy may only exercise the exception at § 401.3(a) (4) with regard to inventions at the facility that are made directly and primarily with funds provided by either the Department's naval nuclear propulsion or nuclear weapons related programs." This comment was not accepted since the statute does not use these terms. Further, all determinations made under section 401(a)(4) by DOE are subject to review by the Department of Commerce under § 401.14(f) and each determination will be examined to ensure compliance with the law.

The second comment points out that in order to make a determination under § 401.3(a) (4), an agency must find one of the conditions set out in § 401.3(a) (1), (2) or (3). We disagree with this interpretation as § 401.3(a) (4) is independent of § 401.3(a) (1), (2) and (3).

A third comment suggests that consideration should be given to adding language to § 401.5(g) requiring the contractor to return a significant or a major portion of income to the facility at which the invention was made. This issue was disposed of in the earlier interim final rule notice of July 14, 1986, on page 25509 under the discussion of § 401.5(f). The matter of royalty disposal is one that is best left to negotiations between the interested parties.

The fourth comment relates to the language in § 401.5(g) regarding the physical location of contractor employees responsible for licensing of facility inventions. The comment suggests that 401.5(g) expressly state that contractors be obligated to maintain personnel responsible for licensing at the facility. However, another person requested that the subsection not be interpreted strictly to *require* that such a person be physically located at the facility. Section 202(c)(7)(C) of Pub. L. 98–620 indicates that licensing be done at the facility, "to the extent it provides the most effective technology transfer . . .". We believe this language precludes arbitrarily requiring that licensing personnel be located at the facility.

A fifth comment recommended requiring DOE funding agreements to conform to the language prescribed by § 401.14(b)(2) when the exception at § 401.3(a)(4) is used. This was not accepted. Although we have, in fact, permitted DOE to use a substitute clause for that set out in § 401.14(b)(2), we will be reviewing all agency regulations including DOE's to ensure compliance with the law and regulations, including all substitute clauses contained in agency regulations.

The final comment of this second person is that we modify the statement in § 401.15(a) that "within 90 days after receiving . . ." to read: Within 90 days after receiving a request and supporting information or sooner if a statutory bar to patenting is imminent, the agency shall either make a determination or inform the contractor of why a determination has not yet been made and when one can reasonably be expected." This comment was not accepted. At this time, this is a matter best left to the parties to determine on a case-by-case basis.

A number of comments were also received regarding a typographical error in the "Background" section on page 25510 of the July 14, 1986 **Federal Register** notice. The word "not" was inadvertently left out of the last sentence of the first paragraph discussing § 401.7. The sentence should have read as follows: "this change has been made because small business preference is not intended to inhibit industrial support of university research."

Two comments were received that relate to the exceptions to be made for handling of inventions if they are under research at a government-owned, contractor-operated facility (GOCO):

The first comment relates to the requirement in § 401.5(g) that specifies that income be used for purposes "consistent with research and development mission and objectives of the facility." The commenter suggests it would be preferable that a university be able to direct the net royalty income to the most promising research needs, which may not necessarily be consistent with the objective of the GOCO facility. We cannot accept this suggestion since the language in the regulation is based on the statute—Pub. L. 98–620.

The second comment goes on to state that § 401.5(g) further specifies that if a licensing program is successful, then above a certain point, 75 percent is to be paid to the U.S. Treasury. The suggestion is that this reduces the incentive to be successful, and recommends the deletion of this requirement. Again, we cannot accept this suggestion since the regulatory language herein is based on the statute—Pub. L. 98–620.

A third comment references the special clause entitled, "patent rights to nonprofit DOE facility operations." The comment states that this clause removes a subject invention funded by the naval nuclear propulsion or weapons related programs of DOE from the normal presumption of rights to the contractor, and requires the petitioning process that was in effect before the enactment of Pub. L. 96–517. The concern is that if these programs are exempted, then there may be additional proposals to delete other programs from the full operations of Pub. L. 96–517. The comment then concludes by recommending that this special clause not be implemented. We cannot accept this recommendation since the statute, Pub. L. 98–620, gives DOE the discretionary authority to use this for its naval nuclear propulsion or weapons related programs.

Another comment received relates to § 401.14(c)(1), which calls for disclosure by a contractor to the contracting government agency of each "subject invention . . ." within two months of the time it is disclosed by the inventor in writing. The commenter complains that two months is "too harsh." We do not accept this comment for two reasons. (1) The statute, Pub. L. 98–620, uses the words "reasonable time" and we think two months is reasonable; and (2) § 401.14(c)(4) allows extensions of time at the discretion of the agency.

One person asked for greater guidance on whether contractor funding of individual scientists at different universities is an educational award within 35 U.S.C. 212 and, if so, what rights such awardees should have. We have not acted on this comment since we do not believe any contractor has the authority to use funding for the educational awards covered by 35 U.S.C. 212.

A comment was submitted that relates to the discussion in the July 14, 1986 notice of § 401.13(b). The concern is that the discussion may be misinterpreted to imply that agencies may not apply the provisions of Pub. L. 98–620 retroactively. This point is well taken. It was our intent in the July 14, 1986 discussion of § 401.13(b) to note only that the Department of Commerce has no authority under the law to require agencies to waive the cap on the term of an exclusive license in a patent clause that predates enactment of Pub. L. 98–620. There is no question that the agencies themselves have authority under the law to waive such cap and the regulations in fact urge them to do so absent a substantive reason to do otherwise.

Another person requested that the Department of Commerce set a time for issuance of draft supplementary regulations relating to foreign filing deadlines at § 401.14(c)(3). As we previously indicated in the interim final rule notice on July 14, 1986, we are considering this matter. Therefore, we see no reason at this time to set a deadline.

Finally, pursuant to requests by two persons, we have included in this final notice, uniform policy guidance in § 401.1(a) to these final regulations similar to that included in OMB Circular A–124. This has been done to ensure clarity and continuity between OMB Circular A–124 and these final regulations with regard to policy.

Rulemaking Requirements

As stated in the proposed notice and the interim final rule, 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 and the interim final 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: March 11, 1987.

D. Bruce Merrifield,

Assistant Secretary for Productivity, Technology and Innovation.

Accordingly, Part 401 of Chapter IV of Title 37, the Code of Federal Regulations is revised to read as follows:

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

Sec.

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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 Sec. 3(g) of DOO 10-1.

§ 401.1 Scope.

(a) Traditionally there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention "conceived or first actually reduced to practice in performance" of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a "subject invention", the challenge is appealable as described in § 401.11(d).

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

(b) This part inplements 35 U.S.C. 202 through 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.

(c) The "march-in" and appeals procedures in §§ 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.

(d) 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 §§ 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i) through (iv) § 401.3(a)(8) through (iv) of this part) is applicable and will be applied. If the exception at § 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by § 401.3(c).

(e) 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. 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 § 401.5 or §401.3, when alternative provisions are used under § 401.3(a)(1) through (4), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in § 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) 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.

(f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A-124 or OMB Bulletin 61-22), 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 consistent with Chapter 18 and this part.

(g) 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 § 401.2(a) of this part.

§ 401.2 Definitions.

As used in this part—

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

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

(c) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

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

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

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

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

(h) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (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.

§ 401.3 Use of the Standard Clauses at § 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions—

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

(2) In exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code; or

(3) When it is determined by a government authority which is authorized by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security to such activities; or

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

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

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

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

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

(f) Except for determinations under § 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

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

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

§ 401.4 Contractor appeals of exceptions.

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

§ 401.5 Modification and tailoring of clauses.

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in

contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause and delete the words "to be performed by a small business firm or domestic nonprofit organization" from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) may be deleted. When either paragraph (g)(2) or paragraphs (g) (2) and (3) are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

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

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

(d) 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 clause at § 401.14 as follows:

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

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

(e) 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 emendment.

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

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

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

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

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

(3) After payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalties or income earned and retained by the *contractor* during any fiscal year on subject inventions under this or any successor *contract* containing the same requirement, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the *contractor* only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by *contractor* employees on location at the facility.

(h) If the contract is for the operation of a government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at § 401.14(a):

(5) The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the *contracting officer* so that the *contracting officer* may evaluate and determine their effectiveness.

§ 401.6 Exercise of march-in rights.

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

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

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 a 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 subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

(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 such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at § 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section, agencies may publish such disclosures.

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

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

§ 401.14 Standard patent rights clauses.

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

Patent Rights (Small Business Firms and Nonprofit Organizations)

(a) Definitions

(1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

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

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

(5) "Small Business Firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 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 (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights

The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a 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 agency*. However, in any case where

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 § 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.

§ 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)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a).

§ 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 as long as they are consistent with 35 U.S.C. 201–206.

§ 401.11 Appeals.

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

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

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

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

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

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

(5) A refusal to grant an extension of the exclusive license period 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 § 401.6 (e) through (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 Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§ 401.12 Licensing of Background Patent Rights to Third Parties.

(a) A funding agreement with a small business firm or a domestic nonprofit organization will not contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the agency head and a written justification has been signed by the agency head. Any such provision will clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The agency head may not delegate the authority to approve such provisions or to sign the justification required for such provisions.

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

§ 401.13 Administration of Patent Rights Clauses.

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

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

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

requirements should be followed for funding agreements covered by and predating this Part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14(a) or such other clause may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a 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 subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

(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 such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at § 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section, agencies may publish such disclosures.

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

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

§ 401.14 Standard patent rights clauses.

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

Patent Rights (Small Business Firms and Nonprofit Organizations)

(a) Definitions

(1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

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

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

(5) "Small Business Firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 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 (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights

The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a 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 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—

(1) 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.

(2) 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.

(3) 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 sucessor 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.

(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 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 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 commerical sale or use, gross royalties received by the contractor, and such other data and information as the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor*.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the *contractor* agrees that neither it nor any assignee will grant to any person the

exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the *contractor* or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commericially feasible.

(j) March-in Rights

The *contractor* agrees that with respect to any subject invention in which it has acquired title, the *Federal agency* has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the *agency* to require the *contractor*, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the *contractor*, assignee, or exclusive licensee refuses such a request the *Federal agency* has the right to grant such a license itself if the *Federal agency* determines that:

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

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

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

(l) Communication

(Complete According to Instructions at 401.5(b))

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

(1) The title of the clause shall be changed to read as follows: *Patent Rights to Nonprofit DOE Facility Operators*

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

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

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

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

§ 401.15 Deferred determinations.

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at § 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations 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 of concerns which originally led the agency to invoke an exception under § 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at § 401.14(a) had been used originally, unless it has been licensed.

(c) If paragraph (b) is not applicable the agency shall make its determination

based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at § 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under § 401.11 of this part.

§ 401.16 Submissions and inquiries.

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

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design, or model in respect of the invention. A United States patent issued to such person, his successors, assigns, or legal representatives shall be invalid, unless the failure to procure such license was through error and without deceptive intent, and the patent does not disclose subject matter within the scope of section 181 of this title.

(Amended Aug. 23, 1988, Public Law 100-418, sec. 9101(b)(2), 102 Stat. 1568.)

35 U.S.C. 186 Penalty.

Whoever, during the period or periods of time an invention has been ordered to be kept secret and the grant of a patent thereon withheld pursuant to section 181 of this title, shall, with knowledge of such order and without due authorization, willfully publish or disclose or authorize or cause to be published or disclosed the invention, or material information with respect thereto, or whoever willfully, in violation of the provisions of section 184 of this title, shall file or cause or authorize to be filed in any foreign country an application for patent or for the registration of a utility model, industrial design, or model in respect of any invention made in the United States, shall, upon conviction, be fined not more than $10,000 or imprisoned for not more than two years, or both.

(Amended Aug. 23, 1988, Public Law 100-418, sec. 9101(b)(3), 102 Stat. 1568.)

35 U.S.C. 187 Nonapplicability to certain persons.

The prohibitions and penalties of this chapter shall not apply to any officer or agent of the United States acting within the scope of his authority, nor to any person acting upon his written instructions or permission.

35 U.S.C. 188 Rules and regulations, delegation of power.

The Atomic Energy Commission, the Secretary of a defense department, the chief officer of any other department or agency of the Government designated by the President as a defense agency of the United States, and the Secretary of Commerce, may separately issue rules and regulations to enable the respective department or agency to carry out the provisions of this chapter, and may delegate any power conferred by this chapter.

CHAPTER [18] 38 — PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

Sec.

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35 U.S.C. 200 Policy and objective.

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

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3018.)

35 U.S.C. 201 Definitions.

As used in this chapter —

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

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

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

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise pro-

funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the last paragraph of section 203(2).

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: And *provided further*, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*,That the funding agreement may provide for such additional rights; including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreements relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information, as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

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

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research, or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operator facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year, up to an amount equal to 5 percent of the annual budget of the facility, 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 provided that if said balance exceeds 5 percent of the annual budget of the

priate, the determination of the Federal agency. In cases described in paragraphs (a) and (c), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3022; amended Nov. 8, 1984, Public Law 98-620, sec. 501(9), 98 Stat. 3367; Oct. 29, 1992, Public Law 102-572, sec. 902(b)(1), 106 Stat. 4516.)

35 U.S.C. 204 Preference for United States industry.

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023.)

35 U.S.C. 205 Confidentiality.

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

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023.)

35 U.S.C. 206 Uniform clauses and regulations.

The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023; amended Nov. 8, 1984, Public Law 98-620, sec. 501(10), 98 Stat. 3367.)

35 U.S.C. 207 Domestic and foreign protection of federally owned inventions.

(a) Each Federal agency is authorized to —

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

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

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

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

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce authorized to -

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023; amended Nov. 8, 1984, Public Law 98-620, sec. 501(11), 98 Stat. 3367.)

35 U.S.C. 208 Regulations governing Federal licensing.

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

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3024; amended Nov. 8, 1984, Public Law 98-620, sec. 501(12), 98 Stat. 3367.)

35 U.S.C. 209 Restrictions on licensing of federally owned inventions.

subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

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

(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) section 30168(e) of title 49;

(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); 82 Stat. 360);

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

(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

(8) section 6 of the Coal Research Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

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

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

(11) subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5);

(12) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5901; 88 Stat. 1878);

(13) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);

(14) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191);

(15) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);

(16) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

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

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

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

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

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

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

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

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions, except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in paragraph 202(c)(4) and section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

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

(e) The provisions of the Stevenson-Wydler Technology Innovation Act of 1980 shall take precedence over the provisions of this chapter to the extent that they permit or require a disposition of rights in subject inventions which is inconsistent with this chapter.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3026.)

(Subsection (c) amended Nov. 8, 1984, Public Law 98-620, sec. 501(13), 98 Stat. 3367.)

(Subsection (e) added Oct. 20, 1986, Public Law 99-502, sec. 9(c), 100 Stat. 1796.)

(Subsection (a)(4) amended July 5, 1994, Public Law 103-272, sec. 5(j), 108 Stat. 1375.)

(Subsection (e) amended Mar. 7, 1996, Public Law 104-113, sec. 7, 110 Stat. 779.)

35 U.S.C. 211 Relationship to antitrust laws.

Yes, America Has a 'New Economy': Technology

Global View

By George Melloan

Federal Reserve Chairman Alan Greenspan gave unexpected support to "New Economy" theorists in a speech at the Gerald R. Ford Foundation in Grand Rapids 13 days ago. Information technology, he said, "has begun to alter, fundamentally, the manner in which we do business and create economic value." By enabling businesses to remove "large swaths of unnecessary inventory," real-time information is accelerating productivity growth and raising living standards. This has contributed to the "greatest prosperity the world has ever witnessed."

That is bullish talk for a man better known for chiding Wall Street for its "irrational exuberance," long before the Dow soared above 11,000. There can be little douht, however, that there is a new, technology-based economy roaring toward the year 2000 and that Americans are its primary driving force. So it is fascinating to contemplate what new technological marvels we're likely to see in the 21st century. Just as engaging is reflection on why it is that the U.S. has become the fountainhead of creativity in science and engineering. A lot of other nations would like to find the secret and bottle it.

But first a look at some of the hot technologies, some gleaned from a bibliography prepared by the Organization for Economic Cooperation and Development in Paris. OECD researchers expect further dramatic advances in information technology, with desktop computers heading onward and upward in memory and speed. Gene-replacement therapy could be widespread by 2025, as the Human Genome Project unlocks further mysteries of the humau body.

Meanwhile, Rand Corp's Critical Technologies Institute, surveying corporate executives, forecasts that over the next 20 years "molecular medicine" will lead to powerful medications and therapies that treat diseases at the genetic level. Therapy will be applied at earlier stages of disease and will be adapted to individual patients. These more precise treatments will further advance life expectancies.

"The same deeper understanding of genetics that is poised to revolutionize health care and its attendant industries also offers the potential for more precisely breeding plants and animals," says the Rand survey. "Depending on consumer acceptance, by the early part of the next century, much of the world's produce may be genetically engineered in some way."

Materials technology is a wide-open field, with possibilities for flexible glass or ceramics and, most fascinating, the marriage of biology and engineering to produce combinations of organic and inorganic materials that are, in effect, self-assembling. Tiny sensors will someday eliminate the need for highway toll booths and regulate automobile engines, in both cases saving enormous amounts of fuel. Imaging technology is progressing toward identifying tinier objects, advancing molecular medicine and genetic engineering.

In transportation, look for the "hybrid car" early in the 21st century, using fuel cells, an advanced electrical battery. "Over the longer term, fuel cells, combined with super-strong, ultra-light polymers or ceramics, could provide true energy savings for the transportation sector," the Rand study says.

The reason the U.S. is leading the technological revolution is partly its great wealth. Its corporations, universities and national laboratories are the world's leading spenders on research and development, with outlays double the nearest rival, Japan. But there is a lot more to this great burst of creativity than just the amount of money spent. Far more important is the environment that Americans have created—or perhaps preserved is a better description—that fosters and rewards creative effort.

The Bayh-Dole Act of 1980 allows recipients of government grants to retain title to their inventions. Says a study on basic research by the Committee for Economic Development: "This law has stimulated intense growth in university patenting and a subsequent technology transfer from basic research institutions to industry. As a result, industry is increasingly involved in collaboration with, and sponsorship of, university-based researchers." For example, the CED report notes that there are 1,000 companies in Massachusetts with relationships with the Massachusetts Institute of Technology. Their worldwide sales are $53 billion. "Similar developments have taken place in California's Silicon Valley and the Research Triangle of North Carolina."

Genetics research will revolutionize health care.

But many places elsewhere in the world are lacking one or more of the magic ingredients that have made the U.S. the great dynamo of the technological revolution. No country, for example, can match America's vast network of colleges and universities, teaching hospitals and private-research institutions, not to mention the labs of its multinational corporations. These centers of research attract aspiring scientists and engineers from all over the world and many find the intellectual climate so much to their liking that they settle permanently in the U.S.

U.S. national laboratories, though suffering from the usual inefficiencies of tax-supported institutions, nonetheless direct grants to thousands of individuals who are pursuing promising lines of research. And the ease with which individuals can start businesses in the U.S., in sharp contrast to Europe and Asia, means that good ideas spawn new firms, which often grow large and provide shelter and stimulation for new generations bent on making their marks in research and development.

But there is more to it than that. The U.S. would never have arrived at this stage without the changes in the public-policy environment that have transpired over the last 20 years. Ronald Reagan set in motion a deregulatory and tax reform process that has survived to this day. Efforts by the Clintons to nationalize the health industry, which surely would have stultified medical research, failed. So did the effort of Vice President Al Gore to whip up "environmental" hysteria and thus expand the regulatory burden, which is a particular curse for small start-up firms, at a faster rate.

Another Rand study comparing the U.S. with the European Union, Japan, China and South Korea shows that the U.S. leads in providing a climate of openness to foreign trade and investment. This helps make the U.S. economy highly competitive. Competition stimulates innovation. That is reflected in Rand statistics showing that American industry sharply expanded its employment of Ph.D. scientists and engineers between the years 1973 and 1991, increasing its share, relative to other employers, to 36% from 24%.

There are lessons in all this. All this new science didn't just happen. It had to be incubated. If the U.S. can preserve the environment that hatches inventions, it can look forward with optimism to the 21st century. Present evidence suggests that the 21st may even outstrip the 20th as a century of science.

resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that funds not otherwise necessary to the conduct of the approved project are not included in the award.

The principal investigator is responsible for being aware of any changes in the other support of key personnel and for notifying the appropriate grants management office of such changes. Updated information on other support may be requested at the time of award when there is a substantial amount of pending support, when there has been a significant time lapse since the time of application, or when potential overlap has been identified.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source.

Commitment overlap occurs when any project personnel has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for key personnel (excluding consultants), **no individuals on the project may have commitments in excess of 100 percent.**

Scientific Overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration; or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

2. Resolution of Overlap

Although applicants are requested to identify potential overlap, the actual resolution of overlap occurs at the time of award in conjunction with applicant institution officials, including the principal investigator, and awarding agency staff. Potential overlap is to be addressed by the IRG *only* by its identification in an Administrative Note in the summary statement.

C. GRANT SOLICITATIONS

Specific program announcements (PAs) and requests for applications (RFAs) are published in the *Federal Register* and in the *NIH Guide for Grants and Contracts*. The *Guide* also contains vital information about policies and procedures and is being transmitted electronically to a number of institutions. To obtain the Guide on a regular basis, see p. 3. Definitions regarding the use of PAs and RFAs are as follows:

Program Announcement: A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, and/or invite applications for grant support. Most applications in response to PAs may be submitted for any appropriate receipt date and are reviewed with all other applications received at that time.

Request for Applications: A formal statement that invites grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. The RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application receipt date(s). Applications submitted in response to an RFA usually are reviewed by an IRG convened by the awarding component that issued the RFA.

D. START DATES

Awarding components may not always be able to honor the requested start date of an application. Therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.

E. INVENTIONS AND PATENTS

Recipient organizations must report inventions promptly to the Extramural Inventions Reports

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PATENT AGENT
ALLEN C. YUN, PH.D.

September 15, 2000

Ms. Yvonne Williamson
4000 Rockville Pike
Bldg. 45, Room 2AN-32
Bethesda, MD 20892

Dear Ms. Williamson:

I would appreciate receiving a copy of funded grant U54GM62114 under the Freedom of Information Act as soon as it is available in your records. If there is problem in obtaining this grant please call at above telephone number.

Sincerely,

Norman J. Latker

SN:dr

F:\User24\njl\Williamson.doc

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. Lowell T. Harmison
Special Assistant to the
Deputy Assistant Secretary for Health

MAR 14 1975

Patent Counsel, DHEW/OS/GCB

Patent Branch Administration and Budget

As you requested, we are providing information on the funding and staffing of the Patent Branch.

GENERAL BUDGET

This office has an annual budget of $30,000 for filing and prosecuting domestic patent applications. Because of inflation, the cost of patent prosecution has increased substantially in recent years, whereas our budget has not been increased since 1969. As a result, for the past four or five years the Patent Branch has been running out of funds before the end of the fiscal year, and each year the funds have become depleted approximately a month earlier than the year before. Our FY 1975 funds ran out at the end of December. In order to continue operating, we have to obtain additional funds from the Office of the Director of NIH. On occasion, the Office of the General Counsel has been able to provide some supplemental funding. This year, as in a number of past years, NIH has allocated $20,000 to sustain Patent Branch operations. However, based upon estimates from our contract attorneys for ongoing work, and upon bills for work already performed, but which have not been paid, it is estimated that the supplemental funds from NIH will be exhausted by the end of the third quarter. At that time we will either have to obtain additional funds from NIH or cease prosecuting patent applications.

PATENT PROSECUTION IN GENERAL

The Patent Branch receives approximately 300 invention reports per year. These are carefully evaluated according to established and time-consuming procedures in order to determine the scientific importance, novelty and potential use of the invention by the Government and/or the public. As a result of this screening procedure and the high standard applied, patent applications are filed by the Department on only 15% of the inventions reported. The only way we can reduce costs is to cut down on the number of patent applications filed each year. In order to operate within our present budget, we would have to reduce the number of patent applications filed by about 50%. We feel that such an economy move would be unwise, since patent protection is often a critical element in technology transfer and failure to patent could deprive the public of the benefits of the best of Government-sponsored research results.

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FOREIGN FILING

Until about 1970 the Patent Branch budget was sufficient to cover the cost of patenting one or two inventions per year in foreign countries. The inventions selected were those which appeared to be of great scientific importance and great foreign commercial potential so that anticipated royalties would exceed the foreign patent prosecution and maintenance costs. For the past five years we have had no funds available for foreign patenting. Accordingly, when an invention report is received which meets the foregoing criteria, it is necessary for us to solicit funds for foreign patenting from the Institute that funded the research or from NTIS of the Department of Commerce, which recently advised that funds for foreign patenting would be available in selected circumstances. At the present time, we are prosecuting foreign patent applications on several inventions which are being paid for by one of the National Institutes of Health. These costs are substantial, since it costs approximately $800 to file a patent application in a non-English speaking country. In some cases we have, at the request of the Institute, filed 15-20 foreign patent applications on a single invention. (The cost of these filings was more than half our present annual budget.) Each Institute handles the funding of foreign patent applications differently, which is confusing and leads to errors and delays in paying our foreign associates.

TRADEMARKS

In recent years the National Institutes of Health and other organizations within DHEW have developed programs which provide services to the public which the program wishes to publicize. In some cases the programs have adopted names or logos which are utilized to advertise the availability of the services and to facilitate public identification of the services with the program. As a result we have been receiving an increasing number of inquiries from programs who wish to protect their names and logos and to prevent unauthorized use by others. In order to obtain maximum legal protection for these marks, we have filed applications for trademark registration on approximately 20 marks in the past five years, including two trademark applications filed on the name "World Health Organization" and the initials "WHO". Since we have no funds allocated for trademark prosecution, the programs requesting trademark protection have had to fund these costs. Here again, coordinating payments from multiple sources has been inefficient and a substantial burden on Patent Branch staff.

TRAVEL

The Patent Branch has no funds of its own for travel, and travel money has been available from OGC only on a very limited basis. During the

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past three years the Department Patent Counsel has received requests to address groups and to participate in seminars and meetings involving intellectual property, technology transfer, patent licensing and other matters directly related to the Department's mission. During this period, Patent Branch personnel attended 8 such meetings. OGC paid for the travel costs in one case, but in the other 7 cases the travel costs were paid for by NIH or the organization extending the invitation. None of these meetings was for a professional legal organization such as the Federal Bar Association, which would further or enhance the staff's expertise or professional competence. All were meetings which involved such things as disposition of grant- and contract-generated inventions, Department Patent Regulations and procedures, and the development and licensing of Department-owned inventions which directly affect the Department and its relationship with grantees, contractors, patent licensees and the public. We have already received invitations to participate in meetings to be held in FY 1976, at least two of which we consider important and should be attended by Patent Branch personnel.

OFFICE SUPPLIES AND EQUIPMENT

The Patent Branch has no separate funds for office supplies and equipment and relies on the OGC to provide these items. However, DRG has provided us with routine office supplies. The rental on a Ty-Data automatic typewriter, which is imperative to our operation because of our large volume of routine correspondence, is paid for by NIH, and most of the other typewriters in the office belong to NIH. The Xerox machines which we use and which are also imperative to our operation belong to NIH.

LEGAL LIBRARY AND SUBSCRIPTIONS

Another item of vital importance to Patent Branch operation in subscriptions to technical journals and publications, including subscriptions to the U.S. Patent Quarterly, the Official Gazette of the Patent Office and the PAtent, Trademark and Copyright Journal. These subscriptions are the responsibility of OGC. In recent years, Patent Branch subscriptions have been allowed to expire, including our subscription to the Manual of Patent Examining Procedure which is kept up to date by periodic changes which reflect changes in the patent laws and in Patent Office procedures and policies. This publication is an absolutely essential part of a practicing patent attorney's library. Our subscription to this service expired three years ago, and we have been unable to have it reinstated. As a result our Manual is out of date and pertinent sections must be verified from an outside source.

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STAFFING

I am attaching a July 20, 1973, memo from Mr. Hiller to the Executive Assistant, OGC, covering the area of staffing. I am making no recommendations in regard to staffing, at this time, and believe Mr. Hiller's memo (the substance of which was generated by our staff) will bring you up to date.

SUMMARY

In summary, the Patent Branch presently must obtain funding from multiple sources in order to carry out its program functions. While these sources have been most generous in the past in meeting our needs, Patent Branch responsibilities and functions have increased to the point where it can no longer operate effectively and efficiently under the present multiple funding arrangements.. The Office of the General Counsel is apparently unable to adequately fund all Patent Branch operations. Accordingly, it appears appropriate and efficient for the Department to consider funding the Patent Branch from a single source other than OGC. A logical source for such funding would be the Office of the Director of NIH since NIH is already providing supplemental funding and support at a higher level than that provided by OGC, or, alternatively, the Office of the Assistant Secretary for Health, who is ultimately responsible for Patent Program functions for the entire Department. Preliminary oral discussions with appropriate OD officials indicate that they would be receptive to working out an interim arrangement to fund the Patent Branch for FY 1976. Attached is a proposed FY 1976 budget which we believe to be an accurate estimate of what Patent Branch operating expenses will be during that period. As to the not yet formulated 1977 budget, we hope that our funding needs might be included in either the ASH or OD budget, whichever is considered most feasible.

We believe this recommendation to be consistent with the organization responsibility of the Patent Branch since the Patent Branch is unique to the entire OGC in that the branch has definite program responsibilities as well as legal advisory ones. The program responsibilies assigned under Chapter 1-901 "Department Patent Activities", copy attached, greatly outweigh in time and importance the legal advisory responsibilities. The program responsibilities must be performed in order that the Assistant Secretary and the operating agencies may meet their policy responsibilities under Chapter 1-901. The definite tilt toward the program responsibilities which the Patent Branch must perform, in our view, may create reluctance on the part of OGC to furnish optimum staffing and funding of the Branch since all the levels above the Branch in the OGC are only peripherally exposed to the program aspects of the Branch.

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We do not fault this peripheral exposure since we believe it parallels the relationship of other programs in the Department to the OGC. But to the extent the OGC controls our funding, it has been detrimental to the program.

Even if the funding situation can be resolved as we request, it should be noted we are still left with a serious shortfall in staff that cannot be made up by increased funding alone.

Further, since it is the office of the Assistant Secretary which must concur in the most important end-products generated by the Patent Branch (as prescribed by Chapter 1901.), it appears that that office would be in the best position to make an objective evaluation of our staffing needs.

Norman J. Latker

Enclosures

cc: Mr. Kettel w/ends

TGFerris:NJLatker:EJB:cam
DHEW/OS/GCB 3/14/75

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PROPOSED PATENT BRANCH BUDGET FOR FY 1976

DOMESTIC PATENT PROSECUTION		
35 new cases per year @ $800.00	$28,000	
100 Patent Office Actions per year @ $200	20,000	
Interference Proceedings, Appeals (Includes extra $10,000)	18,000	
Patent Office Deposit Account (Issue Fees, Licenses for Foreign Filing, Petitions, etc.)	5,000	
	$71,000	$71,000
FOREIGN PATENT PROSECUTION		
5 cases per year: 2 countries @ $300 6 countries @ 800	$27,000	
32 Amendments and other official responses @ $200	6,400	
Maintenance Fees	1,000	
	$34,400	$34,400
TRADEMARK PROSECUTION		
4 Applications at $250	$ 1,000	$ 1,000
TRAVEL	$ 1,000	$ 1,000
OFFICE SUPPLIES AND EQUIPMENT RENTALS		
Office Supplies	$ 500	
Rentals (Ty-Data, Xerox)	3,600	
Equipment replacement and Misc.	1,000	
	$ 5,100	$ 5,100
		$ 111,600

Of the $111,000 estimated only $30,000 is budgeted in the OGC appropriation.

NR

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Info 84-157

OFFICE OF THE DIRECTOR,
CONTRACT POLICY and ADMINISTRATION

Tax Day + 1

Memo for: Mrs.Spector / Col. Guenther

Re: Executive Order involving the retention of rights in Technical Data by Contractors where the government has paid the development costs.

Ah, there is bad news today!

Apparently, we were successful in convincing people that the OIRA technical data policy statement was not the way to go only to gain OFPP as the arbiter of what such a policy should be.

One good point, perhaps, is that we can put this effort into the DARC/CAAC process where it should be and hope that they will be able to reach a consensus on what such a policy should be. The key in this effort will be to mute the voice of Norm Latker, DoC who was the ghost writer of the OIRA policy. We must also ensure that the license is not constrained as was the one in the OFPP policy. NASA, Bob Kempf should support that effort.

Fred. J. Kohout