COMMENTS ON DRAFT FAR SUBPART 27.3 AND CLAUSES

This draft revision is in the form of a Federal Register Notice. It appears to show only the portions of the existing subpart for which changes are proposed. The following comments are based on the assumption that ALL existing provisions of this subpart will remain unless they are shown in the draft to be deleted. The comments correspond with pencil numbers in the margin of the draft revision.

1 (Page E) Should be updated to cite and conform with the March 18 1987 final regulation and Executive Order 12591.

2 (Page A-1) Our regulation only says 13 CFR 121.5. These cites should be checked.

3 (Page A-2) Should cite Executive Order 12591, and include in the statement of objectives, "promote the commercialization, in accord with the Presidential Patent Policy Memorandum of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, inexchange for royalty-free use by or on behalf of the Government".

4 (Page A-4) Should refer to Executive Order 12591.

5 (Page A-4) The new language is based on the statute and our Regulation, but does not include "...and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occuring under the above two programs."

6 (Page A-6) This is what the old FAR said, but our final regulation has a different provision based on the Paperwork Reduction Act.

7 (Page A-6) The new language, "which are marked with restrictions" and "agencies shall not disclose such utilization reports to persons outside the Government without permission of the contractor" are not the same as our regulation provision 401.8(b) that:

> 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 of the Government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

8 (Page A-7) This section on Small Business Preference is entirely new. It is based in part on the provision (k)(4) of the

standard clause in our regulation, but includes language not in the clause and omits the role of the Secretary of Commerce that is outlined in the standard clause.

9 (Page A-9) These deletions have been transferred to a DAR clause supplement and appear to have been made mandatory for all DOD components. The power to inspect and copy the application file is not included in our regulation.

10 (Page A-10) Paragraph (4) seems to be under 27.303(a) which specifies when the short form clause is to be used. It seems to require the use of the 52.227-11 or short form contractor ownership clause with alternate III for all nonprofit GOCOs. Does Energy really agree with this? (5) seems to require use of the short form for all nonprofit GOCO contracts with alternate IV. Alternates I and II dealing with foreign treaty obligations are included in the package. The numbering of pages B-27, B-27(a), and B-27(b) make it hard to see which clauses Alternates III (royalty cap) and IV (contractor management procedures) are to be used in conjunction with.

11 (Page-13) This seems to make no sense at all. The exceptions at 27.302(b)(2) and (3) are the exceptional circumstance and intelligence exceptions where the Government would obtain title. Clause 52.227.11 is the contractor ownership short form. This says to include the greater rights determinations provision of the Government-ownership clause in the short form.

12 (Page A-14) This provision for GOCOs is in the portion that allows but does not require a title-in-the-Government clause. It conflicts with the new (4) and (5) on page A-10(a). (See 10 above)

13 (Page A-16) This removes the flexilbility to limit the impact of treaties or foreign agreements, but keeps the flexibility to expand the impact.

14 (Page A-17) This quote from our regulation omits the following underlined words: "The appeal shall be decided by the head of the agency or designee <u>who is at a level above the person who made the determination</u>."

15 (Page A-19) Our regulation says that "A contractor adversely affected by a determination..." The draft FAR revision says, "In accordance with 35 U.S.C. 203 a small business firm or nonprofit organization contractor adversely..." Does this exclude the appeal right from large contractors with who might otherwise have it under the Executive Order and Presidential Memorandum?

16 (Page A-21) It is not clear what was left out at this

point. The old (f) was Modification, waiver, or omission of rights of the Government or obligations of the contractor. That would make the next paragraph (h) Exercise of march-in rights. The "(g)" could indicate that the old (g) was left out, or that they meant include it and failed to indicate that march-in is now (h).

17 (Page A-17) Two of our regulation provisions have been left out:

> (k) For purposes of this section the term "exclusive licensee" includes a partially exclusive licensee.
>
> (l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in precedings.

While (k) may be obvious, eliminating (l) may be restrictive on particularly the civil agencies.

18 (Page A-27) This paragraph is based on our paragraph 401.13(c)(2), but the net effect of the change is to retain the old FAR provisions that use "should" and "use reasonable efforts." The revised FAR does not include our (c) that mentions the Presidential Memorandum, our (c)(1) that says agencies shall not disclose information under FOIA that relates to applications before there is time to file them, or our (c)(3) and (4) provisions about agency publications programs. Our regulation and the FAR revision are significantly different on the publication issue.

19 (Page B-12) For consistency, these paragraphs should be numbered (1), (2) and (3), not (i), (ii), and (iii).

20 It is hard to figure out where pages 27(a) and 27(b) are to be inserted, and what clause(s) they are meant to modify.

21 THE SHORT FORM APPEARS TO BE AN EXACT COPY OF OUR STANDARD CLAUSE, WITH ONLY THE MODIFICATIONS NECESSARY FOR IT TO MAKE SENSE IN THE FAR CONTEXT.

22 WHILE SOME CHANGES WERE MADE TO THE LONG FORM, THE TIMING REQUIREMENTS FOR ELECTING AND PATENTING WERE NOT CHANGED, SO THE TWO CLAUSES ARE NOT PARALLEL.

23 THE MATERIAL IN 401.15 OF OUR REGULATION ON DEFERRED DETERMINATIONS DOES NOT APPEAR TO HAVE BEEN INCLUDED IN THE REVISION.

24 The revision did not change 27.304-1(c) on Government assignment of rights in Government employees' inventions. It

still refers to OMB Circular A-124, does not mention our regulation, and omits the added sentence, "Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201-206."

TRANSMITTAL SHEET

MAXWELL COMMUNICATIONS
MAXWELL - USET, INC.

1413 RESEARCH BLVD.
ROCKVILLE, MD 20850

FAX NUMBER 301 738 0212

DATE: 3/8/88

TO: Joe Allen

FAX NO: 377-0432

FROM: Norman Latker

TELEPHONE: 301 - 738 - 0213

SUBJECT: _____

NUMBER OF PAGES (INCLUDING THIS COVER): 2

Joe
This came in from Stanford —
It is inconsistent with reporting
requirements of commerce Regs.
It also has No OMB report form
Number and probably illegal on
that grounds. — I sent
Stanford into Nancy Wentzler
who is checking whether his
has OMB clearance.

Norm

SFRC ONR/21 FAX (301) 738-0212
(Revised 04/14/87)

INTELLECTUAL PROPERTY ADMINISTRATION
SPONSORED PROJECTS OFFICE
(415) 723-2570
STANFORD UNIVERSITY
STANFORD, CA 94305

21. X **Innovations** - (Applicable Only to SDI Funded Awards)

The Contractor shall report to the Contracting Officer within two months after any innovation is identified as a result of the work performed under this contract. An innovation is any new idea, method, process or device that has potential or apparent utility in applications different from the specific SDI application for which it was originated and is either a more effective means of accomplishing a work objective or constitutes an advance in the state of the art. An innovation includes inventions but is not limited to inventions. The report on an innovation shall include the following:

a. Title: A short meaningful title identifying the specific nature of the innovation.

b. Graphics: Any illustration which will aid in understanding the nature, function, or application of the innovation.

c. Description: A narrative description in sufficient detail to enable someone else working in the technology area and having a need or application for the innovation to request further details. This section should include technical functional specifications, operational parameters, and status (availability) of the innovation.

d. Characteristics and Potential Applications: A narrative of the unique characteristics and potential applications, including commercial applications, and potential capabilities of the innovation if further developed.

e. Reports: A listing of reports published regarding the innovation or the associated technology by title and report number.

f. Source: The point of contact for obtaining more detailed information regarding the innovation to include name or office, corporation or institution, address, telephone, and contract number.

A copy of the report shall be sent directly to:

Office of Civil Applications
OSD/SDIO/CA
Washington, D.C. 20301-7100

The purpose of establishing a reporting requirement on innovations is to create a computerized data base for the rapid and effective exchange of technical information among all Government contractors and potential Government contractors who have been approved, in accordance with procedures established by the Under Secretary of Defense for Research and Engineering under DoDD 5230.25 (withholding of Unclassified Technical Data from Public Disclosure). The technical information will foster efficient and cost-effective developments of new products both for use by the Government as well as in the commercial field. Exchange, if any, of commercial rights retained by the Contractor in the innovation will be between the non-governmental parties, but the exchange will recognize and acknowledge the rights of the Government obtained under the technical data and patent rights clauses included in the contract between the Government and the owner of the rights in the innovation.

The Contractor shall review all work performed under this contract on a semi-annual basis and provide a report to the Contracting Officer certifying that all innovations have been identified and reported. This requirement for reporting innovations will be included in the schedule of all subcontracts, at any tier, under this contract requiring the performance of experimental, developmental or research work.

549802

Advanced Magnetics Inc.

61 MOONEY STREET • CAMBRIDGE, MASSACHUSETTS 02138-1038

TELEPHONE (617) 497-2071 (800) 343-1346

TELEX: 9102401608 ADMG CAM UQ TELEFAX: (617) 497-6927

December 21, 1987

President Ronald Reagan
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Reagan:

Enclosed is a copy of an agreement between the National Cancer Institute and the Institut fur Diagnostikforschung (IDF). IDF is a wholly owned affiliate of Schering A.G., a two-billion dollar German pharmaceuticals and chemicals giant. In this agreement, under article six, patent rights are granted exclusively to IDF. This is an outrage. Substantial amounts of taxpayer money (read Advanced Magnetics, Inc. and all our employees and shareholders) has gone into the development and ongoing research in Dr. Cohen's laboratory. Why are we giving it away to IDF for a pittance? The salary of one post-doctoral fellow isn't worth spit in the ocean in this business.

The subject of the technical collaboration between IDF and NCI is the development of a family of compounds termed metalloporphyrins for use as human pharmaceuticals. These compounds have recently shown great promise as contrast agents for the detection of cancer, in conjunction with the magnetic resonance imaging technique. A single, commercially successful metalloporphyrin contrast agent could easily have world wide sales of $100,000,000. A family of metalloporphyrin contrast agents could have world wide sales of many times this number.

The early stages of the metalloporphyrin research, which indicated the general feasibility of this approach, were entirely funded by the US government at NCI. After realizing the promise of metalloporphyrins through government funded research and publication, Schering and IDF signed the attached collaborative agreement with NCI. Under the terms of that collaboration, US pharmaceutical firms will have to apply to a foreign company, Schering, for licenses to exploit metalloporphyrins as pharmaceutical MR contrast agents. This raises the following questions.

1. Were American companies offered the same deal?
2. How is the work Schering is funding, to be distinguished from research supported by the US taxpayer, since the facility being used for that research is owned by the US government?
3. Why did the American taxpayer fund the initial, high risk phases of the research, while seeking a foreign commercial partner after the principle had been established?

There are more than a half dozen U.S. companies engaged in the contrast agent business including Advanced Magnetics. No one at NCI contacted us nor was any RFP or other general notification ever circulated to seek funding (for Dr. Cohen's program) outside of normal NCI channels.

It is our understanding that this agreement is now up for renewal. I would respectfully suggest that any renewal not take place and that NCI abrogate this agreement. While it would seem obvious to those of us trying to compete on a global basis that selling American know-how and technology has severely injured the nation, giving it away is clearly ludicrous.

Your assistance in this matter will be greatly appreciated.

Sincerely yours,

Jerome Goldstein
President

Enclosure

JG/kc

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
WASHINGTON, D.C 20201

OFFICE OF THE GENERAL COUNSEL

November 30, 1987

Jennifer Gordon
Associate
1155 Sixth Avenue
Floor 22
New York, New York 10036

Dear Ms. Gordon:

Enclosed is a copy of a collaboration agreement which you requested. I hope this is helpful to you.

Sincerely yours,

William G. Ketterer
Senior Attorney, NIH

Enclosure

Collaboration Agreement

This agreement, effective the 1st day of January, 1987, by and between the Institut fur Diagnostikforschung (Institute for Diagnostic Research; hereinafter "IDF"), Berlin, West Germany, and the National Cancer Institute of the National Institutes of Health (herinafter "NCI"; hereinafter collectively the "Parties");

WITNESSETH:

WHEREAS, the IDF is involved in the research and development of diagnostic compounds, and

WHEREAS, Dr. Jack S. Cohen, Chief, Biophysical Pharmacology Section, Clinical Pharmacology Branch, NCI, is engaged in research on potential contrast agents for magnetic resonance imaging (MRI) of tumors,

NOW, THEREFORE, the Parties agree as follows:

1. General Plan: The Parties shall agree to carry out a collaboration on paramagnetic metalloporphyrins as potential contrast agents for tumors in MRI, the research to be carried out in the laboratories of NCI under the supervision of Dr. Jack S. Cohen. Detailed studies shall include topics as agreed to between the Parties in prior discussions (see Attachment, Berlin, 5/29/86), specifically covering the mechanism of uptake of porphyrins and metalloporphyrins in tumor cells, and the *in vivo* stability and distribution of metalloporphyrins.

2. Level of Support: IDF will support the salary and other expenses of a Post-doctoral Fellow who will work in the NCI laboratory under the supervision of Dr. Jack S. Cohen. NCI will provide laboratory space and equipment as currently available. IDF will provide additional funds as agreed separately to support the provision of supplies and additional equipment to facilitate the research. The Fellow will be a Guest Researcher at NCI. The salary and the research support will be paid through the Foundation for Advanced Education in the Sciences, Inc. In addition other NCI personnel, specifically Dr. Cohen' technician and/or other Fellows, will participate in the research. No salary support for NCI personnel will be paid by IDF, since they are Federal Government employees.

3. Term: This Agreement shall remain in force for a year from its effective date, and may be extended by mutual agreement between the Parties. However, either Party may terminate the agreement provided that 30 days written notice is provided the other Party.

4. Review of Progress: The data is the property of NCI, but IDF will have access to the data at mutually agreeable times. A semi-annual review shall be made to determine the progress of the project, and to make adjustments in plans.

5. Publications: Recognizing the need to publish the data gained from this study, both Parties agree to the publication of the data in a peer-reviewed scientific journal. Published data would then become public information. Data published by either Party will include a recognition statement of the contribution of the other Party. Both Parties reserve the right to review all data for publication at least two weeks prior to submission.

6. Patent Rights: Any patentable product or process developed under this agreement shall be assigned to the Government the United States as represented by the Secretary of the Department of Health and Human Services (DHHS). DHHS agrees to grant, and does hereby grant, IDF an exclusive world-wide, royalty-bearing license, with the right to sub-license, all patentable inventions and data resulting from research projects on MRI contrast agents carried out under this agreement with IDF-supported personnel and IDF-funded research. The form of the license is attached hereto and made a part of this agreement. IDF agrees that it will not hinder the commercial exploitation of the invention described and claimed in U.S. Patent Application serial No. 706,622, filed February 28, 1985. IDF further agrees that it will exercise diligence in sub-licensing any inventions developed under this Agreement and will assure that its sublicensee(s) exercise diligence in bringing such inventions licensed by DHHS, or by the National Technical Information Service (NTIS) on behalf of DHHS, to the point of practical application in the United States as quickly as possible within the limits of sound business practice.

7. IDF agrees not to use the name of the DHHS, NCI or any of their divisions or laboratories in relation to any advertising of any product that might result from this Agreement. The IDF agrees that no Federal Agency endorsement is or will be implied by this Agreement.

8. For day-to-day administration of the Agreement, Dr. Jack S. Cohen shall represent the NCI, and Mr. Ingo Peter will represent the IDF.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their authorized Representative, as of the date and year first written above.

Institut fur Diagnostikforschung

By Ingo Peter

Ingo Peter
General Manager
Insitut fur Diagnostikforschung
Berlin

Date: 14/11/86

National Cancer Institute

Gregory Curt, M.D.
Deputy Director
Division of Cancer Treatment
National Cancer Institute

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

he General Counsel
Maryland 20857

Tom

I haven't read in detail but what I saw is a problem — Maybe a few brief one-line points & a meeting that I would have with Ashley and Langa would be needed

Lowell

TO: D(

FROM: C
P

SUBJECT: S

Attached is Lanman of the signifi elieve are raised by

While ther surface as the Amendm should keep us pr

I suggest the agency heads and sfer Board. Working wi members, a next step rix and a timetable ues.

Attachment

cc: Dr. Windom
Mr. Grinstead

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Bethesda, Maryland 20892
Public Health Division

November 12, 1987

MEMORANDUM

TO: Richard J. Riseberg
Associate General Counsel
for Public Health

FROM: Legal Advisor, NIH

SUBJECT: Legal/Policy Issues raised by Implementation of the Federal Technology Transfer Act of 1986, Public Law 99-502

The enactment of the Federal Technology Transfer Act on October 20, 1986, and the October 14, 1987 delegation of authority under that Act from the Assistant Secretary for Health (ASH) to the Heads of PHS agencies, Centers and Institutes raise a number of legal and policy issues which will have to be addressed as the statutory authority is implemented. Listed below are the sections of the Act pertinent to the Public Health Service (PHS) and some of the important legal and policy issues which I believe are raised by those provisions.

Authority for Licensing Agreements and Cooperative Research and Development Agreements.

Section 2 of the Federal Technology Transfer Act of 1986, Pub. L. 99-502, adds a new section 12, "Cooperative Research and Development Agreements," to the Stevenson-Wydler Act, 15 U.S.C. 3710a. Section 9(e)(1) of Pub. L. 99-502, redesignates the amended sections 11 through 19 of the Stevenson-Wydler Act as sections 10 through 18, so the section entitled, "Cooperative Research and Development Agreements," becomes section 11 of the Stevenson-Wydler Act. That section provides that each Federal agency may permit the Director of any of its Government-operated Federal laboratories to enter into cooperative research and development agreements on behalf of such agency and to negotiate licensing agreements for Government-owned inventions made at the laboratory, and other inventions of Federal employees that may be voluntarily assigned to the Government. Under cooperative research and development agreements, the Heads of PHS Agencies, Centers, and Institutes, may accept, retain and use funds, personnel, services, and property from collaborating parties and provide personnel,

services and property to collaborating parties. It is clear that the Federal Government may not provide funds to collaborating parties under cooperative research and development agreements.

ISSUES.

1. It is not clear to what extent the Heads of PHS Agencies, Centers and Institutes may: enter into grants, contracts or cooperative agreements with institutions and companies with which the Agency, Center or Institute already has a cooperative research and development agreement; or make funds available to another Federal agency, or accept funds from another Federal agency, under an interagency agreement that is made a part of a cooperative research and development agreement.

2. What procedures are necessary to receive, expend and account for funds received from outside collaborators?

3. Does the statute give the Heads of PHS Agencies, Centers and Institutes unlimited authority to transfer title to Government property? Is a quid pro quo required?

4. What is the status of personnel of outside companies who work with the Government and vice versa?

5. What standard terms should be included in cooperative research and development agreements?

Regulations.

15 U.S.C. 3710a(c) states that a Federal agency may issue regulations on suitable procedures for implementing the section, but that implementation is not to be delayed until issuance of those regulations.

ISSUE.

Although this provision does not require regulations, does the Administrative Procedure Act require the issuance of regulations setting forth the procedures for applying for cooperative research and development agreements and the criteria considered by the Heads of PHS Agencies, Centers and Institutes in deciding whether to enter into such agreements?

Conflict of Interest.

15 U.S.C. 3710a(c)(3) provides that agencies and those to whom the authority has been delegated shall review employee standards of conduct to make certain they adequately establish guidelines for situations likely to arise through the use of the authority for entering into cooperative research and development agreements. The particular cases presented by the statute as examples are where present or former employees or their partners negotiate licenses or assignments of title to inventions made by those employees, or negotiate agreements with Federal agencies including the agency with which the employee involved is or was formerly employed. I understand that Darrel Grinstead is gathering examples of potential conflicts that might arise from NIH. I assume this will lead to consideration of necessary amendments to the HHS Standards of Conduct.

As you know, NIH has adopted a policy that prohibits an employee from simultaneously collaborating with a company as part of his or her official duties and consulting for the same company as an outside activity, regardless of whether two different projects are involved. The NIH policy further provides that collaboration and simultaneous consultation by two different employees of a branch or laboratory with the same company may be approved only if the employees are collaborating or consulting on different subjects. It might be questioned whether this restriction is stringent enough.

ISSUES.

1. Shouldn't the NIH prohibition against simultaneous consultation and collaboration be laboratory-wide, in order to avoid any opportunity for a scientist to enhance his private consulting efforts through his public position?

2. Once a patent application is filed, is the scientist/inventor who is seeking development of the product for clinical application precluded from contacts with the FDA or from otherwise taking action that would ultimately enhance the marketing of the drug? (See the attached request for an opinion on this issue.)

3. Is a future possibility of royalty income a financial interest that can directly and predictably affected within the meaning of 18 U.S.C. 208? If so, does it become so at the time an invention is made or at the time negotiations on a cooperative research and development agreement begin.

4. Can a former employee/inventor negotiate an exclusive license to his invention on behalf of a private company?

Preferences.

15 U.S.C. 3710a(c)(4) requires that in considering what agreements to enter into, the laboratory director must (1) give special consideration to small business firms and consortia involving small business firms, and (2) give preference to business units located in the United States which agree that products arising from the agreements will be manufactured substantially in the United States. I believe this provision raises some very difficult issues.

ISSUE.

Does it require that all proposed agreements be advertised so that small business firms and United States firms may compete? At present, agreements are normally instituted at NIH by scientist to scientist contact. There is little or no indication that the scientists are permitting a number of companies to compete for a particular collaboration, or that they are giving special consideration to small business firms or business units located in the United States. However, it does appear that the Cooperative Research and Development Agreements Subcommittee of the NIH Patent Policy Board will, in approving agreements, question the extent to which a scientist has explored whether the types of companies referred to in the statute would be capable of providing the same collaborative support that is being offered by a foreign company, or by a company that is not a small business.

15 U.S.C. 3710a(c)(4) states that the laboratory director must, in the case of any industrial organization or other person subject to the control of a foreign company or government, take into consideration whether or not such foreign government permits United States agencies, organizations or other persons to enter into cooperative research and development agreements and licensing agreements.

ISSUE.

An issue is raised as to the meaning of this language. Does it mean that agreements may not be made with foreign companies or governments unless they have United States subsidiaries that have the authority to enter into those agreements? Does it mean that U.S. companies controlled by foreign companies or governments, which are permitted to enter into cooperative research and development agreements and licensing agreements, are to be given preference over those which are not so permitted? Or do foreign controlled U.S. companies that may enter into agreements have preference over U.S. companies that are not controlled by foreign entities.

Approval by Agency Head.

15 U.S.C. 3710a(c)(5) states that "if the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement, the agreement shall provide a thirty-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of laboratory concerned." By giving the agency head discretion to include this thirty-day review period in the agreement, the statutory provision apparently contemplates that the agreement will be signed by both the laboratory and the collaborating company subject to a thirty-day period of review before the agreement becomes effective. For the reasons stated in my October 26 memorandum to Dr. Chen (attached), I believe implementation of this provision in this manner would be highly impractical. I believe we should construe the provision to permit a review by the appropriate PHS Agency Head prior to the parties signing the agreement.

Laboratory Consortium.

Section 3 of the Federal Technology Transfer Act establishes a Federal laboratory consortium for technology transfer. This provision raises largely policy issues regarding the extent to which the Heads of PHS Agencies, Centers and Institutes will be able to benefit from and cooperate with the coordination, demonstration, and training activities of the consortium. Note that each agency must support the consortium in an amount equal to 0.0005 percent of that portion of the research and development budget of the agency that is to be utilized by the agency laboratories for fiscal years 1987 through 1991.

Cash Awards Program.

Section 6 of the Federal Technology Transfer Act adds a provision to the Stevenson-Wydler Act requiring that a Federal agency making expenditures at a rate of more than 50 million dollars per fiscal year for research and development in its Government-operated laboratories must develop and implement a cash awards program for its scientific, engineering and technical personnel. This section was included in the recent delegation from ASH and by the terms of that delegation, the Head of each PHS Agency is responsible for carrying out this provision. This raises the policy issue of whether a uniform award program should be established for all of the PHS agencies or whether each agency should be free to establish its own program. The issue is also raised as to whether the award program should include cash awards and, if so, how such awards should be funded.

[illegible] largely policy issues [illegible] the extent to

Royalty Payments.

Section 7 of the Federal Technology Transfer Act amends the Stevenson-Wydler Act to provide for the distribution of royalties received by Federal agencies. At least 15 percent of the gross royalties must be paid to the inventor or co-inventors, if the inventor or each such co-inventor was an employee of the agency at the time the invention was made. Since DHHS did not publish in the Federal Register a notice of election to file a Notice of a Proposed Rulemaking (NPRM) setting forth an alternate distribution plan, this 15 percent minimum payment to inventors became effective on October 20, 1986. Because the provision states that an agency may promulgate regulations providing for an alternate program for sharing royalties, the question is raised whether regulations are necessary if the agency wants to pay more than the 15 percent minimum. I do not believe regulations are required for that purpose, but they might be considered desirable in order to assure that Federal scientists are fully informed of what royalty payments they can expect. Once a PHS Agency Head decides upon a royalty amount greater than 15 percent, an issue might be raised as to whether that greater royalty share is to be applied prospectively or retroactively. I do not believe there is any requirement that it be applied retroactively and to my knowledge, NIH has no intention of doing so.

Use of Royalty Payments by Laboratories.

Following payment of the royalty to inventors, the balance of the royalties are to be transferred by the agency to its Government-operated laboratories with the majority share of the royalties going to the laboratory where the invention occurred. Under the delegation, the Heads of PHS agencies receive the balance of the royalties and are responsible for distributing them to the Centers and Institutes within that agency. These royalties may be used by the Institutes and Centers and by the agency for payment of expenses incidental to the administration and licensing of inventions, including the fees or other costs for services of agencies, persons or organizations involved in invention management and licensing services; to reward scientific, engineering and technical employees of the laboratory; to further scientific exchange among the Government-operated laboratories of the agency; or for education and training of employees consistent with the research and development mission and objectives of the agency and for other activities that increase the potential for transfer of the technology of the Government-operated laboratories.

ISSUES.

Several issues are raised by these limitations on the uses of the royalty payments:

- Should these permissible uses be given a broad or narrow reading?
- How will expenditures be monitored to assure that the funds are spent only for these purposes? May funds be used to reward scientific, engineering and technical employees of a laboratory other than the laboratory in which the invention was made? (Note the statutory language "of that laboratory.")
- Will it be possible for the PHS Agencies, Centers and Institutes to expend all the funds received from royalties for these limited purposes, or will some of the funds, despite two-year availability, revert to the Treasury?
- Should the statute be amended to permit broader uses of the royalties that are paid to the agencies?

NTIS Costs.

It must be noted that under 5 U.S.C. 3710c(a)(4), a Federal agency, such as NTIS, receiving royalties as a result of invention management services shall retain such royalties to the extent required to offset the payment of royalties to inventors, for payment of administrative costs and for the cost of foreign patenting and maintenance performed at the request of the agency. Thus, it appears that the payments actually received by the PHS agencies would be net of all NTIS costs.

Assigned Inventions.

15 U.S.C. 3710c(b) provides that if the invention involved is one that was assigned to the Federal agency by a contractor or grantee or participant in a cooperative agreement with the agency or by an employee of the agency who was not working in the laboratory at the time the invention was made, the agency unit that was involved in the assignment shall be consider to be a laboratory for purposes of royalty distribution. This would seem to provide an incentive for agencies to seek assignment of patent rights. However, because of the limited permissible uses of royalty payments, this incentive seems limited.

[illegible] royalties that are paid to the agencies?

I am certain that additional issues are raised by the statutory provisions and that others will come to light as implementation proceeds. I look forward to discussing the issues with you and others involved in implementation of the Act, and to assisting in the resolution of the issues.

Robert B. Lanman

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date October 22, 1987

From Director, Division of Cancer Treatment, NCI

Subject Possible Conflict of Interest

OCT 22 1987

To Mr. Robert B. Lanman
Office of the General Counsel, DHHS

I would like to request your opinion regarding whether you see any actual or perceivable conflict of interest in my current involvement with the drug, trimetrexate. I would like to briefly recapitulate the events leading to this inquiry.

As you know, I am currently Director of the Division of Cancer Treatment of the National Cancer Institute, and as such am responsible for directing the development of both anticancer and anti-AIDS drugs. My official responsibilities with regard to AIDS are to direct the identification and preclinical development of agents for treating AIDS or the opportunistic infections associated with AIDS. In early 1985, my own laboratory, which is part of the Clinical Pharmacology Branch of the NCI, was approached by Dr. Henry Masur, of the Clinical Center, who asked for our help in trying to understand the reasons for failure of AIDS patients to respond to Bactrim as treatment for pneumocystis carinii pneumonia, one of the major opportunistic infections associated with AIDS. With Dr. Masur's help, we found that the parasite's key folate-synthesizing enzyme, dihydrofolate reductase, was relatively insensitive to Bactrim, but was strongly inhibited by an anticancer drug, trimetrexate. We collaborated with Dr. Masur in initiating a clinical trial of trimetrexate, and in 1985, filed a use patent, as Government employees, with myself, Dr. Masur, and two members of the Clinical Pharmacology Branch, Dr. Carmen Allegra and Mr. James Drake, as discoverers. With the help of a collaborative agreement with Warner-Lambert, which holds the materials patent for trimetrexate, we initiated more detailed studies of folic acid metabolism in pneumocystis and toxoplasmosis in the effort to better understand the effects of antifolate-type compounds in these important AIDS parasites.

The preliminary clinical trial was completed in March of 1987, with strikingly positive results. At that time, we entered into discussions with the National Institute of Allergy and Infectious Diseases regarding the expansion of these trials in the AIDS Treatment Evaluation Units across the country, and reached agreement to conduct a large, two-armed trial comparing Bactrim and trimetrexate in patients with pneumocystis. We requested permission from the Food and Drug Administration to initiate this trial in March of 1987, and after five months of negotiation, with several changes in the protocol, received permission to proceed with the trial in September of this year. I actively participated in these discussions, to which the FDA, Warner-Lambert, NIAID officials, and other officials of the NCI were a party. The Director of the NCI, Dr. DeVita, was kept fully

informed of these negotiations, although his feeling was that the larger trial was unnecessary and that the results were sufficiently positive to justify release of the drug immediately, without further testing. At his suggestion, in September of 1987, we asked the NIAID to consider requesting treatment IND status for trimetrexate in order to make it available for immediate use for patients refractory to Bactrim or allergic to Bactrim. Such a request has been filed by the NIAID and is still under active consideration by the FDA. I consulted with Leroy Randall, of the NIH patent office, on September 18, 1987, regarding whether I should remain an active participant in discussions with the FDA on this subject; and while he advised that there was no obvious conflict of interest, I decided to surrender all further responsibility for interactions with the FDA on this subject to Dan Hoth, the Director of the AIDS Treatment Program of NIAID. I have had no further formal interaction with the FDA on this subject, although people from my laboratory (Dr. Allegra in particular) have been asked to present their data in discussions regarding the treatment IND. On Friday, October 16, 1987, Dr. Frank Young, Commissioner of the Food and Drug Administration, called me to discuss the treatment IND. I told Dr. Young that all questions regarding trimetrexate should be referred to Dr. Hoth because of my desire to exclude myself from regulatory transactions regarding this agent.

My question to you is whether you perceive any real or apparent conflict of interest in my past interaction with the FDA regarding trimetrexate, and whether you would advise me to take any further steps to divorce myself from the development of this agent. My interest at present is exclusively in the scientific development of antifolates. Our clinical and laboratory studies of this agent and related compounds continue in the intramural program.

With respect to the patent status of trimetrexate, Mr. Randall has looked into this in some detail. Warner-Lambert has a composition of matter patent, and as yet has not applied for a licence for use of the drug against pneumocystis. If they choose to request a license, my Division would ordinarily handle the competition and negotiations. In this case, I believe it would be appropriate for Dr. DeVita's office to handle this interaction, but I would like your opinion on this matter as well.

Thank you for considering this matter. As you can imagine, I am very eager to remove myself from any apparent or real conflict of interest, but at the same time, am eager to see the most expeditious development of this potentially life-saving treatment.

Bruce Chabner

Bruce A. Chabner, M.D.

Attachment

cc: Dr. DeVita
Dr. Fauci
Dr. Hoth
Dr. Wyngaarden

...whether you perceive any real or apparent conflict of

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Bethesda, Maryland 20892

Public Health Division

October 26, 1987

MEMORANDUM

TO: Dr. Philip S. Chen
Associate Director for Intramural Affairs

FROM: Legal Advisor, NIH

SUBJECT: Delegated Authority for NIH Components to Negotiate Research and Licensing Agreements with Private Sector Organizations

As you know, the Assistant Secretary for Health (ASH) recently signed a Delegation of Authority authorizing the Director of NIH and the Institute Directors to enter into cooperative research and development agreements with Federal agencies, industrial organizations, public and private foundations or other persons and to negotiate licensing agreements for Government-owned inventions made in NIH laboratories and other inventions of Federal employees that may be voluntarily assigned to the Government. The delegation was made pursuant to the provisions of the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3701 et seq. Under this delegation, the NIH and Institute Directors may enter into collaborative research agreements which grant exclusive licenses or waive rights of ownership to future inventions made under those agreements and grant exclusive licenses to existing inventions. Previously, that authority was reserved to the Assistant Secretary.

Of course, this office and the OGC Patent Branch will continue to develop and review these agreements. However, we are somewhat concerned as to how the various Institutes will be exercising their new authority under this delegation. Since the Institute Directors now have final authority to grant exclusive licenses to Government-owned inventions, the criteria used by the Institutes for granting such licenses need to be carefully, but promptly addressed. We are already receiving inquiries from private companies as to the criteria that will be used by the BIDs in granting such licenses. Although the ASH delegation states that guidelines for negotiating cooperative research and development agreements will be developed by the ASH in consultation with the PHS Technology Management Board, the negotiation of agreements is not to be delayed pending the issuance of those guidelines.

Accordingly, we believe that it will be necessary for NIH to take some action to ensure the application of uniform criteria for granting exclusive licenses to inventions developed under cooperative research and development agreements, pending issuance of the PHS guidelines. Given the need for immediate action in this regard, we suggest that NIH continue the present procedural method of assuring uniformity--review of those agreements by the Patent Policy Board's Subcommittee for Cooperative Research and Development Agreements. In this regard, we note that under the conditions accompanying the PHS delegation, cooperative research and development agreements "should include a clause providing the head of. . .[the] PHS agency a 30-day period to disapprove or require the modification of the agreement." We question whether such a clause is practical. It seems to contemplate a final agreement signed by an Institute Director which would be subject to disapproval by the Director, NIH. We believe the Director, NIH, or his delegate should be involved in the clearance process prior to any finalization of an agreement. This would expedite final approval of the agreement, because no 30 day waiting period would be necessary. Accordingly, we believe that the Director's review and approval function should be carried out prior to execution of an agreement. In addition, we believe that review function should be carried out by the Subcommittee because of its experience in doing so. If NIH intends to implement such a review through the Subcommittee, the Director, NIH, should delegate his approval authority to the Chairperson of the Subcommittee.*

Listed below are the collaborative research agreements that we and the Patent Branch are currently negotiating with commercial organizations, in which the private concern is requesting exclusive rights to future Government-owned inventions:

---

* The Federal Technology Transfer Act, Pub. L. 99-502, does not require a review by the agency head (in this case the agency head is the Director, NIH, as a result of the delegation). 15 U.S.C. 3710a(c)(5)(A) states that if the agency head "desires" an opportunity to disapprove an agreement or require modification, the agreement "should provide" a 30-day period in which such action must be taken. We believe this authority to review can reasonably be exercised prior to finalization of an agreement, so no clause would be necessary and that the Director, NIH, could delegate the authority to the Chairperson of the Subcommittee.

	Parties	Study
1.	NCI and ICI Americas, Inc. Principal Investigator (PI) -- Dr. Marc E. Lippman.	The Production of Antitumor Factors by Antioestrogen Treated Breast Cancer Cells.
2.	NCI and Hoffman-La Roche PI -- Dr. Ira Pastan.	The design, implementation and evalutation of toxicological studies involving Diltiazem analogs and Tiapamil analogs to determine usefulness as agents to overcome drug resistance in neoplastic cells and cell lines.
3.	NCI and Merck & Co., Inc. PI -- Dr. Ira Pastan.	To study chemical compounds believed to have activity against multi-drug resistance for cancer therapy.
4.	NHLBI and MCM Laboratories, Inc., PI -- Dr. Martin Leon	To study guidance, control and delivery systems for pulsed laser treatment of atherosclerotic cardiovascular disease including fluorescent spectroscopic plague detection.
5.	NCI and Syntex (U.S.A.) PI -- Dr. Lance Liotta	The biology and molecular genetics of tumor invasion and metastasis: the cloning of tumor motility factors, design and synthesis of synthetic peptides to inhibit binding between laminin and laminin receptor.
6.	NCI and Burroughs-Wellcome Co. PI -- Dr. David G. Poplack	Pediatric Phase I trial of Piritrexim and study of the ONS penetration of the compound in subhuman primates.
7.	NIH and Genetics Institute, Inc., PI -- Multiple PIs. Dr. Eaton has lead.	Research using HIV reverse transcriptase enzyme furnished by GI. GI is seeking an option to negotiate an exclusive license.

disease including fluorescent

The foregoing list does not include agreements that are being negotiated with Merck, Bristol-Myers and some other companies toward the development of an AIDS vaccine. The Deputy Assistant Secretary for Health has been taking the lead in negotiating those agreements and will, we assume, continue to do so, even though there is no longer a requirement for ASH approval. Thus, there would not appear to be any need for the Subcommittee to review those agreements.

In addition to the above research agreements, we are also negotiating several agreements that involve nonexclusive licenses to present and future Government-owned inventions. You may also want to consider having the Subcommittee review those agreements during the interim period prior to issuance of the PHS guidelines. Such an agreement would preclude the Government from issuing an exclusive license to another company that at the time of the invention might be in a better position to make it promptly available for health care. Whatever the scope of the Subcommittee's review function, steps should be taken to assure that it meets often enough to review all pending agreements promptly and that the review requirement is communicated to Institute Directors and all others involved in the preparation, negotiation and review of cooperative research and development agreements.

Please call me at 496-4108 if you would like to discuss these matters. Perhaps these topics will be discussed at today's meeting of the Patent Policy Board.

Robert B. Lamman
Legal Advisor, NIH

cc:
Richard Riseberg, OGC
Darrel Grinstead, OGC
Leroy Randall, OGC
Richard Adamson, NCI

Prepared by: GH:TJefferson:RBLamman:bj:bb:10/26/87, 496-4108 DF# 82

TO: NORM LATKER
TEL: 738-0213
FAX: 738-0212

FROM JOE ALLEN
TEL: 377-8100
FAX: 377-0432

PLEASE CALL JOE ASAP
ON US-USSR FRAMEWORK AGREEMENT

DEC. 2-11-88
2:05 pm

For the US-USSR Framework Agreement:

2. If the invention is made by personnel of one Party (the Assigning Party) while assigned to the other Party (the Receiving Party) in the course of cooperation that involves only the visit or exchange of scientific and technical personnel, (such as student or trainee arrangements) unless provided otherwise in an applicable implementing arrangement:

A. The Receiving Party has the right to obtain all rights and interests in the invention in all countries;

B. In any country where the Receiving Party decides not to obtain such rights and interests, the Assigning Party has the right to do so.

3. Specific agreements involving other forms of cooperation, such as ~~specific~~ joint research projects (with agreed research goals / with an agreed research workscope) shall provide for the mutually agreed upon disposition of rights to an invention made as a result of such ~~a special project~~ activity in accordance with the policies of the Parties and their cooperating organizations on an equitable basis.

[redacted]

3/2/88

DRAFT

February 11, 1988

MEMORANDUM FOR VERA CONNOLY
Department of Energy

FROM Michael Levitt
Department of Commerce

SUBJECT Revisions to Superconductivity Competitiveness Act

Thank you for sending your proposed revisions to the Administration's superconductivity legislation. The following are our Department's comments. If you would like to discuss them, please contact me (377-3151) or Ken Clark of my office (377-8843).

Title II:

Section 201(b)(5)(B), at the top of page 3, raises two problems:

-- "marketing or proprietary information" should be "marketing of ..."; and

-- "copyrights and mask works" should be added (after "trade secrets") to the examples of proprietary information explicitly mentioned as being covered by the provision. This will avoid courts' construing this provision (under the "Inclusio unius ...." maxim) as intentionally omitting these important types of intellectual property.

Title III:

A key proviso concerning process patents that we have consistently supported, and which was part of the Administration's original bill, does not appear in the current draft. For reasons discussed below, we strongly recommend that it be re-inserted into the text as the last sentence of section 301(b)(2). The sentence (as we have slightly revised it) should read:

> A product produced by a patented process shall not be considered under this title to have been so produced after it is materially changed by a subsequent process or becomes a minor or nonessential component of another product.

Without such a proviso, the bill is conspicuously more stringent in protecting holders of process patents than are comparable European provisions, which apply only to products "directly" produced using a patented process. Failure to

correct this imbalance will seriously diminish the bill's chances of passage.

We recommend spelling out the intent of the proviso in a sentence rather than simply incorporating the limiting term "directly" into the operative language of the title. This approach ensures that our proviso will be similar to the limitation in European law, but that it will be interpreted independently.

Title IV:

A. Need for Significant Revision of this Title.

We find a number of serious problems with this title. Most importantly, we believe the Administration would compromise its ability to obtain comprehensive protection for intellectual property developed under federal contracts by offering a bill containing no more than a very limited protection against one among many potential sources of compromise of such property.

Specifically, we question:

-- the title's extremely limited focus -- just on possible compromise of information by mandatory FOIA release, and then only in the context of federal "laboratories or similar facilit[ies]";

-- its arbitrary 20 percent contribution test for coverage;

-- its fixed two-year period of information protection, which has no necessary bearing on the statutory or other appropriate time period for protection of proprietary interests; and

-- its failure to establish any basic proprietary rights in technology created by federal funds as a predicate for their protection in the many contexts (beyond FOIA) in which protection is needed.

B. Technical problems with the current draft.

Whatever approach is ultimately chosen to handle the technology protection issues touched upon by the current draft of title IV should ensure coverage of all government laboratories. Section 401(b), as now drafted, would cover only laboratories that are both owned and operated by the Government, such as the Harry Diamond Laboratories and NBS' laboratories in Boulder, Colorado. Important government-owned-contractor-operated ("GOCO") laboratories, such as

Brookhaven, Los Alamos, Berkeley-Livermore and Argonne would be excluded.

Other technical or drafting questions about the current title IV:

-- Why should this provision be limited to "cooperative" agreements? Would this limitation exclude information resulting from a simple contract for "deliverables" involving R&D?

-- Why must the ability of an agency to protect information from mandatory FOIA release await "receipt... of a request" under FOIA? Does this not limit the ability of the agency to give advance assurances to contractors that would encourage cooperative government/private sector R&D? Does this limitation invite errors by forcing agency judgments to be made under FOIA's tight time constraints?

-- What determines "the date ... information is first recorded" for purposes of measuring the two-year FOIA protection limitation? Recording by a private contractor? Transmittal to the agency (i.e., when the information becomes part of an "agency record" under FOIA)?

We had earlier provided to you an alternative provision to the current title IV, involving a more comprehensive approach to implementing the policies of Executive Order 12591. [Among other things, it would have established a right in the Executive Branch to allow its agency laboratories and contractors to create proprietary rights in technical data and computer software generated through federal funding.] On reconsideration, we believe that the comprehensive treatment of these matters may be misplaced in legislation directed primarily to superconductivity research, development, and production. On the other hand, the present title IV, as we have mentioned, contains needless limitations even for application in the context of superconductivity. We ~~would like~~ an arrangement to work with OFPP and DOE to correct these problems with the current draft.

OUT still want to do it w/ phrase

To: NORM LATKER
TeL: 738-0213
FAX: 238-0212

July 1, 1987

FROM: Joe ALLeN
TeL: 377-8100
FAX: 377-0432

14

R. ~~This~~ is ~~revised~~
a revised version
of f.g. 2 of
the business
plan

[redacted]

A BILL

To encourage innovation and productivity, stimulate trade, and promote the competitiveness and technological leadership of the United States.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SEC. 101. This Act may be cited as the "Superconductivity Competitiveness Act".

TITLE II - JOINT PRODUCTION VENTURES

SEC. 201. The National Cooperative Research Act of 1984 (15 U.S.C. 4301 et seq.) is amended by--

(a) striking the term "joint research and development venture" each place it appears and inserting in lieu thereof in each place "joint research, development, or production venture";

(b) in section 2--

(1) striking the word "or" in subparagraph (a)(6)(D);

(2) striking subparagraph (a)(6)(E) and inserting in lieu thereof the following--

"(E) the production of any product in a jointly owned or operated facility, or

"(F) any combination of the purposes specified in subparagraphs (A), (B), (C), (D), and (E),";

(3) in paragraph (a)(6), inserting "development, or production," after "the conducting of research,";

(4) in paragraph (b)(1), striking the words "research and development" and inserting in lieu thereof "research, development, or production"; and

(5) striking paragraphs (b)(2) and (b)(3) and inserting in lieu thereof the following--

"(2) entering into any agreement or engaging in any other conduct pursuant to which the production of any product by such venture is jointly determined by two or more persons who are party to such venture that is not reasonably required to manage such production,

"(3) entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the marketing of any product, process, or service other than--

"(A) the marketing by such venture of any product, process, or service to any person who is a party to such venture, or

[redacted] the marketing or proprietary information developed through such venture, such as patents and trade secrets, and

"(4) entering into any agreement or engaging in any other conduct--

"(A) to restrict or require the production, sale, licensing, or sharing of products, inventions, or developments not produced by or developed through such venture, or

"(B) to restrict or require participation by such party in other research, development, or production activities,

"that is not reasonably required to prevent misappropriation of proprietary information contributed by any person who is a party to such venture or of the results of such venture.";

(c) in section 3, striking the words "research and development markets" and inserting in lieu thereof "research, development, or product markets"; and

(d) in section 6(a), inserting "(or, with respect to a venture involving the production of any product, not later than 90 days after the effective date of the Superconductivity Competitiveness Act)" after "Act".

[redacted] the marketing or proprietary information developed through such venture, such as patents and trade secrets, and

"(4) entering into any agreement or engaging in any other conduct--

"(A) to restrict or require the production, sale, licensing, or sharing of products, inventions, or developments not produced by or developed through such venture, or

"(B) to restrict or require participation by such party in other research, development, or production activities,

"that is not reasonably required to prevent misappropriation of proprietary information contributed by any person who is a party to such venture or of the results of such venture.";

(c) in section 3, striking the words "research and development markets" and inserting in lieu thereof "research, development, or product markets"; and

(d) in section 6(a), inserting "(or, with respect to a venture involving the production of any product, not later than 90 days after the effective date of the Superconductivity Competitiveness Act)" after "Act".

TITLE III - PROCESS PATENTS

SEC. 301. (a) Section 154 of title 35, United States Code is amended by inserting "and, if the invention is a process, of the right to exclude others from using or selling products produced thereby throughout, or importing products produced thereby into, the United States," after "United States,".

(b) Section 271 of title 35, United States Code is amended by--

(1) redesignating subsection (a) as paragraph (a)(1); and

(2) inserting the following after paragraph (a)(1) as redesignated--

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor, a product produced by such process, infringes the patent.".

(c) Section 287 of title 35, United States Code is amended by--

(1) redesignating the section as subsection (a); and

(2) adding after subsection (a) as redesignated the following--

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process,

[redacted] proof that such infringer knew or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

(d)(1) Chapter 29 of title 35, United States Code is amended by adding after section 294 the following--

"§ 295. Presumption; product produced by patented process

"In actions alleging infringement of a process patent based on use, sale, or importation of a product produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the patented process shall be on the party asserting that it was not so produced.".

(2) The table of sections for chapter 29 of title 35, United States Code is amended by adding after the item relating to section 294 the following:

"295. Presumption; product produced by patented process.".

[redacted] Section 301, and amendments made by such section, shall not apply to any product imported into or made in the United States before the date of enactment of this Act.

TITLE IV - SCIENTIFIC AND TECHNICAL INFORMATION PROTECTION

SEC. 401(a). Upon receipt by a Federal agency of a request under section 552 of title 5, United States Code for scientific or technical information, the head of the agency or his designee shall determine whether the information was generated under, or is the subject of, a cooperative research and development agreement between a private party or entity which is contributing at least 20% of the total cost of the project and a laboratory or similar facility that was owned and operated by the Federal government.

(b) Information determined to be generated under, or the subject of, a cooperative research and development agreement between a private party or entity which is contributing at least 20% of the total cost of the project and a laboratory or similar facility that was owned and operated by the Federal government shall be exempt from disclosure under section 552 of title 5, United States Code for a period of two years after the date that information is first recorded.

[redacted] Notwithstanding any other law, an agency is not required to publicly disseminate information described in subsection (b) for a period of two years after the date that information is first recorded.

UNITED STATES DEPARTMENT OF COMMERCE
National Technical Information Service
5285 Port Royal Road
Springfield, Virginia 22161

January 26, 1988

MEMORANDUM FOR: Joseph F. Caponio
Director

SUBJECT: Beringer Memo of January 15

You asked if I had any information on NTIS actions which might have prompted Barry's memo. Two items:

First is the NTIS - Public Health Service agreement covering operation and financing of the patent licensing program. That agreement awaits signature by Assistant Secretary Windom, but I can't believe that it is a source of problem for Barry. It's been in the works for much of the past year, during which time I've made presentations to and had discussions with staff from PHS, the PHS agencies (including NIH, CDC and FDA), the HHS legal office, and the individual institutes at NIH. All of these players, including the NIH institute directors, have cleared and approved the agreement.

Which is a good lead in to the second item. The delegation Barry refers to apparently was signed by Windom without ever having gone through the normal PHS clearance process. Other PHS players, or at least Forbush (the DAS for Health Operations) became aware of the delegation only after it was signed. Forbush's staff is angry because:

- They have substantial problems with the way the delegation violates elements of good management practice. Among other things, the delegation apparently gives authority to NIH institute directors without first giving the authority to the NIH director. That's like Bob Ortner by-passing you and Bruce to delegate some legal authority to me. Dumb.

- They have procedural problems with the way the PHS clearance system was ignored. It sounds like they think Harmisson deliberately sandbagged Forbush.

I got the above information from Ellen Wormser, who heads the PHS Office of Organization and Management Systems. She works for Forbush and has been my primary PHS contact on the patent licensing agreement negotiations. Ellen is now in the process of revising the delegation.

I think Ellen and I are at a point where we can speak in plain English, so I asked if she knew of anything NTIS had done to prompt, urge or otherwise instigate Forbush's and her reaction to the delegation. I think she was a bit insulted, because her basic response was no, and she didn't need NTIS to tell her when a PHS problem needed to be fixed.

Those are the only two items I know of, and we are clean on both of them. But that still doesn't explain why Barry sent his memo.

TOM

Thomas J. Cox, Jr.
Associate Director for
Administration