In many respects, the chain of events that led up to the passage of Bayh-Dole started at the University of Wisconsin in the late 1950's, when Dr. _____ Heidelberger, with funding from Bristol-Myers, discovered the anti-cancer drug 5-fluorouracil (5FU), which remains a cornerstone of chemotherapy to the current time. After Bristol-Myers had introduced the drug into commerce, certain congressional staffers claimed that the patents should have been assigned to the federal government because federal funds had supported part of the work. Subsequent extensive audits revealed that the extent of federal funding was minuscule and, while the Government did not eventually pursue taking title to its ultimate conclusion and license the rights to another company, the result was that companies started to regard research as being "contaminated" if it had been supported in any way by federal funds. This erected a Chinese wall between academic and industrial researchers that would not be finally torn down until the passage of Bayh-Dole in 1980.

Source: Norman Latker, former Chief Patent Counsel to the National Institutes of Health and to the Department of Health, Education and Welfare, Personal

Communication.



Community Technology Fund 80 E. Concord Street, Suite L307C Boston, MA 02118-2139

Ashley J. Stevens, Ph.D. Director, Office of Technology Transfer

Ph: Fax: (617) 638-4540

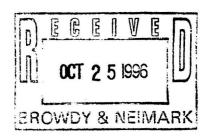
e-mail:

(617) 638-4515 astevens@bu.edu

October 24, 1996

By Facsimile: (202) 737-3528

Norman J. Latker, Esq. Managing Attorney Browdy & Neimark 419 7th Street, Suite 300 Washington, DC 20004



Dear Norm:

It was truly a pleasure talking with you this afternoon and I look forward to further discussions with you in the future. Thank you for your time. I've written to Henry Etzkowitz to tell him about the treasure trove of history in your files and I'll contact you again when I hear back from him.

Enclosed herewith is a short summary of the 5FU story I've written based on our conversation. I would welcome any corrections, amplifications etc. that you care to make.

Yours sincerely,

Enclosure

Sample Lead / Joney Functions

A. Functions Specific to Public Law 96-517:

- Review agency implementation to determine compliance with the Act and OFPP regulations.
- 2. Develop formats and procedures for the collection of utilization information from contractors and grantees. Collect and publish utilization information.
- 3. Provide, as determined necessary, recommendations to OFPP/OMB on changes to Government-wide implementing regulations.
- 4. As part of carrying out of functions of A.I-3, establish and chair an advisory group or groups, including representatives of the agencies and the grantee/contractor community and other private organizations.
- 5. Operate the NTIS Government licensing program under the authority of P.L. 96-517 and provide, when determined necessary, recommendatins on improvements that could be made in this area.

B. General Functions

- 1. Review and evaluate the effectiveness of existing Government policies on the ownership of inventions by Government contractors, and make recommendations to OMB as to how such policies could be improved to more effectively stimulate innovation and productivity.
- Collect and maintain statistics on Government patent policies and practices to provide a base for policy development and evaluation.
- 3. Establish and chair an advisory group or groups, including representatives of agencies and performers of Government research, to discuss issues related to Government policies on ownership of inventions made with Government support. FCSSET & NSF should participate.
- 4. Coordinate administration positions on proposed legislation related to ownership of inventions made with Government support.
- 5. Operate the PTO government-employee invention disposition program and provide, when determined necessary, recommendations on improvements that could be made in this area.

•

THE WHITE HOUSE

Office of the Press Secretary (Los Angeles, California)

For Immediate Release

April 10, 1987

EXECUTIVE ORDER

FACILITATING ACCESS TO SCIENCE AND TECHNOLOGY

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Federal Technology Transfer Act of 1986 (Public Law 99-502), the Trademark Clarification Act of 1984 (Public Law 98-620), and the University and Small Business Patent Procedure Act of 1980 (Public Law 96-517), and in order to ensure that Federal agencies and laboratories assist universities and the private sector in broadening our technology base by moving new knowledge from the research laboratory into the development of new products and processes, it is hereby ordered as follows:

Section 1. Transfer of Federally Funded Technology.

- (a) The head of each Executive department and agency, to the extent permitted by law, shall encourage and facilitate collaboration among Federal laboratories, State and local governments, universities, and the private sector, particularly small business, in order to assist in the transfer of technology to the marketplace.
- (b) The head of each Executive department and agency shall, within overall funding allocations and to the extent permitted by law:
 - (1) delegate authority to its government-owned, government-operated Federal laboratories:
 - (A) to enter into cooperative research and development agreements with other Federal laboratories, State and local governments, universities, and the private sector; and
 - (B) to license, assign, or waive rights to intellectual property developed by the laboratory either under such cooperative research or development agreements and from within individual laboratories.
 - (2) identify and encourage persons to act as conduits between and among Federal laboratories, universities, and the private sector for the transfer of technology developed from federally funded research and development efforts;
 - (3) ensure that State and local governments, universities, and the private sector are provided with information on the technology, expertise, and facilities available in Federal laboratories;

either under such cooperative research or development agreements and from within individual laboratories.

- (2) identify and encourage persons to act as conduits between and among Federal laboratories, universities, and the private sector for the transfer of technology developed from federally funded research and development efforts;
- (3) ensure that State and local governments, universities, and the private sector are provided with information on the technology, expertise, and facilities available in Federal laboratories;
- (4) promote the commercialization, in accord with my Memorandum to the Heads of Executive Departments and Agencies 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, in exchange for royalty-free use by or on behalf of the government;

- (5) implement, as expeditiously as practicable, royaltysharing programs with inventors who were employees of the agency at the time their inventions were made, and cash award programs; and
- (6) cooperate, under policy guidance provided by the Office of Federal Procurement Policy, with the heads of other affected departments and agencies in the development of a uniform policy permitting Federal contractors to retain rights to software, engineering drawings, and other technical data generated by Federal grants and contracts, in exchange for royalty-free use by or on behalf of the government.
- Sec. 2. Establishment of the Technology Share Program. The Secretaries of Agriculture, Commerce, Energy, and Health and Human Services and the Administrator of the National Aeronautics and Space Administration shall select one or more of their Federal laboratories to participate in the Technology Share Program. Consistent with its mission and policies and within its overall funding allocation in any year, each Federal laboratory so selected shall:
- (a) Identify areas of research and technology of potential importance to long-term national economic competitiveness and in which the laboratory possesses special competence and/or unique facilities;
- (b) Establish a mechanism through which the laboratory performs research in areas identified in Section 2(a) as a participant of a consortium composed of United States industries and universities. All consortia so established shall have, at a minimum, three individual companies that conduct the majority of their business in the United States; and
- (c) Limit its participation in any consortium so established to the use of laboratory personnel and facilities. However, each laboratory may also provide financial support generally not to exceed 25 percent of the total budget for the activities of the consortium. Such financial support by any laboratory in all such consortia shall be limited to a maximum of \$5 million per annum.
- Sec. 3. Technology Exchange -- Scientists and Engineers. The Executive Director of the President's Commission on Executive Exchange shall assist Federal agencies, where appropriate, by developing and implementing an exchange program whereby scientists and engineers in the private sector may take temporary assignments in Federal laboratories, and scientists and engineers in Federal laboratories may take temporary assignments in the private sector.
- Sec. 4. International Science and Technology. In order to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad, or an million per annum.
- Sec. 3. Technology Exchange -- Scientists and Engineers. The Executive Director of the President's Commission on Executive Exchange shall assist Federal agencies, where appropriate, by developing and implementing an exchange program whereby scientists and engineers in the private sector may take temporary assignments in Federal laboratories, and scientists and engineers in Federal laboratories may take temporary assignments in the private sector.
- Sec. 4. International Science and Technology. In order to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad,
- (a) The head of each Executive department and agency, when negotiating or entering into cooperative research and development agreements and licensing arrangements with foreign

- (1) to whether such foreign companies or governments permit and encourage United States agencies, organizations, or persons to enter into cooperative research and development agreements and licensing arrangements on a comparable basis;
- (2) to whether those foreign governments have policies to protect the United States intellectual property rights; and
- (3) where cooperative research will involve data, technologies, or products subject to national security export controls under the laws of the United States, to whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls, either through participation in the Coordinating Committee for Multilateral Export Controls (COCOM) or through other international agreements to which the United States and such foreign governments are signatories.
- (b) The Secretary of State shall develop a recruitment policy that encourages scientists and engineers from other Federal agencies, academic institutions, and industry to apply for assignments in embassies of the United States; and
- (c) The Secretaries of State and Commerce and the Director of the National Science Foundation shall develop a central mechanism for the prompt and efficient dissemination of science and technology information developed abroad to users in Federal laboratories, academic institutions, and the private sector on a fee-for-service basis.
- Sec. 5. Technology Transfer from the Department of Defense. Within 6 months of the date of this Order, the Secretary of Defense shall identify a list of funded technologies that would be potentially useful to United States industries and universities. The Secretary shall then accelerate efforts to make these technologies more readily available to United States industries and universities.
- Sec. 6. Basic Science and Technology Centers. The head of each Executive department and agency shall examine the potential for including the establishment of university research centers in engineering, science, or technology in the strategy and planning for any future research and development programs. Such university centers shall be jointly funded by the Federal Government, the private sector, and, where appropriate, the States and shall focus on areas of fundamental research and technology that are both scientifically promising and have the potential to contribute to the Nation's long-term economic competitiveness.
- Sec. 7. Reporting Requirements. (a) Within 1 year from the date of this Order, the Director of the Office of Science and Technology Policy shall convene an interagency task force comprised of the heads of representative agencies and the directors of representative Federal laboratories, or their designees, in order to identify and disseminate creative approaches to technology transfer from Federal laboratories. The task force will report to the President on the progress of and problems with technology transfer from Federal priate, the States and shall focus on areas of fundamental research and technology that are both scientifically promising and have the potential to contribute to the Nation's long-term economic competitiveness.
- Sec. 7. Reporting Requirements. (a) Within 1 year from the date of this Order, the Director of the Office of Science and Technology Policy shall convene an interagency task force comprised of the heads of representative agencies and the directors of representative Federal laboratories, or their designees, in order to identify and disseminate creative approaches to technology transfer from Federal laboratories. The task force will report to the President on the progress of and problems with technology transfer from Federal laboratories.