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TECHNOLOGY TRANSFER COMMERCIALIZATION ACT OF 1998

JULY 14, 1998.—Ordered to be printed

Mr. SENSENBRENNER, from the Committee on Science, submitted the following

REPORT

[To accompany H.R. 2544]

[Including cost estimate of the Congressional Budget Office]

The Committee on Science, to whom was referred the bill (H.R. 2544) to improve the ability of federal agencies to license federally owned inventions, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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I. AMENDMENT

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Technology Transfer Commercialization Act of 1998".

SEC. 2. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Section 12(b)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) is amended by inserting "or, subject to section 209 of title 35, United States Code, may grant a license to an invention which is federally owned, made before the granting of the license, and directly related to the scope of the work under the agreement," after "under the agreement,".

SEC. 3. LICENSING FEDERALLY OWNED INVENTIONS.

(a) AMENDMENT.—Section 209 of title 35, United States Code, is amended to read as follows:

"§ 209. Licensing federally owned inventions

"(a) AUTHORITY.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention only if—

"(1) granting the license is a reasonable and necessary incentive to—

"(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

"(B) otherwise promote the invention's utilization by the public;

"(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical utilization, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

"(3) the applicant makes a commitment to achieve practical utilization of the invention within a reasonable time;

"(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

"(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

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

"(c) SMALL BUSINESS.—First preference for the granting of any exclusive or partially exclusive licenses under this section shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

"(d) TERMS AND CONDITIONS.—Licenses granted under this section shall contain such terms and conditions as the granting agency considers appropriate. Such terms and conditions shall include provisions—

"(1) retaining a nontransferrable, irrevocable, paid-up license for the Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

"(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with; and

"(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that—

"(A) the licensee is not executing its commitment to achieve practical utilization of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has

taken, or can be expected to take within a reasonable time, effective steps to achieve practical utilization of the invention;

"(B) the licensee is in breach of an agreement described in subsection (b);

"(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

"(D) the licensee has been found by a competent authority to have violated the Federal antitrust laws in connection with its performance under the license agreement.

"(e) PUBLIC NOTICE.—No exclusive or partially exclusive license may be granted under this section unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

"(f) BASIC BUSINESS PLAN.—A Federal agency may grant a license on a federally owned invention only if the person requesting the license has supplied to the agency a basic business plan with development milestones, commercialization milestones, or both.

"(g) NONDISCLOSURE OF CERTAIN INFORMATION.—Any basic business plan, and revisions thereto, submitted by an applicant for a license, and any report on the utilization or utilization efforts of a licensed invention submitted by a licensee, shall be treated by the Federal agency as commercial and financial information obtained from a person and not subject to disclosure under section 552 of title 5, United States Code.".

(b) CONFORMING AMENDMENT.—The item relating to section 209 in the table of sections for chapter 18 of title 35, United States Code, is amended to read as follows:

"209. Licensing federally owned inventions.".

SEC. 4. TECHNICAL AMENDMENTS TO BAYH-DOLE ACT.

Chapter 18 of title 35, United States Code (popularly known as the "Bayh-Dole Act"), is amended—

(1) by amending section 202(e) to read as follows:

"(e) In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention—

"(1) license or assign whatever rights it may acquire in the subject invention from its employee to the nonprofit organization or small business firm; or

"(2) acquire any rights in the subject invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction."; and

(2) in section 207(a)—

(A) by striking "patent applications, patents, or other forms of protection obtained" and inserting "inventions" in paragraph (2); and

(B) by inserting ", including acquiring rights for the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention" after "or through contract" in paragraph (3).

SEC. 5. TECHNICAL AMENDMENTS TO THE STEVENSON-WYDLER TECHNOLOGY INNOVATION ACT OF 1980.

Section 14(a)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710c(a)(1)) is amended—

(1) in subparagraph (A)(i), by inserting ", if the inventor's or coinventor's rights are assigned to the United States" after "inventor or coinventors"; and

(2) in subparagraph (B), by striking "succeeding fiscal year" and inserting "2 succeeding fiscal years".

SEC. 6. REVIEW OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT PROCEDURES.

(a) REVIEW.—The Director of the Office of Science and Technology Policy, in consultation with relevant Federal agencies, national laboratories, and any other

person the Director considers appropriate, shall review the general policies and procedures used by Federal agencies to gather and consider the views of other agencies on—

(1) joint work statements under section 12(c)(5)(C) or (D) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(c)(5)(C) or (D)); or

(2) in the case of laboratories described in section 12(d)(2)(A) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(d)(2)(A)), cooperative research and development agreements under such section 12,

with respect to major proposed cooperative research and development agreements that involve critical national security technology or may have a significant impact on domestic or international competitiveness.

(b) PROCEDURES.—Within one year after the date of the enactment of this Act, the Director of the Office of Science and Technology Policy, in consultation with relevant Federal agencies and national laboratories, shall—

(1) determine the adequacy of existing procedures and methods for interagency coordination and awareness; and

(2) establish and distribute to appropriate Federal agencies—

(A) specific criteria to indicate the necessity for gathering and considering the views of other agencies on joint work statements or cooperative research and development agreements as described in subsection (a); and

(B) additional procedures, if any, for carrying out such gathering and considering of agency views.

Procedures established under this subsection shall be designed to the extent possible to use or modify existing procedures, to minimize burdens on Federal agencies, to encourage industrial partnerships with national laboratories, and to minimize delay in the approval or disapproval of joint work statements and cooperative research and development agreements.

II. PURPOSE OF THE BILL

The purpose of H.R. 2544, as reported, is to promote the transfer and commercialization of the technology created in our Nation's system of over 700 federal laboratories, thereby increasing scientific collaboration between federal laboratories and private industry. Specifically, the reported bill improves and streamlines the ability of federal agencies to license federally owned inventions.

III. BACKGROUND AND NEED FOR THE LEGISLATION

For nearly 2 decades, the Committee has encouraged the transfer to United States private industry of unclassified technology created in our federal laboratories. Our federal laboratories have long been considered one of our greatest scientific research and development resources, employing one of every six scientists in the country and encompassing one-fifth of the country's laboratory and equipment capabilities. Effectively capturing this wealth of ideas and technology from our federal laboratories, through the transfer to private industry for commercialization, has helped to bolster our Nation's ability to compete in the global marketplace.

By permitting effective collaboration between our federal laboratories and private industry, new technologies can be rapidly commercialized. Federal technology transfer stimulates the American economy, enhances the competitive position of United States industry internationally, and promotes the development and use of new technologies developed under taxpayer funded research so those innovations are incorporated rapidly and effectively into practice to the benefit of the American public.

To help further these goals, the Committee first reported the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law 96–480). The Committee expanded on that landmark legislation with the passage of the Federal Technology Transfer Act of 1986 (Public

Law 99–502), the National Competitiveness Technology Transfer Act of 1989 (Public Law 101–189), the American Technology Preeminence Act of 1991 (Public Law 102–245), and the National Technology Transfer and Advancement Act of 1995 (Public Law 104–113), among others.

In 1980, the Committee also reported the University and Small Business Patent Procedures Act, now commonly referred to as the Bayh-Dole Act (Public Law 96–517). The Bayh-Dole Act permits universities, not-for-profit organizations, and small businesses to obtain title to scientific inventions developed with Federal Government support. The Bayh-Dole Act also allows federal agencies to license government-owned patented scientific inventions nonexclusively, partially exclusively, or exclusively, depending upon which avenue seems to be the most effective means for achieving commercialization. Additionally, the Committee reported out amendments to the Bayh-Dole Act in the Trademark Clarification Act of 1984 (Public Law 98–620), which permitted decisions on the awarding of licenses for patents to be made at the laboratory level in a government-owned, contractor-operated laboratory (GOCO).

Critical pressures prompted the passage of the Bayh-Dole Act. Prior to its enactment, many of the discoveries that resulted from federally-funded scientific research were not commercialized for the benefit of the American public. Since the Federal Government lacked the resources to market new innovations, and private industry was reluctant to make high-risk investments without the protection of patent rights, many valuable new innovations were left to sit unused on the shelf at federal laboratories.

Widely viewed as an effective framework for federal technology transfer, the Bayh-Dole Act has resulted in successful patent licensing. In a report submitted to the Committee, the Association of University Technology Managers (AUTM) conducted a 1996 study on the effect of the Bayh-Dole Act. AUTM concluded that the law garnered tremendous economic benefits not just for the universities and private industry directly involved in each partnership, but more importantly, for the United States economy as a whole. The AUTM report documented that the effect of the Bayh-Dole Act represented a very real gain to federal agencies and the Nation since it not only encourages the commercialization of government-owned patents that would otherwise gather dust on the shelf, but it also brings in revenues to the Federal Government through licensing fees.

Accordingly, the process for the licensing of government-owned patents should continue to be refined by streamlining the procedures and by removing the uncertainty associated with the licensing process. Both past and prospective private industry partners, however, have voiced their concerns regarding the licensing process. They indicate that the strategic advantages of acquiring intellectual property rights through a Cooperative Research and Development Agreement (CRADA) and/or the licensing of government-owned technology are unfortunately offset by the delays and uncertainty often associated with the lengthy federal technology transfer process which is often out of sync with private sector timing. In addition to the added uncertainty as to whether the license will be

granted, these procedural barriers increase transaction costs and delay commercialization.

The present regulations also make it difficult for a government-owned and government-operated laboratory (GOGO) to bring existing scientific inventions into a CRADA even when inclusion would create a more complete technology package. A GOGO does not have the flexibility that small businesses and non-profits have in managing their inventions under the Bayh-Dole Act. Also, a GOGO, unlike a GOCO, currently faces statutory notification provisions when granting exclusive licenses, and more importantly, it cannot include existing inventions in a CRADA under the Federal Technology Transfer Act of 1986.

By reducing the delay and uncertainty imposed by existing procedural barriers and thus lowering the transactional costs associated with licensing technology transfer from federal laboratories, federal agencies could greatly increase participation by the private sector in their technology transfer programs. This approach would expedite the commercialization of the government-owned invention and reduce the cost to the American taxpayer for the production of new technology-based products.

IV. Summary of Hearings

September 25, 1997: "Promoting Technology Transfer by Facilitating Licenses to Federally Owned Inventions"

On September 25, 1997, the Subcommittee on Technology held a hearing on "Promoting Technology Transfer by Facilitating Licenses to Federally Owned Inventions." The hearing was held to discuss the effectiveness of our federal technology transfer laws and methods in which they may be improved, and to review H.R. 2544, the Technology Transfer Commercialization Act of 1997, which seeks to promote technology transfer by facilitating licenses to federally-owned inventions. Witnesses included: Mr. Joe Allen, Vice President, Market and Technology Assessment, National Technology Transfer Center, Wheeling, WV; Mr. C. Dan Brand, Chair, Federal Laboratory Consortium, Jefferson, AR; Mr. Dan Passeri, Vice President, Business Development and Intellectual Property, Gene Logic, Inc., Columbia, MD; and Mr. John G. Mannix, Associate General Counsel, National Aeronautics and Space Administration, NASA Headquarters, Washington, DC.

Mr. Joe Allen, testifying as Vice President, Market and Technology Assessment, National Technology Transfer Center, stated that linking federal laboratories and universities with American industry holds great promise for our future economic prosperity. Mr. Allen asserted that the passage of the Bayh-Dole Act in 1980, initially considered a bold and radical idea, is now a model that our economic competitors are emulating. This legislation holds the same promise. However, Mr. Allen believes that in order to license government-owned inventions, the Congress must ease the current complex system which a company must go through. For example, a company must publish in the Federal Register its intention to pursue a federally-owned license. Companies, however, are reluctant to do this as it effectively gives away their marketing strategy. In conclusion, Mr. Allen recommended taking a well thought out

incremental approach, such as H.R. 2544, that simplifies current procedures while retaining important safeguards.

Mr. Daniel R. Passeri, testifying as Vice President, Gene Logic, Inc., spoke of the importance for the Federal Government to streamline the procedures and remove the uncertainty associated with the licensing determination process. In doing so, the Federal Government will foster an attractive environment for corporate investment and partnering efforts. Mr. Passeri believes that under the current system there is a tension between the needs of industry to rapidly respond to market demands and opportunities, and the procedural requirements of federal agencies in regards to the exclusive licensing of high risk, early stage technology. He stated that these procedural barriers create increased transaction costs, delays in obtaining the license, as well as the uncertainty of actually being granted the license. The barriers, however, do not exist in university technology transfer. In conclusion, Mr. Passeri welcomed H.R. 2544's proposed improvements to the current law and indicated that in their current form, they will address the frustrations of industry.

Mr. C. Dan Brand, testifying as Chair, Federal Laboratory Consortium, spoke of the Federal Laboratory Consortium's (FLC) importance as the nationwide network of federal laboratories who provide a forum to develop strategies and opportunities for linking government technology to the marketplace. Mr. Brand stated that in advance of this hearing, the FLC solicited and received comments from a number of their member departments and agencies on removing legal obstacles to effectively license federally-owned inventions. He cautioned that these are not an "official" department or agency position, but rather an initial assessment. Mr. Brand stated the FLC's belief, as well as those comments received from departments and agencies, is that the amendments to the Bayh-Dole Act will serve to speed transfer and commercialization of technologies to industry, while maintaining a fair and open competitive environment. Mr. Brand further cautioned that while the initial input from member laboratories was largely positive, the Subcommittee should also consider the views of the FLC Legal Issues Committee and the National Institutes of Health.

Mr. John G. Mannix, testifying as Associate General Counsel, Intellectual Property, National Aeronautics and Space Administration, began by stating that neither NASA nor the Administration had an opportunity to completely review the proposed legislation so neither has had an opportunity to formulate a detailed position. However, Mr. Mannix asserted that having learned many lessons over the years in this regard, he would hope NASA's position would be considered before any changes in the law were made. Mr. Mannix highlighted the two major improvements to the licensing process that he has seen during his career. First, he cited the increased personal involvement of technical experts, and individuals with marketing, negotiation, and business experience in the licensing process. Second, he emphasized the importance of the statutory authority given to NASA negotiators to require written commercialization plans and yearly status reports describing progress toward commercialization. Additionally, Mr. Mannix emphasized the importance of providing some form of notice of the availability of

federally owned licenses. Without such a notice, Mr. Mannix maintained, we will always be subject to claims of favoritism.

March 17, 1998: "Facilitating Licenses to Federally-Owned Inventions: A Legislative Hearing on H.R. 2544, the Technology Transfer Commercialization Act"

On March 17, 1998, the Subcommittee on Technology held a hearing on "Facilitating Licenses to Federally-Owned Inventions: A Legislative Hearing on H.R. 2544, the Technology Transfer Commercialization Act." The hearing was held to review H.R. 2544, the Technology Transfer Commercialization Act of 1997, which seeks to promote technology transfer by facilitating licenses to federally-owned inventions. Witnesses included: The Honorable Ray Kammer, Director, National Institute of Standards and Technology, Gaithersburg, MD; Mr. Randolph J. Guschl, Director of Technology Acquisitions, Central Research and Development, DuPont Chemical Company, Wilmington, DE; Ms. Elizabeth Kraftician, Chief Executive Officer, Touchstone Research Laboratory, Tridelphia, WV.

The Honorable Ray Kammer, testifying as Director, National Institute of Standards and Technology explained the newly formed Interagency Committee on Technology Transfer and the consensus of this Committee on H.R. 2544. Specifically, Mr. Kammer emphasized the need to pay closer attention to the output side of R&D spending. While a greater pecuniary commitment to R&D spending is laudable, the end result is equally important. Further, enabling end results to make their way to the marketplace is equally important, as they can have important societal benefits. He also spoke of the Interagency Committee's suggestions regarding certain provisions of the legislation. For example, the agencies suggest the licensees be subject to the same current notification requirements and the need to retain current requirements for licensees to submit development or marketing plans. Mr. Kammer emphasized the importance of utilizing those plans as an objective basis for deciding whether the prospective licensee is likely to quickly bring the innovation to market. Additionally, bundling innovations should be addressed in the legislation and Mr. Kammer spoke of the improved ability to streamline and allow licensees to derive maximum commercial benefit from inventions by "bundling" similar innovations together. In conclusion he indicated that industry and the government are still learning how to better work together in commercializing the American people's investment in R&D.

Mr. Randolph J. Guschl, testifying as Director, Technology Acquisitions, Central Research and Development, DuPont, Wilmington, DE, expressed support for the legislation and highlighted the fact that H.R. 2544 puts the discoveries of government-owned, government-operated (GOGO) laboratories on terms equal to those of government-owned, contractor operated (GOCO) laboratories. However, Mr. Guschl indicated he had a couple of ideas regarding the legislation. First, revise the wording regarding U.S. manufacture. Better language would require the earliest possible deployment in the United States, but not require it to be substantially manufactured in the United States. This would allow U.S. businesses to compete globally, thereby strengthening the U.S. components of international companies. Second, he supports the bill's recognition

of exclusivity. This provision has been used in GOCO labs and should also be used in GOGO labs. Third, he support the bill's shift from 90+60 day notification process to a 30 day notification process. Fourth, retain requiring submission of a business and marketing plan. This allows agency to determine commitment of prospective licensees. Lastly, consider empowering the technology transfer directors to make quick and final decisions for their labs, but also allow there to be a quick appeals process. In conclusion, Mr. Guschl suggested support for the legislation and commended its improvement of the technology transfer process.

Ms. Elizabeth Kraftician, Chief Executive Officer, Touchstone Research Laboratory, offered her strong support for H.R. 2544. Ms. Kraftician believes this legislation will have a strong impact in moving federal technologies to the marketplace. Additionally, Ms. Kraftician expressed support for this legislation as a way to benefit small businesses in this technology transfer process. Small businesses have traditionally been locked out of the technology transfer arena by the slow, cumbersome, bureaucratic and oftentimes anti-small business process by which Federal Government has traditionally transferred technology to the marketplace. Ms. Kraftician applauded especially H.R. 2544's leveling the notification playing field by allowing advertisement in a wider variety of venues which gives the federal laboratory greater flexibility and no longer forces small business to rely exclusively on the Federal Register. In conclusion, Ms. Kraftician emphasized that in order for this legislation to work, public institutions must be held accountable for how they wield the authorities they are given. With respect to technology transfer, public agencies must be willing to make decisions and take risks.

V. Committee Actions

Subcommittee Markup

On March 26, 1998, the Technology Subcommittee convened to consider H.R. 2544, as introduced. Two amendments were offered and accepted by the Subcommittee. The Subcommittee approved an amendment offered by Mr. Barcia of Michigan and an amendment by Mr. Cook of Utah by voice vote. Both amendments reflected consensus revisions as requested by the Administration. With a quorum present, Mr. Barcia moved that H.R. 2544, as amended, be reported. The motion was adopted by voice vote.

Committee Markup

On May 13, 1998, the Science Committee convened to consider H.R 2544. An Amendment in the Nature of a Substitute, offered by Chairman Sensenbrenner of Wisconsin, was adopted by voice vote. The amendment made technical and conforming changes to H.R. 2544 and added Section 6 (Review of Cooperative Research and Development Agreement Procedures), sponsored by Mrs. Tauscher of California, to the bill. With a quorum present, Mr. Brown moved that H.R. 2544, as amended, be reported. The motion was adopted by voice vote.

VI. Summary of Major Provisions of the Bill

The goal of H.R. 2544 is to remove the procedural obstacles and to the greatest extent possible, within the limits of the public interest, the uncertainty involved in the licensing of government-owned patented inventions created in a GOGO, by applying the successful GOCO provisions in the Bayh-Dole Act to a GOGO. In H.R. 2544, federal agencies would be provided with two important new tools for effectively commercializing on-the-shelf, government-owned inventions: (1) the bill's revised authorities of Section 209 of the Bayh-Dole Act; and (2) the ability to license technology as part of a CRADA. Both mechanisms make federal technology transfer programs much more attractive to United States private industries that seek to form partnerships with federal laboratories. H.R. 2544, as amended, also makes a number of smaller adjustments to the Bayh-Dole Act and the Stevenson-Wydler Act, which are designed to improve these laws, reflecting a series of consensus "lessons learned" during 18 years of experience in technology transfer.

VII. Section-by-Section Analysis

SECTION 1. SHORT TITLE.

The Act shall be called the "Technology Transfer Commercialization Act of 1997."

SECTION. 2. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Section 2 amends the Stevenson-Wydler Technology Innovation Act of 1980 by setting out the circumstances under which federal laboratories may license existing patented inventions as part of a Cooperative Research and Development Agreement (CRADA). The federal laboratory may, subject to Section 209 of title 35 of the United States Code, grant a license to a federally-owned invention, created prior to the granting of the license, if it is directly related to the scope of the work under the agreement.

SECTION 3. LICENSING FEDERALLY OWNED INVENTIONS.

Section 3 rewrites Section 209, title 35 of the United States Code preserving existing preferences while streamlining notice and other procedural requirements.

Subsection 3(a) provides that a federal agency may grant an exclusive or partially exclusive license to a federally owned invention only if granting the license is a reasonable and necessary incentive for commercialization or to promote the invention's utilization by the public. The federal agency must find that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application within a reasonable time or otherwise promote the invention's utilization by the public. The proposed scope of an exclusive or partially exclusive license should not be greater than reasonably necessary. The granting of the license should not substantially lessen competition or create or maintain a violation of the antitrust laws, and in the case of an invention covered by a foreign patent application or patent, must enhance interests of United States industry in foreign commerce.

Subsection 3(b) provides that licenses should be granted only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

Subsection 3(c) provides that the first preference for the granting of licenses should be given to small businesses that have an equal or greater likelihood as other applicants to bring the invention to commercialization within a reasonable time.

Subsection 3(d) provides certain terms and conditions required for licenses, as the granting agency considers appropriate. These include: retaining a nontransferable, irrevocable, paid-up license for a federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the United States; periodic reporting on the use of the invention and commercialization efforts by the licensee, but only to the extent necessary to enable the federal agency to determine whether the terms of the license are being complied with; and providing "march-in rights" that empower a federal agency to terminate the license, in whole or in part, if it determines that the licensee is not adequately executing its commitment to achieve practical utilization of the invention within a reasonable time, if the licensee is in breach of the substantial United States manufacture requirement, if termination is necessary to meet the public use requirements specified by federal regulations issued after the grant of the license, or if the licensee has been found by a competent authority to have violated federal antitrust laws.

Subsection 3(e) provides that no exclusive or partially exclusive license may be granted unless public notice of the intention to grant such a license has been provided in an appropriate manner at least 15 days before the license is granted and the federal agency has considered all comments received in response to that public notice. Subsection 3(e), however, shall not apply to the licensing of inventions made under a CRADA entered into under Section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

Section 3(f) provides that a federal agency may grant a license on a federally-owned invention only if the licensee has supplied a basic business plan with development milestones and/or commercialization milestones.

Section 3(g) provides that any basic business plan submitted by an applicant for a license, and any report on the utilization of the invention, shall be treated as commercial and financial information and not subject to disclosure under the Freedom of Information Act.

SECTION 4. TECHNICAL AMENDMENTS TO BAYH-DOLE ACT.

Section 4 provides that a federal agency, employing a coinventor of any invention made under a funding agreement with a non-profit organization or small business, may consolidate rights in the invention to ease commercialization of the invention. Consolidation under Section 4 may occur either by a federal agency licensing or assigning rights or by the federal agency acquiring rights related to the invention.

SECTION 5. TECHNICAL AMENDMENTS TO THE STEVENSON-WYDLER TECHNOLOGY INNOVATION ACT OF 1980.

Section 5 clears up an ambiguity in current law by providing that the rights of the inventors must be assigned to the Federal Government in order for the inventors to share royalties and that the federal agency may retain royalty income for 2 succeeding fiscal years.

SECTION 6. REVIEW OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT PROCEDURES.

Section 6 provides the Director of the Office of Science and Technology Policy (OSTP), in consultation with relevant national laboratories, shall review the general policies and procedures used by federal agencies to gather and consider the views of other agencies with respect to major proposed Cooperative Research and Development Agreements (CRADA) that involve critical national security technology or may have a significant impact on domestic or international competitiveness. Within 1 year after the date of enactment, the Director of OSTP, in consultation with relevant federal agencies and national laboratories, shall determine the adequacy of existing procedures and methods for interagency coordination and awareness, and establish and distribute to appropriate federal agencies specific criteria to indicate the necessity for gathering and considering the views of other agencies and additional procedures, if any, for carrying out such gathering and considering of agency views. Procedures established shall be designed to the extent possible to use or modify existing procedures, to minimize burdens on federal agencies, to encourage industrial partnerships with national laboratories, and to minimize delay in the approval or disapproval of collaborative relationship with federal laboratories and private industry.

VIII. Committee Views

SECTION 1. SHORT TITLE.

The Act may be cited as "The Technology Transfer Commercialization Act of 1998."

SECTION. 2. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

The Committee recognizes the success of Cooperative Research and Development Agreements (CRADA) for federal technology transfer. Since the inception in 1986 of the CRADA legislation, over 2,000 have been signed, resulting in the transfer of technology, knowledge, and expertise back and forth between our federal laboratories and the private sector. The Committee believes that the broadening of CRADA licensing authority to include pre-existing inventions will make a CRADA more attractive to private industry and increase the transfer of federal technology.

SECTION 3. LICENSING FEDERALLY OWNED INVENTIONS.

While the Committee does not wish to delay the process of issuing exclusive or partially exclusive licenses, the Committee recognizes the importance of public notice. Public notice provides others knowledge of the proposed license and provides an opportunity to comment. The Committee understands that notice of this type has helped the federal agencies find additional or better licensees

than those first proposed. The Committee is more concerned with the effectiveness of notice than its form; public notice should not be construed to require publication in the Federal Register. Other available forms, including electronic forms, of making public the intention to grant an exclusive or partially exclusive license on a federally owned invention should be pursued. The Committee strongly encourages federal agencies to use the Internet to meet the public notice requirement in the Act.

The Committee also recognizes that requiring a basic business plan as part of the application for a license gives the federal agencies an objective basis for selecting the private industry firm best suited to commercialize the invention. The exercise of preparing the plan is also of considerable use in assisting companies, especially small businesses, in defining their own focus with respect to the invention; it also gives agencies valuable insights into the comparative abilities of companies competing for a single license and a more precise understanding of the specific field of use needed to execute a company's commercialization plan. The Committee strongly believes, however, the basic business plan should not be an overly burdensome bureaucratic requirement. A business plan under this section should not be required to include extraneous materials but rather should be specifically focused on providing the federal agency the information it needs to make licensing decisions and to understand the development and commercialization milestones the company plans to meet.

The Committee believes that business plans submitted by a private industry in the licensing process, as well as progress reports under the license such as reports on utilization and utilization efforts should be treated by the federal agency as commercial and financial information not subject to the Freedom of Information Act and should be entitled to protection from disclosure. The Committee understands that, absent protection of its proprietary information, private industry would otherwise be very reluctant to partner with federal laboratories which would cause a chilling effect on federal technology licensing.

SECTION 4. TECHNICAL AMENDMENTS TO BAYH-DOLE ACT.

The Bayh-Dole Act defines the patent rights of small business and non-profit organizations receiving Federal Government funding. A significant percentage of government inventions are co-invented with federally-funded parties, most commonly university researchers. It is often necessary consolidate rights to such co-inventions, under appropriate licenses or assignments, to achieve public benefit through commercialization. Depending on the specific circumstances, it may be advantageous for the unified rights and patent prosecution responsibility to reside with either the co-inventing entity or the federal agency. The Committee believes that the Bayh-Dole Act should be amended to make it clear that both the agency and the co-inventing entity have authority to enter into license agreements with one another in these circumstances.

While Bayh-Dole currently provides specific authority for the Federal Government to assign its rights in a subject co-invention to the co-inventing entity, it does not mention the licensing of such rights. The Committee understands that the absence of specific authority to license in those circumstances has resulted in inconsist-

ent rulings by federal agencies, with some approving such licenses while others reject them. The Bayh-Dole Act is accordingly amended to provide a mechanism whereby the co-inventing entity can voluntarily transfer its rights by license or assignment to the federal agency in return for a share of any subsequent income.

The Committee understands that it is increasingly necessary for an agency to be able to offer a potential licensee access to related inventions in order to practice a government-owned invention. There is, however, no mechanism whereby an agency can "in-license" the rights to related inventions, in return for the payment of a share of any subsequent royalties, so that they can be "bundled" with a government-owned invention and licensed together for commercialization. This section adds in such language.

SECTION 5. TECHNICAL AMENDMENTS TO THE STEVENSON-WYDLER TECHNOLOGY INNOVATION ACT OF 1980.

The Committee understands that there have been widely differing federal agency interpretations regarding whether the rights of the inventors must be assigned to the Federal Government in order for them to share royalties. For example, some federal agencies share with all inventors even though they have not assigned their rights to the Federal Government, while others do not share with non-government inventors who have assigned their rights. Under this section, royalty shares will be due only after assignment of rights by the inventor or co-inventor.

The Committee also understands that there is confusion on how long an agency may retain royalty income. Accordingly, the Committee clarified that federal agencies should be given 2 fiscal years to retain royalty income before transferring outstanding royalty income, if any, to the general treasury.

SECTION 6. REVIEW OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT PROCEDURES.

The Committee is pleased with the blossoming of the CRADA concept into a major tool for industry-government cooperation. At the same time, the Committee has heard of concerns that major, far-reaching CRADA's may now have outgrown the current CRADA approval process. A CRADA, as envisioned at the time of the passage of the Federal Technology Transfer Act of 1986, was designed to help move individual ideas from the federal laboratories into the private sector or lead to cooperation between industry and government labs in areas of mutual interest. A common benefit of such agreements has been the acquisition by small businesses of the technological expertise necessary to succeed that otherwise may not have been available to them. These CRADA's are small enough that they do not raise national issues; therefore, the appropriate approval process is one which is executed quickly without high level signoffs. Most current CRADA's are still of this type and should be approved in the traditional manner.

However, in recent years, a handful of major CRADA's have emerged which involve cutting edge technology, the world's largest companies, and occasionally consortia of federal laboratories. Some recent CRADA's are important enough that they have the potential to affect the future direction of entire industries including their suppliers. These CRADA's generally have a positive impact on the laboratories and companies which participate and should be en-

couraged. However, the issues raised by these major CRADA's if they involve critical national security technology (classified technology or technology subject to export controls), domestic competitiveness issues (competitive advantage for market leaders), or international competitiveness (participation by foreign companies or foreign suppliers) can go beyond the expertise of the laboratory's home agency.

The Committee understands that there are instances where foreign participation and special relations with market leaders are desirable or even essential to the success of a CRADA, but other values within the jurisdiction of other agencies, like the effect on other U.S. companies and the impact on present and future jobs within the United States, must be considered. The Committee, therefore, believes that a careful review, and upgrading if necessary, of existing approval procedures for these major CRADA's with interagency consequences is in order.

Section 6, therefore, instructs the Director of the White House Office of Science and Technology Policy to convene representatives of appropriate federal agencies such as the Office of Management and Budget, the Department of Defense, the Department of Energy, the Department of Commerce, the National Institutes of Health, and NASA and other affected parties to review current approval procedures for these major CRADA's. Special care is to be taken to understand the needs of private sector parties. OSTP is to identify criteria to separate out the small minority of major CRADA's which need interagency review from those which do not. For instance, it makes sense to review only the very largest CRADA's for domestic competitiveness issues. This review is to understand the procedures that currently apply to major CRADA's and the extent to which they lead to a satisfactory airing of national security, domestic competitiveness, and international competitiveness issues.

Within 1 year of enactment, the Director of OSTP is to determine the adequacy of existing procedures and methods for interagency coordination and awareness and to use them as the starting point for procedures established under this section. The Director then is to establish and distribute to appropriate federal agencies specific criteria for triggering an interagency review and procedures for carrying out that review in an expeditious manner. The procedures are to reflect the needs of the private sector parties for prompt, binding decisions on CRADA's and the significant investments private sector partners commit to such endeavors. Existing procedures are to be used to the extent that they are appropriate. The purpose of these changes is to solve potential problems through better interagency coordination rather than to add layers of review. OSTP is to add new procedures only to the extent that existing procedures are inadequate, and to assure that any new procedures lead to expedited, substantive interagency decisions within the spirit of the CRADA concept. Section 6 does not modify any statutory deadlines for CRADA approval and does not grant authority to the OSTP or other agencies to establish a review board or other new bureaucratic structure to carry out this section.

IX. Committee Cost Estimate

Clause 7(a) of Rule XIII of the Rules of the House of Representatives requires each Committee report accompanying each bill or joint resolution of a public character to contain: (1) an estimate, made by such Committee, of the costs which would be incurred in carrying out such bill or joint resolution in the fiscal year in which it is reported, and in each of the 5 fiscal years following such fiscal year (or for the authorized duration of any program authorized by such bill or joint resolution, if less than 5 years); (2) a comparison of the estimate of costs described in subparagraph (1) of this paragraph made by such Committee with an estimate of such costs made by any government agency and submitted to such Committee; and (3) when practicable, a comparison of the total estimated funding level for the relevant program (or programs) with the appropriate levels under current law. However, clause 7(d) of that Rule provides that this requirement does not apply when a cost estimate and comparison prepared by the Director of the Congressional Budget Office under Section 403 of the Congressional Budget Act of 1974 has been timely submitted prior to the filing of the report and included in the report pursuant to clause 2(l)(3)(C) of Rule XI. A cost estimate and comparison prepared by the Director of the Congressional Budget Office under Section 403 of the Congressional Budget Act of 1974 has been timely submitted prior to the filing of this report and included in Section X of this report pursuant to clause 2(l)(3)(C) of Rule XI.

Clause 2(l)(3)(B) of Rule XI of the Rules of the House of Representatives requires each Committee report that accompanies a measure providing new budget authority (other than continuing appropriations), new spending authority, or new credit authority, or changes in revenues or tax expenditures to contain a cost estimate, as required by Section 308(a)(1) of the Congressional Budget Act of 1974 and, when practicable with respect to estimates of new budget authority, a comparison of the total estimated funding level for the relevant program (or programs) to the appropriate levels under current law. H.R. 2544 does not contain any new budget authority, credit authority, or changes in revenues or tax expenditures. Assuming that the sums authorized under the bill are appropriated, H.R. 2544 does authorize additional discretionary spending, as described in the Congressional Budget Office report on the bill, which is contained in Section X of this report.

X. Congressional Budget Office Cost Estimate

Congressional Budget Office
U.S. Congress
Washington, DC. 20515
June E. O'Neill, Director

May 21, 1998

Honorable F. James Sensenbrenner, Jr.,
Chairman, Committee on Science,
U.S. House of Representatives,
Washington, DC. 20515

Dear Mr. Chairman:

The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2544, the Technology Transfer Commercialization Act of 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Kathleen Gramp, who can be reached at 226-2860.
Sincerely,

JUNE E. O'NEILL

Enclosure

cc: Honorable George E. Brown, Jr., Ranking Minority Member

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

MAY 21, 1998

H.R 2544

TECHNOLOGY TRANSFER COMMERCIALIZATION ACT OF 1998

As ordered reported by the House Committee on Science on May 13, 1998

H.R. 2544 would amend existing law regarding the licensing of technologies developed with federal resources. This bill would change the terms and procedures governing such licenses and would expand the scope of inventions that could be included in a license. Royalties collected by federal agencies would be available for obligation for 2 years after they are received rather than the one year allowed under current law. The bill also would direct the Office of Science and Technology Policy (OSTP) to analyze and recommend policies regarding major cooperative research and development agreements (CRADAs) within one year after enactment.

CBO estimates that implementing H.R. 2544 would have no significant effect on the federal budget over the 1999–2003 period. Based on information from OSTP, we expect that preparing the report on CRADAs would involve little additional cost because most of the analyses required by the bill are being done under current law. Provisions affecting the collection and spending of royalties by federal agencies would affect direct spending, so pay-as-you-go procedures would apply to this bill, but CBO estimates that the effects would not be significant. Although receipts from royalties could increase if more licenses are issued as a result of this legislation, any additional collections would be offset by an increase in direct spending by agencies for payments to inventors or for related agency programs. Likewise, giving agencies an additional year to obligate royalty income would have little effect on direct spending, because agencies obligate virtually all of the receipts within the one-year limit specified in current law.

H.R. 2544 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act of 1995 and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Kathleen Gramp, who can be reached at 226–2860. This estimate was approved by Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

XI. COMPLIANCE WITH PUBLIC LAW 104–4

H.R. 2544 contains no unfunded mandates.

XII. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

Clause 2(l)(3)(A) of Rule XI of the Rules of the House of Representatives requires each Committee report to include oversight findings and recommendations required pursuant to clause 2(b)(1) of Rule X. The Committee has no oversight findings.

XIII. OVERSIGHT FINDINGS AND RECOMMENDATIONS BY THE COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Clause 2(l)(3)(D) of Rule XI of the Rules of the House of Representatives requires each Committee report to contain a summary of the oversight findings and recommendations made by the House Government Reform and Oversight Committee pursuant to clause

4(c)(2) of Rule X, whenever such findings and recommendations have been submitted to the Committee in a timely fashion. The Committee on Science has received no such findings or recommendations from the Committee on Government Reform and Oversight.

XIV. Constitutional Authority Statement

Clause 2(l)(4) of Rule XI of the Rules of the House of Representatives requires each report of a Committee on a bill or joint resolution of a public character to include a statement citing the specific powers granted to the Congress in the Constitution to enact the law proposed by the bill or joint resolution. Article I, Section 8 of the Constitution of the United States grants Congress the authority to enact H.R. 2544.

XV. Federal Advisory Committee Statement

H.R. 2544 does not authorize the creation of any new advisory committees.

XVI. Congressional Accountability Act

The Committee finds that H.R. 2544 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of Section 102(b)(3) of the Congressional Accountability Act (Public Law 104–1).

XVII. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

STEVENSON–WYDLER TECHNOLOGY INNOVATION ACT OF 1980

* * * * * * *

SEC. 12. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

(a) * * *

(b) Enumerated Authority.—(1) Under an agreement entered into pursuant to subsection (a)(1), the laboratory may grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, *or, subject to section 209 of title 35, United States Code, may grant a license to an invention which is federally owned, made before the granting of the license, and directly related to the scope of the work under the agreement,* for reasonable compensation when appropriate. The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement or, if there is more than one collaborating party, that the collaborating parties are offered the option to hold licensing

rights that collectively encompass the rights that would be held under such an exclusive license by one party. In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions:

(A) * * *

* * * * * * *

SEC. 14. DISTRIBUTION OF ROYALTIES RECEIVED BY FEDERAL AGENCIES.

(a) IN GENERAL.—(1) Except as provided in paragraphs (2) and (4), any royalties or other payments received by a Federal agency from the licensing and assignment of inventions under agreements entered into by Federal laboratories under section 12, and from the licensing of inventions of Federal laboratories under section 207 of title 35, United States Code, or under any other provision of law, shall be retained by the laboratory which produced the invention and shall be disposed of as follows:

(A)(i) The head of the agency or laboratory, or such individual's designee, shall pay each year the first $2,000, and thereafter at least 15 percent, of the royalties or other payments to the inventor or coinventors*, if the inventor's or coinventor's rights are assigned to the United States*.

* * * * * * *

(B) The balance of the royalties or other payments shall be transferred by the agency to its laboratories, with the majority share of the royalties or other payments from any invention going to the laboratory where the invention occurred. The royalties or other payments so transferred to any laboratory may be used or obligated by that laboratory during the fiscal year in which they are received or during the [succeeding fiscal year] *2 succeeding fiscal years—*

(i) * * *

* * * * * * *

TITLE 35, UNITED STATES CODE

* * * * * * *

PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

* * * * * * *

CHAPTER 18—PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

Sec.
200. Policy and objective.

* * * * * * *

[209. Restrictions on licensing of federally owned inventions.]
209. Licensing federally owned inventions.

* * * * * * *

§ 202. Disposition of rights

(a) * * *

* * * * * * *

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

(e) In any case when a Federal employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention—

(1) license or assign whatever rights it may acquire in the subject invention from its employee to the nonprofit organization or small business firm; or

(2) acquire any rights in the subject invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction.

* * * * * * *

§ 207. Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to—

(1) * * *

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned [patent applications, patents, or other forms of protection obtained] *inventions*, 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*, including acquiring rights for the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention*; and

* * * * * * *

[§ 209. Restrictions on licensing of federally owned inventions

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

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

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

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

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

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

[(D) the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public.

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

[(3) First preference in the exclusive or partially exclusive licensing of federally owned inventions shall go to small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

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

[(e) The Federal agency shall maintain a record of determinations to grant exclusive or partially exclusive licenses.

[(f) Any grant of a license shall contain such terms and conditions as the Federal agency determines appropriate for the protection of the interests of the Federal Government and the public, including provisions for the following:

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

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

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

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

§ 209. Licensing federally owned inventions

(a) AUTHORITY.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention only if—

(1) granting the license is a reasonable and necessary incentive to—

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

(B) otherwise promote the invention's utilization by the public;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical utilization, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical utilization of the invention within a reasonable time;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government

or United States industry in foreign commerce will be enhanced.

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

(c) SMALL BUSINESS.—First preference for the granting of any exclusive or partially exclusive licenses under this section shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

(d) TERMS AND CONDITIONS.—Licenses granted under this section shall contain such terms and conditions as the granting agency considers appropriate. Such terms and conditions shall include provisions—

(1) retaining a nontransferrable, irrevocable, paid-up license for the Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with; and

(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that—

(A) the licensee is not executing its commitment to achieve practical utilization of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical utilization of the invention;

(B) the licensee is in breach of an agreement described in subsection (b);

(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

(D) the licensee has been found by a competent authority to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(e) PUBLIC NOTICE.—No exclusive or partially exclusive license may be granted under this section unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

(f) BASIC BUSINESS PLAN.—A Federal agency may grant a license on a federally owned invention only if the person requesting the license has supplied to the agency a basic business plan with development milestones, commercialization milestones, or both.

(g) NONDISCLOSURE OF CERTAIN INFORMATION.—Any basic business plan, and revisions thereto, submitted by an applicant for a license, and any report on the utilization or utilization efforts of a licensed invention submitted by a licensee, shall be treated by the Federal agency as commercial and financial information obtained from a person and not subject to disclosure under section 552 of title 5, United States Code.

* * * * * * *

XVIII. COMMITTEE RECOMMENDATIONS

On May 13, 1998, a quorum being present, the Committee favorably reported H.R. 2544, the Technology Transfer Commercialization Act of 1998, by a voice vote, and recommends its enactment.

XIX. EXCHANGE OF COMMITTEE CORRESPONDENCE

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CONSTANCE A. MORELLA, Maryland
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KEVIN BRADY, Texas
MERRILL COOK, Utah
PHIL ENGLISH, Pennsylvania
GEORGE R. NETHERCUTT, Jr., Washington
TOM A. COBURN, Oklahoma
PETE SESSIONS, Texas
Vacancy

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE

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Ranking Minority Member

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BART GORDON, Tennessee
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LOIS CAPPS, California
BARBARA LEE, California
Vacancy

June 25, 1998

The Honorable Henry J. Hyde, Chairman
House Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On May 13, 1998, the Committee on Science ordered reported H.R. 2544, The Technology Transfer Commercialization Act of 1998. The bill was introduced on September 25, 1997, by Mrs. Morella and was referred to the Committee on Science and sequentially to the Committee on the Judiciary.

It is my understanding that your staff has reviewed the legislation and has determined that your Committee will forego a markup of H.R. 2544. By doing do, the Committee on Science recognizes the jurisdictional rights of the Committee on the Judiciary and by agreeing to expedite floor consideration the Committee on the Judiciary does not waive any of its jurisdictional prerogatives.

It has long been the history of our two committees to work cooperatively on technology transfer issues. I appreciate your willingness to continue this tradition in order to expedite consideration of this measure. Our exchange of letters will be included in the Science Committee's report to be filed on this bill.

Sincerely,

F. JAMES SENSENBRENNER, JR.
Chairman

MAJORITY MEMBERS
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ONE HUNDRED FIFTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON THE JUDICIARY

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RICK BOUCHER, VIRGINIA
JERROLD NADLER, NEW YORK
ROBERT C. "BOBBY" SCOTT, VIRGINIA
MELVIN L. WATT, NORTH CAROLINA
ZOE LOFGREN, CALIFORNIA
SHEILA JACKSON LEE, TEXAS
MAXINE WATERS, CALIFORNIA
MARTIN T. MEEHAN, MASSACHUSETTS
WILLIAM D. DELAHUNT, MASSACHUSETTS
ROBERT WEXLER, FLORIDA
STEVEN R. ROTHMAN, NEW JERSEY

June 25, 1998

The Honorable James Sensenbrenner
Chairman
Committee on Science
U.S. House of Representatives
2320 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Sensenbrenner:

Thank you for your letter of June 25 in which you address the jurisdiction of the Committee on the Judiciary as it relates to H.R. 2544, the "Technology Transfer Commercialization Act of 1998."

I have reviewed the legislation and have determined that it is not necessary for the Committee on the Judiciary to conduct a markup on the bill. As you stated in your letter, the Committee on the Judiciary does not waive any of its jurisdictional prerogative in this area.

I appreciate your cooperation with the Committee on the Judiciary and I look forward to working together on technology transfer issues in the future.

Sincerely,

HENRY J. HYDE
Chairman

H. Rept. 105-620

XX. PROCEEDINGS OF THE SUBCOMMITTEE MARKUP

SUBCOMMITTEE MARKUP OF H.R. 2544, THE TECHNOLOGY TRANSFER COMMERCIALIZATION ACT

THURSDAY, MARCH 26, 1998

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE,
SUBCOMMITTEE ON TECHNOLOGY,
Washington, DC.

The Subcommittee met at 10:12 a.m., in room 2318 of the Rayburn House Office Building, Hon. Constance A. Morella, Chairwoman of the Subcommittee, presiding.

Mrs. MORELLA. Good morning, everybody. Pursuant to notice, the Subcommittee on Technology is meeting today to consider the following measures: H.R. 2544, which is a bill to improve the ability of federal agencies to license federally owned inventions; and H.R. 3007, the Commission on the Advancement of Women in Science, Engineering, and Technology Development Act.

I ask unanimous consent of this Subcommittee for the authority to recess at anytime. If there is no objection, I need to have somebody offer—hearing no objection, it is so ordered.

So, welcome everybody to today's markup of the two bills that I have mentioned, that have received very strong support in legislative hearings before our Subcommittee.

This morning, we're going to consider H.R. 2544, the Technology Transfer Commercialization Act, which is a bill to improve the ability of federal agencies to license federally owned inventions, and, as I mentioned H.R. 3007, the Commission on the Advancement of Women in Science, Engineering, and Technology Development Act.

Our first bill, H.R. 2544, continues the Science Committee's long and rich history of advancing technology transfer from our federal laboratories to help boost United States international competitiveness.

As a result of technology transfer legislation advanced by this Committee, in almost 2 decades, the ability of the United States to compete in the global marketplace has been strengthened, a new paradigm for greater collaboration among the scientific enterprises that conduct our Nation's research and development—government, industry, and universities—has been developed. As a result, the quality of life for the American people, we believe, has been improved.

By spinning off and commercializing technology developed in our Nation's over 700 federal laboratories, the result of our federal re-

search and development enterprise are used today to enhance our ability to compete in the global marketplace.

In two legislative hearings on H.R. 2544, witnesses enthusiastically endorsed the bill's intent to streamline technology licensing to make it more effective.

The bill removes the legal obstacles to effectively license federally-owned inventions created in government-owned, government-operated laboratories by adopting the successful Bayh-Dole Act as a framework.

Under the bill, agencies would be provided with two important new tools for effectively commercializing on-the-shelf, federally-owned technologies, either licensing them as stand-alone inventions under the bill's revised authorities of Section 209 of the Bayh-Dole Act, or by including them as a part of a larger package under the Cooperative Research and Development Agreement.

In so doing, this will make both mechanisms much more attractive to U.S. companies that are striving to form partnerships with federal laboratories.

I think that H.R. 2544 is yet another important step in refining our Nation's technology transfer laws to remove existing impediments to enhance government and industry collaboration.

As we have prepared this bill for today's markup, I'm pleased to have worked very closely with Ranking Member Barcia, and Mr. Cook of Utah, as well as the Administration, to fashion consensus revisions to the original bill that incorporate suggestions made by the affected parties.

Mr. Barcia and Mr. Cook will be offering amendments to H.R. 2544 which will reflect the consensus revisions this morning.

I appreciate the Administration's strong support for the bill's goal of simplifying the requirements imposed on federal laboratories in the licensing of their inventions, and I can assure the Administration that their views and their proposed amendments were sufficiently considered.

This Committee's previous technology transfer efforts have been successful, in part because of the collaboration and bipartisan nature of the legislation, and the result of today's markup should be no different.

The second bill under consideration today is H.R. 3007, the Advancement of Women in Science, Engineering, and Technology Development Act. Currently eight Science Committee members are cosponsors of the bill; others can certainly join in today.

I would like to especially thank the Subcommittee members who are cosponsors, for their strong support of women in the science, engineering and technology fields:

Our Subcommittee Vice Chairman, Gil Gutknecht, who has done yeoman's work on the bill, our Ranking Member, Jim Barcia, Full Committee Vice Chair, Vern Ehlers, Congressman Tom Davis, Congresswoman Debbie Stabenow.

In addition to these distinguished members of the Subcommittee, the Institute of Electrical and Electronics Engineers, the IEEE, the American Society of Mechanical Engineers, ASME, the American Chemical Society, the American Association of Engineering Societies, Women in Technology, and the Association of Women in Science, have all endorsed the bill.

The bill, as drafted, will establish a Commission on Women in Science, Engineering, and Technology Development. This Commission will identify and examine the number of women in the fields of science, engineering, and technology, and the specific occupations where they are underrepresented.

The Commission also will describe the practices and policies of employers relating to the recruitment, retention, and advancement of women in science, engineering, and technology.

The Commission will then determine if these practices and policies are comparable to their male counterparts, and issue recommendations to government, academia, and private industry, based on successful programs.

H.R. 3007 will be a first step in countering the roadblocks for women in our rapidly evolving high-tech society. The bill will help women break through that glass ceiling, as well as the silicon ceiling, and it will help the Nation's high-tech economy to continue to flourish in the 21st Century by ensuring we have a sufficient pool of trained, high-tech workers in the United States.

Countering the barriers for women in the fields of science, engineering, and technology development will bring our Nation closer to creating a highly effective, high-tech workforce which, in turn, will both help women and promote economic prosperity.

During the markup, I will offer a substitute amendment to streamline the Commission process by: One, requiring the Commission to be appointed in 90, not 180 days; second, giving the Commission 1 year, not 18 months, to report; third, terminating the Commission 30 days, not 1 year after it reports; fourth, reducing the size of the Commission from 18 to 11 members; and, fifth, replacing a requirement that the National Science Foundation conduct a study, with language that would require NSF to transmit the data it currently collects to the Commission.

In addition, the substitute will ensure that the States are active participants in the Commission by allowing the National Governors Association's Chairman and Vice Chairman to appoint 4 of the 11 Commissioners, and by requiring the Commission's report be transmitted to all 50 States, the District of Columbia, and the U.S. Territories.

Finally, the substitute includes the phrase, nondiscriminatory, in its description of what kinds of recommendations we expect from the Commission.

During our hearing on March 10th of this year, all our witnesses stressed that quotas were not the answer, not a viable solution to the problem of the underrepresentation of women in the scientific and engineering fields.

The purpose of this Commission is to lift women scientists and engineers up, not drag men down by discriminating against them. As a supporter of affirmative action, but an opponent of quotas, I'm interested in increasing the pool of qualified high-tech workers in America by increasing the number of women in science and engineering.

The recommendations that come out of H.R. 3007 should do just that, not simply change the ratio of men to women in the field. In addition to the substitute amendment, we have cleared five Democrat amendments to the bill which are all consistent with the bill's

purpose, and so I now turn, after that lengthy introduction, to the Technology Subcommittee Ranking Member, the gentleman from Michigan, Mr. Barcia, for his opening statement.

Mr. BARCIA. Thank you very much, Madam Chairwoman. I have no statement at this time, but will be making remarks on the bills before the Subcommittee in a few minutes.

Mrs. MORELLA. Thank you, Mr. Barcia.

Are there any other members seeking recognition for an opening statement on the bills?

[No response.]

Mrs. MORELLA. Hearing none, then we'll now consider H.R. 2544, a bill to improve the ability of federal agencies to license federally-owned inventions.

Mr. Barcia, would you like to make a statement at this point?

Mr. BARCIA. Madam Chairwoman, I might reserve some time later. I understand one of our members may have a conflict in Committees.

Mrs. MORELLA. The first reading of the bill, I would ask unanimous consent that the bill be considered as read and open to amendment at any point.

There are two amendments on the roster. Are there any members who wish to offer an amendment?

Mr. COOK. Yes.

Mrs. MORELLA. I recognize Mr. Cook.

Mr. COOK. Madam Chairwoman, I have an amendment at the desk.

Mrs. MORELLA. The gentleman is recognized for 5 minutes to offer the amendment.

[The text of H.R. 2544, a section-by-section analysis of the bill, the amendment roster, and the text of the amendments follow:]

105TH CONGRESS
1ST SESSION

H. R. 2544

To improve the ability of Federal agencies to license federally owned inventions.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 1997

Mrs. MORELLA introduced the following bill; which was referred to the Committee on Science, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve the ability of Federal agencies to license federally owned inventions.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Technology Transfer
5 Commercialization Act of 1997".

6 **SEC. 2. COOPERATIVE RESEARCH AND DEVELOPMENT**
7 **AGREEMENTS.**

8 Section 12(b)(1) of the Stevenson-Wydler Technology
9 Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) is

1 amended by inserting "or, subject to section 209 of title
2 35, United States Code, in a federally owned invention di-
3 rectly related to the scope of the work under the agree-
4 ment," after "under the agreement,".

5 **SEC. 3. LICENSING FEDERALLY OWNED INVENTIONS.**

6 (a) AMENDMENT.—Section 209 of title 35, United
7 States Code, is amended to read as follows:

8 **"§ 209. Licensing federally owned inventions**

9 "(a) AUTHORITY.—A Federal agency may grant an
10 exclusive or partially exclusive license on a federally owned
11 invention if—

12 "(1) granting the license is a reasonable and
13 necessary incentive to—

14 "(A) call forth the investment capital and
15 expenditures needed to bring the invention to
16 practical application; or

17 "(B) otherwise promote the invention's uti-
18 lization by the public;

19 "(2) the Federal agency finds that the public
20 will be served by the granting of the license, as indi-
21 cated by the applicant's intentions, plans, and ability
22 to bring the invention to practical application or oth-
23 erwise promote the invention's utilization by the
24 public;

1 "(3) the applicant makes a commitment to
2 achieve practical utilization of the invention within a
3 reasonable time;
4 "(4) granting the license will not substantially
5 lessen competition or create or maintain a violation
6 of the antitrust laws; and
7 "(5) in the case of an invention covered by a
8 foreign patent application or patent, the interests of
9 United States industry in foreign commerce will be
10 enhanced.
11 "(b) MANUFACTURE IN UNITED STATES.—Licenses
12 shall normally be granted under this section only to a li-
13 censee who agrees that any products embodying the inven-
14 tion or produced through the use of the invention will be
15 manufactured substantially in the United States.
16 "(c) SMALL BUSINESS.—First preference for the
17 granting of licenses under this section shall be given to
18 small business firms having equal or greater likelihood as
19 other applicants to bring the invention to practical appli-
20 cation within a reasonable time.
21 "(d) TERMS AND CONDITIONS.—Licenses granted
22 under this section shall contain such terms and conditions
23 as the granting agency considers appropriate. Such terms
24 and conditions—
25 "(1) shall include provisions—

1 "(A) requiring periodic reporting on utili-
2 zation of the invention, and utilization efforts,
3 by the licensee; and
4 "(B) empowering the Federal agency to
5 terminate the license in whole or in part if the
6 agency determines that—
7 "(i) the licensee is not adequately exe-
8 cuting its commitment to achieve practical
9 utilization of the invention within a reason-
10 able time;
11 "(ii) the licensee is in breach of an
12 agreement described in subsection (b); or
13 "(iii) termination is necessary to meet
14 requirements for public use specified by
15 Federal regulations issued after the date of
16 the license, and such requirements are not
17 reasonably satisfied by the licensee; and
18 "(2) may include a requirement that the li-
19 censee provide the agency with a plan for develop-
20 ment or marketing the invention.
21 Information obtained pursuant to paragraph (1)(A) shall
22 be treated by the Federal agency as commercial and finan-
23 cial information obtained from a person and privileged and
24 confidential and not subject to disclosure under section
25 552 of title 5, United States Code.

1 "(e) PUBLIC NOTICE.—No license may be granted
2 under this section unless public notice of the availability
3 of a federally owned invention for licensing in an appro-
4 priate manner has been provided at least 30 days before
5 the license is granted. This subsection shall not apply to
6 the licensing of inventions made under a cooperative re-
7 search and development agreement entered into under sec-
8 tion 12 of the Stevenson-Wydler Technology Innovation
9 Act of 1980 (15 U.S.C. 3710a).".

10 (b) CONFORMING AMENDMENT.—The item relating
11 to section 209 in the table of sections for chapter 18 of
12 title 35, United States Code, is amended to read as fol-
13 lows:

"209. Licensing federally owned inventions.".

H.R. 2544, the Technology Transfer Commercialization Act of 1997

Section-by-Section Analysis

Purpose: To improve the ability of federal agencies to license federally-owned inventions.

Introduced: On September 25, 1997 by Congresswoman Constance A. Morella, Chair of the Technology Subcommittee, House Science Committee

Jurisdiction: Referred to the Committee on Science, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

SECTION 1. SHORT TITLE.

The Act shall be called the "Technology Transfer Commercialization Act of 1997."

SECTION. 2. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Section 2 of H.R. 2544 amends Section 12(b)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) by inserting "or, subject to section 209 of title 35, United States Code, in a federally-owned invention directly related to the scope of the work under the agreement." This amendment allows federal laboratories to include already existing patented inventions into a cooperative research and development agreement (CRADA).

SECTION 3. LICENSING FEDERALLY OWNED INVENTIONS.

Section 3 amends Section 209, title 35 of the United States Code.

Subsection 3(a) provides that a federal agency may grant an exclusive or partially exclusive license on a federally-owned invention if granting the license is a reasonable and necessary incentive for commercialization or to promote the invention's utilization by the public. The licensee must develop a plan to bring the invention to practical application and make a commitment for commercialization within a reasonable time. The granting of the license should not substantially lessen competition or create or maintain a violation of the antitrust laws and in the case of an invention covered by a

foreign patent application or patent, the interests of United States industry in foreign commerce will be enhanced.

Subsection 3(b) provides that licenses should be granted only to a licensee who agrees that any products derived from the patents are manufactured substantially in the United States.

Subsection 3(c) provides that the first preference for the granting of licenses should be given to small businesses that have an equal or greater likelihood as other applicants to bring the invention to commercialization within a reasonable time.

Subsection 3(d) provides certain terms and conditions required for licenses. These include periodic reporting on the use of the invention and commercialization efforts by the licensee, and providing "march-in rights" that empower a federal agency to terminate the license in whole or in part: 1) if it determines that the licensee is not adequately executing its commitment to achieve practical utilization of the invention within a reasonable time; or 2) if the licensee is in breach of the U.S. manufacturing requirement; or 3) or if termination is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and those requirements are not reasonably satisfied by the licensee. Additionally, an agency may ask the licensee for a plan for development or marketing the invention. This information shall be treated as commercial and financial information that is privileged and confidential and not subject to disclosure under section 552 of title 5, United States Code.

Subsection 3(e) provides that no license may be granted unless public notice of the availability of a federally-owned invention for licensing in an appropriate manner has been provided at least 30 days before the license is granted. This subsection, however, shall not apply to the licensing of inventions made under a CRADA entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

COMMITTEE ON SCIENCE

SUBCOMMITTEE ON TECHNOLOGY

March 26, 1998

AMENDMENT ROSTER

MARKUP OF H.R. 2544, the Technology Transfer Commercialization Act of 1997.

No.	Sponsor	Description	Results
1	Mr. Barcia	En Bloc	
2	Mr. Cook	En Bloc	

AMENDMENT TO H.R. 2544

OFFERED BY MR. BARCIA

Page 2, line 2, strike "in a federally owned invention" and insert "may grant a license to an invention which is federally owned, made before the granting of the license, and".

Page 2, lines 9 and 10, strike "an exclusive or partially exclusive" and insert "a".

Page 2, line 11, insert "only" after "invention".

Page 2, line 24, insert ", and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical utilization, as proposed by the applicant, or otherwise to promote the invention's utilization by the public" after "by the public".

Page 3, line 4, insert "tend to" after "license will not".

Page 3, line 6, insert "Federal" after "violation of the".

Page 3, lines 11 and 12, strike "Licenses shall normally be granted under this section" and insert "A Fed-

eral agency shall normally grant a license to use or sell any federally owned invention in the United States".

Page 4, before line 1, insert the following new subparagraph:

1 "(A) retaining a nontransferrable, irrev-
2 ocable, paid-up license for the Federal agency
3 to practice the invention or have the invention
4 practiced throughout the world by or on behalf
5 of the Government of the United States;

Page 4, lines 1 and 4, redesignate subparagraphs (A) and (B) as subparagraphs (B) and (C), respectively.

Page 4, line 3, insert ", but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with" after "by the licensee".

Page 4, line 7, strike "adequately".

Page 4, lines 9 and 10, strike "within a reasonable time" and insert ", including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical utilization of the invention".

Page 4. line 12, strike "or".

Page 4, line 17, strike "and" and insert "or".

Page 4, after line 17, insert the following new clause:

1 "(iv) the licensee has been found by a
2 competent authority to have violated the
3 Federal antitrust laws in connection with
4 its performance under the license agree-
5 ment.

Page 4, strike lines 18 through 25.

Page 5, line 5, insert ", and the Federal agency has considered all comments received in response to that public notice" after "license that is granted".

Page 5, at the end of the bill, insert the following new section:

6 **SEC. 4. TECHNICAL AMENDMENTS TO THE STEVENSON-**
7 **WYDLER TECHNOLOGY INNOVATION ACT OF**
8 **1980.**

9 Section 14(a)(1) of the Stevenson-Wydler Technology
10 Innovation Act of 1980 (15 U.S.C. 3710c(a)(1)) is amend-
11 ed—

12 (1) in subparagraph (A)(i), by inserting ", if
13 the inventor's or coinventor's rights are assigned to

1 the United States" after "inventor or coinventors";
2 and
3 (2) in subparagraph (B), by striking "succeed-
4 ing fiscal year" and inserting "2 succeeding fiscal
5 years".

AMENDMENT TO H.R. 2544

OFFERED BY MR. COOK

Page 5, after line 9, insert the following new subsections:

1 "(f) DEVELOPMENT PLAN.—A Federal agency may
2 grant a license on a federally owned invention only if the
3 person requesting the license has supplied to the agency
4 a basic business plan with commercialization milestones.
5 "(g) NONDISCLOSURE OF CERTAIN INFORMATION.—
6 Information (other than the name of an applicant or li-
7 censee and type of license) obtained from an applicant or
8 licensee pursuant to this section shall be treated by the
9 Federal agency as commercial and financial information
10 obtained from a person and not subject to disclosure under
11 section 552 of title 5, United States Code.".

Page 5, at the end of the bill, insert the following new section:

12 **SEC. 4. TECHNICAL AMENDMENTS TO BAYH-DOLE ACT.**
13 Chapter 18 of title 35, United States Code (popularly
14 known as the "Bayh-Dole Act"), is amended—
15 (1) by amending section 202(e) to read as fol-
16 lows:
17 "(e) In any case when a Federal employee is a co-
18 inventor of any invention made under a funding agreement

1 with a nonprofit organization or small business firm, the
2 Federal agency employing such coinventor may, for the
3 purpose of consolidating rights in the invention—
4 "(1) transfer or assign whatever rights it may
5 acquire in the subject invention from its employee to
6 the nonprofit organization or small business firm; or
7 "(2) acquire any rights in the subject invention
8 from its employee or from the nonprofit organization
9 or small business firm, but only to the extent the
10 party from whom the rights are acquired voluntarily
11 enters into the transaction."; and
12 (2) in section 207(a)—
13 (A) by striking "patent applications, pat-
14 ents, or other forms of protection obtained" and
15 inserting "or licensed inventions" in paragraph
16 (2); and
17 (B) by inserting ", including acquiring
18 rights for the Federal Government in any in-
19 vention, but only to the extent the party from
20 whom the rights are acquired voluntarily enters
21 into the transaction, to facilitate the licensing
22 of a federally owned invention" after "or
23 through contract" in paragraph (3).

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE
SUITE 2320 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
TTY: (202) 226-4410

March 25, 1998

MEMORANDUM

TO: TECHNOLOGY SUBCOMMITTEE MEMBERS

FROM: CHAIRWOMAN MORELLA

SUBJECT: SUBCOMMITTEE MARKUP ON H.R. 2544, THE TECHNOLOGY TRANSFER AND COMMERCIALIZATION ACT OF 1997.

Pursuant to notice, the Subcommittee on Technology will meet **on Thursday, March 26, 1998 at 10:00 A.M.** in 2318 Rayburn to consider; **H.R. 2544, the Technology Transfer Commercialization Act of 1997.**

H.R. 2544 streamlines the reporting requirements for technology transfer agreements allowing them to proceed in a more timely manner. It provides parallel authorities for government-owned, government-operated federal laboratories to those currently in place under the Bayh-Dole Act for licensing university or university-operated federal laboratory inventions. The bill also amends the Stevenson-Wydler Act to allow federal laboratories to include already existing patented inventions into a cooperative research and development agreement (CRADA).

Through these changes, agencies would be provided with two important new tools for effectively commercializing on-the-shelf federally-owned technologies -- either licensing them as stand-alone inventions, under the bill's revised authorities of Section 209 of the Bayh-Dole Act, or including them as part of a larger package under a CRADA.

H.R. 2544 was introduced by Technology Subcommittee Chairwoman Constance Morella on September 23, 1997. It was referred to the Committee on Science, and sequentially to the Committee the Judiciary. The Technology Subcommittee has held two hearings on H.R. 2544. The first hearing was held on September 25, 1997, and the second hearing was held on March 17, 1998.

H.R. 2544, the Technology Transfer Commercialization Act of 1997

Section-by-Section Analysis

Purpose: To improve the ability of federal agencies to license federally-owned inventions.

Introduced: On September 25, 1997 by Congresswoman Constance A. Morella, Chair of the Technology Subcommittee, House Science Committee

Jurisdiction: Referred to the Committee on Science, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

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The Act shall be called the "Technology Transfer Commercialization Act of 1997."

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Section 2 of H.R. 2544 amends Section 12(b)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) by inserting "or, subject to section 209 of title 35, United States Code, in a federally-owned invention directly related to the scope of the work under the agreement." This amendment allows federal laboratories to include already existing patented inventions into a cooperative research and development agreement (CRADA).

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Section 3 amends Section 209, title 35 of the United States Code.

Subsection 3(a) provides that a federal agency may grant an exclusive or partially exclusive license on a federally-owned invention if granting the license is a reasonable and necessary incentive for commercialization or to promote the invention's utilization by the public. The licensee must develop a plan to bring the invention to practical application and make a commitment for commercialization within a reasonable time. The granting of the license should not substantially lessen competition or create or maintain a violation of the antitrust laws and in the case of an invention covered by a

foreign patent application or patent, the interests of United States industry in foreign commerce will be enhanced.

Subsection 3(b) provides that licenses should be granted only to a licensee who agrees that any products derived from the patents are manufactured substantially in the United States.

Subsection 3(c) provides that the first preference for the granting of licenses should be given to small businesses that have an equal or greater likelihood as other applicants to bring the invention to commercialization within a reasonable time.

Subsection 3(d) provides certain terms and conditions required for licenses. These include periodic reporting on the use of the invention and commercialization efforts by the licensee, and providing "march-in rights" that empower a federal agency to terminate the license in whole or in part: 1) if it determines that the licensee is not adequately executing its commitment to achieve practical utilization of the invention within a reasonable time; or 2) if the licensee is in breach of the U.S. manufacturing requirement; or 3) or if termination is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and those requirements are not reasonably satisfied by the licensee. Additionally, an agency may ask the licensee for a plan for development or marketing the invention. This information shall be treated as commercial and financial information that is privileged and confidential and not subject to disclosure under section 552 of title 5, United States Code.

Subsection 3(e) provides that no license may be granted unless public notice of the availability of a federally-owned invention for licensing in an appropriate manner has been provided at least 30 days before the license is granted. This subsection, however, shall not apply to the licensing of inventions made under a CRADA entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

Mr. COOK. Thank you. I want to thank you, Madam Chairwoman, for your commitment and leadership in improving our Nation's laws promoting technology transfer from our Nation's federal laboratories.

This technology transfer has the potential for bolstering our ability to compete internationally, and I commend you for your efforts on behalf of H.R. 2544.

You've assembled endorsements for the bill from an impressive array of large industry, small business, technology transfer organizations, and the Administration, and I'm very pleased to support your bill as it is considered by the Committee.

As a former businessman, I understand how difficult it is to interact with the government. This is especially onerous in our technology transfer laws when we're trying to attract incentives for industry to partner with government and not to create additional reasons for them to run away from working with government.

For that reason, I'm offering a set of en bloc amendments to H.R. 2544, which I believe will further knock down some of the obstacles and concerns of industry when they seek to license technology from our federal laboratories.

First, my amendment would underscore that at a minimum, the development plan required under the current law should simply be a basic business plan with commercialization milestones.

My amendment would also extend the protection from disclosure by the industry partner of information submitted by private properties in connection with licensing. I believe that all such information, with the exception of the name of the licensee and type of such license, should be entitled to protection from disclosure.

My amendment also allows for an agency to be able to offer a potential licensee access to related inventions in order to practice a government-owned invention.

Although federal law addresses the issue of out-licensing of government owned inventions or rights thereto, there is no specific governmentwide authority for the opposite transaction, for example, to authorize an agency to in-license or accept an assignment of rights from a nongovernment party.

Unfortunately, relatively few inventions can be commercialized without access to related inventions. However, there is presently no mechanism whereby an agency, with the exception of the Department of Commerce, can in-license the rights to other inventions in return for the payment of a share of any subsequent royalties so that they can be bundled with a government-owned invention and licensed together for commercialization.

Finally, my amendment makes it clear that both the agency and an co-inventing entity should have authority to license to one another in those circumstances.

This is important because a significant percentage of government inventions are co-invented with federally funded parties, most commonly, university researchers, and it's often necessary to unify ownership of such co-inventions under appropriate royalty-sharing arrangements such as licensing or assignments to achieve public benefit through commercialization.

Madam Chairwoman, thank you for the opportunity to work with you in crafting these en bloc amendments to H.R. 2544, and I be-

lieve my amendment complements your bill, and I appreciate your consideration.

I urge all of my colleagues to support this amendment.

Mrs. MORELLA. Thank you, Mr. Cook. I would agree.

Does any other member seek recognition on that amendment offered by Mr. Cook, en bloc?

[No response.]

Mrs. MORELLA. Not hearing any, then the vote is going to occur on the amendment.

All in favor, say aye.

[Chorus of ayes.]

Mrs. MORELLA. Those opposed, no.

[No response.]

Mrs. MORELLA. The ayes have it, and the amendment is agreed to.

Do we have another amendment?

Mr. Barcia?

Mr. BARCIA. Yes, Madam Chairwoman, I have an amendment at the desk, an en bloc amendment.

Mrs. MORELLA. The amendment can be considered as read, and the gentleman has 5 minutes to explain his en bloc amendment.

Mr. BARCIA. Thank you very much, Madam Chairwoman.

While we all agree with H.R. 2544's goals in making sure that the products in federal labs are commercialized as quickly and efficiently as possible, there was widespread concern about the price that H.R. 2544, as introduced, extracted for that efficiency.

I am happy to report that we have been able to develop a bipartisan compromise which keeps the beneficial portions of H.R. 2544, while restoring provisions designed to promote fairness of opportunity, to increase due diligence on the part of licensees, and to create American jobs.

Notice requirements, which my amendment will restore, are essential to ensure that the public gets full benefit from its research investment. They, and the requirement that exclusive licenses be drawn as narrowly as possible, make sure that every American company, no matter how small, has a chance to make its case for a license before exclusive rights are awarded.

NIST Director Ray Kammer's testimony last week vividly portrayed why these parts of my amendment are necessary. Time and time again, public notice of the intent to grant exclusive licenses has produced dramatic results.

Companies, often small businesses, previously unknown to the laboratory with the innovation, have responded to the notice with revolutionary ideas which otherwise could have been lost.

The National Institutes of Health first learned of companies with the capability to turn two NIH innovations into a cystic fibrosis gene therapy, and the cervical cancer vaccine this way.

Agriculture uncovered an important way of immunizing poultry, and a way to make formaldehyde out of permanent press cotton fabrics after giving notice, yet these innovations could have been stopped in their tracks, had the public notice not been given.

This amendment, however, is not a status quo amendment. It retains the Chairwoman's innovations, including shortening the period of public notice. I hope the report language will reflect the

Committee's consensus that an effective 21st Century notice has to include the Internet.

My amendment, when coupled with Mr. Cook's amendment, also restores planning requirements under the act to a reasonable level.

Balance is necessary here. It is unfair to business if laboratories which license technologies are permitted to establish unnecessary paperwork requirements.

It is also unfair to the taxpayer if licenses are awarded without enough information to tell who has the best ideas for commercial products based on the innovation, and which companies have the ability to take those ideas to market.

Agencies also have legitimate needs for specific information on a company's performance under a license. My amendment is clear that we want reports to be lean, timely, and targeted, and as unobtrusive as possible.

Finally, federal licensing must lead to high quality research and manufacturing jobs, right here in the United States of America. In the 1980's, this Committee showed wisdom in requiring a fair share of the jobs coming out of federal innovations to be located in the United States. My amendments will continue this important principle into the next century.

Madam Chairwoman, you know and I know that the Administration did us a major favor in putting such a high level of effort into perfecting H.R. 2544. Every federal agency with major research laboratories, including NIH, USDA, FDA, EPA, DOD, DOE, NASA, NOAA, and NIST, were involved in developing the Administration's views.

This Subcommittee, in a bipartisan manner, has invested a large amount of energy in gathering the information necessary to perfect the Administration's suggestions. It is now time to reap the harvest.

I urge my colleagues to support the en bloc amendments, and I want to commend the Chairwoman for her diligent effort on perfecting this very progressive legislation.

Mrs. MORELLA. Thank you, Mr. Barcia, and thank you for that excellent input in offering the amendments.

Is there any further discussion to the en bloc amendments offered by Mr. Barcia?

[No response.]

Mrs. MORELLA. Not hearing any, the vote occurs on the amendment.

All in favor of the amendments offered by Mr. Barcia will say aye.

[Chorus of ayes.]

Mrs. MORELLA. Those opposed, no.

[No response.]

Mrs. MORELLA. The ayes have it, and the amendment is agreed to.

Are there any other amendments to come before the Subcommittee?

[No response.]

Mrs. MORELLA. I'd like to recognize Ms. Stabenow for any comment she may have.

Ms. STABENOW. Thank you, Madam Chairwoman. I have just a brief comment in support of H.R. 2544, and also to indicate that in testimony and again today, we have heard comments about the importance in the area of agriculture of technology transfer.

I would just like to emphasize, as a member of the Agriculture Committee, the Research Subcommittee, as the sponsor of the Safe Food Action Plan, which is in the Agriculture Committee, it is incredibly important to be focusing on research and technology transfer, developing new tools for farmers, for processors, in order to protect our food supply.

This particular bill is an important step, and it works in tandem with the Safe Food Action Plan that we have introduced in the Agriculture Committee, and I think it's important that we have strengthened the technology transfer piece as it relates to our ability to protect our food.

So, I would like to commend you, and I look forward to the opportunity to seeing this particular bill work in tandem with a number of different efforts as we look at the importance of research and transferring our technologies to practical use.

Thank you.

Mrs. MORELLA. Thank you, Ms. Stabenow, and thank you for indicating that linkage, the connection with the example in terms of food safety.

I'd like to recognize Ms. Tauscher.

Ms. TAUSCHER. Thank you, Madam Chairwoman. I appreciate your leadership on this important issue of technology transfer.

This legislation is a positive step towards enhancing opportunities for moving technologies developed in our national laboratories into the marketplace where they will benefit all Americans.

I had intended to offer today, an amendment to this legislation regarding the criteria used by the Department of Energy and other federal agencies to evaluate proposed Cooperative Research and Development Agreements.

It is essential that the federal agencies provide proper oversight of CRADA's that the laboratories enter into with private business, but it is equally important that the oversight not unduly delay the approval of CRADA's.

I will not offer this amendment today because I understand that some people have expressed concern about its wording. Instead, I would like to reserve the right to offer this amendment at the Full Committee markup of this bill, and I ask the Chair for her assistance in working out acceptable language as we move to Full Committee for consideration.

Thank you.

Mrs. MORELLA. Ms. Tauscher, we'll certainly consider it, and look forward to working with you on that.

Are there any other amendments to be offered?

[No response.]

Mrs. MORELLA. Not hearing any, then the question is on the bill, H.R. 2544, a bill to improve the ability of federal agencies to license federally owned inventions, as amended.

All those in favor will say aye.

[Chorus of ayes.]

Mrs. MORELLA. All opposed will say no.

[No response.]

Mrs. MORELLA. In the opinion of the Chair, the ayes have it.

I'd like to now recognize the honorable Ranking Member, Mr. Barcia, for a motion.

Mr. BARCIA. Madam Chairwoman, I ask unanimous consent that the staff be instructed to make technical and conforming corrections to H.R. 2544.

Also, I move that the Subcommittee report the bill, as amended, and that the Chairwoman take all necessary steps to bring the bill before the Full Committee for consideration.

Thank you.

Mrs. MORELLA. Thank you, Mr. Barcia. The Subcommittee has heard the motion.

Those in favor will say aye.

[Chorus of ayes.]

Mrs. MORELLA. Those opposed, no.

[No response.]

Mrs. MORELLA. The ayes have it, and the motion is agreed to without objection. The motion to reconsider is laid upon the table.

XXI. PROCEEDINGS OF THE FULL COMMITTEE MARKUP

FULL COMMITTEE MARKUP OF H.R. 2544

WEDNESDAY, MAY 13, 1998

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE,
Washington, DC.

Chairman SENSENBRENNER. The next order of business is H.R. 2544, the Technology Transfer Commercialization act of 1997. And the Chair will recognize himself for a brief opening statement.

In the past 2 decades, Congress by direction of the Science Committee has established a system to transfer and commercialize technology from our federal laboratories to bolster our Nation's ability to compete in the global market place. From the Stevenson-Wydler Technology Innovation Act of 1980 to the National Technology Transfer and Advancement Act of 1995, the Committee has strengthened and improved the process of technology transfer from our federal labs. This bill continues the Science Committee's long and rich history of advancing technology transfer to help boost the United States international competitiveness.

I congratulate the Chairwoman of the Technology Subcommittee, the gentlewoman from Maryland, Mrs. Morella, for introducing this bill and for her efforts to work cooperatively with members of the Minority in the Administration to craft this bill.

I am pleased that the Administration has informed us of their strong support for the bill's goal of simplifying the requirements imposed on the federal labs, and the licensing of their inventions. Shortly, I will be offering an amendment to H.R. 2544, which reflects technical corrections to the bill as suggested by the Administration and includes language affecting cooperative research and development agreements suggested by Ms. Tauscher of California.

This bill is yet another important step in refining our Nation's technology transfer laws, to remove existing impediments to advance government and industry collaboration and I urge its adoption.

Does the gentlewoman from Maryland have any opening comments for the remainder of my 5 minutes?

Mrs. MORELLA. Yes, Mr. Chairman. I do. And I'll talk quickly, because it is a good bill.

As a result of technology transfer legislation advanced by this Committee, in almost 2 decades, the ability of the United States to compete globally has, indeed, been strengthened in a new paradigm for a greater collaboration among the scientific enterprises that conduct our Nation's research and development—government industry and academia has been developed. By spinning off and com-

mercializing technology developed in our Nation's over 700 federal laboratories, the results of our federal research and development enterprises as successfully being used today to improve our ability to compete internationally.

Given the importance and benefits of technology transfer, the Technology Subcommittee has continued to refine the technology transfer process to facilitate greater government, university, and industry collaboration. In the past Congress, we enhanced and simplified the process for CRADAs with the National Technology Transfer and Advancement Act, and now in H.R. 2544 we have attempted to remove the obstacles to effectively license federally-owned inventions which are created in government-owned, government-operated laboratories by adopting this successful Bayh-Dole Act as a framework.

So under the bill, agencies would be provided with two important new tools for effectively commercializing on the shelf federally-owned technologies. Either licensing them as stand-alone inventions under the bill's revised authorities of Section 209 of the Bayh-Dole Act, or by including them as part of a larger package under a cooperative research and development agreement. So by doing that, this will make both mechanisms much more attractive to our companies that are striving to form partnerships with federal laboratories.

In the Technology Subcommittee's two legislative hearings on this bill, H.R. 2544, the witnesses all enthusiastically endorsed the bill's intent to streamline technology licensing, to make it more effective. We've heard from the Administration, as you mentioned, large corporations, small businesses, federal laboratories, and tech transfer organizations, among others, that this bill is really going to improve the process.

I'm pleased that the bill is now before the Committee as we push toward its enactment by the close of this Congress. And Chairman Sensenbrenner, you will be offering an amendment on our behalf, which further clarifies the intent of the bill and refines certain language in the bill.

So, I'm pleased that we've worked closely with the members of the Minority to reach the consensus revisions since the bill was originally introduced. I want to thank all of the members of the Technology Subcommittee. I look forward to working with the Full Committee and with you Mr. Chairman, and having H.R. 2544 signed into law in the coming months.

Chairman SENSENBRENNER. My time is expired. The Chair recognizes the gentleman from California for an opening statement. And without objection, the text of all member's opening statements will appear in the record following the gentleman from California's time.

Mr. BROWN of California. Mr. Chairman, I would like to compliment the Subcommittee and Mrs. Morella and Mr. Barcia, in particular, for their diligence in bringing this before us today. And for your flexibility in working out the differences in the legislation. The law of federal inventions may very well be the most difficult area of the law that this Committee deals with and I commend my colleagues for having the endurance to get the legislation this far.

We now have a compromise text which I hope the entire Committee can support.

Mr. Chairman, I ask unanimous consent that any statement from Mr. Barcia be entered into the record following mine.

Chairman SENSENBRENNER. Without objection.

Mr. BROWN of California. I ask unanimous consent that the full text of my statement be entered in the record. And I'd like to commend Ms. Tauscher for her very important contribution to the Amendment in the Nature of a Substitute. Her amendment deals with that small group of cooperative research and development agreements which are so important that they affect policies of more than one agency in either national security, domestic competitiveness, or international competitiveness. I feel that Ms. Tauscher has come up with an unobtrusive way to address these concerns, and I therefore commend here for her keen understanding of these issues and her diligence on behalf of our Nation's laboratories.

Mr. Chairman if you will indulge me for just another short period. I recall when this Act—Technology Transfer Act—was originally adopted, it bears the name of a distinguished senior Senator, Mr.—Senator Stevenson. Not the present Senator Stevenson but an earlier one, Adlie Stevenson, Jr. And the name of the Ranking Member of this Committee, Mr. Wydler, who worked diligently to insure the passage to this Act in its original form. I was proud to be a co-sponsor then and I'm proud that it has been as successful as it has in forging a better cooperation between the Federal Government and its research activities, and the private sector and their research activities.

Chairman SENSENBRENNER. The gentleman's time has expired.

Without objection, the bill will be considered as read, and the Amendment in the Nature of a Substitute reported by the Committee—Subcommittee—on Technology will be considered as the original text of the bill for purposes of amendment. The bill is now open for amendment. Without objection, the bill will be open for amendment at any point. And I would like to offer an Amendment in the Nature of a Substitute which has been agreed upon.

[The prepared statements of Mr. Brown and Mr. Barcia and the amendment roster and the text of the amendments follow:]

Hon. GEORGE E. BROWN, JR.
STATEMENT ON
TECHNOLOGY TRANFER BILL

Mr. Chairman:

I would like to compliment the Subcommittee on Technology, especially Mrs. Morella and Mr. Barcia on their dilligence in bringing the Technology Transfer Commercialization Act of 1998 before us today and Chairman Sensenbrenner on his flexibility in working out differences on this legislation. The law of Federal inventions may very well be the most difficult area of the law this Committee deals with and I commend my colleagues for having the endurance to get the legislation this far. We now have a compromise text which I hope the entire committee can support.

The text before us contains two clarifications which I requested in the version as reported by the subcommittee. We have tightened the language of the FOIA exemption so that it is drafted in terms of the existing exemptions in Title 5 of the US Code. We also have made it clear that there must be public notice of the intent to grant exclusive or partially exclusive licenses to Federal inventions and that the agency wishing to grant such a license must first address all comments received during the notice period before granting the license. I consider this to be a fair balancing of two values: making sure that parties are aware of opportunities to license and making sure that the government's licensing timetable is short enough to be responsive to the needs of industry.

I would also like to commend Mrs. Tauscher for a very important contribution to the amendment in the nature of a substitute. Mrs. Tauscher's amendment deals with that small group of cooperative research and development agreements which are so important that they affect policies of more than one agency in either national security, domestic competitiveness, or international competitiveness. It is crucial to the country, the agencies involved, and the companies who are willing to advance these major technologies that parties to a CRADA are not second-guessed on these matters after a CRADA has been signed, and I feel that Mrs. Tauscher has come up with an unobtrusive way to address these concerns. I, therefore, commend Mrs. Tauscher on her keen understanding of

these issues and her diligence on behalf of our nation's Federal laboratories.

At this point I would like to yield the balance of my time to the distinguished ranking Democrat on the Technology Subcommittee Mr. Barcia for any introductory comments he might have.

Statement

Hon. James A. Barcia

Technology Transfer Commercialization Act

Mr. Chairman,

I am pleased with the progress we have made on the Technology Transfer Commercialization Act. This legislation, from the beginning, has been developed in a bipartisan manner and I feel it has been much improved through the adoption of the best ideas of everyone concerned. Mr. Cook and I offered a series of amendments at Subcommittee which addressed problems in patent licensing and technology transfer which have been brought to the attention of

the Committee over the past several years. Since Subcommittee we have addressed a number of concerns by Mr. Brown and the bill has been improved through the suggestions of Mrs. Tauscher regarding CRADA policy. I feel that this bill substantially improves the environment for companies wanting to do joint research with the Federal laboratories or to license technologies developed at these laboratories and I urge my colleagues to support it.

COMMITTEE ON SCIENCE

FULL COMMITTEE MARKUP

MAY 13, 1998

AMENDMENT ROSTER

H.R. 2544, Technology Transfer Commercialization Act of 1998, As Amended by the Subcommittee on Technology

No.	Sponsor	Description	Results
1.	Mr. Sensenbrenner	Amendment In The Nature Of A Substitute to H.R. 2544	

AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2544 OFFERED BY MR. SENSENBRENNER

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the "Technology Transfer
3 Commercialization Act of 1998".

4 **SEC. 2. COOPERATIVE RESEARCH AND DEVELOPMENT**
5 **AGREEMENTS.**

6 Section 12(b)(1) of the Stevenson-Wydler Technology
7 Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) is
8 amended by inserting "or, subject to section 209 of title
9 35, United States Code, may grant a license to an inven-
10 tion which is federally owned, made before the granting
11 of the license, and directly related to the scope of the work
12 under the agreement," after "under the agreement,".

13 **SEC. 3. LICENSING FEDERALLY OWNED INVENTIONS.**

14 (a) AMENDMENT.—Section 209 of title 35, United
15 States Code, is amended to read as follows:

16 **"§ 209. Licensing federally owned inventions**

17 "(a) AUTHORITY.—A Federal agency may grant an
18 exclusive or partially exclusive license on a federally owned
19 invention only if—

1 "(1) granting the license is a reasonable and
2 necessary incentive to—
3 "(A) call forth the investment capital and
4 expenditures needed to bring the invention to
5 practical application; or
6 "(B) otherwise promote the invention's uti-
7 lization by the public;
8 "(2) the Federal agency finds that the public
9 will be served by the granting of the license, as indi-
10 cated by the applicant's intentions, plans, and ability
11 to bring the invention to practical application or oth-
12 erwise promote the invention's utilization by the
13 public, and that the proposed scope of exclusivity is
14 not greater than reasonably necessary to provide the
15 incentive for bringing the invention to practical utili-
16 zation, as proposed by the applicant, or otherwise to
17 promote the invention's utilization by the public;
18 "(3) the applicant makes a commitment to
19 achieve practical utilization of the invention within a
20 reasonable time;
21 "(4) granting the license will not tend to sub-
22 stantially lessen competition or create or maintain a
23 violation of the Federal antitrust laws; and
24 "(5) in the case of an invention covered by a
25 foreign patent application or patent, the interests of

1 the Federal Government or United States industry
2 in foreign commerce will be enhanced.
3 "(b) MANUFACTURE IN UNITED STATES.—A Federal
4 agency shall normally grant a license to use or sell any
5 federally owned invention in the United States only to a
6 licensee who agrees that any products embodying the in-
7 vention or produced through the use of the invention will
8 be manufactured substantially in the United States.
9 "(c) SMALL BUSINESS.—First preference for the
10 granting of any exclusive or partially exclusive licenses
11 under this section shall be given to small business firms
12 having equal or greater likelihood as other applicants to
13 bring the invention to practical application within a rea-
14 sonable time.
15 "(d) TERMS AND CONDITIONS.—Licenses granted
16 under this section shall contain such terms and conditions
17 as the granting agency considers appropriate. Such terms
18 and conditions—
19 "(1) shall include provisions—
20 "(A) retaining a nontransferrable, irrev-
21 ocable, paid-up license for the Federal agency
22 to practice the invention or have the invention
23 practiced throughout the world by or on behalf
24 of the Government of the United States;

1 "(B) requiring periodic reporting on utili-
2 zation of the invention, and utilization efforts,
3 by the licensee, but only to the extent necessary
4 to enable the Federal agency to determine
5 whether the terms of the license are being com-
6 plied with; and
7 "(C) empowering the Federal agency to
8 terminate the license in whole or in part if the
9 agency determines that—
10 "(i) the licensee is not executing its
11 commitment to achieve practical utilization
12 of the invention, including commitments
13 contained in any plan submitted in support
14 of its request for a license, and the licensee
15 cannot otherwise demonstrate to the satis-
16 faction of the Federal agency that it has
17 taken, or can be expected to take within a
18 reasonable time, effective steps to achieve
19 practical utilization of the invention;
20 "(ii) the licensee is in breach of an
21 agreement described in subsection (b);
22 "(iii) termination is necessary to meet
23 requirements for public use specified by
24 Federal regulations issued after the date of

1 the license, and such requirements are not
2 reasonably satisfied by the licensee; or
3 "(iv) the licensee has been found by a
4 competent authority to have violated the
5 Federal antitrust laws in connection with
6 its performance under the license agree-
7 ment.
8 "(e) PUBLIC NOTICE.—No exclusive or partially ex-
9 clusive license may be granted under this section unless
10 public notice of the intention to grant an exclusive or par-
11 tially exclusive license on a federally owned invention has
12 been provided in an appropriate manner at least 15 days
13 before the license is granted, and the Federal agency has
14 considered all comments received in response to that pub-
15 lic notice. This subsection shall not apply to the licensing
16 of inventions made under a cooperative research and de-
17 velopment agreement entered into under section 12 of the
18 Stevenson-Wydler Technology Innovation Act of 1980 (15
19 U.S.C. 3710a).
20 "(f) BASIC BUSINESS PLAN.—A Federal agency may
21 grant a license on a federally owned invention only if the
22 person requesting the license has supplied to the agency
23 a basic business plan with development milestones, com-
24 mercialization milestones, or both.

1 "(g) NONDISCLOSURE OF CERTAIN INFORMATION.—
2 Any basic business plan, and revisions thereto, submitted
3 by an applicant for a license, and any report on the utiliza-
4 tion or utilization efforts of a licensed invention submitted
5 by a licensee, shall be treated by the Federal agency as
6 commercial and financial information obtained from a per-
7 son and not subject to disclosure under section 552 of title
8 5, United States Code.".
9 (b) CONFORMING AMENDMENT.—The item relating
10 to section 209 in the table of sections for chapter 18 of
11 title 35, United States Code, is amended to read as fol-
12 lows:

"209. Licensing federally owned inventions.".

13 **SEC. 4. TECHNICAL AMENDMENTS TO BAYH-DOLE ACT.**
14 Chapter 18 of title 35, United States Code (popularly
15 known as the "Bayh-Dole Act"), is amended—
16 (1) by amending section 202(e) to read as fol-
17 lows:
18 "(e) In any case when a Federal employee is a co-
19 inventor of any invention made under a funding agreement
20 with a nonprofit organization or small business firm, the
21 Federal agency employing such coinventor may, for the
22 purpose of consolidating rights in the invention—
23 "(1) license or assign whatever rights it may
24 acquire in the subject invention from its employee to
25 the nonprofit organization or small business firm; or

"(2) acquire any rights in the subject invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction."; and

(2) in section 207(a)—

(A) by striking "patent applications, patents, or other forms of protection obtained" and inserting "inventions" in paragraph (2); and

(B) by inserting ", including acquiring rights for the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention" after "or through contract" in paragraph (3).

SEC. 5. TECHNICAL AMENDMENTS TO THE STEVENSON-WYDLER TECHNOLOGY INNOVATION ACT OF 1980.

Section 14(a)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710c(a)(1)) is amended—

(1) in subparagraph (A)(i), by inserting ", if the inventor's or coinventor's rights are assigned to the United States" after "inventor or coinventors"; and

1 (2) in subparagraph (B), by striking "succeed-
2 ing fiscal year" and inserting "2 succeeding fiscal
3 years".

4 **SEC. 6. REVIEW OF COOPERATIVE RESEARCH AND DEVEL-**
5 **OPMENT AGREEMENT PROCEDURES.**

6 (a) REVIEW.—The Director of the Office of Science
7 and Technology Policy, in consultation with relevant Fed-
8 eral agencies, national laboratories, and any other person
9 the Director considers appropriate, shall review the gen-
10 eral policies and procedures used by Federal agencies to
11 gather and consider the views of other agencies on—

12 (1) joint work statements under section
13 12(c)(5)(C) or (D) of the Stevenson-Wydler Tech-
14 nology Innovation Act of 1980 (15 U.S.C.
15 3710a(c)(5)(C) or (D)); or

16 (2) in the case of laboratories described in sec-
17 tion 12(d)(2)(A) of the Stevenson-Wydler Tech-
18 nology Innovation Act of 1980 (15 U.S.C.
19 3710a(d)(2)(A)), cooperative research and develop-
20 ment agreements under such section 12,

21 with respect to major proposed cooperative research and
22 development agreements that involve critical national se-
23 curity technology or may have a significant impact on do-
24 mestic or international competitiveness.

1 (b) PROCEDURES.—Within one year after the date of
2 the enactment of this Act, the Director of the Office of
3 Science and Technology Policy, in consultation with rel-
4 evant Federal agencies and national laboratories, shall—
5 (1) determine the adequacy of existing proce-
6 dures and methods for interagency coordination and
7 awareness; and
8 (2) establish and distribute to appropriate Fed-
9 eral agencies—
10 (A) specific criteria to indicate the neces-
11 sity for gathering and considering the views of
12 other agencies on joint work statements or co-
13 operative research and development agreements
14 as described in subsection (a); and
15 (B) additional procedures, if any, for car-
16 rying out such gathering and considering of
17 agency views.
18 Procedures established under this subsection shall be de-
19 signed to the extent possible to use or modify existing pro-
20 cedures, to minimize burdens on Federal agencies, to en-
21 courage industrial partnerships with national laboratories,
22 and to minimize delay in the approval or disapproval of
23 joint work statements and cooperative research and devel-
24 opment agreements.

Chairman SENSENBRENNER. The Clerk will report the Amendment in the Nature of a Substitute.

The CLERK. "Amendment in the Nature of a Substitute to H.R. 2544, offered by Mr. Sensenbrenner.

"Strike"——

Chairman SENSENBRENNER. Without objection, the Amendment in the Nature of a Substitute is considered as read and open for amendment at any point and the Chair recognizes himself for 5 minutes.

This amendment incorporates technical revisions as suggested by the Administration to the text of the bill as reported out by the Subcommittee on Technology. I am offering this amendment with Mrs. Morella, the Chairwoman of the Subcommittee on Technology. The amendment, in part, clarifies certain requirements applied to exclusive and partially exclusive licenses; clarifies that in deciding whether to license exclusively or partially exclusively, consideration should be given to Federal Government interest or whether the interests of the United States industry and foreign commerce will be enhanced; clarifies that an agency co-owner may exclusively license its undivided interest to the other co-owner in lieu of an assignment; clarifies the bill's intention of enabling an agency to license inventions whether or not they are covered by a patent or application for a patent; and clarifies that any business plan and any reports submitted by a licensee relating to the utilization of an invention is deemed commercial and financial information which is not subject to the Freedom of Information Act, and shortens the period for the delay in obtaining an exclusive or partially exclusive license which results from the requirements of public notice from 30 to 15 days.

In addition, the amendment contains language pertaining to the review of cooperative research and development agreements as suggested by the gentlewoman from California, Ms. Tauscher. And I commend her and thank her for her very constructive work in this area. The amendment is bi-partisan and is supported by the Minority and I yield back the balance of my time.

Is there any further discussion on the amendment?

Ms. TAUSCHER. Mr. Chairman?

Chairman SENSENBRENNER. The gentlewoman from California is recognized for 5 minutes.

Ms. TAUSCHER. Thank you Mr. Chairman. I want to express my appreciation to you Mr. Chairman, as well as Ranking Member Brown and Subcommittee Chairwoman Morella, for your assistance with an amendment that I had prepared for this legislation.

The amendment, which you have graciously incorporated into your substitute to H.R. 2544, would require the White House Office on Science and Technology Policy to review the policies and procedures used by federal agencies to gather and consider the views of other agencies on joint work statements, and cooperative research and development agreements. This amendment implies only to major CRADAs that involve critical national security technologies or may have a significant impact on domestic or international competitiveness.

After completing its review, OSTP is directed to establish, if necessary, guidelines for federal agencies to use in assessing CRADAs.

Any new guidelines should be designed to make use of current procedures and minimized any delay in the approval or disapproval of joint work statements and CRADAs. The intent of this amendment, Mr. Chairman, is to insure that federal agencies work cooperatively to provide necessary review of CRADA applications in a timely manner. In no way are we encouraging OSTP to establish additional burdensome procedures for agencies or National laboratories. On the contrary, a coordinated review process should insure that National security and domestic competitiveness issues are protected while providing expedited consideration of CRADA applications.

To further clarify the intent of this amendment Mr. Chairman, I would appreciate your assistance in developing report language to accompany H.R. 2544 that makes clear that we expect review of only the most significant CRADAs. And that clearly defines the term "Critical National Security Technologies" and "Domestic and International Competitiveness."

I understand that work is already underway at some agencies to examine the interagency process. I would expect this OSTP review to make full use and consideration of any ongoing agency efforts to improve the CRADA review process. It is not clear to me, Mr. Chairman, that any changes are necessary in procedures used by federal agencies to review CRADAs. What is clear, however, is that an OSTP-led review will provide greater certainty to those in government as well as industry that the federal agencies can adequately review CRADAs in a timely and effective manner.

Again I appreciate your support for this amendment and I congratulate you on a fine piece of legislation. And I yield back the balance of my time.

Chairman SENSENBRENNER. Before you yield back, let me say that we will work with you in developing the proper report language to implement what you just advocated.

Ms. TAUSCHER. Thank you, Mr. Chairman.

Chairman SENSENBRENNER. Is there further debate on the amendment?

Mr. ROHRABACHER. Mr. Chairman, I have a few questions about the basic bill, and whether or not I should bring it up now with the amendment or should I wait until the amendment passes?

Chairman SENSENBRENNER. Why don't we get the amendment adopted first?

Mr. ROHRABACHER. All right.

Chairman SENSENBRENNER. The question is on the adoption of the amendment.

All those in favor will signify by saying aye.

Opposed, no.

The ayes appear to have it. The ayes have it. And the amendment is agreed to.

The gentleman from California is recognized for 5 minutes to strike the last word.

Mr. ROHRABACHER. Okay. I just would—not being in the Subcommittee that dealt with this piece of legislation—I would like to know—maybe I could ask Mrs. Morella—is the intent of this bill to make it easier to commercialize patents that are in conflict?

Mrs. MORELLA. It is to make it easier to recognize patents and to expedite even further the transfer of technology from our federal laboratories to the private sector. And what it gives—it gives two important new tools to effectively commercialize this on-the-shelf federally-owned technologies, to license them either as stand-alone inventions or by including them as part of a CRADA.

So therefore, our companies are going to find them far more attractive and it's going to expedite the partnership. That was the intent of it.

Mr. ROHRABACHER. Okay. I understand that this bill would make it easier to cooperate, and thus—for example, in dealing with the anti-trust laws and other regulatory complications to the utilization of new technology and technology that usually going through the patent system. But it is not the intent then—it is not your intent and the intent of the authors of this legislation, to make it easier to commercialize patents that are in conflict—that they're in a conflict situation? In terms of ownership.

Mrs. MORELLA. These would be patents in which the United States is the title holder. That I think takes care of your problem.

Mr. ROHRABACHER. Okay. That takes care of that problem. Thank you very much.

Chairman SENSENBRENNER. Are there further amendments to the bill?

[No response.]

If not, the Chair will recognize the gentleman from California or his designee to make a motion to report the bill.

Mr. BROWN of California. Mr. Chairman I move that the Committee report the bill and that the Committee direct the Chairman to take all necessary steps to bring it to the Floor as quickly as possible.

Chairman SENSENBRENNER. The question is on the motion. The Chair notes the presence of a reporting quorum.

All those in favor of reporting the bill favorably will signify by saying aye.

Opposed, no.

The ayes have it. And the bill is favorably reported.

Without objection, the bill will be reported in the form of a single Amendment in the Nature of a Substitute reflecting amendments adopted this morning by the Committee. Without objection, members will be given the appropriate number of days in which to file additional, Minority or dissenting views. And without objection and pursuant to House Rule 20, the Chair will authorized to make whatever motions will be necessary to send the bill to conference.

Hearing no objection to any of these requests, so ordered.