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Rm 5519

To: Perry Phelps

From: Jackie Pickett

1/11/01

TO: Barry Phelps

FROM:  Jen Paugh

SUBJECT: Administrative History

I am attaching some copies of documents relating to the legislative history of the Technology Transfer Commercialization Act of 2000, in which we prepared positions on behalf of the Administration, along with copies of two recently printed reports. There are a large number of additional reports on various topics in technology policy that were published during the Clinton Administration and that are accessible through our web site, <http://www.ta.doc.gov/OTPolicy/Reports.htm>. Unfortunately, I don't have extra copies of those reports to provide you. Let me know if I can be of any further help.



#23
UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Technology
Washington, D.C. 20230

JUL 1 1999

The Honorable Patrick J. Leahy
Ranking Minority Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Senator Leahy:

On July 13, 1998, the Office of Management and Budget (OMB) issued a Statement of Administration Policy (SAP) in support of the Technology Transfer Commercialization Act, which was introduced as H.R. 2544 in the previous Congress. The SAP indicated the Administration's support for the legislation because "[t]he bill will significantly facilitate the licensing of Government-owned inventions by Federal agencies."

On May 10, 1999, in another SAP, OMB reiterated the Administration's current and on-going support for the enactment of the Technology Transfer Commercialization Act, reintroduced as H.R. 209 in the 106th Congress. Additionally, the Administration viewed positively the consensus changes which were made to H.R. 209 at the suggestion of both the Senate Committee on the Judiciary and the Senate Committee on Commerce, Science, and Transportation.

After the House of Representatives considered and passed H.R. 209 on May 11, 1999, we understand that an organization known as the Consumer Project on Technology (CPT) circulated a letter to you and other members of Congress that raised concerns about the bill. We discussed these concerns with the Interagency Working Group on Technology Transfer, which includes representatives from the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Interior, and Transportation and of the National Aeronautics and Space Administration.

We support the principle that the benefits of federal research should be widely available at reasonable prices. But, we are not convinced that the concerns raised in the CPT letter are sufficiently valid to warrant substantive amendments to H.R. 209. Rather, we believe that the changes proposed in H.R. 209 are long overdue and that the overall impact of the bill will be positive. Because you have requested NIH to provide its response to the CPT concerns, we have communicated directly with the technology transfer office staff at NIH, and understand that they will provide their agency's comments in a separate transmittal.

For your review, our comments on each of the points raised by the CPT letter are addressed in the enclosed attachment. We urge the Senate to begin its expeditious consideration of this legislation in the near future and we look forward to its enactment into law.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary R. Bachula". The signature is fluid and cursive, with a large initial "G" and "B".

Gary R. Bachula
Acting Under Secretary for Technology

Enclosure



11
UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Technology
Washington, D.C. 20230

AUG 12 1998

The Honorable Ernest F. Hollings
Ranking Minority Member, Subcommittee
on Communications
Committee on Commerce, Science and Transportation
Washington, DC 20510

Dear Senator Hollings:

I am writing to express the views of a number of executive branch departments and agencies concerning S. 2120. The Interagency Working Group on Federal Technology Transfer, an interagency group the Department chairs, prepared these comments. They reflect the views of the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Interior, and Transportation and of the National Aeronautics and Space Administration.

We believe the provisions of S. 2120 will improve the ability of government agencies to license their inventions fairly and efficiently. We appreciate the care you and Senator Rockefeller have taken in drafting the legislation and believe its provisions will prove useful both to the agencies and to businesses seeking to license from the government. In the attached comments, we have suggested a few ways in which the bill could be strengthened.

We look forward to the opportunity to work with you and your staff on this important bill.

Sincerely,

Kelly Caves for Gary Bachula
Gary R. Bachula
Acting Under Secretary for
Technology

Enclosure

Consensus Comments on S. 2120

The agencies have reviewed the bill carefully and believe the provisions of the bill will help to make agency licensing procedures more efficient, without sacrificing protections built into the existing law. We note, however, that the bill differs from its House counterpart, H.R. 2544, in several respects and we believe that some of those differences do not serve the purpose of the bill. Accordingly, we recommend that the following provisions of the bill be revised:

1. *The Business/Development Plan and Subsequent Related Documents Submitted by the Applicant/Licensee Should be Exempted from Disclosure Under the Freedom of Information Act*

Proposed section 209(g) relates to the non-disclosure of certain information supplied in connection with the licensing of Federal inventions. This provision requires the exemption from disclosure under the Freedom of Information Act of a "subdocument" to be included in all license applications. The subdocument is to include specific information concerning the applicant's plans for commercializing the invention, such as the fields of use and geographic areas in which the applicant wishes to practice the invention.

This provision appears to be aimed at defining with precision the scope of the information that may not be disclosed. While the agencies fully support the objective of making the mandatory exemption as clear and as narrow as possible, they believe the bill's provisions are too detailed to be workable. First, it is not clear from the bill's language whether the protected "subdocument" is intended to be the same document as the "development plan" described in the preceding section. If they are, then this section appears to be unnecessarily limiting the types of information that may be required in the "development plan" and that may be considered by an agency in making its licensing decision. If they are different, then the application of the Freedom of Information Act becomes extremely complicated. Information contained in the subdocument will automatically be exempted from disclosure while the same information contained in the "development plan" will have to be scrutinized carefully under the Freedom of Information Act and may well be disclosed, at least in part.

In addition, the bill's constraints on the disclosure of information concerning fields of use and geographic limitations in a license would make it difficult to advertise or negotiate other field of use or geographic license opportunities involving the same invention. Finally, the bill does not include within the exemption information submitted by the licensee once the license is obtained concerning its commercialization efforts. This information is routinely required as a check on the licensee's performance but because of its confidential commercial nature should be entitled to exemption from disclosure.

The Committee recommends that the bill follow the approach of H.R. 2544, recently passed by the House of Representatives. That bill exempts business or development plans submitted by the licensee and subsequent utilization reports from disclosure under the Freedom of Information Act while leaving the content of those documents to be defined by the agencies consistent with the purposes of the law.

2. *Small Businesses Should Not Be Exempted From The Requirement Of A Business Plan (§ 209(f))*

Proposed section 209(f) requires that applicants submit business plans before a technology can be licensed to them. However, agencies are required to consult with the Small Business Administration (SBA) to develop standards for exempting small businesses from this requirement when applying for a nonexclusive license.

The agencies agree that the licensing process should be structured to take into account the needs of small business whenever possible. For example, there is presently a preference for small businesses in 35 USC 209(c)(3) when agencies are granting an exclusive license. However, the agencies believe that allowing a small business a non-exclusive license without providing a business plan creates the potential for frustrating the primary purpose of expediting the commercialization of some inventions.

The agencies are concerned that a small business could retard or even prevent the commercialization of an agency technology if it is permitted to seek a non-exclusive license without submitting a plan. For example, a small company, seeing an agency notice of intent to grant an exclusive license to another company, could contest the grant by offering instead to non-exclusively license the invention. However, without a business plan to review, the agency would be unable to determine whether the small business had a realistic chance of bringing the invention to the marketplace if it were granted a nonexclusive license. The exemption of small businesses would also severely compromise an agency's ability to terminate the nonexclusive license for lack of performance (as authorized elsewhere in the bill). With no business plan to consider as a basis for judging the small business's conduct, the agency would have a much more difficult time evaluating the commercialization performance of the small business and taking the requisite action. We also note that small businesses generally seek an exclusive license and so the exemption would offer little advantage to them.

For these reasons, the agencies recommend that the second sentence of proposed Section 209(f) be dropped.

3. *The License Retained by the Government Should Be Broadened*

Section 3 (proposed Section 209(d)(1)(A)) authorizes the federal agency to retain a license for itself when granting an exclusive license. Under existing regulation, agencies secure a license for the entire government, rather than just their agency. This enables other agencies to claim the benefits of the license. The agencies recommend

that the bill's language be expanded to permit any agency to use the licensed invention by inserting "any" before "federal".

4. *The Requirement for a Review of CRADA Procedures Needs to be More Carefully Defined*

Section 4 of the bill requires the Executive Branch to review the procedures used in entering into certain CRADAs under the Stevenson-Wydler Technology Innovation Act. The agencies believe, however, that this portion of the bill should be clarified to make clear that the review is not intended to unduly complicate the process of entering into cooperative research and development agreements. The agencies would be pleased to work with the Committee to accomplish this as the bill proceeds.



#2
UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Technology
Washington, D.C. 20230

MAY 13 1998

Congressman Jim Sensenbrenner, Jr.
Chairman
Committee on Science
U.S. House of Representatives
Suite 2320, Rayburn House Office Building
Washington, DC

Dear Chairman Sensenbrenner:

I am writing to express the Department's views on H.R. 2544, which the Committee on Science will be considering on Wednesday, May 13. We earlier submitted written comments on H.R. 2544 (a copy of which is enclosed), to Mrs. Morella and the staff of the Technology Subcommittee. These comments were prepared by the Interagency Working Group on Federal Technology Transfer, an interagency group which we chair, and reflected the views of the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Interior, and Transportation and of the National Aeronautics and Space Administration.

We are pleased that most of our comments have been incorporated into the bill. However, the bill still fails to address the most important issue raised in our written comments and in the earlier testimony of Ray Kammer, Director of the National Institute of Standards and Technology, on this bill. That issue relates to the question of the notice to be given to the public in connection with the exclusive licensing of a government technology.

At present, the agencies are required to give separate public notices of both the availability of the invention and of their intention to grant an exclusive license. The agencies agree that this dual-notice requirement is a cumbersome process of little public benefit. The experience of all of the agencies is that the initial "notice of availability" rarely, if ever, elicits any public response or interest in the technology. Conversely, as Mr. Kammer's earlier testimony indicates, the "notice of intent to license" has frequently helped the agencies make the best possible decision concerning the licensing of the technology by providing an opportunity for other potential applicants to come forward and present their proposals for commercializing the technology. The bill would effectively turn current practice upon its head by requiring that the notice instead focus on the "availability" of the technology -- and thus have to be issued very early, instead of at the critical time when an agency intends to grant an exclusive or partially exclusive license.

MAY 13 1998

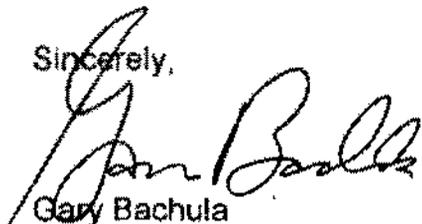
The notice called for by the bill would have to be given when there is much less information available concerning the technology and its possible commercial applications. As a result, potentially interested parties are unlikely to have a basis for evaluating the technology and offering their suggestions for alternative uses. Instead, agencies would likely have to proceed to license to the first party properly requesting an exclusive license, thus compromising the agencies' ability to select the best plan for the development and commercialization of the government technology.

We do not believe that requiring a notice of intent to grant an exclusive license will result in delay as compared with the notice procedure proposed in the bill. The time required to negotiate a license agreement, from the formation of the intent to license to the signing of the agreement, is always substantially longer than 30 days. In the majority of cases, where no comments are filed in response to the notice, little if any delay would occur. Where comments are filed, some additional time would be required to analyze the comments, but any such delay would be more than offset by the benefits to the public of ensuring the most expeditious commercialization and competitive use of the technology.

In addition, we have been working with Committee staff concerning a proposed amendment by Mrs. Tauscher, which is included as section 6 in the May 11 draft of H.R. 2544, in order to make sure it does not unduly complicate the approval process for cooperative research and development agreements. We look forward to continuing to work with you and staff on this proposal as H.R. 2544 proceeds through the legislative process.

Thank you for the opportunity to present our views. We look forward to the opportunity to work with you and your staff on this important bill.

Sincerely,



Gary Bachula

Enclosure



UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Technology
Washington, D.C. 20230

FEB 23 1998

Honorable Constance A. Morella
Chairwoman, Subcommittee on Technology
Committee on Science
U.S. House of Representatives
Washington, D.C. 20515-6301

Dear Madam Chairwoman:

In response to the request of the Subcommittee staff, we have prepared comments on H.R. 2544. These were developed by the Interagency Working Group on Federal Technology Transfer, which includes the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Interior and Transportation, as well as the National Aeronautics and Space Administration.

We fully support the goal of H.R. 2544 to simplify the requirements imposed on Government-owned and operated federal laboratories in the licensing of their inventions. An additional important goal is ensuring federal agencies maintain the ability to exercise proper stewardship over the commercialization of government technologies. Each federal agency has a mission which ultimately provides benefit to the public. To achieve that mission, each agency must be able to exercise its stewardship responsibilities and ensure that commercialization is achieved in an appropriate and timely manner.

However, we believe several provisions of the bill should be revised in order to better achieve these goals. A few technical changes to related statutes are recommended to facilitate the transfer of federal technologies. They are included, per the request of Subcommittee staff.

The Office of Management and Budget advises that there is no objection to the transmission of this report from the standpoint of the Administration's program.

We look forward to working with you and your staff on this important bill.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Bachula", written over a horizontal line.

Gary Bachula
Acting Under Secretary
for Technology

Enclosure: Consensus Comments

Consensus Comments on H.R. 2544

Proposed amendment of Section 12(b)(2) of the Stevenson-Wydler Act

Comments:

We support the broadening of CRADA licensing authority to include pre-existing inventions but believe that the authority should be limited to the licensing of federally owned inventions directly related to the statement of work under the CRADA and that such licenses should be subject to the public notice requirement of proposed § 209(a)(6) if they are exclusive and the general requirements of proposed § 209(b)(1)-(3).

We also believe the grant of authority should be limited to government-owned and operated laboratories and not extend to contractor-operated laboratories, which have independent licensing authority and are not subject to 35 U.S.C. §§ 207 and 209. Furthermore, the contractor usually has the right to own its inventions. In addition, there is a need to make an editorial change to provide only for licensing and not assigning rights in pre-existing inventions.

Proposal:

Add to section 2 of the bill the following:

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, in the case of a government-operated laboratory and subject to sections 209(a)(6) and (b)(1)-(3) of title 35, United States Code, may license any pre-existing federally owned invention directly related to the scope of work under the agreement," after "under the agreement".

Setting the Terms for Nonexclusive Licenses and Clarifying the Scope of Application of Proposed § 209

Comments

Section 3 of the bill appears to be directed to the granting of exclusive licenses (due to the use of the phrase "under this section" in subsections (b)-(d) of proposed § 209), even though many of the requirements in existing § 209 apply to all licenses. We think that the requirements in § 209(b) and (d) should also apply to nonexclusive licenses as well as the express retention of a royalty free license for the Government. HR 2544, as introduced, does not mention any license for the Government. The scope of such a license should be equivalent to that in 37 CFR 404.7(a)(2)(I) and (b)(2)(I), which permits use by foreign governments and international organizations pursuant to a treaty or agreement.

Further, the small business preference in (c) should be for exclusive licenses only because it is not necessary for the granting of non-exclusive licenses.

However, we believe that not every license granted by the Government should be subject to the requirements of § 209, which is designed to ensure appropriate commercialization. We propose excluding the types of transactions currently excluded by regulation (37 CFR 404.1), as well as research licenses not involving any commercialization, and licensing of the Government's undivided rights in inventions jointly owned with a private party to that party. This change would make it clear that licenses otherwise authorized by statutes such as the Federal Technology Transfer Act covering inventions under cooperative research and development agreements, and 35 U.S.C. § 202(e) permitting the transfer of rights in a joint invention to a small business or nonprofit contractor/joint owner, are not subject to the requirements of 35 U.S.C. § 209. Also exempted would be licenses under treaties and international agreements including science and technology memoranda of understanding.

Proposals:

Revise the first part of proposed § 209(a) as follows:

(a) EXCLUSIVE LICENSES -A Federal agency may grant an exclusive, co-exclusive or partially exclusive license in a federally owned invention only if -

Add a new subpart consolidating the requirements of proposed § 209(b) and (d) with the following preface:

(b) ALL LICENSES-A Federal agency may grant a license on a federally owned invention only if the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention. Such licenses shall be subject to the following restrictions:

Move proposed § 209(c) to a new paragraph (a)(6):

(6) first preference for granting the license has been given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time; and

Add the following new subparagraph (b)(4) to proposed § 209:

(4) EXCEPTED PATENT LICENSES-The provisions of section 209 shall not apply to a research license, an exchange of patent rights by a Federal agency to settle a patent dispute, a license of the government's

undivided rights in a jointly owned invention to the joint owner, or a license otherwise authorized by a law, treaty or international agreement.

Add the following new subparagraph (A) to proposed § 209(d)(1)(A) and change "A" and "B" to "B" and "C", respectively:

(A) retaining a royalty-free right for the Government of the United States and for any foreign government or international organization, pursuant to an existing or future treaty or international agreement, to practice or have practiced a federally owned invention on behalf of the Government of the United States, the foreign government or international organization;

Providing Criteria for Setting the Scope of a License

Proposed § 209(a) would eliminate the current requirement that an agency find, in granting an exclusive license, that the terms and scope of a license are no greater than reasonably necessary to provide the applicant with incentive to commercialize the invention. This language has had a positive influence on agency licensing decisions. Many patents contain multiple claims and multiple fields of application and may need licensees with differing resources to commercialize them. Existing statutory language, which requires commercialization plans, gives the agencies a clear basis for determining the proper scope of a license.

Proposal:

Add at the end of § 209(a)(2):

and that the proposed scope of exclusivity is 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

Providing for a Development or Marketing Plan Prior to Licensing Comments:

We believe that the requirement for a development or marketing plan in proposed § 209(d)(2) should not be part of the license but rather the application for a license as is in existing § 209(a). Requiring the plan as part of the licensing process as set forth in our proposed § 209(b) gives the agencies an objective basis for selecting the 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. To help ensure that the goal of commercialization is achieved, we believe it is also important to preserve the agency's ability to modify or terminate the license for sustained failure or inability to carry out the plan.

Proposals:

Delete the requirement for a plan in proposed § 209(d)(2) and revise the first ground for termination in (d)(1)(B)(i):

(i) 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 application of the invention;

Maintaining Existing Requirements for U.S. Manufacture by Licensees

Comments:

Proposed § 209(b) would broaden the scope of the existing U.S. manufacturing requirement but limit its application to exclusive or partially exclusive licenses. Existing § 209(b) applies to both exclusive and nonexclusive licenses but requires manufacturing substantially in the U.S. only where the licensee intends to use or sell the licensed invention in the United States. Licenses covering foreign distribution are now not subject to this requirement. The bill's language would apply the "substantial manufacturing" requirement to both domestic and foreign sales and distribution. This change does not appear to be necessary to achieve the bill's purpose. Further, it would be inconsistent with the trade policy position the U.S. Government has taken in international fora. For these reasons, we recommend that the present statutory language be retained. If Congress would define or explain what is meant by "substantially," this might promote uniform interpretation and application by the agencies of this requirement.

Proposal:

Move proposed § 209(b) to a new subparagraph (b)(1) and revise as follows:

(1) MANUFACTURE IN UNITED STATES. 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.

Modifying the New Single Public Notice Requirement

Comments:

As regards public notice, we believe that the purpose of the bill would be advanced by focusing on the intent to grant an exclusive license rather than the

availability of the invention for licensing. Agencies will likely publicize their available inventions at various times and in many different ways in order to encourage license applications. A copy of the notice should be sent to the Attorney General (as is currently required by 37 CFR 404.9).

We also recommend deleting the bill's requirement that the notice be given "in an appropriate manner" since that language might be construed to require publication in the Federal Register. Further, there should be an explicit requirement as in 37 CFR 404.7(a)(1)(ii) that the announcing Federal agency will consider any timely responses to the notice. There would be no need to exempt inventions made under cooperative research and development agreements as set forth in proposed § 209(e) of the bill because of the general exclusion in our proposed new § 209(b)(4).

Proposal:

Move proposed § 209(e) to a new subparagraph (a)(7) and revise as follows:

(7) a notice of the intent to grant the license has been published, and a copy sent to the Attorney General, at least 30 days before the license is granted and the Federal agency has considered all the timely responses to that notice.

Authorizing Agencies to License "Inventions" Requires Revision of Other Statutory Sections

Comments:

Section 3 of the bill would significantly broaden the scope of authority to license federally owned inventions insofar as this authority would not depend upon whether or not an invention is covered by a patent or patent application. In existing 35 U.S.C. § 207(a)(2), licensing authority is limited to patents and patent applications. Thus, the differing language should be deleted from 35 U.S.C. § 207(a)(2) and replaced with "invention." The term "invention" is defined in 35 U.S.C. § 201(d) and is considered to cover biological materials and computer software. A reference to this statutory definition should be included in this section. Also, § 207(a)(2) should be revised to specifically authorize co-exclusive licenses because they are better recognized in the private sector than are "partially exclusive" licenses.

Proposal:

Add a new paragraph (c) to section 3 of the bill:

(c) AMENDMENT-Section 207(a)(2) of title 35, United States Code, is amended by adding after "exclusive," "co-exclusive" and replacing "patent applications, patents, or other forms of protection obtained" by

"invention". The term "invention" shall have the same meaning as in section 201(d) of this title.

Revising the Antitrust Considerations

Comments:

Proposed § 209(a)(4) addresses the problem that current § 209(c)(2) and (d) effectively require agencies to make full antitrust determinations which are beyond their expertise. However, the proposed section could still be interpreted as requiring the licensing agencies to make antitrust judgments beyond their level of expertise. The interpretation problem could be addressed through regulations that require the agencies to consult with the Antitrust Division of the Department of Justice when they have reason for concern about the competitive consequences of a contemplated exclusive license. We note that some of the terms in proposed § 209(a)(4) are not consistent with the Federal antitrust laws and therefore should be revised. Also, the Attorney General should be sent a copy of the agency's notice of intent to grant an exclusive license as discussed under the prior section on the public notice requirement. Further, any exclusive license should be subject to termination if a competent authority has determined that the licensee has violated the Federal antitrust laws.

Proposals:

Revise proposed § 209(a)(4):

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

Add a new subsection to § 209(b)(2) as follows:

(iv) the licensee has been found by competent authority to violate the Federal antitrust laws in connection with its performance under the license agreement.

Clarify Applicability of FOIA Exemption

Comments:

We are concerned that the final sentence of proposed § 209(d)(2) extends protection from disclosure only to reporting data and not to other information submitted by private parties in connection with licensing. We believe that all such information (with the exception of the name of the licensee and type of license) is entitled to protection from disclosure. This can be accomplished by providing an express exemption from disclosure under 5 U.S.C. § 552 (FOIA).

Proposal:

Add a new subparagraph (b)(3) to proposed § 209:

(3) NON-DISCLOSURE OF CERTAIN INFORMATION-- Information (other than the name of the licensee and type of license) obtained from an applicant or licensee pursuant to this section shall be exempt from disclosure under section 552 of title 5, United States Code.

Clarifications to P.L. 104-113 "National Technology Transfer Act of 1995"

Comments:

Some of the recent changes made by Public Law 104-113 need clarification as explained below.

a. It is not clear that the rights of the inventors must be assigned to the Government in order for them to share royalties because that requirement in 15 U.S.C. § 3710c(a)(1)(A)(I) was deleted by the new law. This has led to widely differing agency interpretations. For example, some agencies share with all inventors even though they have not assigned their rights to the Government, while others do not share with non-government inventors who have assigned. Accordingly, we recommend adding in 15 U.S.C. § 3710c(a)(1)(A)(I) after "coinventors", ", whose rights are assigned to the Government".

b. 15 U.S.C. § 3710d was amended by P.L. 104-113 to allow an agency to return rights to its employee inventor if it did not want to continue prosecution of a patent application or maintain a patent. Unfortunately, the amendment was silent on those circumstances and did not allow the agency the discretion not to assign its rights back to the inventor. Accordingly, we recommend deleting "obtain or" in the first sentence and adding at the end of § 3710d(a):

The agency may reassign its rights to the inventor(s) if it chooses not to continue prosecution of the patent application or to maintain the patent on the invention or otherwise to commercialize the invention.

c. There appears to be a conflict on how long an agency may retain royalty income. Compare 15 U.S.C. § 3710c(a)(B) with (C). We recommend deleting the last sentence of 15 U.S.C. § 3710c(a)(B) which would result in (C) being controlling, thereby giving the agencies one additional year, consistent with the legislative history of P.L. 104-113.

Proposal:

Add a new section 4 to the bill:

Sec. 4. TECHNICAL AMENDMENTS TO THE FEDERAL TECHNOLOGY TRANSFER ACT.

a. Add in 15 U.S.C. § 3710c(a)(1)(A)(I) after "coinventors", ", whose rights are assigned to the Government."

b. Delete "obtain or" in the first sentence of 15 U.S.C. § 3710d(a) and add at the end of section:

The agency may reassign its rights to the inventor(s) if it chooses not to continue prosecution of the patent application or to maintain the patent on the invention or otherwise commercialize the invention.

c. Delete the last sentence of 15 U.S.C. § 3710c(a)(B).

Consolidation of Rights to Joint Inventions Under Bayh-Dole

Comments:

The Bayh-Dole Act defines the patent rights of small businesses 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, and it is often necessary to unify ownership of such co-inventions (under appropriate royalty-sharing arrangements such as 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 Bayh-Dole Act should be amended to make it clear that both the agency and the co-inventing entity have authority to license one another in these circumstances.

While 35 U.S.C. § 202(e) currently provides specific authority for the 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 absence of specific authority to license in these circumstances has resulted in inconsistent rulings by agency counsel, with some approving such licenses while others reject them. Even where approved by agency counsel, the absence of specific statutory licensing authority could leave licenses concluded under that section subject to subsequent legal challenge, and in fact one agency is currently involved in litigation on this issue. Likewise, Bayh-Dole does not specifically 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.

Proposal:

Add a new section 5 to the bill:

Sec. 5. JOINT INVENTIONS UNDER THE BAYH-DOLE ACT.

Amend 35 U.S.C. § 202(e) by replacing "transfer" with "license", inserting after "such co-inventor" "the nonprofit organization or small business firm" and deleting "to the contractor subject to the conditions set forth in this chapter."

Consolidation of Invention Rights through "In-Licensing"

Comments:

Although federal law addresses the issue of "out-licensing" government-owned inventions or rights thereto, there is no specific government-wide authority for the opposite transaction, i.e. to authorize an agency to "in-license" or accept an assignment of rights from a non-Government party. Relatively few inventions can be commercialized without access to related inventions. Thus, 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. However, there is presently no mechanism whereby an agency 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. Similarly, the Government should be able to acquire rights in a joint invention from the other joint owner so that the Government can exclusively license the invention. Once such authority is provided for the Government, there is a need to provide the agency with the right to license these rights in addition to exclude the resulting royalties from the royalty sharing requirement with the inventor(s) of the federally owned invention.

Proposal:

Add a new section 6 to the bill:

Sec. 6. RIGHTS IN PRIVATELY OWNED INVENTIONS.

1. Add after "contract" in 35 U.S.C. § 207(a)(3) ", including the acquiring of rights for the Federal Government in any invention when necessary to facilitate the licensing of a federally owned invention".
2. Add after "federally owned" in 35 U.S.C. § 207(a)(2) "or licensed".
3. Add after "other payments" in 15 U.S.C. § 3710c(a)(1)(A) "for rights in any federally owned invention".

**NIST**

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899
OFFICE OF THE DIRECTOR

APR 13 1998

The Honorable Constance Morella
Chairwoman
Subcommittee on Technology
Committee on Science
House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

At the March 17, 1998, hearing on Facilitating Licenses to Federally Owned Inventions: H.R. 2544, the Technology Transfer Commercialization Act, you and Representative Gutknecht asked me to provide several anecdotal stories on successful licensing interactions between Federal laboratories and companies.

I am enclosing success stories from the National Institute of Standards and Technology, the Agriculture Research Service, the Department of the Interior, and the National Institutes of Health, all members of the Interagency Committee. These stories are but a few of the successful interactions Federal agencies have to date.

If we can provide any additional information, my Acting Director of Congressional and Legislative Affairs, Verna Hines, will be pleased to assist you. She can be reached at 301-975-3080.

Sincerely,

A handwritten signature in black ink that reads "Ray".

Raymond G. Kammer
Director

Enclosure

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology

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ORIGINAL SIGNED BY
RAYMOND G. KAMMER

Raymond G. Kammer
Director

Enclosure

bcc:
100

LACIERTO:din:301-975-3080:04/09/98:OFFICE/CORESP/MORELLA2

official file copy

CONTROL#		WRITER: L. ACIERTO <i>LB</i>	
SURNAME	DATE	SURNAME	DATE
L. ACIERTO <i>LB</i>	4/09/98	B. HEBNER	
V. HINES <i>VBH</i>	4/09/98		

National Institute of Standards and Technology (NIST)

Examples of Successful Licenses

A Novel Method For Making Single Crystals Of Proteins

NIST invented and patented a new method for making large crystals of biomolecules, to enable measurement of their structure.

The ability to reliably make large, perfect single crystals of proteins and other biological macromolecules is essential for biotechnology. Protein engineering is built upon uncovering the three-dimensional structure of proteins by using x-ray crystallography. This information is essential to understand how and why a protein (such as an enzyme) works---why it causes a disease or how to design a drug to fight the disease.

The method that NIST invented is particularly well suited for operation in space flight, where the lack of gravity allows the growth of the best crystals for analysis. NIST licensed the invention exclusively to Instrumentation Technology Associates (ITA), a small U.S. company, for use in microgravity and space related research on board the Space Shuttle, the MIR Space Station, the U.S. Space Station, orbital re-entry vehicles, sounding rockets, and low "g" research aircraft. ITA is a recognized expert in the field, having commercially demonstrated space-based protein growth technology on several Shuttle missions.

Quality Assurance for Automotive Airbags

Morton International's Automotive Safety Products Division, based in Utah, has adapted a NIST-invented ultrasonic system to inspect airbag inflators. Morton-ASP is the leading supplier of airbag inflators to the automotive industry. Auto makers require quality assurance on these components because of their critical role in passenger safety.

Morton-ASP licensed the NIST invention to inspect the mass-produced inflators, which have complicated welds. A unique feature of this inspection system is the use of electromagnetic acoustic transducers (EMATs) that can test the welds at high speed, without contaminating the part or the environment with couplant fluids. Off-line trials involved examining up to 100,000 inflators, and were so successful that Morton contracted with Sonic Sensors of San Luis Obispo, Calif., to build three commercial units. These units are now installed on the production lines and provide process control information on the welding operations.

Quality Assurance for Mammography

Each year 200,000 new cases of breast cancer are diagnosed in the U.S. Early detection provides the best opportunity for cure.

The Mammography Quality Standards Act of 1992 requires accreditation of the nation's 15,000 mammography machines. Upon passage of the Act, state clinical health inspectors urged NIST

to provide calibration standards for "kVp," the high-voltage applied to mammographic x-ray sources. A variation as small as 1 kVp can lead to false readings.

Researchers in the NIST Atomic Physics Division responded by developing and patenting a self-calibrating curved-crystal spectrometer system which determines kVp to 0.1 kVp. This new device represents an enormous improvement over the precision and convenience of existing non-contact calibration instruments. The technology has been licensed to the Radcal Corporation, and it will be marketed as soon as component supply problems are resolved.

**U.S. Department of Agriculture (USDA)
Agricultural Research Service (ARS)**

Examples of Successful Licenses

Improved Poultry Vaccination -- ARS patented a new method to immunize poultry by injecting vaccines into the egg. This technology was exclusively licensed in 1987 to **EMBREX Inc.**, a start-up company with two employees in Research Triangle Park, North Carolina. The technology allowed **EMBREX** to develop **INOVOJET™** which can inoculate 20 to 50 thousand hatchery eggs per hour. Today, this method protects 65 percent of the U.S. poultry market and 70 percent of the Canadian producers. **EMBREX** also employs more than 120 people, and opened an international operation in London where it has entered the European and African markets. The company is also working on similar arrangements with the Japanese to enter the Asian market. **EMBREX**, which is listed on the NASDAQ Exchange, reported \$20.6 million in revenues in fiscal year 1996. The company continues to partner with ARS, with seven Cooperative Research and Development Agreements.

Pathogen Control -- Developed by ARS scientists in College Station, Texas, the technology uses beneficial organisms to control the presence of *Salmonella* and other pathogens in poultry. The patented technology was subsequently licensed to **Milk Specialties**. When applied to animal feed or water, the technology is designed for rapid growth of beneficial organisms to out compete *Salmonella* and other pathogens. This technology reduces the risk of animals ingesting pathogenic bacteria to enhance food safety efforts in poultry production. Since the technology was licensed to **Milk Specialties**, the company has created a BioSciences Division in Madison, Wisconsin that uses the ARS technology as its anchor. Not only does this technology have a positive food safety consequence, but it is also having an impact on new employment in Wisconsin. The product manufactured at the Wisconsin division is also being exported to Japan, bringing the ARS technology to the Pacific Rim. Federal regulatory approval of the new **Milk Specialties** product will provide poultry farmers with a new tool to combat these pathogens, with an overall benefit to consumers.

A separate technology also incorporates beneficial organisms to control the presence of pathogens such as *Salmonella* and *Campylobacter* in poultry. The technology developed by ARS in Athens, Georgia was licensed to **Continental Grain** of Gainesville, Georgia. The company is developing product lines that can be applied to poultry feed to reduce pathogen growth.

Fantestk Starch-Oil Combination -- A variety of food and non-food applications are being commercialized using a stable, nonseparable composition made from starch and oil. Known as **Fantestk**, it was developed by ARS scientists in Peoria, Illinois. **Union Camp Corporation** of Wayne, New Jersey, was granted an exclusive license to the technology to make environmentally friendly adhesives, glues, and coatings. The technology could capture a significant share of the \$100 million per year adhesive and coating market for wood-based products. **Opta Food Ingredients** of Bedford, Massachusetts, licensed the technology for a variety of food applications, such as fat replacements. Additional companies are working with Opta on sublicensing the technology to develop commercial products. The total market for fat

replacements and food ingredients exceeds more than \$300 million per year. The starch-oil combination also attracted the attention of **Seedbio**, Inc. of Caldwell, Idaho, which will use the technology to encapsulate fertilizers and biological pesticides and herbicides in compositions that can be used to coat seeds to reduce surface-level application of these compounds. Additional applications of the technology include pharmaceuticals, lubricants, and personal care products.

Oatrim -- A fat substitute from soluble oat fiber called *Oatrim* was developed and patented by USDA's Agricultural Research Service. The product, which reduces fat and calories and fights blood cholesterol, is commercialized and is an ingredient in many meats, dairy, bakery and other food items. This development has been licensed by **ConAgra Inc.**, **Rhone-Poulenc** and **Quaker Oats**, selling products in excess of \$25 million per year. Most recently, the oatrim technology has led to the creation of a new company that was started by two elderly women in San Diego. The two entrepreneurs opened **Jean's Posh Pastry**, a manufacturer of mail-order cookies and baked goods. Increased demand for the products has led the company to search for expanded manufacturing capacity.

Hypoallergenic Latex -- A process to make hypo-allergenic latex products from the domestic guayule plant was licensed to the **Yulex Corp.** of Philadelphia, Pennsylvania. Latex derived from guayule doesn't contain allergenic proteins found in the *Hevea* plant species, which is the primary source used to make latex products. **Yulex** intends to manufacture products for the health care industry, such as surgical gloves, condoms and catheters as alternatives to current latex products that contain allergenic proteins. This technology could have a significant impact on the \$3.1 billion U.S. latex glove market alone. The Bureau of Indian Affairs is evaluating guayule, a native plant of the desert Southwest, as a way to stimulate economic development on Native American lands.

Super Slurper -- Research has opened new markets for the cornstarch-based absorbent dubbed *super slurper*. Super slurper, which absorbs 2,000 times its weight in water, has proved to be a valuable alternative to petroleum-based chemical absorbents, like carboxymethyl, which was discontinued in feminine hygiene products because it was found to contribute to toxic shock syndrome. At least four companies are manufacturing a variety of environmental products using the starch-absorbent technology. Products currently on the market that use super slurper range anywhere from baby diapers to absorbent mats used to sow grass along construction areas to help prevent erosion, as well as fuel filters.

One of the company's manufacturing super slurper -- **Bandz Inc.** of Smelterville, Idaho was literally built on the USDA technology. When Bandz was incorporated in 1985 in Idaho's Silver Valley, the region was suffering from 30 percent unemployment. This technology led to the creation of 12 new jobs in this economically depressed region. This year Bandz reported \$2 million in sales from its four major product lines and is expected to double its sales next year, as it increases markets both domestically and in the Pacific Rim.

Natural Fungicides – ARS licensed a patented fungicide to Ecogen Inc. of Langhorne, Pennsylvania. The product known as **ASPIRE™** is registered by the Environmental Protection Agency and is an effective control against fruit rot in pears and apples. The technology uses the yeast *Candida oleophila* as an environmental alternative to methyl bromide and other petrochemical fungicides. Discovered by scientists in Kearneysville, West Virginia, this control is yet another example of how agricultural research is providing business and environmental advantages.

National Institutes of Health

Examples of Successful Licenses

• **Leading NIH Technologies That Impact Public Health**

This listing was determined by analysis of NIH technologies on the market which have improved public health. Reagents, research tools and other technologies that may affect the research enterprise are not included in this listing. The technologies are listed in alphabetical order.

Antibodies Against Human Pneumocystis Carinii
Breast Cancer Monoclonal Antibodies
Cancer Chemotherapeutic Drug, 2-F-AraA
Clinical Development of Paclitaxel
Diagnostic for Human Malaria
erb-2 Oncogene Receptor
Human Breast Cancer 1 Gene (BRCA-1)
Isolation of Hepatitis A Virus Strain HM-175 (Vaccine)
Serological Detection of Antibodies to HIV-1
Serological Detection of Antibodies to HTLV-I
Specific and Sensitive Diagnostic Test for Lyme Disease.
Treatment of HIV with ddC
Treatment of HIV with ddI
Trimetrexate as an Anti Parasitic Agent

• **Financial Information on NIH Technology Transfer Activities**

In FY1997, NIH generated nearly \$36 million (\$35,692,000) in income from its technology transfer licensing activities

NIH currently administers 718 royalty generating licenses, of which 208 were signed in FY1997

In FY1997, NIH had 16 employee inventors meet the legislative annual cap of \$150,000 income from their federal inventions

Additional details on licensing

1. ANTIBODIES AGAINST HUMAN PNEUMOCYSTIS CARINII

Monoclonal antibodies specific to human Pneumocystis carinii can be used to detect the presence of the organism that causes pneumonia in immunocompromised individuals, particularly those with AIDS. The use of these antibodies provides a reliable, efficient, and simple diagnostic tool for detection of this organism, which cannot be cultured in humans. The invention is licensed co-exclusively to three companies.

2. BREAST CANCER MONOCLONAL ANTIBODIES

This invention describes monoclonal antibodies demonstrating a reactivity with human breast cancers. The invention has been licensed by a large number of companies for diagnostic test kit and therapeutic purposes as well as for research reagent use involving breast cancer and related cancers.

3. CANCER CHEMOTHERAPEUTIC DRUG, 2-F-AraA

This compound, a DNA polymerase inhibitor, has been shown to have potent activity in the treatment of B-cell leukemia. Licensed exclusively to Berlex Laboratories, a subsidiary unit of Schering AG, 2-F-AraA has been approved by the FDA as a cancer therapeutic drug and is marketed under the trade name "Fludara."

4. CLINICAL DEVELOPMENT OF PACLITAXEL

Development of an improved method for administering Taxol (paclitaxel) has significantly improved the treatment of cancerous tumors, particularly ovarian tumors and breast cancer. Taxol, a recently identified compound derived from the bark of the Western Yew tree, has been found effective in treating patients with breast cancer and advanced stage epithelial ovarian cancer. This technology was developed under a RADA and has been licensed exclusively to Bristol Myers Squibb.

5. DIAGNOSTIC FOR HUMAN MALARIA

A fragment of PfHRP-II gene of *Plasmodium falciparum* was developed using recombinant DNA techniques. This technology is capable of encoding PfHRP-II protein, a water soluble, histidine-rich molecule that may be effective in the detection, diagnosis, and treatment of human malaria, which is caused by the parasite *P. falciparum*. This protein may be particularly useful in the development of an anti-malaria vaccine. This invention is licensed to Becton Dickinson and is marketed under the trade name "Parasight F."

6. erb-2 ONCOGENE RECEPTOR

erb-2 is a retroviral oncogene expressed in human breast cancer. Proteins encoded by this gene and antibodies against those proteins are useful as diagnostic tools in the detection and treatment of cancers. This invention has been licensed on a non exclusive basis to several companies.

7. HUMAN BREAST CANCER 1 GENE (BRCA1)

A gene, BRCA1, that causes the inherited form of breast cancer has been isolated and cloned. Women who inherit a mutated form of BRCA1 have an 85% chance of contracting breast cancer by age 65, as well as elevated risk of ovarian cancer. The gene will be useful in a test for BRCA1 mutations. Such a diagnostic test could be used to identify the estimated 600,000 women at risk of developing the inherited form of breast cancer. Exclusively licensed to the University of Utah/Myriad Genetics, Inc.

8. ISOLATION OF HEPATITIS A VIRUS STRAIN HM-175

Hepatitis A is probably the most widespread of viral hepatitis diseases and is an endemic childhood disease in the underdeveloped countries of the world. The vaccine for Hepatitis A is now being sold in the U.S. and abroad by SmithKline Beecham under the trade name "Havrix."

9. SEROLOGICAL DETECTION OF ANTIBODIES TO HIV-1

The product from this invention is the AIDS Test Kit, which is used as a diagnostic to determine whether patients are HIV positive and to screen blood supplies. The invention is licensed non-exclusively to a number of companies and sold throughout the world.

10. SEROLOGICAL DETECTION OF ANTIBODIES TO HTLV-1

Infection from Human T-Cell Lymphotropic Virus Type I (HTLV-I) can be diagnosed through the use of test kits based upon the cloned HTLV-I envelop genes of this invention. This invention is licensed on a non-exclusive basis to several companies.

11. SPECIFIC AND SENSITIVE DIAGNOSTIC TEST FOR LYME DISEASE

This invention serves as a probe for Lyme borreliosis. Due to the identification of related DNA sequences in *Borrelia burgdorferi*, this invention is unique because it is not limited in specificity. This technology is licensed non-exclusively to GENBIO and is marketed under the trade name "Immuno P39 Lyme Diagnostics."

12. TREATMENT OF HIV INFECTION WITH ddC

ddC, similar in action to AZT, inhibits the replication of HIV by interfering with the production of the critical enzyme reverse transcriptase. Because it may be better tolerated or have different patterns of toxicity than AZT, patients may find it useful in either individual or combination treatment therapy. Licensed exclusively with Hoffman LaRoche and is marketed under the trade name of "Trivid."

13. TREATMENT OF HIV INFECTION WITH ddI

ddI, similar in action to AZT, selectively inhibits the replication of HIV by interfering with the production of a critical enzyme known as reverse transcriptase. Because it may be better tolerated or have different patterns of toxicity than AZT, patients may find it useful in either individual or combination treatment therapy. Licensed exclusively to Bristol Myers Squibb, it completed clinical testing in 1991 and was approved for use by the FDA. It is marketed under the trade name "Videx."

14. TRIMETREXATE AS AN ANTI-PARASITIC AGENT

Infections due to *Toxoplasma gondii* and *Pneumocystis carinii*, often seen in AIDS patients and extremely refractory to standard therapy, can be effectively treated by administering trimetrexate. This invention is licensed exclusively to U.S. Bioscience and is marketed under the trade name "Neutrexin."

U.S. Department of Interior

Example of a Successful License

Desalination Filter -- The Department of Commerce licensed nonexclusively eight companies under domestic and foreign patents owned by the Department of Interior on a reverse osmosis membrane invention made by one of its contractors. This has led to extensive use throughout the world of the membrane which has become a standard in the water purification field. The licenses produces about \$2 million annually in royalties.

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Tech Transfer 2000:

Making Partnerships Work

