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Thank you.

"Promoting Technology Transfer by Facilitating Licenses to Federally-Owned Inventions"

Mr. C. Dan Brand, Chair

Federal Laboratory Consortium for Technology Transfer

Prepared for the Committee on Science

Subcommittee on Technology

U.S. House of Representatives

The Honorable, Constance Morella, Chair

September 25, 1997

Introduction

Madam Chair, it is a privilege to come before you and the Subcommittee to discuss this extremely important issue on " Promoting Technology Transfer by Facilitating Licenses to Federally-Owned Inventions." I wish to thank you for the invitation to address the committee and would also like to express the gratitude on behalf of the Federal Laboratory Consortium for your untiring efforts to promote, and sponsor legislation which serves to better equip our Federal laboratories with the necessary tools, to deal with many of the challenges facing the diverse technology transfer community.

As you know, I serve as Chair, of the Federal Laboratory Consortium for Technology Transfer which is comprised of over 700 research and development federal laboratories, from seventeen federal agencies and departments. We are the nationwide network of Federal laboratories that provides a forum to develop strategies and opportunities, for linking government technology with the mission and the market place.

In preparing for this hearing we have solicited and received comments from a number of our member departments and agencies on removing the legal obstacles to effectively license Federally-owned inventions, created in government - owned and government - operated laboratories (GOGO). Please recognize that we have not, in all cases, received the "official" department/agency position, but rather an initial assessment and reaction to a draft of your bill i.e. Technology Transfer Commercialization Act of 1997.

First, I think it is important for us to not loose sight of the fact, that within our vast Federal Laboratory system, there are different customers and challenges in implementing legislation brought across Agencies, Departments and Laboratories. Clearly the aerospace community needs are not the same as those of the agriculture or health community or the United States Geological Survey and Defense community. Nevertheless, through the years with support from your committee, we have been able to craft legislation that largely addresses the needs and concerns of many, while minimizing if not eliminating altogether unforeseen negative impacts on the Federal research and development community. It is in this spirit, that we have come to testify today, in hopes that you and members of your committee will continue to openly seek the input of our federal laboratory system. So that as we strive to improve upon the foundation of technology legislation that you have contributed so much too, that we not impair the ability of one agency to perform its job at the expense of another.

With those thoughts in mind, I would like to share the input we have received from some of our member agencies, which we would ask that you consider as you begin to finalize legislation on today's hearing.

In regard to key provisions of your draft legislation, the input we have received is in favor of minimizing the time necessary to enter into an exclusive license. The reduction of time for public notification, i.e. 30 days was viewed as striking a balance between expediting the process and ensuring fairness of access to government technology.

With regard to a second provision we call commercial development, rather than eliminate the requirement for a business plan from industry, you are providing the agencies flexibility and allowing them to exercise their best judgment on the need for such plans. Given the breadth and scope of our federal laboratory system, it is quite conceivable where there is greater market pull, rather than government push, that the need for a business plan is paramount to helping ensure a competitive environment. Not solely for the benefit of the laboratory, but to protect the federal investment in technology, and facilitate obtaining a greater return on our investment.

The combination of these amendments to Bayh-Dole we believe will serve to speed the transfer and commercialization of technologies to industry, while still maintaining a fair and open competitive environment.

While the initial input from our laboratory members is largely positive, we feel there are a number of other issues which we would like the Subcommittee to consider. In this regard, we have relied largely on the views of the FLC Legal Issues Committee and the National Institutes of Health (NIH). I should note that the legal issues committee is comprised of agency attorneys who regularly interact with laboratory technology transfer agents in the field. NIH as you know has extensive experience in licensing and is the most financially successful federal laboratory. In FY1996 they generated $27 million in royalty income and will approach $35 million this year--well over 75% of the royalty income to the federal government (per Dept. of Commerce 1994).

Additional related issues including background and recommendations are provided in detail in the balance of my written testimony regarding: Royalty Sharing, Transfer of Intellectual Property Rights, and Inventions.

Conclusion:

Madam Chair, I look forward to answering your questions and those of the committee, and hope that at the conclusion of this hearing, we can continue to provide you and the committee input on science and technology issues.

Licensing of Government Intramural Inventions

Issue: Public Notice of invention availability and intent to license

Background:

Current law requires that, to ensure fairness of access to government technology, a public announcement be made before the government's rights in an invention can be exclusively licensed. The implementing regulation (CFR) specifically requires that this announcement be broken down into two announcements: a 90 day announcement of the "availability" of the license and another 60 day announcement of the agency's intent to exclusively license its rights to a particular company (naming the invention, the company, field of use and other relevant information). The two periods may run concurrently. Current interpretation is that both announcements should be published in the Federal Register. Public announcements are not required on non-exclusive licenses.

It has been suggested that the announcement requirements of the CFR cause excessive delays in the licensing process without providing a concomitant benefit to the public or the federal agency granting the license.

The notice of "availability" could be a useful marketing tool if the federal agencies had some flexibility on where the notice was published (not many potential licenses read the Federal Register, particularly small and medium sized firms).

The "notice of intent" performs a valuable function in that it provides a definitive "cutoff" date for public comment. This allows the federal agency to give thoughtful consideration to any comments received, without subjecting the process to interminable challenges and delays.

A related issue has to do with the information that must be included in the notice of intent. Occasionally, the identity of the eventual licensee may change between the time a notice of intent is first issued and a license negotiated. Also, public comments received may result in "exclusive" licenses becoming "co-exclusive." When this happens, some agencies simply move ahead with the grant of the license without further public notice under the theory that the public has already been informed of the government's "intent." Others start the whole notification process all over again, naming the new potential licensee, thus introducing considerable delay.

Recommendations:

A. Revise the Statutes/Regulations to make it clear that the requirement for federal agencies to publish in the Federal Register does not prevent them from publishing the notice of availability anywhere else they think is useful.

B. Revise the Regulations to shorten the comment period for the notice from 60 days to a minimum of 30 days for exclusive licenses only.

C. Revise the Statute/Regulations to remove the requirement that the notice of intent specifically identify the potential licensee.

D. Extend the notice requirements to Federal-owned, Contractor-operated (GOCO) Laboratories.

Issue: "Commercial Development"

Background

The proposed amendment removes current subparagraph 209(a) requiring a license applicant to submit a commercial development plan, but permits an agency to require such a plan. It also removes corresponding language regarding the ability of an agency to modify or terminate license if a licensee fails to execute a commercial development plan, currently subparagraph 209(f)(2).

The impact of this proposal will be to grant agencies the discretion to use this requirement as necessary. A commercial development plan is necessary because without such a plan there will be no objective method to distinguish between those firms interested in a license, to ensure that their intent is to commercialize rather than use the license for defensive purposes or to ensure that their approach is in the best interest of the agency's mission. If the intent of the proposal is to move away from technical evaluations of the applicants toward providing federally funded technology to the highest bidder, this proposal would meet the intent. However, we do not believe it is in the best interest of the government and the public to have agencies market their technologies solely to maximize income.

For example, how would the public react if the NIH were to sell important new health technology to a single firm that may or may not move the technology quickly to market and has no competition to impact pricing? We have been told that the NIH for example has walked away from deals which have promised great funding opportunities because they would not have been in the best interest of public health by bringing a product to market quickly and for the lowest possible cost.

We understand that there was an intent to provide a level playing field for federal labs and university labs. However, universities are not federal agencies and they are not responsible for carrying out a federally mandated mission nor are they responsible to the public for their activities in the sale of technology. They are seeking income, period. We have missions to accomplish which may or may not mean taking the highest bid for federal technologies.

The proposal also removes from legislation the use of any such plan for monitoring and/or enforcement. Should an entity decide not to move expeditiously in the development of a technology for competitive or other reasons, the government would be at a loss to revoke the license and provide a license to a new organization.

Recommendation:

We recommend that the legislation maintain the current language to enforce licenses through the commercial development plan where required.

Issue: Royalty Sharing

Background:

It is the understanding of the Consortium, that the previous changes to 15 USC 3710c were intended to increase the rewards to the Government inventor. In some instances the opposite has occurred because of changes to the wording and the omission in 3710c(a)(1)(A)(i) of any reference to the inventors being the inventors who had assigned their rights to the Government. The present law is being interpreted by some agencies as requiring royalty sharing with ALL inventors whether or not they assigned their rights in the invention to the Government. This has resulted in moneys received by the Government being shared with non-assigning inventors receiving payments from both their employer and the Government while the Government inventor and the Government Laboratory receive a reduced share. An example, in a breakthrough invention in the medical field, the CRADA partner was willing to pay an exclusive license fee of $100,000 exclusive license fee for a group of patents developed under CRADA. There was only one Government inventor and several corporate and university partners. Under the interpretation of the statue as requiring sharing with all inventors, the royalties were divided between 47 inventor shares of which the Government inventor received 12. When $2,000 + at least 20% was divided into 47 shares, the Government assigning inventor received less than $24,000 dollars, a share equal to his collaborators who also received shares from their University and the laboratory received $16,000. The laboratory director felt the effort wasn't worth it and the inventor was upset because he felt his money was going to others that already were rewarded. Under a rule where division was only with inventors assigning their rights to the Government, the Government inventor would have received about $39,000 and the laboratory about $61,000. Some agencies read the missing language into existing law causing inconsistencies between Government and inventors.

Recommendation:

Amend 15 USC 3710c(1)(A)(i) to read, "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 whose rights in the invention have been assigned to the United States". (underscoring shows the amendment). This language would limit the sharing of royalties or other payment with only those inventors who have assigned their rights to the United States, whether directly or through their employer.

Issue: Transfer of Intellectual Property Rights Under Bayh-Dole

Background:

The Bayh-Dole Act set forth the patent rights of small businesses and non-profit institutions receiving government funding. A significant percentage of government inventions are co-invented with federally funded parties, most commonly university researchers. It is often necessary to unify ownership of such co-inventions (under appropriate royalty-sharing agreements 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 government agency or the co-inventing party.

Bayh-Dole currently provides specific authority for the government to assign its rights in a subject co-invention to the co-inventing party. However, no mention is made of licensing such rights. (Assignment is an irrevocable act, while licensing is not.) The absence of specific authority to license has resulted in agency counsel sometimes approving such licenses while rejecting them in other cases. If nothing else, the absence of specific licensing authority under Bayh-Dole could leave licenses concluded under the Act subject to subsequent legal challenge.

Likewise the Act does not specifically provide a mechanism whereby the co-inventing entity can voluntarily transfer its rights to the federal agency in return for a share of subsequent income, other than a complete abandonment of its rights (which can take up to two years.)

Recommendations:

A. Modify the Statute/Regulations such that the government's rights in a co-invention can be licensed as well as assigned to a co-inventing party.

B. Modify the Statute/Regulations such that a co-inventing entity can voluntarily assign its Bayh-Dole rights in an invention to a government agency having co-inventing rights.

Issue: "Invention"

Background:

Just what constitutes an "invention" is not always consistent in the Statutes/Regulations covering government funded inventions (Bayh-Dole), Government-owned inventions, patent statutes, Federal Technology Transfer Acts, CRADAs, etc. This results in contradictions that impair the effectiveness of the government licensing practitioners and created confusion among the public, especially when they move from one agency to another or from one type of technology transfer agreement to another. For example: the Bayh-Dole Act addresses inventions "conceived or first actually reduced to practiced" (i.e. made) with government funding; rules on the licensing of government-owned intramural inventions address patentable (usually taken to mean those on which a patent application has been filed) or patented inventions; and patent statues allow the filing of a patent application itself to be a "constructive" reduction to practice. (In practice, the "constructive" reduction to practice is actually permitted in some, but not all, art fields - biotechnology inventions being one notable exception.) One could easily envision a situation wherein a government researcher conceived an invention, filed a patent application before reducing it to practice, then provided funding (via an SBIR award or other contract, grant or

collaborative agreement) for the purpose of reducing it to practice. Other agencies report that they also often encounter situations where outside expertise is needed to construct a prototype or even determine if a concept will work. There is a school of thought that both of these and other plausible scenarios would constitute an illegal transfer of government property and/or be contrary to the doctrine of fairness of access.

Similar situations regularly encumber "background" inventions and CRADAs.

A closely related issue has to do with the type of intellectual property that should fall under the definition of "invention" or be available for licensing. For most government owned/operated laboratories (GOGO) this is presently limited to patentable/patented inventions, copyrighted material that has been assigned to the government by non-government entities or organizations, and plant varieties. (There are specific additions for some agencies, such as HHS). On the other hand, the definition of licensable intellectual property resulting from research at Government owned/contractor operated Laboratories (GOCO) or that falling under Bayh-Dole legislation is much broader. This may include not only patentable/patented inventions but copyright, know-how, biological materials plant germ lines, etc.

It has been suggested that it would be much more convenient for U.S. industry if the licensing statutes/regulations applied equally to all government owned and government funded intellectual property. In its most extreme form, this would necessitate either a substantial broadening of the definition of the types of intellectual property that could be licensed by government agencies or a severe restriction of the licensing authority of Bayh-Dole rights. While there may be good arguments put forward on both sides of the issue, it is doubtful that either of these extremes would be in the public interest (or politically palatable.)

However, some degree of unification is warranted in that it would serve to reduce the confusion engendered by having different statutes/regulations apply to government laboratories that, to the public eye, are operated by government agencies which should be operating under the same rules. This could be achieved by extending the statutes/regulations that apply to GOGO laboratories to those GOCO laboratories that are not subject to Bayh-Dole.

The Statutes/Regulations addressing the licensing of government-owned inventions exacerbate an already confusing situation by including "other intellectual property" in the definition of what can be licensed, without defining what this is. Some practitioners maintain that it refers to foreign patents while others have taken it to mean anything that suites their needs, including "copyrightable" works (primarily software) and provisional patent applications.

Recommendations:

A. Develop a consistent definition of "invention." To provide a clear line of demarcation on when the inventive act has an occurred, base of definition on "conceived" and remove any reference to "actually reduced in practice" in all applicable Statutes/Regulations dealing with Federally-owned and/or funded inventions. Specifically state that the conception establishes inventorship/ownership of Federally-owned and/or funded inventions.

B. Do not attempt to expand the definition of licensable government-developed intellectual property to include "copyrightable" material or know-how to GOGO laboratories or to provide government agencies with broad copyright authority.

C. Apply the definition of licensable intellectual property equally between GOGO and GOCO laboratories run by private industry.

D. Either remove the phrases such as "other intellectual property" and " or otherwise protected" from the Statutes/Regulations or define exactly what they mean.

Issues of Concern Principally to NIH

Comments on Pertinent Revisions

Background:

Section 2 of the proposed bill speaks to an amendment to the Stevenson Wydler Act which would expand the authorities under CRADAs to license federally owned inventions.

Federal labs could license technology through CRADA relationships which emanates from non CRADA related activities. This creates a second licensing authority for federally owned inventions under Stevenson Wydler Act where the other authority is under the Bayh Dole Act. This creates confusion and may be viewed as a means of circumventing the licensing requirements of the Bayh Dole Act. Under the new authority federal labs could exclusively license any federal technologies, even those not directly related to the CRADA, to the CRADA partner on an exclusive basis without being subject to the procedures required under Bayh Dole. Companies may be tempted to offer CRADA partnerships to labs primarily to obtain rights to other federal technologies which they may not have been successful in receiving had they competed for the license with other companies.

Recommendation:

It is recommended that the proposed language be modified to state that authority is limited to the licensing of federal technologies directly related to the scope of work under the CRADA and such licenses are subject to the requirements of Section 209 of the Bayh Dole Act.

Background:

The proposed amendment deletes current subparagraph 209(c)(1)(B), requiring a finding by the agency that the desired practical application will not be achieved through non-exclusive licensing (i.e., the preference for non-exclusive licensing);

This will delete the preference for non-exclusive licensing which is beneficial to competition and bring down the cost of products brought to the market. Lower cost to consumers is directly related to competition. In many instances, the granting of an exclusive licensing, whenever requested, may not be in the best interest of the public. However, if the case can be made for an exclusive license, then agencies should be able to grant those types of licenses. The NIH in previous testimony to the Congress on the Reasonable Pricing Clause, specifically cited this legislative requirement to ensure to Congress that competition for licenses would exist and would help to keep down the cost of drugs etc. developed with input from federal laboratory technology.

Recommendation:

We suggest that the legislation should continue to state that it is preferable to have non exclusive licenses but permit the use of exclusive licensing as deemed appropriate by the federal agency.

Background:

The proposed amendment removes current subparagraph 209(c)(1)(D), requiring that the terms and scope of an exclusive license be not greater than reasonably necessary to provide the applicant with incentive to develop the invention;

This will make difficult the narrowing of the scope of licenses to only that which is necessary to provide the applicant with incentive and ability to develop an invention. Many inventions have numerous claims that are being considered for licensing. One firm may not be the best firm to commercialize all of the claims under the license. Therefore, it is important that the licensing office be able to limit the scope of the license to only that which is necessary. To remove the language from the statute will provide the wrong message to industry and to federal lab managers. Again, we desire competition and granting broad licenses generally would not be in the best interest of the government.

Recommendation:

We recommend that the original language be retained.

Background:

The proposed amendment retains language aimed at antitrust considerations, but revises it to delete consideration of "undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates," currently contained in 209(c)(2) and (d).

The concern with this item is that we question what purpose this would serve in encouraging competition, effective and efficient development, or provision of the low prices for final products.

Recommendation:

We recommend that the impact of this item receive additional analysis and discussion before it is adopted.

Background:

Changes in the termination language (d) (1) (B) (I) which deletes the demonstration to the satisfaction of the government that the licensee has taken or is likely to take steps to achieve practical utilization of the invention.

This language changes the burden of proof from the licensee to the government. It should be the licensee's responsibility to provide information to the government that indicates there continued progress and has taken or is likely to take steps to achieve practical utilization of the invention.

Recommendation:

It is recommended that the current language be retained.

FEDERAL LABORATORY CONSORTIUM

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