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Thank you.

June 12, 1997

TO: TY TAYLOR
NORM LATKER

FROM: JOE ALLEN

SUBJECT: PROPOSED RESPONSE TO NIH COMMENTS ON LICENSING AMENDMENT

The National Institutes of Health has raised two objections to the revision to Bayh-Dole and the Federal Technology Transfer Act intended to speed up licensing of on-the-shelf inventions and to include these patents in CRADAS. NIH objects that they need to provide adequate public notice that inventions are available for licensing and need to require applicants to provide them with a commercialization plan before exclusive licenses are granted.

The language below attempts to answer both objections through legislative language rather than through changing the bill itself. I would appreciate your comments before we talk with Rep. Morella's staff about this response.

PROPOSED LANGUAGE FOR REP. MORELLA IN EXPLAINING PUBLIC NOTICE AND SELECTING INDUSTRY PARTNERS PROCEDURES UNDER HER BILL

While removing language requiring onerous public notification procedures in the current law, it is the intent of this amendment that agencies will continue to widely disseminate public notices that inventions are available for licensing. Agencies should approach this in the same manner that they are now providing notice that opportunities for cooperative research and development agreements (CRADAS) are available under the Federal Technology Transfer Act, and universities advertise that licenses are available under the Bayh-Dole Act. In neither case does the law require such notices. Agencies and universities have routinely done so in order that there is fairness of opportunity for all applicants to find and commercialize promising discoveries.

In advertising that their technologies are available for licensing agencies should make the greatest possible use of the Internet which is readily available to companies regardless of size. Electronic postings provide instantaneous notice that commercial partners are being sought for developing federal patents. This is by far more effective than mere publication in the **Federal Register.**

It is not my intent that Congress micromanage this process. Agencies should exercise good judgment in alerting the greatest number of companies to know that licenses are available. It is also not my intent that agencies stray so far in providing such notices, and in attempting to avoid criticism in making decisions, that the process gets bogged down in bureaucratic procedures. Thus, we should not penalize companies who are actively seeking technologies by requiring them to wait arbitrary periods before they can partner with our federal laboratories. Commercialization is difficult enough, particularly with the public sector, not to make it even more cumbersome through these procedures. U.S. industry must be treated like a valued customer by our laboratories, not as someone seeking special favors. collaborators toward a common goal

I intend to follow the same good-sense precedent that the drafters of the Federal Technology Transfer Act showed in crafting that legislation. Each agency should find the method most appropriate for its needs, and be held accountable for the results. Agencies should trade models and find how they can best reach out to the private sector-- particularly innovative small businesses-- and bring them into commercial partnerships. This model has worked well in alerting industry that CRADAS are available. There is no reason to believe that they will not work well again in the more limited area of licensing existing patents.

It must be kept in mind that licensing an on-the-shelf invention is a much better defined procedure than a CRADA . In a CRADA rights are promised to inventions not even created yet. In licensing an existing invention, agencies are much better able to predict market value and impact. If agencies have been able to provide CRADA notices for 10 years without widespread problems, surely they can also devise appropriate mechanisms for licensing their inventions without legislative-- and bureaucratic--micromanagement.

Government-owned contractor-operated laboratories have licensed their patents under exactly the same provisions as those in my bill for many years without apparent problems. Universities are routinely outperforming federal laboratories in licensing their portfolios under the same procedures as in my bill. Agencies should model their practices on these successes.

Agencies also have the ability in implementing revised Section 209 (b) [regarding the intentions, plans and ability of an applicant for an exclusive license to bring the invention to practical application], to require the submission of such intent in the form of a simplified business plan, if desired. In providing this administrative discretion, I expect agencies to use their good judgment in not making this an onerous requirement. Such plans should be simple and concise. Requiring lengthy, overly detailed plans can drive away the very innovative companies that make the best partners. Again, the emphasis must be on determining whether or not the company really can bring the discovery to market effectively, not the creation of another bureaucratic hurdle for industry to leap.

Federal agencies have very limited experience in evaluating business plans. The only purpose of this section is that companies provide reasonable documentation to substantiate their claims that they are both interested in moving the technology to market, (and are not seeking licenses defensively to block competing products or frustrate rivals), and that they have the ability to accomplish their goals.

Agencies must also use good judgment in such reviews. Obviously small companies will not have the wherewithal of larger competitors, but have demonstrated in their past history an astounding success in creating new products and jobs. In seeking to avoid criticism agencies might tend to pick an established company over an innovative start-up business. Avoiding hard choices is not the intent of this language, picking the right partner is my clear goal.

Congress has gone to great lengths to provide the federal agencies with unprecedented authorities to enter into R&D partnerships with the U.S. private sector. It is only fair that as public stewards these agencies be held accountable for aggressively applying these mechanisms. Too many times the private sector's perception is that the bureaucracy's main concern is avoiding criticism in making decisions, not in completing the deal. I hear this complaint too many times not to believe that there is some truth behind the charge. Speeding up the process was my intent in introducing the National Technology Transfer and Advancement Act of 1995, and it is my intent with this legislation.

Innovation is always a difficult task and must be approached both aggressively and prudently. These are not contradictory goals. They require good judgment combined with the willingness to take risks. I intend to use both standards in evaluating how the various agencies have used their technology transfer authorities, and whether or not their industry customers agree with agency's laudatory self appraisals.

I will use the authorities of my Subcommittee to ask each agency how they have applied the laws, and what economic metrics they can provide to justify the claims they are sure to make. I am disappointed that the Department of Commerce has stopped providing such information as required under the Federal Technology Transfer Act in their biennial report. Without this data, it is very difficult for Congress to evaluate how successfully federal R&D is being commercialized.

Agencies have also had a hard time creating objective metrics for evaluating their technology management strategies. This void is too important to remain unfilled. The provision to the Congress on a regular basis as envisioned in the Federal Technology Transfer Act of a report by the Secretary of Commerce with hard data on the number of CRADAS, patent disclosures, royalties, and licensing trends broken out by agency, along with other relevant information is a minimal requirement. The inability to receive even this from the Administration invites Congressional involvement. The stakes are simply too high.

1. Add to FTTA, section 3710 (b)(2):

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 to a federally-owned invention*** ... (new language emphasized.

2. Delete Section 209, P.L. 96-517, as amended, and insert in lieu thereof:

Section 209 Licensing federally owned inventions

(a) Any federal agency may grant exclusive or partially exclusive licenses on federally owned inventions when such actions are reasonable and necessary incentives to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization to the public.

(b) In making determinations to grant exclusive or partially exclusive licenses, the federal agency shall also consider that the public will be served by such licenses in view of the applicant's intentions, plans, and ability to bring the invention to practical applications or otherwise promote the invention's use by the public.

(c) A Federal agency shall not grant such exclusive licenses under this subsection if it determines that the grant of such licenses will tend to substantially lessen competition or to create or maintain other situations inconsistent with the antitrust laws.

(d) In making such determinations, the federal agency shall normally grant the right to use or sell the invention 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.

(e) First preference in granting exclusive or partially licensing of federally owned inventions shall go to small business firms having equal likelihood as other applicants to bring the invention to practical application within a reasonable time.

(f) After consideration of whether the interests of the Federal Government, the public interest, or those of 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 unless it determines that the grant of such licenses will tend to substantially lessen competition, or create or maintain other situations inconsistent with antitrust laws.

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

(h) 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 of the invention: *Provided,* That any such information shall 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 their commitment to achieve practical utilization of the invention within a reasonable time:

(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 (d) of this section; and

(4) the right of the Federal agency to terminate such license in whole or in part if the licensee 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.