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Thank you.

June 17, 1997

TO: BEN WU
BARRY BERINGER

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 also included language about the need to provide Congress with information on agencies' success in applying the Federal Technology Transfer Act to monitor their progress. I asked Ty Taylor and Norm Latker to review the explanation and both have given me comments and support the draft.

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 partner by our laboratories, not as someone seeking special favors.

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.

Agencies have had a difficult time creating objective metrics for evaluating their technology management performance. 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 was a minimal requirement. I am disappointed that the Department of Commerce has stopped providing even this 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.

The inability to receive even this minimum from the Administration invites Congressional involvement. The stakes are simply too high in managing $26 billion of R&D in our federal laboratory system for us not to know by some reasonable measures how we are doing. 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.

cc: Ty Taylor
Norm Latker