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Date: September 15, 1997

To: Norm Latker

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Total number of pages: 5 **(including this cover sheet)**

Original mailed? _____ **Yes** XX **No**

From: Joe Allen

Please call immediately if the telecopy you received is incomplete or illegible.

Telephone number: 304/243-2130 **Fax number: 304/243-4389**

Thank you.

September 15, 1997

TO: BEN WU

FROM: JOE ALLEN

SUBJECT: REVISED AMENDMENT

As you requested, attached is a revised bill with a 30 day public notification procedure for **inventions made outside of the Federal Technology Transfer Act (see new (c) of the bill.**

Norm Latker drafted the language and made the excellent point that we need very strong legislative language emphasizing that this provision only applies to inventions made outside of Cooperative R&D Agreements under the FTTA. The amendment is pretty clear on this, but emphasizing it again in your report language won't hurt. If you would like us to draft something, please let me know.

As you well know, Rep. Morella's 1995 amendment to the FTTA promised collaborating companies exclusive field of use licenses to inventions coming from the CRADA. There is no reason to advertise these inventions. The revised language allows agencies to advertise already existing inventions which they can license or include in CRADA's as appropriate.

Hopefully this should answer the primary objection you have received to the bill.

One other point Jim raised was the deletion of the requirement of a commercial development plan. I believe your current language should be sufficient to meet this concern.

The amendment requires [revised Section 209 (b)] that agencies consider the applicants "intentions, plans, and ability to bring the invention to practical applications or otherwise promote the invention's use by the public." This allows agencies like NIH to obtain whatever information they feel necessary before granting an exclusive license.

Further, in negotiating exclusive licenses it is common practice in industry, universities and Government-owned Contractor-operated labs to include "due diligence" clauses. These are legally binding agreements with the licensee on how they intend to develop and market the invention. They usually include "milestones" for monitoring progress. Since most public sector technologies are a long way from commercial development, this procedure is much more realistic in actually monitoring progress than a plan submitted before the agency and the company have even negotiated a license.

If it appears that the company can't or won't develop the invention, the licensor can revoke the license, or modify it to make it non-exclusive. These procedures are sufficient to protect the public and the agencies' interest in moving discoveries rapidly to the marketplace.

Section 209 (i) underscores the agency's ability to obtain needed information for license enforcement, and their ability to revoke licenses "in whole or in part if it determines that the licensee is not excuting their commitment to achieve practical utilization of the invention within a reasonable time."

cc: Norman Latker

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.

NEW

(c) ***After a federal agency has filed patent applications to protect government ownership to inventions made outside of cooperative research and development agreements under the authorities of Public Law 96-517, as amended, such agency shall make the invention available through public notice in an appropriate manner for 30 days prior to the grant of any license thereon.***

(d) 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.

(e) 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.

(f) 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.

(g) 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.

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

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(i) 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 (e) 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.

change from (d) to (e)