NATIONAL TECHNOLOGY TRANSFER CENTER
MARKET AND TECHNOLOGY ASSESSMENT
Wheeling Jesuit University/ 316 Washington Ave./ Wheeling, WV 26003
Phone: (304) 243-2130 Fax: (304) 243-4389

FACSIMILE TRANSMISSION

Date: May 5, 1997

To: Norm Latker

Organization:

Telephone number: 202-628-5197

Fax number: 202-737-3528

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

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

From: Joe Allen

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

Thank you.

Please review the following information on the amendment to expedite the licensing of federally owned inventions and give me your comments as soon as possible.

Thank you.

Amendment to Expedite the Licensing of Federally Owned Inventions

In enacting the landmark *Bayh-Dole Act of 1980,* Congress began what was to become a steady stream of legislation removing legal roadblocks to the commercialization of federally-funded R&D by the U.S. private sector.

The primary purpose of *Bayh-Dole* was to allow universities to license their federally-supported patents to industry. This has proven to be a tremendous economic boon to the United States. The most recent survey by the Association of University Technology Managers estimated that university licensing alone contributes $21 billion annually to the U.S. economy and licensing has increased 68% between 1991-1995.

Bayh-Dole assured federal agencies that they should seek licensees for their technologies, but did not fundamentally alter the status quo. The question of what to do to improve management of patents owned by the federal government was not the purpose of the Act. Section 209 of *Bayh-Dole* regarding such licenses was a holding action until Congress revisited the issue. At the time of enactment, the inability of the Government to license 28,000 on the shelf discoveries was one of the main reasons why universities were allowed to manage their patent portfolios with a minimum of agency interference.

Beginning in 1984, Congress began addressing the issue of improving technology transfer in the federal laboratory system. With the proven successes of *Bayh-Dole* at universities, the same model of decentralized management of technology was applied to university-operated federal laboratories.

In 1986 the historic *Federal Technology Transfer Act* was enacted allowing Government owned and operated laboratories to perform cooperative research and development agreements (CRADAS) with industry and to provide exclusive licenses to resulting inventions. These incentives were extended to laboratories operated by for profit organizations in 1989.

In order to speed up the commercialization of resulting technologies, Congress enacted the *National Technology Transfer and Advancement Act of 1995* which guaranteed industry collaborators rights to exclusive field of use licenses to inventions made under the law.

The clear trend in all of these initiatives is removing legal obstacles to partnerships between the public and private sectors, recognizing that industry must undertake great risks and expenditures to bring new discoveries to the marketplace.

In all of this time, nothing has been done to speed up the licensing and commercialization of the billions of dollars of on the shelf patents owned by the federal government. The very name of Section 209, "Restrictions on licensing federally owned inventions," is indicative of the approach taken. While many of the provisions in licensing Government owned patents parallel considerations with regard to licensing university owned inventions, (e.g. domestic manufacture, preference to small businesses, reasonable time to commercialization, etc.) there is one important difference. Section 209 requires agencies seeking exclusive licensees to provide public notice and an opportunity for others to file written objections to the action.

Federal regulations normally require **three months** notification of the availability of the invention for exclusive licensing in the **Federal Register.** If someone responds, there follows another notice providing for a **60 day** period for filing objections. The prospective licensee is identified along with the invention during this second notice.

This built in delay of at least 5 months, along with public notification that a specific company is seeking the license is a great disincentive to commercializing on the shelf Government inventions. Additionally, it is a very rare small company which scans the **Federal Register** looking for new technologies. These provisions were made before the advent of electronic communications, which are have become the norm for posting the availability of patents available for licensing.

No such requirements exist for public notification for licensing university patents or patents made by **contractor operated federal laboratories.** No such restrictions apply to companies seeking cooperative research and development agreements under the *Federal Technology Transfer Act* now guarantees companies the right to an exclusive field of use license.

Changing this provision would not only make the commercialization of on the shelf technologies more attractive, it would also allow these discoveries to be included in CRADAS.

Finally, these build in delays fundamentally exacerbate industries' biggest complaint about dealing with the federal government as an R&D partner-- that it simply takes too long to complete a deal. Waiting almost one- half of a year to receive a license that both parties want to grant makes no sense.

Removing this restriction will remove the last significant legal roadblock to expediting licensing and commercialization of federally-funded patents with a potential boost to our economic growth.

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 such determinations, the federal agency shall also consider that the public will be served by exclusive 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 license 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 whether 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.