And may obtain additional rights

license arrangement as being negotiated by treaty or agreement

Consensus Comments on H.R. 2544

Proposed amendment of Section 12(b)(2) of the Stevenson-Wydler Act

Comments:

We support the broadening of CRADA licensing authority to include pre-existing inventions but believe that the authority should be limited to the licensing of federally owned inventions directly related to the statement of work under the CRADA and that such licenses should be subject to the public notice requirement of proposed § 209(a)(6) if they are exclusive and the general requirements of proposed § 209(b)(1)-(3).

Dumb

We also believe the grant of authority should be limited to government-owned and operated laboratories and not extend to contractor-operated laboratories, which have independent licensing authority and are not subject to 35 U.S.C. §§ 207 and 209. Furthermore, the contractor usually has the right to own its inventions. ~~In addition, there is a need to make an editorial change to provide only for licensing and not assigning rights in pre-existing inventions.~~

Why? unnecessary limitation

Proposal:

unnecessary limitation

Add to section 2 of the bill the following:

NO

> Section 12(b)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) is amended by inserting "or, in the case of a government-operated laboratory and subject to sections ~~209(a)(6) and (b)(1)-(3) of title 35, United States Code,~~ may license ~~any pre-existing~~ federally owned invention directly related to the scope of work under the agreement," after "under the agreement".

New draft

Setting the Terms for Nonexclusive Licenses and Clarifying the Scope of Application of Proposed § 209

Comments

Section 3 of the bill appears to be directed to the granting of exclusive licenses (due to the use of the phrase "under this section" in subsections (b)-(d) of proposed § 209), even though many of the requirements in existing § 209 apply to all licenses. We think that the requirements in § 209(b) and (d) should also apply to nonexclusive licenses as well as the express retention of a royalty free license for the Government. HR 2544, as introduced, does not mention any license for the Government. The scope of such a license should be equivalent to that in 37 CFR 404.7(a)(2)(I) and (b)(2)(I), which permits use by foreign governments and international organizations pursuant to a treaty or agreement.

NO! NO!

Why?

because 96-517 doesn't

Right

Further, the small business preference in (c) should be for exclusive licenses only because it is not necessary for the granting of non-exclusive licenses.

but not consistent with [illegible] draft

However, we believe that not every license granted by the Government should be subject to the requirements of § 209, which is designed to ensure appropriate commercialization. We propose excluding the types of transactions currently excluded by regulation (37 CFR 404.1), as well as research licenses not involving any commercialization, and licensing of the Government's undivided rights in inventions jointly owned with a private party to that party. This change would make it clear that licenses otherwise authorized by statutes such as the Federal Technology Transfer Act covering inventions under cooperative research and development agreements, and 35 U.S.C. § 202(e) permitting the transfer of rights in a joint invention to a small business or nonprofit contractor/joint owner, are not subject to the requirements of 35 U.S.C. § 209. Also exempted would be licenses under treaties and international agreements including science and technology memoranda of understanding.

NO

Proposals:

Revise the first part of proposed § 209(a) as follows:

> (a) EXCLUSIVE LICENSES -A Federal agency may grant an exclusive, co-exclusive or partially exclusive license in a federally owned invention only if -

Add a new subpart consolidating the requirements of proposed § 209(b) and (d) with the following preface:

> (b) ALL LICENSES-A Federal agency may grant a license on a federally owned invention only if the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention. Such licenses shall be subject to the following restrictions:

Move proposed § 209(c) to a new paragraph (a)(6):

O.K.

> (6) first preference for granting the license has been given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time; and

Add the following new subparagraph (b)(4) to proposed § 209:

?

> **(4) EXCEPTED PATENT LICENSES-The provisions of section 209 shall not apply to a research license, an exchange of patent rights by a Federal agency to settle a patent dispute, a license of the government's**

undivided rights in a jointly owned invention to the joint owner, or a license otherwise authorized by a law, treaty or international agreement.

NO

Add the following new subparagraph (A) to proposed § 209(d)(1)(A) and change "A" and "B" to "B" and "C", respectively:

> (A) retaining a royalty-free right for the Government of the United States and for any foreign government or international organization, pursuant to an existing or future treaty or international agreement, to practice or have practiced a federally owned invention on behalf of the Government of the United States, the foreign government or international organization;

NO.

Providing Criteria for Setting the Scope of a License

Proposed § 209(a) would eliminate the current requirement that an agency find, in granting an exclusive license, that the terms and scope of a license are no greater than reasonably necessary to provide the applicant with incentive to commercialize the invention. This language has had a positive influence on agency licensing decisions. Many patents contain multiple claims and multiple fields of application and may need licensees with differing resources to commercialize them. Existing statutory language, which requires commercialization plans, gives the agencies a clear basis for determining the proper scope of a license.

Proposal:
Add at the end of § 209(a)(2):

Partially exclusive

> and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public

Providing for a Development or Marketing Plan Prior to Licensing

Agree

Comments:
We believe that the requirement for a development or marketing plan in proposed § 209(d)(2) should not be part of the license but rather the application for a license as is in existing § 209(a). Requiring the plan as part of the licensing process as set forth in our proposed § 209(b) gives the agencies an objective basis for selecting the firm best suited to commercialize the invention. The exercise of preparing the plan is also of considerable use in assisting companies, especially small businesses, in defining their own focus with respect to the invention. To help ensure that the goal of commercialization is achieved, we believe it is also important to preserve the agency's ability to modify or terminate the license for sustained failure or inability to carry out the plan.

Proposals:
Delete the requirement for a plan in proposed § 209(d)(2) and revise the first ground for termination in (d)(1)(B)(i):

> (i) the licensee is not executing its commitment to achieve practical utilization of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

Maintaining Existing Requirements for U.S. Manufacture by Licensees

Comments:
Proposed § 209(b) would broaden the scope of the existing U.S. manufacturing requirement but limit its application to exclusive or partially exclusive licenses. Existing § 209(b) applies to both exclusive and nonexclusive licenses but requires manufacturing substantially in the U.S. only where the licensee intends to use or sell the licensed invention in the United States. Licenses covering foreign distribution are now not subject to this requirement. The bill's language would apply the "substantial manufacturing" requirement to both domestic and foreign sales and distribution. This change does not appear to be necessary to achieve the bill's purpose. Further, it would be inconsistent with the trade policy position the U.S. Government has taken in international fora. For these reasons, we recommend that the present statutory language be retained. If Congress would define or explain what is meant by "substantially," this might promote uniform interpretation and application by the agencies of this requirement.

Proposal:
Move proposed § 209(b) to a new subparagraph (b)(1) and revise as follows:

agree

> (1) MANUFACTURE IN UNITED STATES. A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States 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.

?Modifying the New Single Public Notice Requirement

How would this work?

Comments:
As regards public notice, we believe that the purpose of the bill would be advanced by focusing on the intent to grant an exclusive license rather than the

availability of the invention for licensing. Agencies will likely publicize their available inventions at various times and in many different ways in order to encourage license applications. A copy of the notice should be sent to the Attorney General ~~(as is currently required by 37 CFR 404.9)~~.

We also recommend deleting the bill's requirement that the notice be given "in an appropriate manner" since that language might be construed to require publication in the Federal Register. Further, there should be an explicit requirement as in 37 CFR 404.7(a)(1)(ii) that the announcing Federal agency will consider any timely responses to the notice. There would be no need to exempt inventions made under cooperative research and development agreements as set forth in proposed § 209(e) of the bill because of the general exclusion in our proposed new § 209(b)(4).

Proposal:
Move proposed § 209(e) to a new subparagraph (a)(7) and revise as follows:

too specific

> (7) a notice of the intent to grant the license has been published, and a copy sent to the Attorney General, at least 30 days before the license is granted and the Federal agency has considered all the timely responses to that notice.

Authorizing Agencies to License "Inventions" Requires Revision of Other Statutory Sections

Comments:
Section 3 of the bill would significantly broaden the scope of authority to license federally owned inventions insofar as this authority would not depend upon whether or not an invention is covered by a patent or patent application. In existing 35 U.S.C. § 207(a)(2), licensing authority is limited to patents and patent applications. Thus, the differing language should be deleted from 35 U.S.C. § 207(a)(2) and replaced with "invention." The term "invention" is defined in 35 U.S.C. § 201(d) and is considered to cover biological materials and computer software. A reference to this statutory definition should be included in this section. Also, § 207(a)(2) should be revised to specifically authorize co-exclusive licenses because they are better recognized in the private sector than are "partially exclusive" licenses.

must be

no

Proposal:
Add a new paragraph (c) to section 3 of the bill:

> (c) AMENDMENT-Section 207(a)(2) of title 35, United States Code, is amended by adding after "exclusive," "co-exclusive" and replacing "patent applications, patents, or other forms of protection obtained" by

"invention". The term "invention" shall have the same meaning as in section 201(d) of this title.

Revising the Antitrust Considerations

Comments:

Proposed § 209(a)(4) addresses the problem that current § 209(c)(2) and (d) effectively require agencies to make full antitrust determinations which are beyond their expertise. However, the proposed section could still be interpreted as requiring the licensing agencies to make antitrust judgments beyond their level of expertise. The interpretation problem could be addressed through regulations that require the agencies to consult with the Antitrust Division of the Department of Justice when they have reason for concern about the competitive consequences of a contemplated exclusive license. We note that some of the terms in proposed § 209(a)(4) are not consistent with the Federal antitrust laws and therefore should be revised. Also, the Attorney General should be sent a copy of the agency's notice of intent to grant an exclusive license as discussed under the prior section on the public notice requirement. Further, any exclusive license should be subject to termination if a competent authority has determined that the licensee has violated the Federal antitrust laws.

Proposals:

Revise proposed § 209(a)(4):

> (4) granting the license will not tend to substantially lessen competition or create, facilitate or maintain a violation of the Federal antitrust laws.

Add a new subsection to § 209(b)(2) as follows:

> (iv) the licensee has been found by competent authority to violate the Federal antitrust laws in connection with its performance under the license agreement.

Clarify Applicability of FOIA Exemption

Comments:

We are concerned that the final sentence of proposed § 209(d)(2) extends protection from disclosure only to reporting data and not to other information submitted by private parties in connection with licensing. We believe that all such information (with the exception of the name of the licensee and type of license) is entitled to protection from disclosure. This can be accomplished by providing an express exemption from disclosure under 5 U.S.C. § 552 (FOIA).

Proposal:
Add a new subparagraph (b)(3) to proposed § 209:

> (3) NON-DISCLOSURE OF CERTAIN INFORMATION-- Information (other than the name of the licensee and type of license) obtained from an applicant or licensee pursuant to this section shall be exempt from disclosure under section 552 of title 5, United States Code.

Clarifications to P.L. 104-113 "National Technology Transfer Act of 1995"
Comments:
Some of the recent changes made by Public Law 104-113 need clarification as explained below.

a. It is not clear that the rights of the inventors must be assigned to the Government in order for them to share royalties because that requirement in 15 U.S.C. § 3710c(a)(1)(A)(I) was deleted by the new law. This has led to widely differing agency interpretations. For example, some agencies share with all inventors even though they have not assigned their rights to the Government, while others do not share with non-government inventors who have assigned. Accordingly, we recommend adding in 15 U.S.C. § 3710c(a)(1)(A)(I) after "coinventors", ", whose rights are assigned to the Government".

O.K.

b. 15 U.S.C. § 3710d was amended by P.L. 104-113 to allow an agency to return rights to its employee inventor if it did not want to continue prosecution of a patent application or maintain a patent. Unfortunately, the amendment was silent on those circumstances and did not allow the agency the discretion not to assign its rights back to the inventor. Accordingly, we recommend deleting "obtain or" in the first sentence and adding at the end of § 3710d(a):

> The agency may reassign its rights to the inventor(s) if it chooses not to continue prosecution of the patent application or to maintain the patent on the invention or otherwise to commercialize the invention.

~~must read~~ not necessary

c. There appears to be a conflict on how long an agency may retain royalty income. Compare 15 U.S.C. § 3710c(a)(B) with (C). We recommend deleting the last sentence of 15 U.S.C. § 3710c(a)(B) which would result in (C) being controlling, thereby giving the agencies one additional year, consistent with the legislative history of P.L. 104-113.

Proposal:
Add a new section 4 to the bill:

Sec. 4. TECHNICAL AMENDMENTS TO THE FEDERAL TECHNOLOGY TRANSFER ACT.

a. Add in 15 U.S.C. § 3710c(a)(1)(A)(I) after "coinventors", ", whose rights are assigned to the Government."

b. Delete "obtain or" in the first sentence of 15 U.S.C. § 3710d(a) and add at the end of section:

> The agency may reassign its rights to the inventor(s) if it chooses not to continue prosecution of the patent application or to maintain the patent on the invention or otherwise commercialize the invention.

c. Delete the last sentence of 15 U.S.C. § 3710c(a)(B).

Consolidation of Rights to Joint Inventions Under Bayh-Dole

Comments:

The Bayh-Dole Act defines the patent rights of small businesses and non-profit organizations receiving Federal government funding. A significant percentage of government inventions are co-invented with federally-funded parties, most commonly university researchers, and it is often necessary to unify ownership of such co-inventions (under appropriate royalty-sharing arrangements 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 co-inventing entity or the Federal agency. The Bayh-Dole Act should be amended to make it clear that both the agency and the co-inventing entity have authority to license one another in these circumstances.

While 35 U.S.C. § 202(e) currently provides specific authority for the government to assign its rights in a subject co-invention to the co-inventing entity, it does not mention the licensing of such rights. The absence of specific authority to license in these circumstances has resulted in inconsistent rulings by agency counsel, with some approving such licenses while others reject them. Even where approved by agency counsel, the absence of specific statutory licensing authority could leave licenses concluded under that section subject to subsequent legal challenge, and in fact one agency is currently involved in litigation on this issue. Likewise, Bayh-Dole does not specifically provide a mechanism whereby the co-inventing entity can voluntarily transfer its rights by license or assignment to the federal agency in return for a share of any subsequent income.

Proposal:
Add a new section 5 to the bill:

Sec. 5. JOINT INVENTIONS UNDER THE BAYH-DOLE ACT.
Amend 35 U.S.C. § 202(e) by replacing "transfer" with "license", inserting after "such co-inventor" "the nonprofit organization or small business firm" and deleting "to the contractor subject to the conditions set forth in this chapter."

Consolidation of Invention Rights through "In-Licensing"

Comments:
Although federal law addresses the issue of "out-licensing" government-owned inventions or rights thereto, there is no specific government-wide authority for the opposite transaction, i.e. to authorize an agency to "in-license" or accept an assignment of rights from a non-Government party. Relatively few inventions can be commercialized without access to related inventions. Thus, it is increasingly necessary for an agency to be able to offer a potential licensee access to related inventions in order to practice a Government-owned invention. However, there is presently no mechanism whereby an agency can "in-license" the rights to other inventions (in return for the payment of a share of any subsequent royalties) so that they can be "bundled" with a government-owned invention and licensed together for commercialization. Similarly, the Government should be able to acquire rights in a joint invention from the other joint owner so that the Government can exclusively license the invention. Once such authority is provided for the Government, there is a need to provide the agency with the right to license these rights in addition to exclude the resulting royalties from the royalty sharing requirement with the inventor(s) of the federally owned invention.

Proposal:
Add a new section 6 to the bill:

Sec. 6. RIGHTS IN PRIVATELY OWNED INVENTIONS.

1. Add after "contract" in 35 U.S.C. § 207(a)(3) ", including the acquiring of rights for the Federal Government in any invention when necessary to facilitate the licensing of a federally owned invention".

2. Add after "federally owned" in 35 U.S.C. § 207(a)(2) "or licensed".

3. Add after "other payments" in 15 U.S.C. § 3710c(a)(1)(A) "for rights in any federally owned invention".