

Government Grants and Patent Rights: SBIR, STTR, and Your IP

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Overview

Bayh-Dole Act of 1980 and its provisions

Types of grants for companies

Invention reporting and protection requirements

The Bayh-Dole Act of 1980



Senators Birch Bayh and Bob Dole at the U.S. Capitol on Feb. 21, 1978.

"provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development" *Bayh-Dole Act*

Definitions

• Subject Invention. any invention conceived or first actually reduced to practice in the performance of work under a funding agreement

 Conception. Formation in the mind of inventor of a definite and permanent idea of complete and operative invention; conception and *means* of putting idea into practice

• First Actual Reduction to Practice. Embodiment or a performed process meets every element of the claimed invention; and the embodiment or process operated for its intended purpose.

In re Eddie L. King

What constitutes first actual reduction to practice?

 Does the subject invention need to be tested to ensure it functions for its intended purpose?

Ideal Innovations, Inc. v. United States, CFC 2021

Reversed and Remanded

- Patent apps filed by Ideal Innovations in 2006
- Ideal Innovations tested the material for impact in 2006 alleged "first actual reduction to practice"
 - Court indicated this was a test of the armor, not of the invention
 - Actual test was needed to determine whether prototype worked for its intended purpose
- Ideal Innovations signed licensing agreement with U.S. in 2007

Bayh-Dole Provisions

1. Disclose each *subject invention* to the Federal agency within 2 months

- 2. Make a written election within two years after disclosure to the Federal agency or within 60 days of any statutory period
- 3. Agree to file a patent application prior to any statutory bar date and corresponding patent applications in U.S. within 1 yr. and other countries within 10 mo. (both are extendable upon request)

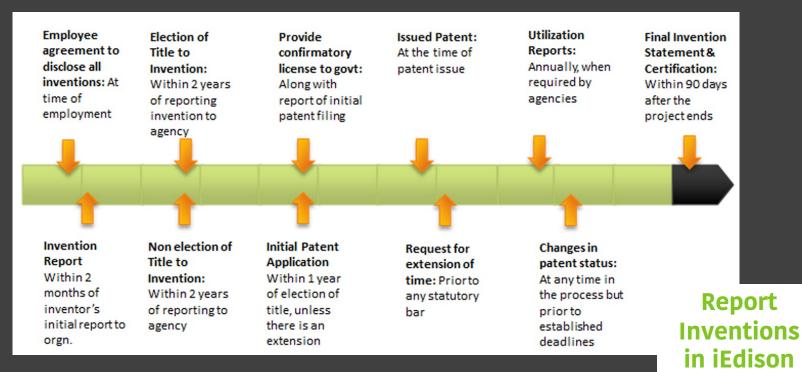
Bayh-Dole Provisions

4. For elected inventions, Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice any subject invention throughout the world

5. Federal agency to require periodic reporting on the utilization of any subject invention

6. Obligation to include, in patent applications, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

Subject Invention Reporting Timeline



Gov't Retains March-In Rights

Federal agency can **require** the contractor to an assignee or exclusive licensee of a subject invention to **grant a nonexclusive, partially exclusive, or exclusive license** in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances

March-In Rights

- Practical Application. Effective steps were not taken to achieve practical application of the subject invention in such field of use.
- 2. Health and Safety. Need to alleviate health or safety needs which are not currently reasonably satisfied.
- **3. Public Use.** Requirements set by agency are not reasonably satisfied.
- **4. Breach of Agreement.** Licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement underBayh-Dole.

What types of grants are applicable for our clients?

Small Business Technology Transfer (STTR) & Small Business Innovation Research (SBIR)

<u>STTR</u>

- Stimulate scientific and technological innovation between small business concerns and research institutions
- 3 Phase structure
 - 1. Feasibility
 - 2. R&D
 - 3. Commercialization (can't use STTR funds)

SBIR

- Stimulate technological innovation in private sector, for-profit institutions for ideas that have potential for commercialization
- 3 Phase structure
 - Feasibility
 - 2. R&D
 - Commercialization (can't use SBIR funds)

Do SBIR/STTR Grants Cover IP Costs?

- Technical and Business Assistance (TABA) funds. May be authorized for patent prosecution costs related to obtaining U.S. patent protection for Subject Inventions of this award.
 - \$6,500 in Phase I
 - \$50,000 in Phase II
- Budget Location. Include patent costs in commercialization assistance budget ("other direct costs"). Patent costs include practitioner and USPTO fees.

Do SBIR/STTR Grants Cover IP Costs?

- Filings. USPTO related to provisional, PCT, non-provisional, continuation, and continuation-in-part patent applications.
- Search. Freedom to operate, market analysis, competitor IP landscape and products, searching costs may be allowable.

• Exclusions.

- Foreign related costs (e.g., foreign attorney, foreign patent office, or translation fees).
- Licenses not allowable since typically not a required cost in performance of the award.

SBIR/STTR Inventions vs. Data

- Patent it. Idea, concept, design or method visible to the naked eye.
- Keep it Secret. Recorded or written technical information or data developed under SBIR funding agreements. Data/Information can be kept secret under a government's nondisclosure obligation. Only applies when it has been written down. Fixed protection period of 20 years.
- Don't Include privately funded data.

Advice for Gov't Grant Recipients

- Mark your data. Can be marked in a Final Report.
- Report Subject Inventions. Report all inventions through iEdison, not just patentable ones
- Track statutory bars. Report to your practitioner and agency through iEdison.
- Understand U.S. Manufacturing requirements. Consult agency early with questions.

Gov't Grant Gotchyas

- 1. If hire subcontractor to perform some of the work, any subject invention from the subcontractor cannot be assigned to your company—subcontractor retains ownership.
- 2. If subject invention is <u>unelected</u> at 2 years, then **gov't receives title of invention.**
- 3. **No exclusive licenses,** unless approved by NIH in advance and is manufactured substantially in the United States.