

Bayh-Dole and Technology Transfer Considerations for Funding Agreements

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Technology Transfer

STATUTES: Bayh-Dole Act 1980

REGULATIONS

POLICY

Binding

Hortatory

Bayh-Dole Act of 1980

- ✍ Provide incentives for industry to commercialize new technologies by vesting title in grantee or contractor institutions
- ✍ Use patents as such an incentive without unduly encumbering future research and discovery (Bayh-Dole Amendment 2000)

Bayh-Dole Act

✍ If Recipient Institution Elects Title to Subject Inventions, it...

- can patent and license
- has obligation to move technology toward commercialization
- can retain royalties
- but cannot assign title to patent without agency approval
- grants Gov't a use license

Government Use License to “Subject Inventions”

- ✍ Non-exclusive, Non-transferable, Paid-up
- ✍ To Practice or Have Practiced By or On Behalf of the United States
 - Government itself
 - Contractors
- ✍ Throughout the World
- ✍ Expeditious but does not include materials or know how

Funding Mechanisms Terms of Award

- ✍ Guidelines for the Conduct of Research (“Research Tool Guidelines”)
 - Academic Freedom and Dissemination of Results
 - Sharing unique Research Tools
- ✍ Special provisions for disposition of data and materials as proposed by applicant
- ✍ Deliverables under Contracts
- ✍ Declaration of Exceptional Circumstances (DEC)

DATA

- ✍ If data describes invention, public disclosures eliminate patentability in most countries (1 year grace period in US)
- ✍ Generally no exclusive rights, except perhaps use of clinical data for regulatory purposes
- ✍ Copyright can be held in works when they are fixed (written, photographed, recorded)
- ✍ No copyright in data (facts) per se but in their presentation or description
- ✍ No copyright in works of govt employees

Rights in Data—Grants

- ✍ Recipients have rights in data, including copyright
- ✍ Government has free license to use copyright
- ✍ Government can use and distribute copyrighted material for Government purposes
- ✍ Grants or Cooperative Agreements may have special terms and conditions

Rights in Data—Contracts

- ✍ Contractor cannot assert copyright in its works without permission of agency
- ✍ If agency allows contractor to assert ©, govt has free license to use and distribute work
- ✍ However, govt has no right to distribute software if contractor asserts ©, unless contract states otherwise
- ✍ Need deliverable of data/software and right to use it

Research Tool Guidelines

Sharing Biomedical Research Resources:
Principles and Guidelines for Recipients
of NIH Research Grants and Contracts

December 1999

The Principles

- ✍ Academic Freedom and Publication
- ✍ Appropriate Implementation of Bayh-Dole
- ✍ Broad dissemination of NIH-funded tools
- ✍ Minimizing Impediments to the Research Enterprise



Guidelines for Implementing the Principles

- ✍ Importing tools into NIH-funded research
- ✍ Disseminating tools developed with NIH funds
- ✍ Uniform one-page MTA proposed
- ✍ Strategic licensing to achieve balance

Best Practices for the Licensing of Genomic Inventions (2005)

- ✍ Not All Innovations Require Further R&D to Meet Goals of Public Use
- ✍ If significant R&D is not needed, consider NOT patenting
- ✍ Not all Patents Require Exclusive Licensing
- ✍ In Exclusive Licenses, keep scope narrow and ensure public health goals addressed

FFI

OTT

www.ott.nih.gov

Sharing Biomedical Research Tools

www.ott.nih.gov/policy/research_tool.html

A Plan to Insure Taxpayers' Interests are Protected

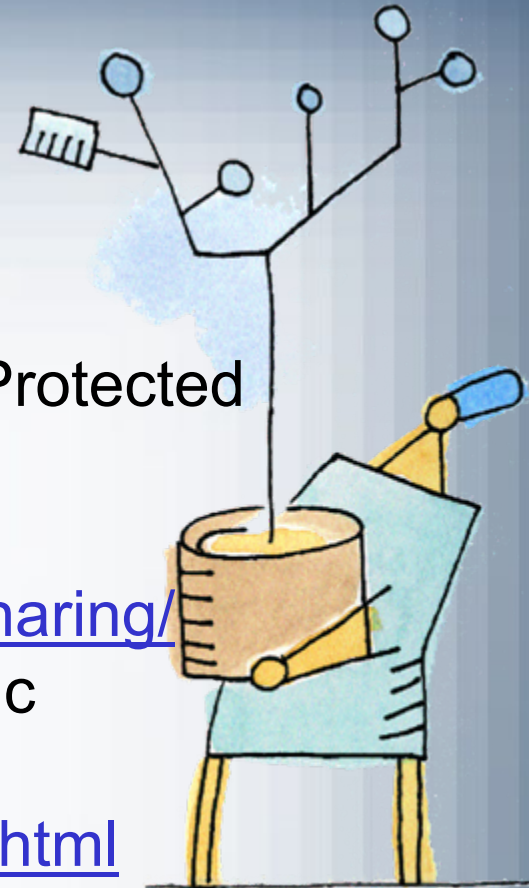
www.nih.gov/news

Data Sharing Policies

http://grants2.nih.gov/grants/policy/data_sharing/

Best Practices for the Licensing of Genomic Inventions

www.ott.nih.gov/policy/genomic_invention.html



Science. Ideas. Breakthroughs.