

# Exceptional Circumstances to the Bayh-Dole Act: An NIH Perspective

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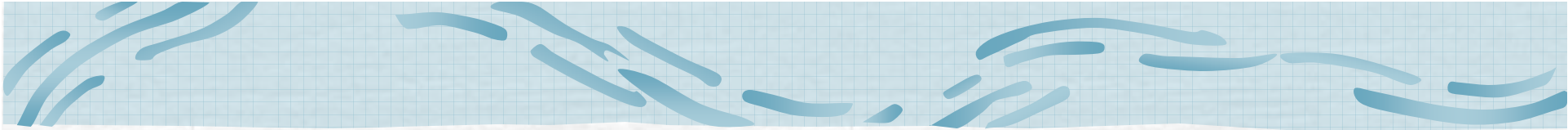
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# Presentation Outline


- The Bayh-Dole Act
- What is a DEC?
- Examples of Exceptional Circumstances at NIH
- Building & Implementing a DEC
- Approval of a DEC at NIH
- FAR Clause Deviations

**DEC**=Determination of Exceptional Circumstances



# The Bayh-Dole Act

35 U.S.C. § 200-212

- Prior to 1980 inventions made by Federal funding recipients were owned by the Government.
  - The Bayh-Dole Act allows recipients of Federal funding to elect right and title to inventions.
  - This includes contracts, grants and cooperative agreements.
  - The Act was designed to stimulate economic growth and the commercialization of Federally funded inventions.
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# The Bayh-Dole Act

## **Exceptions** when the Government Retains Patent Rights (35 U.S.C. § 202(a))

- Funding recipient is outside the U.S. or under foreign control.
- **“Exceptional circumstances”**: Better promotes the objectives of the Bayh-Dole Act.
- Intelligence and counter-intelligence activities.
- GOCO facilities of DOE involved in naval nuclear or weapons related programs.

# What is a DEC?

- A DEC is a document drafted by an Agency to justify the restriction or elimination of patent rights of those awarded a contract, grant or cooperative agreement.
- A DEC may only apply to a narrowly identified contract or class of contracts and does NOT automatically flow down to subcontractors.
- Typically, NIH will not approve a DEC for grants or cooperative agreements.
- Final approval for the DEC is made by the Agency Director after extensive review.

DECs are rare and truly exceptional!!

# When is a DEC appropriate?

35 USC 202 (a) (ii)

“....in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter...”

# Examples of Exceptional Circumstances

## Community Resources

- Making certain research resources and data widely available to the research community without IP constraints.
- Put tools of scientific discovery into the hands of researchers to accelerate future development of therapeutics and diagnostics.
- DECs are narrowly tailored to maximize the rights of the funding recipient while still meeting programmatic goals and objectives.

# Examples of Exceptional Circumstances

## Community Resources (cont.)

### Full-length cDNA Initiative

- Produce and distribute human and other mammalian cDNA clones for research use without IP constraints.
- Therapeutic or diagnostic inventions not anticipated.
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- Patent rights to the research tools go to the Government under the DEC then dedicated to the Public Domain.

# Examples of Exceptional Circumstances

## Community Resources (cont.)

### Initiative for Chemical Genetics

- Chemical probes, assays and screening directed at cancer targets available to the research community without IP constraints.
- Acknowledgment that inventions may be produced that would benefit from patent protection (i.e. potential therapeutics)
- Under the DEC the Government returned Blanket Greater Rights to the contractor to operate as if under Bayh-Dole as long as the community resource goals are met.

# Examples of Exceptional Circumstances

## Community Resources (cont.)

### Mouse Proteomics Initiative

- Initiative designed to use animal models to develop and standardize technologies that help improve the accurate measurement of proteins and peptides linked to cancer processes.
- Identification of “Research Resources” as a separate narrow class of inventions to be made available to the research community (i.e. reagents, assays).
- Only the Research Resources were under the DEC and dedicated to the public by the Government.

# Examples of Exceptional Circumstances

## **The NCI-Frederick FFRDC**

- The NCI-Frederick is a Federally Funded Research and Development Center (FFRDC).
- The FFRDC is operated by the Operations and Technical Support Prime Contractor (OTS).
- Unlike other FFRDCs, Government and OTS prime contractor employees work side-by-side in the research labs often leading to joint inventions.
- The OTS prime contractor operates under a DEC and assigns its patent rights to the Government or designee.
- OTS contractor and NCI inventors share equally in royalties and Technology Transfer Awards.

# Examples of Exceptional Circumstances

## The NCI-Frederick FFRDC

### The OTS Prime Contract DEC

- Reduces IP encumbrances on NCI-Frederick inventions thereby more efficiently and effectively developing technology to benefit to the Public Health.
- Encourages collaboration with NIH and permits access to cutting-edge research materials by protecting third-party technology (often grantees!) provided to NIH and used by the OTS contractor.
- Permits the Government to widely disseminate research tools produced to the research community.

# Examples of Exceptional Circumstances

## Use of Proprietary Technology

### Rapid Access to Intervention Development (RAID)

- Approved RAID drug candidates submitted by academic investigators have access to NCI drug development resources often provided by the OTS prime and subcontractors.
- Encourages collaboration with NCI and adds value to promising cancer drugs by protecting third-party technology provided to NCI and used by the OTS prime contractor or subcontractors.
- Protects the Bayh-Dole rights of the RAID recipient institution by not diluting its IP thereby making the improved drug candidate more attractive to prospective downstream developers.
- The DEC obligates the contractor to assign its patent rights related to RAID inventions to the Government or a designee (i.e. the RAID recipient institution)

# Building & Implementing a DEC

- Deviation of the standard patent rights for the exceptional circumstances noted is considered essential to achieve programmatic objectives.
- The programmatic objectives and proposed DEC will be discussed with known or anticipated funding recipients.
- A DEC will better promote the policy and objectives of the Bayh-Dole Act and implementing regulations.
- The proposed DEC is as narrowly tailored as possible to achieve the articulated programmatic objective.
- None of the accompanying deviations in the standard Federal Acquisition Regulation (FAR) clauses, or any other provision, affect the right of the funding recipients to freely publish.

# Building & Implementing a DEC

- Allow for public comment on the proposed DEC prior to any solicitation for proposals.
- Justify why the Government is restricting Bayh-Dole rights (not easy to do).
- How does the DEC better promote the intent of Bayh-Dole and benefit the public?
- The DEC is tailored as narrowly as possible.
- Funding recipients may freely publish.

# Building & Implementing a DEC


- Consider programmatic goals and outcomes to narrowly tailor the DEC.
- Provide the Contractor with the opportunity to request Greater Rights.
- Deviation of a FAR Patent Rights Clause may be needed to give rights to the Government and to tailor the clause to meet programmatic goals.
- Review by the Dept. of Commerce and the Small Business Administration may be required after execution of the contract.

# DEC Approval at NIH

- Institute (i.e. NCI) and Program approval
- NIH Office of Acquisition Management and Policy
- Office of the General Counsel, NIH Office, HHS
- NIH Office of Technology Transfer
- NIH Office of Extramural Research
- NIH Head of Contracting Activity
- NIH Office of Administration
- NIH Office of Management
- NIH Director



# FAR Clause Deviations

- To implement a DEC you may need a deviated FAR Patent Rights Clause.
  - To achieve Program goals you may also need a deviated Rights in Data Clause.
  - A DEC is NOT required to deviate a Rights in Data Clause.
  - All FAR Clause deviations requested by NIH require HHS approval.
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# Approval of FAR Clause Deviations

- Institute (i.e. NCI) and Program approval
- NIH Office of Acquisition Management and Policy
- Office of the General Counsel (HHS, NIH Office)
- NIH Office of Technology Transfer
- NIH Office of Extramural Research
- NIH Head of Contracting Activity
- HHS Office of Acquisition Management and Policy

# Summary

- **A DEC is the rare exception not the common solution.**
- A DEC is difficult to obtain.
- Preparation and implementation of a DEC is time consuming.
- Planning for a DEC begins during the conception of a project well before any public announcement.



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