

# *Doing Business with Academic Institutions*

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# Overview

- Academic Institutions' Perspective
- Technology Transfer
- Legal Framework
- Deals with Academia
- Practical Tips

# Academic Institutions' Perspective

- Types of Academic Institutions
  - Colleges/Universities (private and public)
  - Research institutes
  - Academic medical centers
  - Government laboratories/institutes
  - Foreign institutions

# Academic Institutions' Perspective

- Motivations
  - Education
  - Basic/applied research
  - Charitable purposes (e.g., improving patient care, supporting local community, being good stewards of assets)
  - Make resources available to others

# Academic Institutions' Perspective

- Pressures
  - Budgetary
  - Prestige
  - Attracting faculty and students
  - Economic development
  - Political

# Technology Transfer

- Different things to different people
- One view:
  - Enterprise created by academic institution to capture, manage and disseminate intellectual property

# Technology Transfer

- Many different approaches
  - Centralized in-house office
    - Univ. of Washington
  - Centralized licensing office with multiple TT offices for different schools or campuses
    - Harvard - TT office for medical/dental schools and another for all other schools
    - UC System - semi-autonomous TT offices at different campuses, with policy set in a centralized fashion
  - Combined model, with TT and other functions together
    - Stanford - OTL incorporates Industrial Contracts Office
  - External technology licensing model
    - WARF (proceeds are gifted back to school)

# Technology Transfer

- Many different responsibilities
  - Manage invention disclosures and IP protection
  - CDAs, MTAs
  - Sponsored research agreements
  - Interinstitutional agreements
  - Educate researchers about IP protection
  - Commercialize IP through licensing, spin-outs and enforcement



# Technology Transfer

- Many different stakeholders
  - Faculty
  - Management
  - Licensees
  - Research sponsors

# Technology Transfer

- Glimmers of proactive efforts, but still largely a reactive endeavor
- Personnel are getting more sophisticated
- Deals are getting more complex

# Legal Framework: *Bayh-Dole Act*

- Federal law that enabled university technology transfer in United States
- Prior to 1980
  - U.S. Government had no uniform patent policy/statute regarding ownership/disposition of inventions developed through use of federal funds
  - Federal agencies took different approaches
  - Title to inventions vested with U.S. Government
  - Patented technologies rarely commercialized

# Legal Framework: *Bayh-Dole Act*

- Enacted December 12, 1980
  - Pub. L. No. 96-517, codified as amended at 35 U.S.C. §§200-212; implemented through 37 CFR 401 *et seq.*
- Grants certain organizations the right to retain title to inventions arising from federally supported research

# Legal Framework: *Bayh-Dole Act*

- Requirements
  - Report inventions to funding agency
  - Submit written election to retain title
  - File for patent protection
  - Grant limited license to U.S. Government
  - Promote the invention
  - Do not assign the invention
  - Share any income with inventors
  - Use remaining income for research and education
  - Prefer small businesses and U.S. industry

# Legal Framework: *Bayh-Dole Act*

- Failure to comply may result in:
  - Federal agency taking title to invention
  - Federal agency exercising march-in rights
  - Discontinuation of federal research funding to organization

# Legal Framework: *Bayh-Dole Act*

- March-in Rights - agency can require grant of a license to a responsible applicant if:
  - Recipient is not taking effective steps to achieve practical application of the invention
  - To alleviate health or safety needs that are not reasonably satisfied by Recipient
  - To meet requirements for public use specified by federal regs not reasonably satisfied by Recipient
  - An exclusive licensee has failed to give preference to U.S. manufacturing where required

# Legal Framework: *Bayh-Dole Act*

- Never exercised
  - CellPro
  - Abbott Laboratories (Norvir)
  - Pfizer (Xalatan)
  - Genzyme (Fabrazyme)



# Legal Framework: *Bayh-Dole Act*

- Academic institutions often treat all technology as though it were developed using federal funds
  - Avoids errors
  - Easier to administer
- Bayh-Dole only applies to inventions/patents, not to copyrights or other forms of IP

# Legal Framework: *Tax-Exemption*

- Tax-exempt status
  - May be jeopardized if considerable and recurring private inurement
- Tax-exempt bond regulations
  - TEOs may build facilities or purchase equipment through use of tax-exempt bonds
  - Bonds become tax-bearing if facilities or equipment are used more than 5%/10% (depending on the nature of the use) for “private business use”

# Legal Framework: *Tax-Exemption*

- 1997 IRS guidance (Rev. Proc. 97-14)
  - Safe harbor for research agreements with private entities, if sponsor pays a competitive price for any license/use of resulting technology
    - Competitive price must be determined at the time the technology is available for use
- 2007 IRS guidance (Rev. Proc. 2007-47)
  - Replaces Rev. Proc. 97-14, although similar
  - Applies to research agreements entered into, modified or extended on/after June 26, 2007, and TEOs can apply to earlier agreements

# Legal Framework

- Other general legal obligations
- Academic standards (publication, ethics)
- Certifications/licensure
- Institutional policies
  - Intellectual property
  - Risk management
  - Equity investments

# Deals with Academia

- IP Licensing
  - Bayh-Dole provisions
    - License, not assignment
    - Development milestones
    - Retained rights for U.S. Government
  - Academic use and publishing
  - Cost reimbursement
  - Economic development provisions

# Deals with Academia

- Spin-off company
  - Bayh-Dole preference for small businesses
  - Equity
    - Minority position, if any
    - Desire to cash out as soon as possible
  - Management
    - Usually no board seat; sometimes observer
  - Conflicts of interest

# Deals with Academia

- Sponsored Research
  - Maybe nonexclusive, royalty-free license
  - Anything more must be determined once technology is available for use
  - Right of first negotiation is okay
  - Difficult to restrict/control publication
  - Clinical trial agreements are an emerging issue

# Deals with Academia

- Material Transfer Agreements
  - IP ownership
  - IP licensing
  - Legal and practical challenges of...
    - Preventing mixtures/sharing of materials
    - Enforcing pre-publication review



# Deals with Academia

- Interinstitutional Agreements
  - Multi-party transactions due to...
    - Collaborative research
    - Relocation of faculty

# Deals with Academia

- Obtaining government funding
  - Grant/Contract Subcontractor
    - Budget established in advance
    - Letter of support
  - SBIR/STTR Programs
    - Small Business Innovation Research (SBIR)
      - May involve university, but not required
    - Small Business Technology Transfer (STTR)
      - University/researcher required to play significant role

# Practical Tips

- Use their forms
- Be reasonable
  - They're not your competitor
  - Transactions may not be top priority
  - Certain things can't be done
- Consider what value you can bring to an academic institution
  - Scholarships
  - Long-term funding/support
  - Other products/resources

# Questions?

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