The Impact of Patenting and Licensing Practices on Research

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Talk Overview

• Capitalizing on Research
• IPR Management
• Case Studies

Capitalizing on Research

Funding Sources

• Public Funding
  – Usually PI-initiated Research
  – Subject to Government Rules and Regulations
  – Expectation of Public Benefit
  – Subject to Public Scrutiny

• Private Funding
  – Usually has a commercial endpoint
  – Subject to IPR/publication restrictions
  – Less Public Scrutiny
Capitalizing on Research
The Authorities: US Technology Transfer Laws

- Bayh-Dole Act
- Stevenson-Wydler Act
- FTTA and Amendments

IPR Management

Principles

- Supportive of Academic Mission
  - Academic Freedom
  - Publication Rights
  - Research Funding
  - Education
- Balance commercialization with public benefit
  - Appropriate Patenting
  - Strategic Licensing
- Access to Research Tools
IPR Management

Appropriate Patenting

- Critical Element for Further R&D Investment
- Scope Commensurate with Invention
- No Blocking or Defensive Patenting
- No Patenting if Technology Ripe for Transfer

On Gene Patents

The NIH Position

- Full-length sequence with known utility
- No support for patents on EST or partial sequence
- Breadth commensurate with invention

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Strategic Licensing

- Promote Public Health
- Ensure Exception for Non-Commercial Research Purposes
- Promote Market Competition:
  - Preference to non-exclusive licensing
  - Limits on Fields of Use and/or Territory
- Ensure dissemination of results
- Attain Appropriate Financial Returns

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IPR Management

The NIH Research Tool Guidelines

- Ensure Academic Freedom & Publication
- Appropriate Implementation of Bayh-Dole
- Minimize Administrative Burdens
- Ensure Dissemination of NIH-funded RT
**Case Study: Notes on the Human Genome**

- ELSI
- Bermuda Principles
- DECs on Selected Grants and Contracts
- SNP Consortium
- Action with US PTO
- Publication

**Case Study: Access to Stem Cells**

**Background**

- NIH funded primate studies
- WARF obtained broad patent on primate stem cells and methods
- Geron funded human Stem Cell studies
- WARF obtained broad patent on human stem cells and methods
- WARF licensed 6 cell types to Geron
- WARF Created WiCell for scale-up and distribution of stem cells

**The Challenge: Getting the Cells to the Scientists**

- Abiding by the RT Guidelines
- Timing Pressures
- Public Scrutiny
The NIH-Wicell MOU

Critical features

- Research and commercial uses segregated
- IP remains with inventors – no "reach through" provisions
- Third party materials covered
- NIH grantees can have same terms

The NIH-Wicell MOU

Details

- Cells transferred under an MTA
- For non-commercial purposes
- Cell re-distribution with WiCell consent only
- Uses only as provided by law
- No cost – only reimbursement fee to WiCell

The NIH-Wicell MOU

Quid pro Quo

- Publications acknowledge source of cells
- Yearly compliance certification to WiCell
- Separate license for commercial uses
- No third-party reach-through
Final Thoughts:

- IPR important strategic tool
- Academic core mission must be preserved
- Attain balance between social and commercial benefits