



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

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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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IPR Management

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