

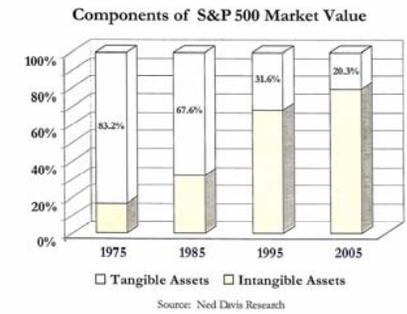
NIH Technology Transfer: An Overview

Jack Spiegel, Ph.D
Senior Advisor for
Technology Transfer Operations
Office of Technology Transfer
National Institutes of Health

What is Technology Transfer?

- Exchange of information, materials, intellectual property rights;
- Between (and among) government, academic, or industry laboratories;
- To facilitate further research and commercialization
- Intramural v. Extramural

Economic Inversion



What is a Patent?

- Government sanctioned monopoly
- Issued by U.S. Patent & Trademark Office (PTO)
- Right to exclude others from making, using and selling claimed invention
- Applies to machines, devices, processes, and compositions of matter (including organisms)
- The *quid pro quo* -- alternative to Trade Secrets
- Most countries issue and enforce patents

Technology Transfer NIH Policy Issues:

- Public health benefit is paramount
- Good science happens at NIH, academia and industry -- need mutual exchange
- IP necessary for product development
- Research tools (knowledge and materials) are part of that exchange

NIH Patent Policy

- NIH seeks patents where further investment needed to develop a product
- Vaccines, diagnostics, and therapeutics
- Usually not on research tools

What Are Research Materials/Tools?

Resources used to further investigate biological systems or to identify new products (e.g., drugs)

Properties of Research Tools

- Useful lifecycle is generally short
- Does not require significant R&D
- Generally does not require IP incentive to make/use
- Desire broad access and availability

Examples of Research Tools

- Animal Models
- Cell Lines
- Bulk DNA Sequences
- Drug Targets
- Clones/Cloning Tools
- Libraries
- Software
- Databases
- Lab Techniques
- Antibody Reagents

The Toll-Road Analogy

- Prefer Freeways
- Willing to Accept Occasional Tolls
- Avoid Tollbooth Gridlock



Patentability

- Utility--credible, specific & substantial
- Enabled--able to make and use
- Novel--exact invention not in public domain
- Nonobvious--starting with information in the public domain, the "ordinary" skilled worker would not have been motivated to make the invention or have had a reasonable expectation of success in doing so

What is a License ?

- Agreement to allow a third party to use an owner's property
- Can have patent and non-patent licenses
- Patent licenses usually a prerequisite to product development
- Exclusive, co-exclusive, or non-exclusive

NIH License Policy

- Non-exclusive where possible
- Exclusive when necessary
- Ensure appropriate scope
- Ensure expeditious development
- Ensure continuing availability of tools

Top 10 Licensed Products (\$)

- | | |
|--------------|--------------------------------|
| • Angiotech | TAXUS Express2 (Stents) |
| • MedImmune | Synagis (RSV mAb) |
| • Abbott* | HIV Ab (AIDS Test Kit) |
| • Merck | Gardasil (HPV vaccine) |
| • Genzyme | Thyrogen (rTSH) |
| • BMS* | Videx (ddl) |
| • Millennium | Velcade (Multiple Myeloma) |
| • BMS | Taxol (paclitaxel) |
| • GSK* | Twinrix (hepatitis A & B) |
| • B & L | Ocuvite (Macular Degeneration) |

Groundbreaking FDA Approvals

- | | |
|----------------|----------------------------------|
| • Merck | Gardasil (HPV Vaccine) |
| • Millennium | Velcade (multiple myeloma) |
| • MedImmune | Synagis (RSV mAb) |
| • Isis | Vitavene (Antisense CMV) |
| • Biotrin | Parvovirus B19 assay |
| • Coulter/IDEC | Zevalin (NH Lymphoma) |
| • PDL/Hoffman | Zenapax (Kidney Transplant) |
| • Diatide | AcuTect (DVT Imaging) |
| • Baxter/NAV | Certiva (DPT vaccine) |
| • Amgen | Kepivance (Chemo 2nd effects) |
| • Tibotec | Prezista (DR HIV Protease Inhib) |
