

NIH Technology Transfer: An Overview

February 19, 2008

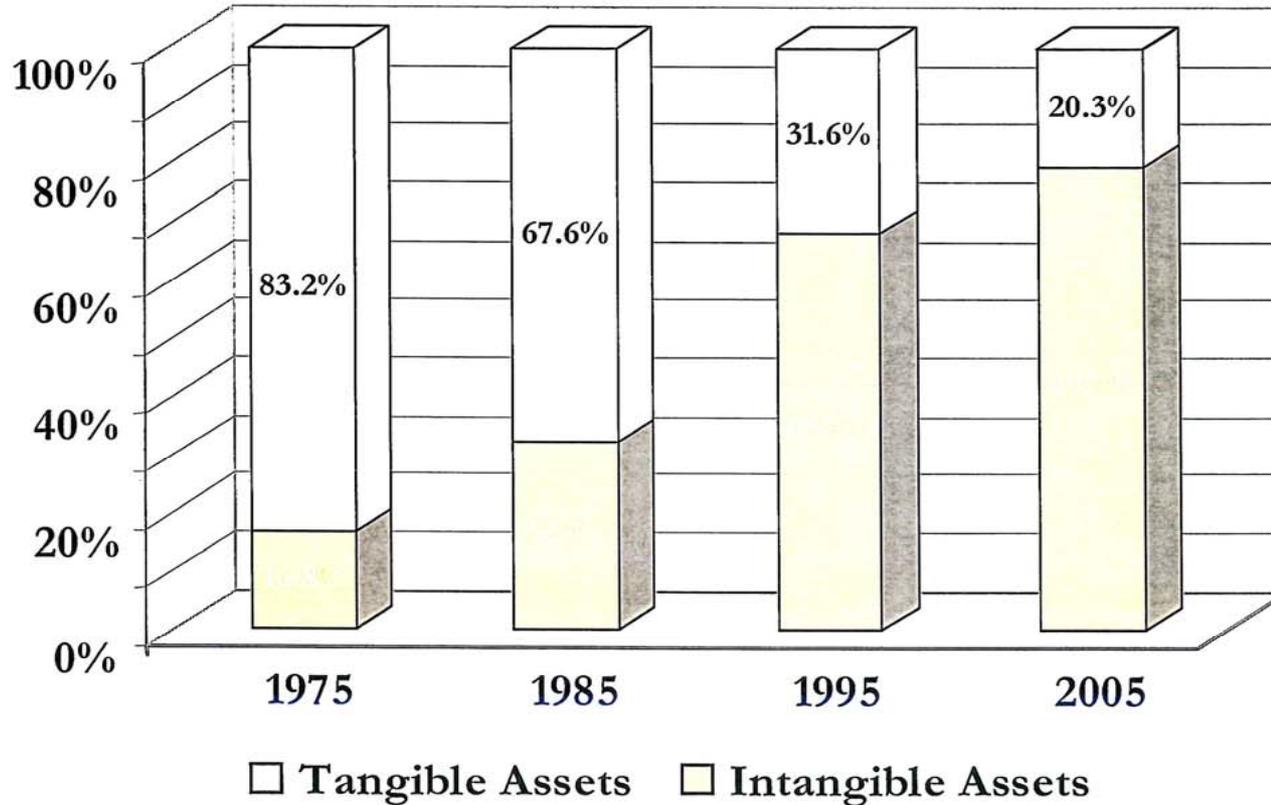
**Jack Spiegel, Ph.D
Senior Advisor for
Technology Transfer Operations
Office of Technology Transfer
National Institutes of Health**

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

Components of S&P 500 Market Value



Source: Ned Davis Research

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** **Vitravene (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)**