Technology Transfer Seminar

October 21, 2005
Nathan S. Kline Institute
Orangeburg, NY
Program

I. Role of RFMH in Technology Transfer
II. OMH/OMRDD Patent Policy
III. NIH Requirements for Inventions & Intellectual Property
IV. Pitfalls of MTAs
V. Panel Discussion “Opportunities & Challenges of Licensing Research Tools”
I. Role of RFMH in Technology Transfer
Role of RFMH in Technology Transfer

- What is technology transfer?
- Why do we transfer technology?
- What is our role?
- Who are we?
- What exactly is it that we do?
- How can you contact us?
- Examples of success?
What is technology transfer?

Movement of information, materials and technologies from research laboratories to commercial enterprises for the purpose of further development and commercialization.

- Patented inventions
- Research tools and reagents
- Computer software
- Diagnostics
- Vaccines
- Therapeutic compounds
Why do we transfer technology?

Completing the Circle

Public/Private Investment  Research

Products – Benefit Society  Discovery

Technology Transfer

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What is our role?

- Private, not-for-profit corporation organized in 1952, for the purpose of assisting and enhancing the research and training objectives of the New York State Department of Mental Hygiene and its component agencies.
- Administer +100 million dollars in annual sponsored research grants and contracts.
- Title to invention conceived or first reduced to practice in performance of sponsored research.
What is our role?

- Protect interests of the inventor(s), the Foundation, NYS, the sponsor & the public
- PARTNER!
- Resource/service
- Facilitator between worlds of science, law & business
Who are we?
What do we do?

- Identify new technologies
- Protect inventions – patents, copyrights & trademarks
- Form commercialization strategies
  - market and license to existing companies
  - create new start-up companies
- Negotiate agreements
- Administration & compliance
How can you contact us?

Dan Potvin, Ph.D.
Technology Transfer Associate
Research Foundation for Mental Hygiene, Inc.
150 Broadway, Suite 301
Menands, NY 12204
Phone: (518) 408 2186
dpotvin@omh.state.ny.us
http://corporate.rfmh.org
Examples of success?

1. Commercial products
   - Taurine – component of infant formulas
   - Travil – medical food for treatment of tardive dyskinesia
   - Copyright protected clinical & educational materials
   - Research tools – monoclonal antibodies

2. Industry sponsored research funding
II. OMH/OMRDD Patent Policy

Robin Goldman, Esq.
Assistant Counsel, OMH
III. NIH Requirements for Inventions & Intellectual Property
NIH Requirements for Inventions & Intellectual Property

- What is a subject invention?
- What is the Bayh-Dole Act?
- What are the NIH requirements for inventions?
- What about research tools & model organisms?
- Where can you go for help?
What is a subject invention?

Any invention or discovery conceived or first reduced to practice in the performance of work under a funding agreement (grant or contract) with the U.S. federal government.

- Patented & unpatented inventions
- Compositions of matter, machines, methods, manufacture & processes
- Software, business practices & algorithms
- Research tools
- Model organisms
What is the Bayh-Dole Act?

- Bayh-Dole Act (Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs.

- The Act is “perhaps the most inspired piece of legislation to be enacted in America over the past half-century,” according to The Economist.
Bayh-Dole Act

AUTM Licensing Survey™: FY 2003
What are the NIH requirements for inventions?

1. Invention disclosure
   - Failure to disclose invention to NIH can result in loss of rights.

2. Annual reports & final report

3. Diligently protect & commercialize invention

4. Grant license to U.S. Government
What about research tools & model organisms?

NIH Guidelines & Principles:
- Ensure academic freedom and publication
- Ensure implementation of Bayh-Dole Act
  - Licensing allowed (nonexclusive preferred)
- Minimize administrative impediments to research
- Ensure dissemination of research resources
  - MTAs
Where can you go for help?

- Yours truly
- Colleen Corcoran, RFMH
- Institute grant office
- Program manager
- http://corporate.rfmh.org
- http://iEdison.gov

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IV. Pitfalls of MTAs
Outline

- What is an MTA?
- What is the # 1 pitfall?
- What are the pitfalls of incoming agreements?
- What are the pitfalls of outgoing agreements?
- Where can I find the forms?
- Where can I go for help?
What is an MTA?

**Material Transfer Agreement – MTA:** Agreement or contract that governs the transfer of tangible research materials between organizations.

1. Academic ↔ Academic
2. Academic → Industry
3. Industry → Academic
Why do we transfer materials?

- Foster scientific collaboration
- Comply with NIH guidelines, federal statutes and publication requirements
- Facilitate licensing
- Encourage industry sponsored research
What is the #1 pitfall?

Not having one!
What are the pitfalls of incoming agreements?

- Freedom to publish
- Ownership
  - Data
  - Inventions, Intellectual Property
- Conflicts with sponsored research
- Reach through royalties and compelled licenses
What are the pitfalls of outgoing agreements?

- Noncommercial use
- Distribution to third parties
- Liability & Warranties
- Modifications and derivatives
Where can I find the forms?

RFMH website [http://corporate.rfmh.org](http://corporate.rfmh.org)

### Forms

<table>
<thead>
<tr>
<th>Name of Form</th>
<th>Online Fillable Forms</th>
<th>Online Printable Forms</th>
<th>Other (*.doc, etc)</th>
</tr>
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<tbody>
<tr>
<td>Biological Material Disclosure</td>
<td>Download</td>
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<tr>
<td>Invention Disclosure</td>
<td>Download</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material Transfer Agreement</td>
<td>Download</td>
<td>Download</td>
<td></td>
</tr>
<tr>
<td>Confidentiality Agreement</td>
<td>Download</td>
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Where can I go for help?

Dan Potvin
518 408- 2186
dpotvin@omh.state.ny.us

- NKI – Tom O’Hara
- NYPI – Frank Mucha
- IBR – Dr. Ted Brown
V. “Opportunities & Challenges of Licensing Research Tools”

Panel Discussion
Panel

Dan Potvin – Moderator

Dr. Richard Kascsak - Director Monoclonal Antibody Facility & Research Scientist, Institute for Basic Research

Mr. Joe Bertelsen - Neuroscience Product Manager, Signet Laboratories

Dr. Ricardo Mesa-Tejada - Senior Vice President, Thieme Consulting
Richard J. Kascsak, Ph.D.

Regina Kascsak, B.S
Daryl Spinner, Ph.D..
Cheng-Mo (James) Chen, M.S.
Henı Hong, B.S.
Victor Sapienza, M.S.
Monoclonal Antibody Facility (MAF)

Importance of Biotech/Pharmaceutical Industry Partnership to New York State

Companies Collaborating/Partnering with MAF: Bayer, Pfizer, Wyeth, Q-RNA Inc., Pall Corp., Senetek / Signet Laboratories
MAF MISSION

Developmental and Utilization of Monoclonal Antibodies:

Achieve OMRDD Research Goals

Develop Diagnostic Antibodies

Develop Therapeutic Antibodies

Provide Reagents and Expertise to Senetek PLC/Signet Laboratories
CURRENTLY AVAILABLE ANTIBODIES

Down’s Syndrome/Alzheimer’s Disease
i.e., beta amyloid, tau, ERAB, synuclein, apoprotein E

Fragile-X Syndrome
i.e., FMRP

Batten’s Disease
i.e., NCL2, NCL3

Infectious Agents
i.e., CMV

Autism
MAF GOALS

Assist Scientists and Physicians in the study and treatment of Developmental Disabilities

Expand and Improve Repertoire of Monoclonal Antibodies available through IBR MAF/Signet Laboratories
Panel

Dan Potvin – Moderator
Dr. Richard Kascsak - Director Monoclonal Antibody Facility & Research Scientist, Institute for Basic Research
Mr. Joe Bertelsen - Neuroscience Product Manager, Signet Laboratories
Dr. Ricardo Mesa-Tejada - Senior Vice President, Thieme Consulting
Signet Laboratories, Inc.

Business Overview
Signet Laboratories: Background

Signet Background
- Founded 1989, spinout of J&J Cambridge Research Labs
- Initial specialization in cancer markers and infectious disease
- Major expansion of product line in 2000 to include antibodies for neurodegenerative disease
- FDA-registered, GMP manufacturer of over 800 products worldwide

Core Competency
- Recognized leader in immunopathology
- Experts in tissue-based assays and binding phenomena
- Development and manufacturing of antibodies and assays
- Sales and distribution of antibodies and assay kits
### Signet Laboratories' Customer Base / Distribution Channels

<table>
<thead>
<tr>
<th></th>
<th>Immunohistochemistry</th>
<th>Research/Neurodegenerative</th>
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</thead>
<tbody>
<tr>
<td><strong>Customer Base</strong></td>
<td><strong>Hospitals/Clinics</strong></td>
<td><strong>Biotech/Pharma Research Institutes</strong></td>
</tr>
<tr>
<td><strong>Distribution Domestic</strong></td>
<td><strong>Direct/OEM/VAR</strong></td>
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</tr>
<tr>
<td><strong>Distribution International</strong>*</td>
<td><strong>Distributor</strong></td>
<td><strong>Distributor/Direct</strong></td>
</tr>
</tbody>
</table>

*Note: All major international markets covered by at least one distributor*
Top Five Products for Each Sector of Signet’s Business

**ImmunoHistoChemistry**
- Breast Cancer Marker, Clone D6, Monoclonal, Gross Cystic Disease Protein
- Cancer Marker, Clone D2-40, Lymphatic Invasion
- Breast Cancer Marker, Clone B72.3, Monoclonal, Membrane Protein
- Ewing’s Sarcoma Marker, Clone CD99, Monoclonal
- Multi Drug Resistance Marker, Clone C219, Monoclonal

**Research/Neurodegenerative**
- Monoclonal Ab – 6E10
- Monoclonal Ab – 4G8
- Monoclonal Ab – 3F4
- Polyclonal Ab – ABeta 1-40
- Polyclonal Ab – ABeta 1-42
Production and Development Capabilities

- FDA registered cGMP facility
- Full antibody production and purification capabilities
- Research use and diagnostic assay development
  - ELISA based readouts
  - IHC
Signet’s Role in Licensing of Technologies

- Aggressively identify target markets for new technologies
- Identify technologies to address market needs
- Negotiate license with institution’s tech transfer office
- Produce consistent, high quality products through our FDA approved laboratory
- Promote the products worldwide to all pertinent market segments
- Generate revenue for all parties involved
Value of Licensing Technologies Through Signet

• **REDUCE TIME** researcher spends on promoting and distributing inventions
• Realize commercial value for technologies not considered blockbusters
• Utilize our core competencies to optimize efficacy and commercial value of technologies
• Feed back market information to inform researchers of new target areas
• **GENERATE REVENUE**
Panel

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## Monoclonal Antibodies on the Market

<table>
<thead>
<tr>
<th>Type</th>
<th>Product</th>
<th>Marketer</th>
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<tbody>
<tr>
<td>Murine</td>
<td>Orthoclone OKT3</td>
<td>Johnson &amp; Johnson</td>
<td>June 1986</td>
</tr>
<tr>
<td>Chimeric</td>
<td>ReoPro</td>
<td>Lilly</td>
<td>December 1994</td>
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<tr>
<td>Chimeric</td>
<td>Rituxan</td>
<td>Genentech</td>
<td>November 1997</td>
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<tr>
<td>Chimeric</td>
<td>Simulect</td>
<td>Novartis</td>
<td>May 1998</td>
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<tr>
<td>Chimeric</td>
<td>Remicade</td>
<td>Johnson &amp; Johnson</td>
<td>August 1998</td>
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<tr>
<td>CDR-grafted</td>
<td>Zenapax</td>
<td>Roche</td>
<td>December 1997</td>
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<td>Synagis</td>
<td>Medimmune</td>
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<td>Mylotarg</td>
<td>Wyeth</td>
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<td>CDR-grafted</td>
<td>Campath</td>
<td>Millennium</td>
<td>July 2001</td>
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</table>
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<tr>
<th>Type</th>
<th>Product</th>
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<tr>
<td>Murine Radiolabeled</td>
<td>Zevalin</td>
<td>IDEC Pharmaceuticals and Schering AG</td>
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<td></td>
<td>Non-Hodgkin's Lymphoma (relapsed or refractory low-grade, follicular, or transformed B cell)</td>
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<td>Phage Display</td>
<td>Humira</td>
<td>Abbott Laboratories</td>
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<td></td>
<td>Rheumatoid arthritis</td>
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<td>CDR-grafted</td>
<td>Xolair</td>
<td>Genentech and Novartis</td>
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<td>Moderate to severe persistent asthma</td>
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<tr>
<td>CDR-grafted</td>
<td>Bexxar</td>
<td>Corixa and GlaxoSmithKline</td>
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<td>CD20 positive, follicular, Non-Hodgkin’s Lymphoma (NHL)</td>
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<td>CDR-grafted</td>
<td>Raptiva</td>
<td>Genentech and Xoma</td>
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<td>Chronic moderate-to-severe psoriasis</td>
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<tr>
<td>Chimeric</td>
<td>Erbitux</td>
<td>Imclone and Bristol-Myers Squibb</td>
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<tr>
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<td>Colorectal cancer</td>
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<tr>
<td>CDR-grafted</td>
<td>Tysabri</td>
<td>Biogen-Idec and Elan</td>
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<tr>
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<td>Multiple sclerosis</td>
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