Technology Transfer with Institutions in Lesser Developed Countries

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Science . Ideas . Breakthroughs
NIH TT Cooperation with LDCs

• Administrative Infrastructure Development
  – Conferences and training in and w/ LDCs
  – Visits to individual institutions
  – Coordination with other organizations
  – Policies that represent Best Practices

• Transfer of Technologies to LDCs
  – Indirectly through licensees w/ Western companies
  – Directly to institutions in Emerging Markets
  – Multi-national, multi-institutional collaborations
Why?

• Lack of incentives for Western Companies to enter most LDC Markets
• Requirements in licenses for Western companies to enter LDC markets
• Direct Involvement of Institutions in LDCs
  – Identify Regional Capacities and Expertise
  – Transfer technologies from NIH to LDC institutions with greatest capacity
  – Meet regional needs with lower cost
  – Enhance local competence
  – LDC institutions can/will develop their own technologies
Technology Transfer Goals

- Benefit the Public Health
- Ensure Public Availability of New Technologies
- Utilize IPR Appropriately as Incentive for Commercial Development of Technologies
- Attract New R&D Resources
- Obtain Return on Public Investment
- Stimulate Economic Development
USG Authorities

• Bayh-Dole Act:
  – Institutions receiving grants and contracts own their inventions
  – Have an obligation to patent and seek commercialization as appropriate
  – USG retains license for USG itself and contractors

• Stevenson-Wydler Act: US Government Labs

• Federal Technology Transfer Act:
  Only one mechanism for Gov’t Labs to offer collaborator a license option to new inventions, i.e. Cooperative Research and Development Agreement (CRADA); no work for hire or sponsored research
## NIH IP in Neglected Disease Areas

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<th>TECHNOLOGIES</th>
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<tr>
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Lack of IPRs in LDCs

- Public Institutions rarely have IPR in LDCs
- Structure licenses with LDCs in mind
- Transfer Know-how through partnerships
- If unique materials involved, license under Biological Materials License, e.g. expression vectors, vaccine constructs and strains
General Principles For Licensing To Promote Public Health

• Receive a Development Plan From Licensee
• Grant Only Appropriate Scope of Rights
  – Fields of Use
  – Licensed Territory
• Enforceable Benchmarks In Agreement
• Link Public Policy Issues To Benchmarks
• Review Licensee’s Progress At Least Annually
Examples Of Public Policy Issues Linked To License Benchmarks ("White Knight Clauses")

- Supply back of Licensed Products or Services
- Health education programs (web or print)
- Indigent access programs for Licensed Products
- Biodiversity compliance for natural products
- Developing country access for Licensed Products
Biodiversity Issues For Licensing Natural Products

- Loss of species due to habitat destruction
- Resource management problems
- Sharing of benefits
- Patent rights vs. resource ownership
- Agreement structures
  - Letter of Collection (National Cancer Institute)
  - Patent License Agreement
General Principles Natural Products Licensing

• Prospective licensees aware of sourcing agreements
• Licensee obligated to provide benefit to source country
• Benefits provided for development of direct isolate or synthetic material
• Source country preferred supplier of bulk natural product
Natural Products Language For Licensed Agreements

• Letter of Collection – See ttb.nci.nih.gov/nploc.html

• License Agreement - Begin negotiations for an agreement with Source Country as to the extent of return to Source Country from eventual marketing of Licensed Product within one (1) month of the Effective Date. Complete agreement with Source Country within nine (9) months of the Effective Date.
Credit for Source Country Payments

LICENSEE shall be entitled to 100% credit against NIH earned royalty payments for earned royalty payments LICENSEE must pay to the Government of COUNTRY for the manufacture and sale of Licensed Products. Said reduction, however, shall not reduce the earned royalty payment to NIH below half of the rate provided under Paragraph X above.
Technology Transfer to LDCs: Natural Products

Calanolide A, an HIV antiretroviral in clinical trials
SARAWAK-Medichem, MALAYSIA
Facilitating Developing Country Access To Licensed Products

- "Worldwide" Licensed Territory means meeting worldwide need for Licensed Product
- By direct sales, joint venture or sublicensing
- New Commercialization Plan required
- Plan due after First Commercial Sale (U.S. or Europe)
Facilitating Developing Country Access To Licensed Products

Within six (6) months of NDA/BLA approval in the US or its equivalent in Europe, Licensee shall send a written report to Licensor detailing the potential Public Sector market to fulfill the public health need for the approved drug or vaccine in Developing Countries, including the impact of any approved competing drug or vaccine.
Facilitating Developing Country Access To Licensed Products

The report shall also include Licensee’s proposed amendment to the Commercial Development Plan and the Benchmarks and Performance to address the needs for Licensed Products in Developing Countries.
Facilitating Developing Country Access To Licensed Products

*Licensee* will diligently consider if it is possible from a commercial and technical point of view, to satisfy said potential *Public Sector* market either directly with *Licensee’s* own resources and/or through joint ventures with third parties. Acceptance of this report and amendment is required by *Licensor* in writing, such acceptance will not be unreasonably denied.
Exploring Ways to Enhance Technology Transfer to LDC
Developing Economies with Manufacturing Capabilities
Collaborative work with institutions in developing countries has revealed needs and opportunities for transfer of NIH technologies related to:

- HIV/AIDS
- Tuberculosis
- Malaria
- Dengue
- Diarrheal Diseases (Rotavirus)
- Meningitis
- Cancer (including HPV)
- Diabetes
OTT has already transferred technologies to, or has negotiations in process with:

- Brazil
- China
- Egypt
- India
- Indonesia
- Korea
- Mexico
- South Africa
- Tunisia
- Other Sub-Saharan African Countries
Recent License Approaches

- **ddI** – PROTEIN, S.A. de C.V., MEXICO
- **Conjugated Meningococcal Vaccine** – PATH and WHO, produced in India for distribution in Sub-Saharan Africa, Latin America, Caribbean, Middle East, Eastern Europe and Asia

  - Biological materials for conjugated vaccine against typhoid fever to the International Vaccine Institute (IVI) based in Korea and to be produced in partnership with a public institution in Indonesia and a private entity in India for distribution in Southeast Asia

  - Human-Bovine Rotavirus Vaccine proposed multi-licensing approach (8 institutions in India, China, Brazil, and the US)
Strategic Alliances
We Cannot Do It Alone

- Provide expertise advice, information sharing, joint publications, participation in key international meetings, and TT/IPM workshops in the field
- MIHR, DCVM, PATH, WHO, PAHO, IDB, DNDi, Rockefeller Foundation
Holistic Approach

• Participating institutions should have
  – Some level of R&D capabilities
  – Clear objectives to address national and regional public health needs

• Need to work with public AND private institutions in those countries
Gaps in Capacity building

• Cadre of scientists and managers
• Long-term sustainable approach
• Knowledge of IP Management
OTT’s Input

• Providing TT Expertise Training
• Internship Program targeted to scientists and technology managers from developing countries.
• Developing Needs Assessment aimed to understand the capacity building/training needs including implementation of policies relating to:
  – IPRs
  – Clinical trials
  – PPPs
Outcomes

- Help NIH meet its global mission to reduce disease burden in LDCs
- LDCs able to address some critical public health needs by enhancing prevention and care of infectious and non-communicable diseases through access to key technologies and models of successful product development
NIH Web Links

• NIH  http://www.nih.gov
• OTT  http://ott.od.nih.gov
• Sharing Biomedical Research Tools  
  http://ott.od.nih.gov/NewPages/RTguide_final.html
• A Plan to Insure Taxpayers’ Interests are Protected (7/01)  
  http://www.nih.gov/news
• Model Organisms  http://www.nih.gov/science/models/
• General OTT Contacts:  301-594-7700
  NIHOTT@od.nih.gov

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