IP Management/Tech Transfer Strategies for Improved Global Health:
Selected Illustrative Deals with the Private Sector

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DNDi
Drugs for Neglected Diseases initiative

BIO2009, Atlanta, USA
Neglected Diseases: Current Treatment Limitations

We Need Safe, Effective, Easy-to-Use Drugs

- Ineffective (resistance)
- Toxic
- Expensive
- Painful when delivered
- Difficult to use
- Not adapted to the field
- Not registered in endemic regions
- Restricted by patents

Melarsoprol  Eflornithine
A New Model for Drug Development: DNDi

- Non-profit drug research & development (R&D) organization founded in 2003
- Addressing the needs of the most neglected patients
- Harnessing resources from public institutions, private industry and philanthropic entities

7 Founding Partners

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation Brazil
- Medecins Sans Frontieres (MSF)
- Institut Pasteur France
- WHO/TDR (permanent observer)

7 support offices

Coordination team Geneva + consultants

USA

Japan

Brazil

DRC

Kenya

India

Malaysia
Major focus on kinetoplastid diseases:

Sleeping Sickness
Chagas Disease
Visceral and cutaneous Leishmaniasis
Malaria
3 New Treatments Developed So Far

**2007**
- **ASAQ (Malaria)**
  - Fixed-Dose Artesunate/Amodiaquine

**2008**
- **ASMQ (Malaria)**
  - Fixed-Dose Artesunate/Mefloquine

**2009**
- **NECT**
  - Nifurtimox - Eflornithine Co-Administration (HAT)

**Partners**
- Sanofi-Aventis (France)
- Farmanguinhos (Brazil)
- Cipla (India)

**National Control Programs**
- MSF
- WHO

- Easy to Use
- Affordable
- Field-Adapted
- Non-Patented
Partnership is Key

Implementers
NCP, WHO, NGOs (MSF)

Platforms
LEAP, HAT, FACT, Chagas

Distributors
IDA

Manufacturers
sanofi-aventis, Farmanguinhos, Cipla, Lafepe

Networks - studies
INESS, WWARN, Epicentre, TDR

Other PDPs
FIND, iOHW, MMV, DNDi
DNDi IP Policy

• Affordable treatment and equitable access
• Develop drugs as public goods
• Decisions regarding ownership of patents and of licensing terms are made on a case-by-case basis
• Reflecting characteristics of DNDi’s products:
  – No commercial value
  – Distributed mainly through the public sector
  – Outsourcing
Major issues to negotiate:

- **FIELD**: NTD, malaria+kinetoplastids, kinetoplastids
- **TERRITORY**: endemic countries, production countries
- **DISTRIBUTION SECTOR**: public vs private
- **LOWEST POSSIBLE COSTS**: no royalties, “at cost” production
- **SUB-LICENSING**: essential to work with third parties
- **DISSEMINATION OF INFORMATION**: publications (and patents)
Case 1: DNDi-sanoﬁ-aventis Agreement

**AS-AQ**: a product *out-licensed* to pharma

Deal characteristics:

- Developed by DNDi: formulation & clinical studies
- Out-licensed to sanoﬁ-aventis:
  - further development, scale-up, registration, distribution,
  - collaboration through post-registration
- **Not patented**
- Registered in 2007: now in 26 countries
- Public price: “at cost”:
  - < US$1 for adult, US$0.50 for children

Simplified dosing with ASAQ
(artesunate-amodiaquine)
Accessing the R&D resources of pharma

Deal characteristics:

• Access to selected Merck’s *compounds libraries*
• Access to Merck’s *know-how*
• **Joint IP** generated through early development
• Non-exclusive, royalty-free, and sub-licensable license granted to DNDi for NTDs
• Opt-in option for Merck to undertake late clinical development and registration:
  – at its own expenses
  – commitment to provide the final product at the least possible cost to the public sector
Case 3: DNDi-Anacor Agreement

Harnessing biotech creativity

Deal characteristics:

- Access to proprietary class of compounds:
  - no upfronts or milestones
  - collaboration with Anacor’s scientists

- IP generated gets back to Anacor:
  - rights for NTDs in endemic countries
  - no royalties on sale in public markets
Some Keys to Success

- Buy-in top management…
- Insure understanding of PDPs goals and business model
- Build trust
- Demonstrate successful examples and achievements
- Favour “out-of-box” thinking
By working together in a creative way, PDPs, large and small pharma, and the public sector can bring innovation to neglected patients!