IP management in R&D for Neglected Tropical Diseases

Jean-Pierre Paccaud, PhD, DNDi, Director Business Development

Tropical diseases and tuberculosis account for 12% of the global disease burden but only 1.3% of new drugs developed.

Source: Chirac P, Torreele E. Lancet. 2006 May 12; 1560-1561.
The Patients & The Neglected Diseases: DNDi’s Focus

Malaria
Visceral Leishmaniasis (VL)
Sleeping Sickness (HAT)
Chagas Disease

Product Development Partnerships (PDPs): Addressing unmet medical needs
A Solid and Global Foundation

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)

5 Regional Support Liaison Offices
- Coordination team, Geneva + consultants
- USA
- Brazil
- Kenya
- Malaysia

2 Project Support Offices

DNDi Objectives

Primary:
- **Deliver 6 - 8 new treatments by 2014** for leishmaniasis, sleeping sickness, Chagas disease, & malaria
- **Establish a robust portfolio** for new generation of treatments

Secondary:
- Use and **strengthen existing capacity** in Disease Endemic countries
- Raise **awareness** and **advocate** for increased public responsibility
Scope of Activities for DNDi

Major focus on kinetoplastid diseases
(HAT / VL / Chagas)

Leader
Research
Kitasato Natural Substances (HAT)
Microtubule Inhibitors (HAT)
GSK (All)
Kitasato Natural Substances (HAT)
CDRI (HAT)
Eskitis Natural Products (HAT)
IPK (VL)

Preclinical
Fexinidazole (HAT)
Nifurtimox - Eflornithine Co-Administration (HAT)
Amphotericin B Polymer
Buparvaquone (VL)
Fexinidazole (HAT)

Development
ASMQ (Malaria)
Fixed-Dose Artesunate/Amodiaquine
Norumix - Eflornithine Co-Administration (HAT)

Access
Paromomycin (VL in Africa)
AmBisome (VL in Africa)
Paediatric Benznidazole (Chagas)
Combination Therapy (VL in India)

A Robust and Dynamic Portfolio 2004-2008

Available
Paromomycin (VL in Africa)
AmBisome (VL in Africa)
Paediatric Benznidazole (Chagas)
Combination Therapy (VL in India)
Norumix - Eflornithine Co-Administration (HAT)
ASMQ (Malaria)
Fixed-Dose Artesunate/Amodiaquine

Exploratory Screening:
Anacor, Chemroutines, Univ of Ouro Preto, Fiocruz, ICB, IRD, LAC, LSHTM, MerLion, Otsuka, STI, TDR, Univ of Antwerp, University of Dundee, WEHI, ...
Virtual structure:
>400 Agreements, 214 People, 5 continents

DNDi’s 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:
  - Little commercial value
  - Distributed through the public sector
  - Developed in partnerships
DNDi’s IP policy

Contracts typology:

- MTAs:
  - To test compounds
  - Mainly with academic institutions
  - IP rights generally not negotiated (faster to access compounds) => rights to be negotiated if follow-up...

- R&D contracts (CROs and academia)
  - Involve testing and improving (med. chemistry)
  - Ownership of IP sorted out => generally owned or co-owned by DNDi

- R&D + License contracts (mainly private sector)
  - Results of R&D mostly remain with partner
  - License rights fully negotiated => ensure access up to fully developed product

IP/know-how generated through DNDi’s sponsored R&D

a) DNDi owns IP:
   - CRO, sponsored public or private institutions
   ⇒ Publication(s), evaluation of interest to do protective patenting

b) DNDi shares IP with partner:
   - Public or private institutions, private companies
   ⇒ If DNDi does not want to file, party grant license to DNDi

c) Partner owns rights derived:
   - Private companies
   ⇒ License to ensure freedom to operate within the field/territory
DNDi’s IP policy

Essential license rights to be negotiated:

• **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)

Conclusions:

• Results of the work carried out by DNDi are considered public goods
  ⇒ Publications, communications,
• DNDi does not seek to finance its work through IP revenues
  ⇒ Development for Neglected Diseases is considered to be a public duty
• DNDi may on a case by case enforce its IP rights through patenting
  ⇒ Patenting only as protective measure to ensure access to medicine
• Whenever IP rights are negotiated, ensure access
  ⇒ License rights without impediments for follow-on research, development and distribution of new treatments in endemic countries
Thank you!