Rummaging Through Pharma’s Attic: DNDi’s model and patent pools

Robert Don
DNDi

DNDi Vision

A collaborative, patients’ needs-driven, virtual, non-profit drug R&D organisation to develop new treatments against the most neglected communicable diseases
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)

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
**DNDi R&D Portfolio – June 2009**

- **Compound mining**
  - Nitroimidazoles, macrolides, ...
  - Chemical classes
    - GSK, Merck, ...
  - Target-based
    - Dander’s Drug Discovery Unit (DDU), Microtubule inhibitors...
- **Screening**
  - Natural products (Kitasato, Eklent), new technology (Institut Pasteur Korea), DDU at Dundee, CDRI screening...

**Reference screening centres:**
- LSHTM, Swiss Tropical Institute, University of Antwerp

**Screening**
- Preclinical
- Clinical Development
- Ph 4

**VL:** visceral leishmaniasis (kala azar)
**HAT:** human African trypanosomiasis (sleeping sickness)

---

**DNDi Pharma Partnerships**
**Fexinidazole**

Clinical Candidate for Treatment of African Trypanosomiasis – Currently in Phase I

Originally developed by Hoechst
Partnered with Sanofi-aventis

**Ravuconazole**

C14 α demethylase inhibitor
To enter clinical development for treatment of Chagas' Disease

Licensed from Eisai Co.
Pediatric Benznidazole

Standard therapy for treatment of Chagas’ Disease

Co-development with Lafepe (Brazil)

Oxaboroles for HAT

Under development as clinical candidates for treatment of Stage 2 African Trypanosomiasis

Licensed from ANACOR Inc.
Lead Optimization with SCYNEXIS Inc.
Access to Compound Libraries

GSK
Merck & Co., Inc.
Scynexis Inc.
Pfizer
Genomics Institute of the Novartis Research Foundation
Novartis Institute for Tropical Diseases
Basilea

Patent Pools
Patent Pooling

- March 2009
  - GSK initiates patent pool for Neglected Tropical diseases 80+ families
- July 2009
  - Alnylam joins the pool with RNAi technology

In patent law, a **patent pool** is a consortium of at least two companies agreeing to cross-license patents relating to a particular technology. The consortium may also license the patents to third parties. Pools usually have standardized licensing terms between partners and with third parties.

Examples:
- The Radio Frequency Identification Domain RFID Consortium picked Via Licensing to administer its patent pool in September 2006 (20 companies)
- DVD Six Licensing Group – DVD Formats (9 Companies)
A compound according to formula (I)

R1 and R1a are independently hydrogen; hydroxy; (C1-6)alkoxy unsubstituted or substituted by (C1-6)alkoxy, amino, piperidyl, guanidino or amidino any of which is optionally N-substituted by one or two (C1-6)alkyl, acyl or (C1-6)alkylsulphonyl groups, CONH2, hydroxy, (C1-6)alkylthio, heterocyclylthio, heterocyclyloxoy, anyloxy, acylthio, acyloxy or (C1-6)alkylsulphonyloxy; (C1-6)alkoxy-substituted (C1-6)alkyl; halogen; (C1-6)alkyl; (C1-6)alkylthio; trifluoromethyl; trifluoromethoxy; nitro; cyano; azido; acyl; acyloxy; acylthio; (C1-6)alkylsulphonyl; (C1-6)alkylsulphoxide; arylsulphonyl; arylsulphoxide or an amino, piperidyl, guanidino or amidino group optionally N-substituted by one or two (C1-6)alkyl, acyl or (C1-6)alkylsulphonyl groups;

provided that when Z1, Z2, Z3, Z4 and Z5 are CR1a or CH, then R1 is not hydrogen;

A is a substituted or unsubstituted 5 membered aromatic heterocyclic ring of formula (C):

wherein:

W1 and W2 are each independently selected from N, O, S, and CR8;

W3 is N or C;

W4 is N, O, S, or CR8;

each R8 is independently selected from hydrogen; hydroxy; halogen; trifluoromethyl; trifluoromethoxy; cyano; nitro; azido; acyl; acyloxy; acylthio; amino, mono- and di-(C1-6)alkylamino; and substituted and unsubstituted (C1-6)alkoxy, (C1-6)alkyl, (C3-7)cycloalkyl, aminocarbonyl, (C1-6)alkylthio, (C1-6)alkylsulphonyl, and (C1-6)alkylsulphoxide;
Pharma patents

Pharma patents cover chemical space
They do not usually divulge useful SAR
What can a neglected diseases patent pool offer?

Patent Pool Opportunities

Standardized license agreements
– Between patent holders
– With development partners
– Value current IP and improvements

“Throw it in the pool”
Access to “Intellectual Capital”
A mechanism to deal with IP contamination
Access to compounds/representative libraries
Patent Pool

The model is evolving

GSK Seeks partners and suggestions

Coordination by an independent third party is anticipated

An Opportunity exists to build a new collaborative model

Thank you!