

IP management in R&D for the Neglected Tropical Diseases

Mission

Founded in 2003 by partners from the public sector in neglected disease-endemic countries and MSF, DNDi (Drugs for Neglected Diseases initiative) mission is to develop safe, effective and affordable treatments for patients suffering from neglected diseases such as sleeping sickness (HAT), visceral leishmaniasis (VL), Chagas disease, and malaria.

Collaborative Mode of Operation

DNDi follows the virtual research model adopted by other product development partnerships (PDPs), whereby most research is outsourced and actively managed by DNDi personnel

Current Portfolio

DNDi has 18 projects in its portfolio as of January 2008: 9 discovery, 3 preclinical, 4 clinical, and 2 post-clinical projects. Discovery projects range from library screening on validated targets, reformulation studies, to therapeutic switching. Three preclinical projects will be ready to enter clinical studies by 2009; and clinical projects are ongoing for VL (combination therapies, regional extension of existing drugs) and for HAT (nifurtimox-eflornithine combination therapy [NECT]).

Delivered Products

Two fixed-dose antimalarial ACTs (FACTs 'ASAQ' and 'ASMQ') have been developed and registered by DNDi and its FACT Project partners. Its fixed-dose combination (FDC) of artesunate and amodiaquine (ASAQ is now registered and distributed in 21 African countries, and received WHO prequalification, while ASMQ has been recently registered in Brazil.

IP management strategy

The DNDi IP approach is guided by the following principles:

- The need to ensure that drugs are affordable to and access is equitable for patients which need them.
- The desire to develop drugs as public goods when possible.

Thus the DNDi approach will be pragmatic, and decisions regarding the possible acquisition of patents, ownership and licensing terms will be made on a case by case basis.

The basic guidelines state that:

- Results of the work carried out by DNDi are considered public goods.
- DNDi shall insure the largest dissemination of the results of its work whenever possible.
- When necessary to promote DNDi's mission and goals, patents may be filed.
- DNDi does not seek to finance its work through IP revenues.
- When IP is generated through DNDi-sponsored research, it should be used to achieve DNDi's mission.
- DNDi recognizes that it may have to acquire, manage or enforce IP to pursue its mission. In doing so, efforts will be made to avoid prohibitive costs, lengthy procedures, or any measures that may prevent rapid adoption of the invention to the benefit of developing countries.
- DNDi shall insure that whenever IP rights are negotiated, DNDi retains full freedom to operate so that no impediments will result for additional follow-on research, development or distribution of new treatments in endemic countries.

In practice, DNDi must insure that in any IP negotiations stringent definitions of the field of use, the territory, the distribution sector, the costs, the out-licensing rights, as well as the dissemination of information has been clearly defined, in order to secure the best possible access conditions for patients in needs.