Intellectual Property Policy

DND*i* POLICIES

DNDi
Drugs for Neglected Diseases *initiative*

June 2004

DND*i* hereby adopts the following intellectual property (IP) policy:

I. Preamble

The mission of DND*i* is to develop safe, effective and affordable new treatments for patients suffering from neglected diseases, and to ensure equitable access to these.

The DND*i* IP policy will be guided by the following principles as laid down in the business plan:

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

The DND*i* IP 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. DND*i* will put the needs of neglected patients first, and will negotiate to obtain the best possible conditions for them. The DND 's decisions regarding IP will contribute to ensuring access and encouraging further innovations. DND*i* regards drug research as a public good that should primarily lead to the advancement of health.

In addition to a pragmatic day to day approach on IP the DND*i* is committed to contribute to the thinking and development of IP approaches in health R&D that are aimed at serving the public good.

II. Definitions

For the purpose of this policy, the term "intellectual property" includes, but is not limited to, intangibles that are protected by the principles of patents, copyrights, trademark and trade secrets.

III. Intellectual Property and DND*i*'s Work: Basic Principles

In implementing the IP strategy, DND*i* will adhere to the following basic principles:

- DND*i* will ensure that the results of the work carried out under its auspices are disseminated as widely as possible and its products made readily available and affordable in developing countries. Where the acquisition of IP is not necessary to promote its mission and goals, DND*i* will make all possible efforts to ensure that the results of its work are placed and remain in the public domain. However, it is possible that promoting DND*i*'s mission and goals will sometimes require outputs to be protected by IP (see Sections IV and V). Given the costs involved, patenting is likely to be the exception rather than the rule. Other non-patent types of IP such as confidential information ("trade secrets") and copyrights will also need to be considered.
- To make the results of its work useful and encourage the research community to engage in additional or follow-on research in the field of neglected diseases, DND*i* will seek – whenever possible and without undermining its rationale for acquiring IP – to disseminate

its research through publications, presentations, the internet (emulating the Human Genome Project) and other appropriate channels.

- DND*i* does not seek to finance its research and operations through IP rent revenues. Although they will constitute an exception rather than the rule, patents might be sought to strengthen DND*i*'s ability to ensure control of the development process and to negotiate with partners.
- When IP is generated through DND*i*-sponsored research projects, it should be used to achieve DND*i*'s mission. To this end, DND*i* will pursue creative and innovative strategies to make the fruits of research projects readily available to patients affected by neglected diseases. This will require avoiding prohibitively costly approaches, restrictive IP strategies, or other issues that may inhibit or delay the rapid adoption of the invention to the benefit of developing countries.

IV. Rationale for Acquiring or Otherwise Dealing with Intellectual Property

DND*i* recognizes that in pursuing its mission it may find it necessary to acquire or otherwise manage and enforce IP. In this regard, DND*i* acknowledges that it will have to deal with IP to:

- conclude contracts and undertake research with its research partners, contractors, collaborators and founders;
- obtain rights to work on and develop molecules, including facilitating DND*i*'s or its partners' access to proprietary research materials;
- ensure equitable access to, and affordability of, the end products of its research for patients.

V. Acquisition, Management and Enforcement of Intellectual Property

Where it is considered necessary to acquire or otherwise manage IP, DND*i* will put in place measures to ensure the timely acquisition of IP by itself or its project partners, collaborators or founders for and on behalf of DND*i*. When necessary to achieve DND*i*'s objectives, enforcement may include legal actions to protect the DND*i* IP.

DND*i* will ensure that IP, however acquired, allows the initiative full freedom to operate, including retaining the right to use the inventions on which IP is obtained for DND*i*'s further research, including with other partners. To this end, DND*i* will use various mechanisms such as assignment of the IP to DND*i*, exclusive licences and licences of right. It will negotiate terms with partners to ensure that they will not use the acquired and/or held IP in a manner that impedes equitable and affordable access to the products of the research, or that impedes additional or follow-on research by DND*i*, its partners and other researchers, especially those undertaking research on neglected diseases.

DND*i* will not accept projects in which IP is obviously going to be an insurmountable barrier to follow- up research on behalf of DND*i* and/or equitable and affordable access. Either at the onset

of a project or when problems arise, it will be important that negotiations with the public and/or private sector are backed with advocacy support.

VI. Transfer and Licensing of Intellectual Property

DND*i* seeks to enhance R&D activities for neglected disease therapeutics and may wish to in-license technologies developed by others that would help bring such products to the public. To ensure the availability and affordability of neglected disease therapeutics, it will transfer or out-license its technologies to facilitate manufacturing and distribution of its products. As a general policy:

- DND*i* will ensure that the terms of each transfer or licensing agreement take into consideration, the impact of the technology on research in medicine and more broadly, public health; the level of support provided by DND*i*; the stage of scientific and clinical development of the technology; DND*i*'s portfolio and drug pipeline requirements; and timing and other business and economic considerations;
- DND*i* will ensure that the terms and conditions of any licensing or transfer agreement allow the continuing availability of technology that supports further research in the field of neglected diseases;
- DND*i* will ensure that technologies developed under DND*i* sponsorship are brought to practical application in a timely manner, and made affordable and accessible to the public;
- DND*i* will negotiate and award licenses which may be exclusive, for specific indications, fields of use, or geographic areas, and other terms as circumstances allow;
- DND*i* will monitor the performance of licensees and ensure that licensed technology is fully developed;
- DND*i* will develop and use model agreements, where appropriate, to enable alternative forms of dispute resolution and therefore avoid litigation.

VII. Communities' Involvement in DND*i*'s Research and Benefit Sharing

When DND*i* will consider patenting an invention resulting from work with communities on traditional medicine or on community genetics, that community will be assured of receiving all eventual benefits from this work.

VIII. Amendments and Changes to the Policy

DND*i* retains the right to review, revise and/or amend this policy or any of its terms at its discretion, at any time. When warranted and in agreement with the Chair of the Board, the Executive Director will recommend the review, revision or amendment of this policy for further approval of the DND*i* Board of Directors.

IX. Administration and Implementation of the Policy

The Executive Director will ensure the full implementation of this policy and put in place, subject to Board approval, administrative, financial, technical, and other mechanisms and procedures to ensure its full implementation.