# STRIKING FAIR DEALS FOR EQUITABLE ACCESS TO MEDICINES

## THE CASE OF PRO-ACCESS IP POLICIES OF DNDi

*Pascale Boulet, IP & Access Leader*

DNDi
Best Science
for the Most Neglected

# Key elements to ensure Equitable and Sustainable Access

**Commitment to Equitable Access** starts at the conception phase of every DNDi R&D project, not once a product is in late-stage clinical development or has received regulatory approval (end-to-end approach)

**Access not only targeted in contracts but deeply embedded in R&D strategies**:

- Design of Target Product Profiles (TPPS) that respond to population needs (including a target price) with local experts, clinicians, regulators, and affected communities
- Selection of partners based on a shared vision, incl. the approach to IP and licensing, regulatory strategy and 'post-registration' efforts to introduce and scale up access.

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# Collaboration and Licensing agreements guided by DNDi IP Policy

- **Basic principles:**
  - Ensure equitable access and affordability of end-products
  - Make results of DNDi research available to the wider research community
  - Develop drugs as public good when possible
- **Terms & conditions** ensure DNDi Partners cannot use IP to impede access to DNDi products, or follow-on research.
- **IP ownership and licensing terms decided on a case-by-case basis**, with main objective to disseminate results of DNDi work as widely as possible and patenting exceptional.

# DNDi IP Policy

## Adopted in 2004 - First DNDi policy - Reflects DNDi vision and mission

- Best possible conditions for neglected patients
- IP generated through DNDi-sponsored research projects *used to achieve DNDi's mission*
- DNDi *full* freedom to operate

- DNDi activities *not* financed by IP rent revenues
- No partnership *without overcoming IP barrier*
- *Avoid* prohibitively costly approaches and restrictive IP strategies

- All possible efforts to ensure that the results of DNDi work are *placed and remain* in the public domain

- Contribute to the thinking and development of IP approaches in health R&D that are aimed at serving the public good.

# Terms and conditions of DNDi license agreements

**Reflect the characteristics of DNDi's products:**

- Developed in partnership – sub-licensable rights needed
- Little commercial value of Neglected Diseases (exception of Hepatitis C)
- Distributed mainly through the public sector

**Variations depending on:**

- whether compounds/molecules are available in the public domain or privately owned
- the level of technical/scientific support provided by DNDi and the Partner(s)
- the stage of development of the product
- Donors' requirements

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# Key Terms & Conditions to ensure Equitable Access & the development of Public Goods

- Partner's commitment to affordable and equitable access
- Publication of research data
- IP ownership and/or non-exclusive licensing rights
- Survival of rights upon expiry or early termination of the Collaboration

# Commitment to affordable and equitable access

**Affordability** included as a key objective in early-stage license agreements.

Affordability defined as “pricing the Product at the lowest sustainable level that includes only:

- full production costs, as optimized without compromising the quality of the Product
- direct distribution costs; and
- a reasonable margin to ensure manufacturing and distribution of the Product on a sustainable basis. ”

A more detailed obligation in late-stage development agreements based on a cost-plus scheme.

**License territory**: all endemic countries, as defined by WHO.

DNDi’s **right to audit** Partner’s implementation of affordable pricing.

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# Developing Public Goods, whenever possible

**Timely and open access publication of *all* results** from DNDi research.

In cases where compound/molecule is publicly available and unencumbered by any private rights, the **Public Domain Clause** ensures the release of new data (generated within the partnership) in the public domain, free of IP rights.

> *All data, analysis of data, methods, processes and descriptions thereof, information, documentation and other materials whatsoever generated through the performance of the Services (Results) will be placed into the public domain in accordance with section XX on publications and presentations. The Parties agree not to seek to get any protection of, nor claim any registered or unregistered IP rights in or pertaining to the Results, including without limitation patents, trade secrets and copyright relating thereto.*

**Examples**: Drug Discovery Booster, Moonshot consortium

# IP ownership and/or licensing rights

Sharing of **Background IP** (necessary or useful confidential know-how/data or patents pre-existing or outside the Collaboration)

- through non-exclusive, sub-licensable rights in the Field (eg. NTDs) and Territory (endemic countries).

Ownership of **Collaboration IP** (know-how/data or patents developed during the collaboration):

- Owned by the Party that has developed/funded it, or
- Jointly owned if jointly developed, and
- Non-exclusive, sub-licensable cross-licensing rights between the Parties.

Rights in **regulatory dossier** belong to the market authorization holder but commitment of the Parties to **waiving regulatory/market exclusivity**

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# DNDI "GOLD STANDARD" LICENSING TERMS

**Licensing terms to ensure equitable and affordable access to treatments:**

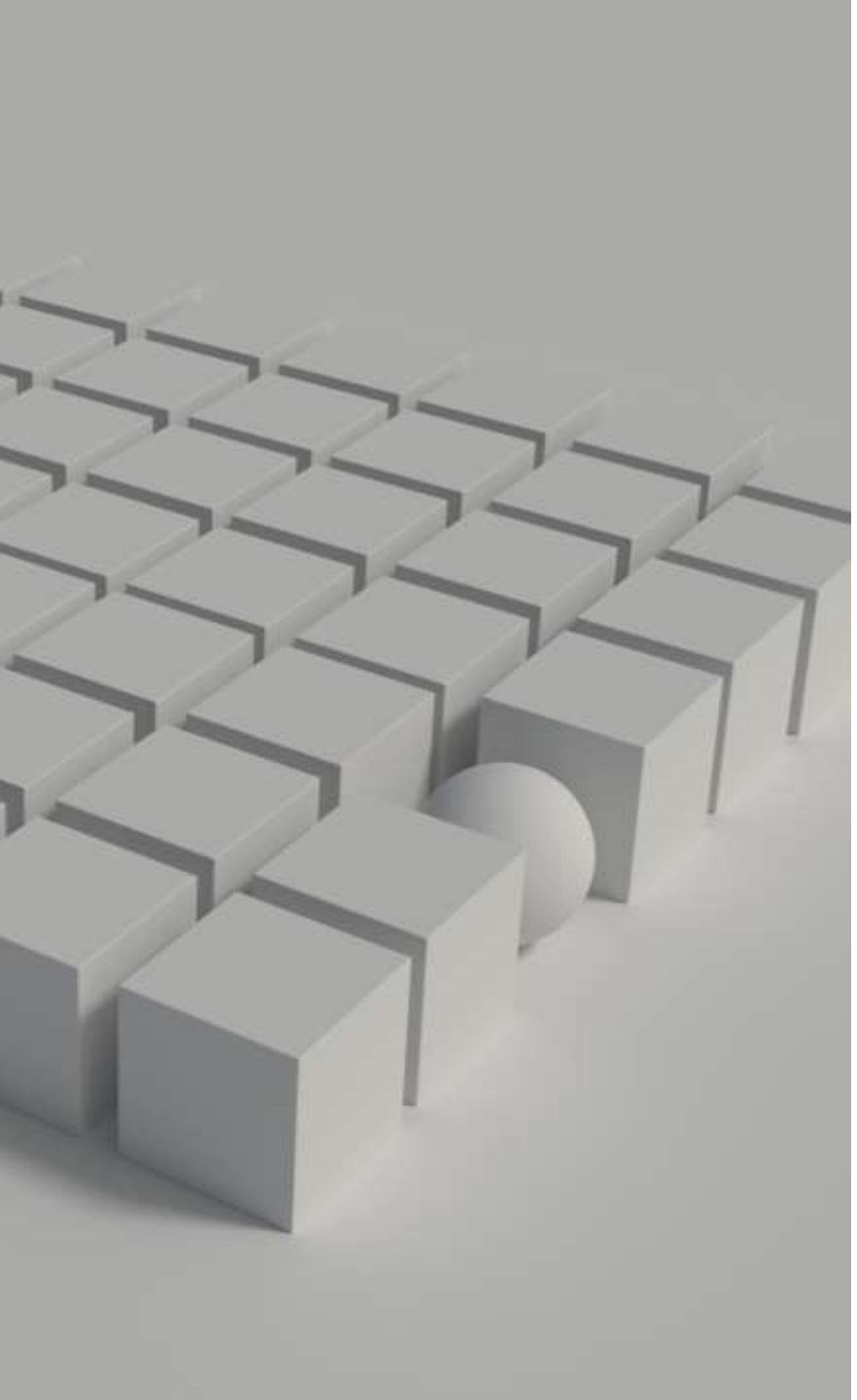
- Perpetual, royalty-free, nonexclusive, sub-licensable licenses in the specific disease areas
- Worldwide research and manufacturing rights
- Commitment to make the final product available at cost, plus a minimal margin, in all endemic countries, regardless of their income level;
- Non-exclusivity, enabling technology transfer and local production to multiply sources of production and decrease cost of product

*Source: Ten years of experience and lessons learned by DNDi (2014)*

# Patenting exceptional, as a defensive strategy

**DNDi IP Policy:** *Although they will constitute an exception rather than the rule, patents might be sought to strengthen DNDi's ability to ensure control of the development process and to negotiate with partners.*

- Pragmatic approach - decision on possible acquisition of patents on a case-by-case basis.
- 2 patents filed by DNDi with defensive objectives:
  - DNDi-6174: to control and/or prevent the use of DNDi-6174 in canine leishmaniasis (more profitable than human leishmaniasis), which may generate drug resistance in the treatment human leish.
  - Fexinidazole synthesis process: defensive patent to prevent third party patenting. Patent application assigned to Sanofi in 2015 with a worldwide non-exclusive licence-back to DNDi.



# Limited & controlled exclusivity to DNDi partners, if needed

On an exceptional basis, DNDi agreed to few exclusivities :

- To provide a time-limited (3-5 years) market entry advantage for partner to recoup significant investments in infrastructure or equipment
- To provide assurance that DNDi would not work in parallel with third parties while development is-ongoing
- To use the product for other indications outside of NTDs and/or for animal health

**Exclusivity is systematically balanced by Partner's obligation to ensure equitable and affordable access to the treatment developed, and the possibility of exclusive license becoming *non-exclusive* in case of lack of diligent efforts/abuses.**

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# Effect of Expiry /Early termination of the Collaboration Agreement

- Upon expiration of the Agreement: survival of licensing rights to DNDi, enabling continuation of project and possible tech. transfer to a third party
- If partner withdraws or underperforms (eg. product unaffordable or unavailable)
    - Rights secured to ensure full freedom to operate to DNDi (if not already done through licenses), and
    - Partner's commitment to transfer technology and all necessary documentation and approvals, free of charge, to a new DNDi partner (+ any stock of API or Product)

# HEPATITIS C

## Accelerating access to affordable treatment and supporting global elimination efforts

**FACTS**

**50 million**
people are living with HCV globally

**Only 20%**
have had access to treatment

**600**
people die from HCV every day

### CHALLENGES

Direct-acting antiviral (DAA) treatments are safe, simple, and highly effective, but **unaffordable for most people** living with hepatitis C.

### OUR WORK

We developed **ravidasvir for use as part of an effective, simple-to-use, affordable treatment** for hepatitis C.

We are **expanding our partnerships to bolster affordable and sustainable supply of DAAs and foster the political will and financing** needed for wide-scale roll-out of lifesaving testing and treatment

### OUR GOALS

**2021-2028: Help make treatment a reality for missing millions of people unaware of their infection**

- Promote **access to diagnosis and treatment** for hepatitis C in **low- and middle-income countries**
- **Positioning ravidasvir strategically** within the landscape of other DAAs
- Optimize development of **collaborations** towards hepatitis **elimination** in LMICs

**MAIN PARTNERS:** *Pharco Pharmaceuticals, Pharmaniaga, Presidio, Médecins Sans Frontières, Ministries of Health of Malaysia and Thailand*

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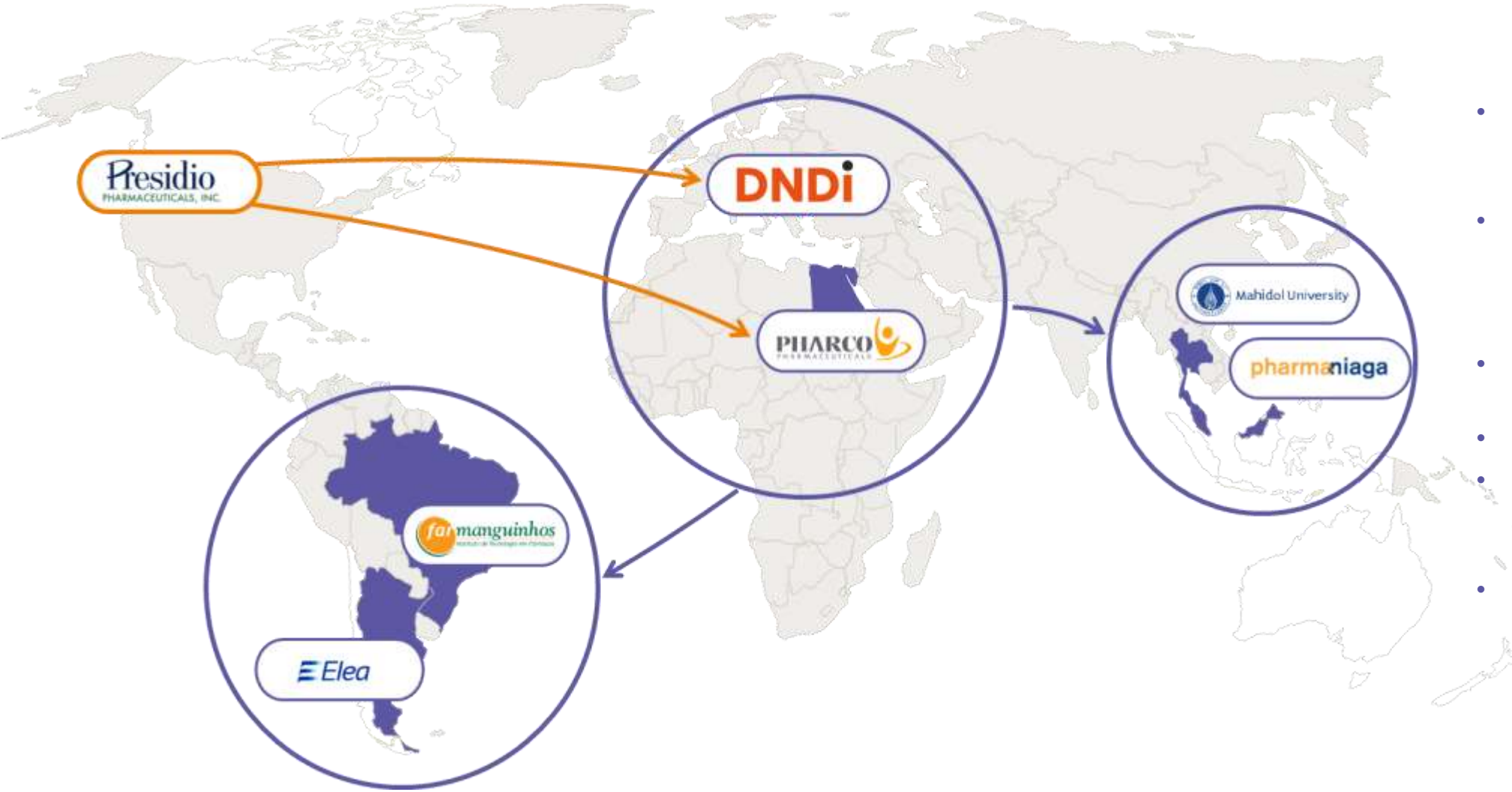
# THE POWER OF PARTNERSHIP: RAVIDASVIR

## A global collaboration to address public health needs




- Develop a **new chemical entity, ravidasvir**, for the treatment of HCV, **priced** as close as possible to a **generic**
- **Targeting UMICs** with high HCV burden, excluded from voluntary licenses
- Phase II/III **clinical studies co-sponsored by Malaysia & Thailand,** using patent research exemption
- **First registered in Malaysia and Egypt**
- Added to **WHO EML**
- **Affordability** a primary concern from the outset: US$ 300-500, depending on sofosbuvir price
- **Non-exclusive licensing** with tech transfer agreements in Malaysia, Argentina, Brazil, Thailand

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# THE POWER OF PARTNERSHIP to eliminate Sleeping Sickness

## A patient-needs-driven alternative R&D model is possible

NATIONAL PROGRAMMES AND MINISTRIES OF HEALTH

SANOFI

World Health Organization

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# SLEEPING SICKNESS

## Delivering breakthrough treatments and expediting access

**FACTS**

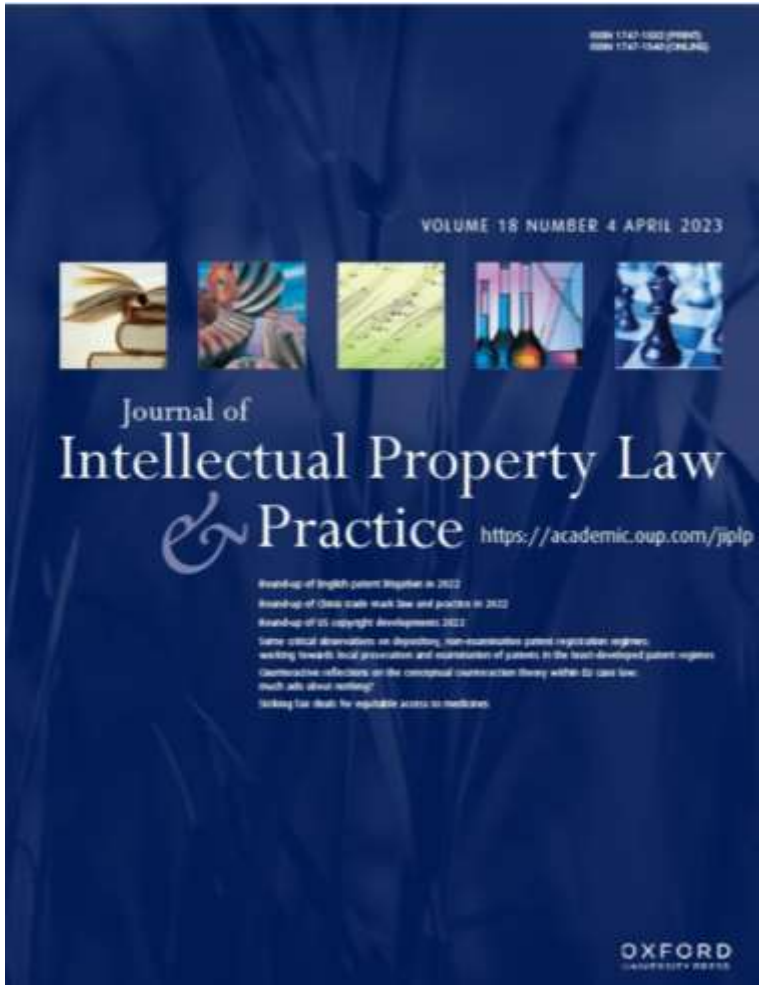
**3 million**
people with moderate to high risk of being infected

**61%**
of reported cases in the last 5 years were in the DRC

**97%**
reduction in reported cases in the last 20 years

| 15 YEARS AGO | 2009 | 2018 | 2023 | GOAL |
|---|---|---|---|---|
| **MELARSOPROL** | **NECT** | **FEXINIDAZOLE** | **FEXINIDAZOLE for r-HAT** | **ACOZIBOROLE** |
| ‘Fire in the veins’ | **Effective and safe** but hospital-based and complex logistics. | **All-oral. Once a day for 10 days for *T.b. gambiense*.** | **EMA positive opinion Dec 2023** | **An innovative single-dose oral treatment to sustain elimination** |

# Conclusions




***Striking fair deals for equitable access to medicines***
Dominique Junod Moser, Pascale Boulet, Michelle Childs, Mae Shieh and Bernard Pécoul

- DNDi views drug research as a public good that should primarily lead to the advancement of health
- DNDi partnerships are driven by a shared understanding of patients' needs and equitable access objectives
- DNDi Collaboration and Licensing agreements ensure IP generated by DNDi research activities (knowledge, data, patents, etc) remains available to DNDi and the research community, through publication & non-exclusive licensing.
- DNDi model agreements are available at: https://dndi.org/advocacy/pro-access-policies-intellectual-property-licensing/

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# Thank You

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