TRIPS and R & D Alternatives for Drugs for Neglected Diseases (DNDs)

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Médecins Sans Frontières (MSF)

- Emergency medical relief, and health crises
- Humanitarian action and witnessing
- Founded in 1971, France
- 2,500+ overseas volunteers per year, 15,000 national staff
- 400+ projects in 80+ countries
- Funding: independence
  - Annual budget US$ 300 million
  - >78% private donations from individuals
- Recipient of 1999 Nobel Peace Prize

Photo S. Salgado

MSF's response to the crisis in access to essential medicines

- Access Campaign launched in 1999

- With Three pillars of action:

1) Overcoming barriers to access to treatment for selected diseases

2) Assessing and responding to the health impacts of globalization – TRIPS

3) Stimulating research and development for neglected diseases

What does TRIPS do or not do for R&D for DNDs*?

Conceptually:

- There is a clear overlap between TRIPS and the stimulation of R&D for drug development

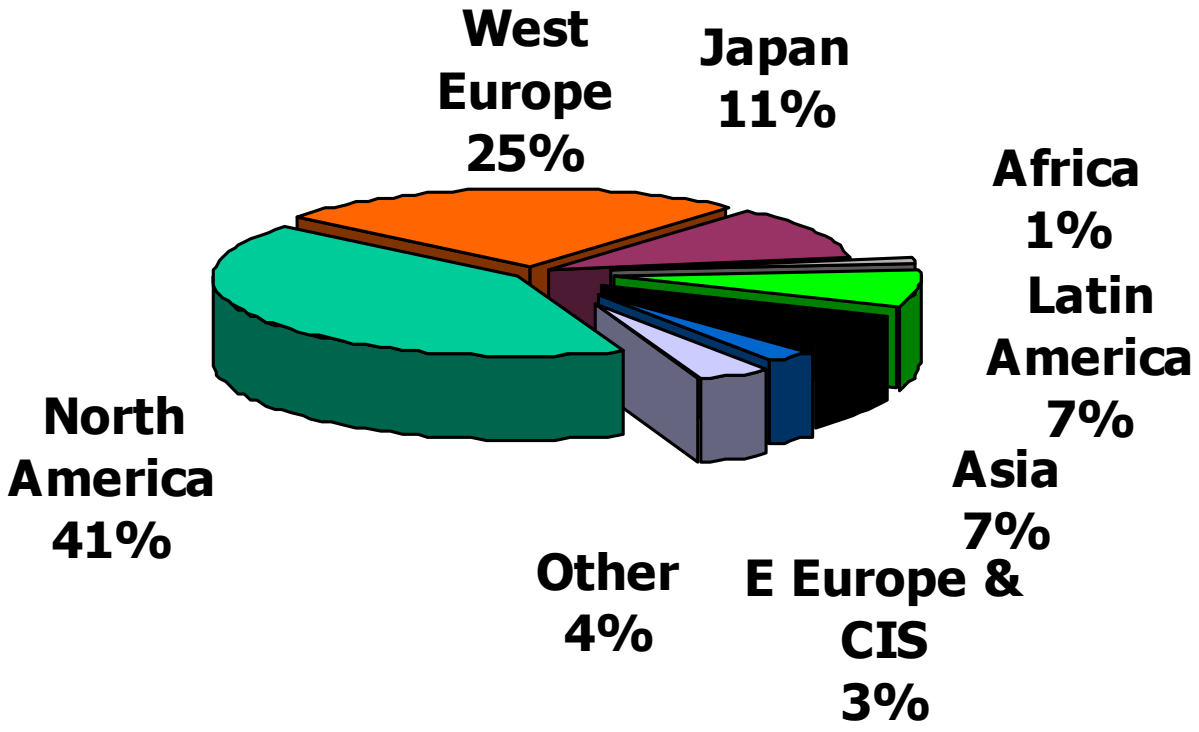
- But which drugs for which diseases?

*DND: Drugs for Neglected Diseases

Improving access to medicine

Research-based pharma industry

Projected global pharmaceutical market (US$406 B in 2002)



*IMS Health, 1997

Rationale for IPR Protection

- Financial return on investment to

  Reward / Protect / Enhance innovation capacity

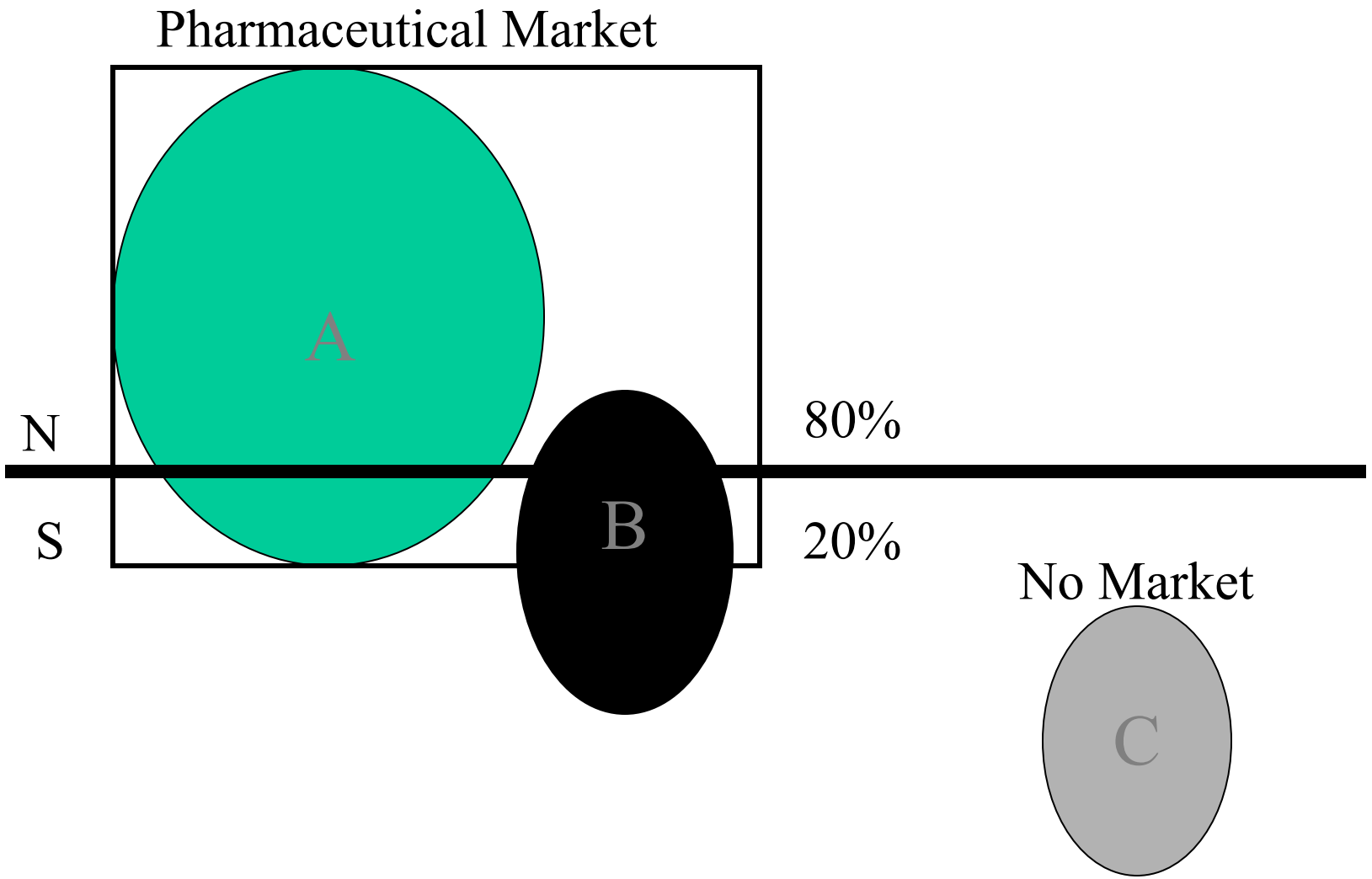
- Yet incentive for innovation is

  market driven, not ***needs*** driven

What does this mean for R&D?

- 1393 New Chemical entities approved between 1975 and 1999
- Only 13 therapeutic innovations for tropical diseases
- <1 %
- 6 / 13 were from veterinary or military research

3 types of Disease



Category C: Some diseases for which there is need but no viable market

- Trypanosomiasis
- Leishmaniaisis
- Chagas
- Dengue
- Lymphatic filariasis
- Onchoceriasis
- Leprosy
- TB
- Chloroquine- resistant Malaria
- Shistosomiasis
- Trichariaisis
- Burelli Ulcer
- Etc

In Principle,

- TRIPS ***does*** explicitly take the interests of developing nations into account:

- ***Preamble of TRIPS***
- protection of IPR is not an end in itself, but
- has a functional role to play in relation to the priority objectives of public policy for which these rights were created.
- TRIPS should be harnessed to the service of development

In Principle,

Re: TRIPS and Technology transfer

- Enhance measures to encourage and improve pharmaceutical technology transfer

- with the aim to encourage local and regional production of quality essential medicines (Obligation under article 66.1).

In Principle,

- ***Art 7/8/66:***
- Attempt to balance the rights of patent holders and their obligations vis a vis society

- ***Safeguards:***
- have practical application for access to existing drugs, but

TRIPS safeguards

- do not accommodate a ***needs based*** stimulation of R&D for new drugs

- least of all for for needs-based neglected diseases for which there is ***no market***.

Basic Problem:

Private incentives to meet public ends is effective when a market exists. However,

- ***If no market, no means to meet public ends.***

“No Market, no Means”

- In South, a long-standing problem
- limited R&D capacity for needs-based DNDs
- Shrinking or non-existent R and D capacity
- TDR / PPPs are not sufficient responses
- TRIPS will exacerbate this problem of “no market no means” in the South

In practice, TRIPS consolidates monopolies for maximum ROI

- Does not ensure Southern access to

  new processes, products, knowledge, technology and capacity transfer.

The net effect is to concentrate these in existing advanced market economies, with only secondary peripheral effects in the South.

In Practice, TRIPS & IPR

- **Fails to achieve** an adequate incentive structure to ensure R&D for needs-based DNDs

- IPR leading to increased consolidation of R and D capacity that is market and not needs focused

- As a whole, the practical effect of TRIPS is not stimulation of R&D for DNDs, though this was the key public argument of the PI for the implementation of TRIPS in the developing world

Lanjouw & Cockburn Paper

(2001, ***World Development***, 29(2), pp265-289.)

- Early baseline analysis 1975 to 1997
- Changes in the pattern of research expenditure and US patent applications secondary to TRIPS

- Indian US patent applications are up, for high market diseases, and for innovative Tx delivery mechanisms
- Bibliometric data shows no increase in R&D for DND, except malaria (2 to MMV/RBM, technology change)
- New technology (DNA sequencing, genomics, proteomics) driving patents for market diseases
- Harder to reverse engineer

Are patents alone sufficient to stimulate R&D for DNDs?

- Not yet!!
- What to do?

At TRIPS Council:

- Use TRIPS Council to demand that the stated intent of TRIPS in the service of essential medical research and development to address public health needs is forwarded
- Or to expose the weakness / failure of TRIPS
  - Increases bargaining power in other trade sectors
  - Increases bargaining power to demand alternatives that increase R&D capacity in the S

Establish viable alternatives:

- Establish a system for global sharing of the research burden related to a country's stage of development and ability to pay

MSF Proposals

- NfPI : Not-for- Profit- Initiative for R&D for DNDs

- Treaty/Convention for R & D with a

  Global Health Security Subsidy

R&D Not-for-Profit-Initiative for DNDs

- MSF is funding feasibility study
- Social Vision: Equitable access to effective, affordable, easy-to-use drugs for neglected diseases of the developing world
- Pursued in the public interest, in collaboration with the public and private sectors in the North and South
- CB/ TT in the South is a complementary focus

NfPI

- Virtual drug portfolio management using R&D partners in the N and S
- Sound science / business management
- 100 million USD in 5 yrs
- 70% public funding, 30% private

NfPI Elements to be evaluated:

- Detailed business plan
- Evaluation of legal issues
- Methods of pharmacoeconomics analysis for DNDs
- Criteria for target disease selection

NfPI: Key Questions

- Are important potential partners (i.e.: P16) willing to collaborate?
- Is there sufficient political support?
- Can sufficient financial support be marshaled to achieve its vision and mission?

R&D Treaty / convention

- Working paper on R&D for DNDs

1. Burden sharing
2. Focus on basic R&D for DNDs
3. IP in public domain
4. Funding though Global Health Security Subsidy

DND Working Group

- Independent, established by MSF in 1999
- 35 academics, IPR experts, drug developers from public and private sector, from N&S

- 4 areas of Focus:

1. R&D Agenda and Advocacy
2. Capacity building and Technology transfer
3. Legal & Regulatory affairs
4. Finance and market access

DND Working Group

- Offer support to Partners in 4 areas
- Meeting Oct 2-4, 2001
  - NY City
  - Review and Present findings to date
  - Plan strategy for the future
  - All Partners MOH are invited to actively participate

For more information

- Websites
  - www.accessmed-msf.org
  - www.neglecteddiseases.org
  - www.msf.org
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