

TRIPS, Incentives for R&D and New Drugs for Neglected Diseases in India

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Summary of:

WHO CIPIH sponsored study:

***R&D for Development of New Drugs for
Neglected Diseases: How Can India
Contribute***

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Story of India is well known:

- Product patents in pharmaceuticals abolished in 1972 through Patents Act, 1970
- Remarkable growth of pharmaceutical industry since then
- India and Japan: only two countries where western MNCs do not dominate
- India: net exporter and self sufficient in drugs
- Drug prices among the lowest in the world
- Source of good quality cheap drugs for the rest of the world
- In line with TRIPS, a product patent regime has again been introduced again from 1 January, 2005

Product Patent Regime Before 1972

- No positive effect
- MNCs, who held the patents were not keen on manufacturing (and R&D) activities
- MNCs prevented the Indian companies from doing so by using their patent rights.

Abolition of Product Patent Protection in 1972

- operated as a pull mechanism
- provided the Indian companies the space of operations and the opportunity to develop and innovate

R&D for New Drugs Before TRIPS

- Some new drugs were developed
- Ciba-Geigy (Novartis), Hoechst (Aventis) and Boots set up set up facilities in India
- Central Drug Research Institute: one of the few public sector organizations in the world to have own drug development infrastructure
- Indian private sector did not pursue new drug R&D

R&D for New Drugs After TRIPS

- MNCs: AstraZeneca has set up a research facility in Bangalore for anti-TB drugs
- Indian private sector has started investing in R&D for new drugs
- Public sector laboratories, now also involved in Public-Private partnerships

Two implications of product patent protection under TRIPS

- supposed to provide incentives to Indian companies to undertake new drug R&D themselves
- result in a shrinkage of market opportunities of the Indian companies because they will no longer be able to reverse engineer and produce the new drugs invented abroad and protected by patents

New Drug R&D by Indian Companies

- More a response to the latter (market shrinkage)
- Rather than a result of the former (product patent incentives)

Status of New Drug Development programmes of Indian companies

- Indian companies are not yet ready to undertake R&D independently
- They do not have all the skills and the resources to do so
- Developing new molecules and license out these to the MNCs in the early phase of clinical development
- As a result Indian companies are not targeting the neglected diseases of the developing countries but the global diseases which interest the MNCs
- While some of the molecules developed at clinical trials stages, no new drug has yet been approved for marketing.

R&D Expenditure by top MNCs, 2003

MNC	R&D Exp, \$ billion	As % of sales
Pfizer	7.13	17.99
GSK	4.54	15.23
Merck	3.17	9.47
Top 10 MNCs	35.98	16.63

R&D Expenditure by Indian Companies, 2003-04

Company	R&D Exp, \$ million	As % of sales
Ranbaxy	60	7.80
Dr Reddys Labs	49	12.99
Sun Pharma	23	10.20
Total: 12 companies	218	7.73

Thus TRIPS has not led to much
R&D for developing drugs for
neglected diseases

What Other Incentives Can Be
Put in Place?

Push Incentives: provide funds and inputs and reduce costs

- Direct public spending
- R&D tax credits
- R&D grants to private sector
- Public-private partnerships

Pull Incentives: create or increase the certainty of a market

- Patent system
- Transferable market exclusivity
- Advance purchase contracts
- Tax credit on sales
- Patent buyouts
- Prizes/other rewards
- Fast track regulatory approval

Basic issue in a developing country

- How to develop the new drug infrastructure and how to fund it
- Indian companies lack experience, skills and resources
- Hence Push mechanisms more important than Pull incentives, which presuppose that companies have the capacity and capability to undertake R&D

Options: collaborate with:

- MNCs
- Government
- International agencies

Public-Private Partnerships in India

- Two promising PPPs - Drugs and Pharmaceuticals Research Programme (DST) and New Millennium Indian Technology Leadership Initiative (CSIR)
- Of the two new drug development projects which have made substantial progress, one belongs to a global disease, cancer and another to a neglected disease, TB. As of now there has not been much progress in initiating and developing projects for most neglected diseases

But ..

- Funds earmarked are abysmally small
- Budget of DST programme is only \$ 5.5 million. That of NMITLI (CSIR) only \$ 14 million including those on non-pharma projects

Improving the PPPs

- Mandatory contribution @ 1 per cent of formulation sales by all the pharmaceutical companies would fetch about \$ 48 million

Cross subsidy

- Projects of relevance to developing countries:
 - Those for which market incentives exist – global diseases and some neglected diseases (e.g., cardiovascular, cancer, TB)
 - Those for which market incentives are absent – most neglected diseases (e.g., leishmaniasis, sleeping sickness, Dengue fever)
- Ideally, government should earn some return from the former group of projects to cross subsidize the latter group which require most public support and no projects have been initiated yet

How India can contribute to International efforts

- Process development of NCEs: About 19% of new drug development cost goes for production process
- India's world class skills in chemical synthesis and process engineering can be used by the International initiatives to reduce the cost of new drug development and hence make these more accessible

Clinical research

- About 40 per cent of the new drug development cost goes towards clinical trials
- There are significant advantages of doing such trials in India and international initiatives can reduce both the time and the cost for developing new drugs for neglected diseases by organizing such trials in India
- The regulatory environment has improved – guidelines have been issued and laws have been changed for making it mandatory to conduct clinical trials as per GCP norms

Thank you

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