

Economic Aspects of Access to Medicines after 2005

A Study for the WHO-CIPIH

By

Padmashree Gehl Sampath,
United Nations University-INTECH

Structure of the Presentation

- Study Objective
- Analysis
- Main Findings
- Recommendations

Study Objective:

Was to investigate the effect that the introduction of product protection for pharmaceuticals in India is likely to have on:

- Emerging R&D and business strategies of Indian brand name and generic manufacturers in the new environment, particularly with respect to Africa?
- How important this change will be, when compared to other factors affecting access to new medicines, especially for diseases that disproportionately affect India and other such countries?
- To what extent can compulsory licensing still be an economically feasible alternative for generic producers?

Analysis:

- Study relied on secondary and primary data sources
- Central focus of the analysis was an empirical investigation of the Indian pharmaceutical industry.
- 103 firms out of the top 135 firms (ranked on the basis of export potential, R&D investment and total sales) were surveyed.

Analysis:

- Using country-level data collected, firms were classified into three main groups:

Group 1: Annual turnover of 300 crores and above (60 million Euros and above)

Group 2: Annual turnover of 100-300 crores (20 to 60 million Euros)

Group 3: Annual turnover of below 100 crores

Main Findings:

IPRs were not a significant factor promoting innovation in the Indian drug industry until now, both for product and process innovation.

- Indian system of pharmaceutical innovation – still has several limitations in addition to its strengths.
- But India's TRIPS compliance – imposes costs on the industry – of dealing with barriers to entry and sale in export markets and the local Indian market.
- Emerging firm strategies are targeted at dealing with these costs.

Main Findings: Emerging R&D and business strategies

Indian firms are adopting a mix of cooperative and collaborative strategies.

- Group 1 firms: moving into regulated markets in order to have greater profits from sale of products, seek their own IPRs, and use higher profits from sale into of invest into more R&D
- Group 2 firms: little R&D investment capabilities, moving into semi-regulated and unregulated markets, (a) will remain pure generic suppliers or (b) specialize.
- Group 3 firms: Contract manufacturing for larger Indian firms in the other two groups (effects of Schedule M of Drugs and Cosmetics Act).

Main Findings: Impact of Patents on R&D and Emerging Patenting Strategies

Table 9: Reasons for difficulties in accessing new technologies after India's TRIPS compliance

Firm group/Effect	Too many patents on research tools	Restricted access	Royalty stacking	High licensing fees
1	3.17 (12)	3.33 (12)	2.33 (12)	3.33 (12)
2	3.91 (11)	3.64 (11)	2.55 (11)	3.91 (11)
3	3.35 (20)	3.55 (20)	2.79 (19)	3.58 (19)
Average mean/ Firm total	3.44 (43)	3.51 (43)	2.60 (42)	3.60 (42)

Source: Field Survey, 2005

Main Findings: Impact of Patents on R&D and Emerging Patenting Strategies

Table: Patents Tabulated by Regions

Firm Group	Patents India		Patents US		Patents EU	
	Freq	Mean	Freq	Mean	Freq	Mean
Firm-Group 1	18	22.8	14	24.9	10	24.4
Firm-Group 2	8	12.1	8	11.8	4	8.3
Firm-Group 3	15	8.3	5	6.4	2	12.0

Mean: patents per firm

Total number of firms that have patents: 57

Computed from UNU-INTECH/ WHO Survey, 2005

Main Findings: Emerging business strategies and access to medicines in third countries in Africa

Firm Group	Present exports to Africa	Projections of future export intentions under sec. 92(A)
Group 1	15	6
Group 2	12	4
Group 3	15	15
Total	42	25
Source: Field survey, 2005		

Main Findings: Access to Medicines in Local Market

- Will depend on:
 - (a) Interpretation of the Indian Patent (Amendments) Act, 2005
 - (b) Competition Law Issues and how they are dealt with locally
 - (c) Compulsory Licensing for the Domestic Indian Market
 - (d) Price control and its effectiveness *post-2005*

Main Findings: Access to Medicines in Local Market

Table: Research amongst Indian firms on local disease conditions

FIRM GROUP	All research on local conditions	50% research on local conditions	Less than 25% research on local conditions
1	3	6	17
2	2	1	19
3	10	9	25
Total	15	16	62

Source: Field Survey, 2005.

Recommendations

- The economic viability of 30 August 2003 Decision should be re-considered and the provision amended accordingly.
- Other measures for R&D into neglected diseases should be considered.
- Indian government should:
 - strengthen existing institutions on local competition enforcement, patent examination, etc.
 - enable rules to help local industry with other aspects, such as data protection
 - Provide expedient procedure for Section 92(A) and promote awareness
 - Reduce hurdles to pharmaceutical R&D for the local industry