Pricing and Manufacture of Generic Drugs in India -- post 2005 Scenario

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IP ACT and Generic Manufacturing in India

- 1970 Patent Act -- key instrument in promoting the generic industry.
- Led to India emerging as a major centre of generic drug production in the world
- A substantial amount of drugs (40%) produced in the country being exported.
- New IP Regime has implications for future of generic production in India after 2005 and also the future of the export of generic drugs from the country.
- Other factors : domestic regulatory changes, changes in the global pharmaceutical market and influences of global trading regime.
- Ability of Indian companies to produce generic versions of on-patent drugs would be seriously compromised by the Product Patent regime.

Strong Patent Protection Means High Prices

Comparative Costs of Older Drugs (Not Patent Protected)

	COST IN $ OF 100 UNITS						Av.Cost for 6 drugs (Ind.=1)	Adjusted Cost with GDP
	Ampi-cillin	Co-Trim	Diaze-pam	Eryth-romycin	Fruse-mide	Propa-nolol		
India	9.00	3.00	3.00	12.00	1.00	3.00	1.00	1.00
B'Desh	6.00	3.00	—	10.00	1.00	1.00	0.77	1.00
Pakistan	5.00	3.00	3.00	5.00	0.60	1.00	0.65	0.50
S'Lanka	4.00	1.00	0.14	5.00	0.60	0.60	0.34	0.19
Canada	8.00	6.00	0.50	6.00	0.50	—	0.81	0.06
U.K.	7.00	5.00	1.00	6.00	—	—	0.82	0.08

Note: Data from mid 1990s

Comparative Costs of Newer Drugs (Patent Protected or recently off Patent)

	COST IN $ OF 100 UNITS			Av.Cost for 3 drugs (Ind.=1)	Adjusted Cost with GDP
	Ranitidine	Diclofenac	Ni' depin		
India	3.00	2.00	2.00	1.00	1.00
B' Desh	5.00	2.00	20.00	4.22	5.49
Pakistan	14.00	7.00	2.00	3.06	2.35
S' Lanka	63.00	2.00	9.00	8.83	5.03
Canada	31.00	30.00	28.00	13.11	1.02
U.K.	73.00	16.00	11.00	12.61	1.17

Note: Data from mid 1990s

Drug Prices and Patent Protection

Drug prices in a regime with strong Patent protection depend on:

- **Competition or the lack of it in the Pharma Market**
- **Indigenous Manufacturing Capability**
- **Price Control Mechanisms**

Promoting Competition:

Compulsory License

Promoting Competition

Compulsory Licensing

- Compulsory Licensing provisions in the Indian Patent Act and the extent to which the same can and will be used to allow production of generic versions of on-patent drugs.
- The section on CL marks a compromise between two kinds of divergent interests.
- The CL provisions in the Indian Act are not perfect, but are capable of being used.
- Whether they will be used depends as much on political as on legal considerations.
- It also depends on where powerful lobbies in the Indian Industry choose to align.
- Sentiments against prohibitive drug prices of new drugs, are likely to take time to crystallize, as one doesn't expect the Indian market to be flooded with high priced patented drugs overnight.

Compulsory License Provisions:

84. (I) At any time after the expiration of three years from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied

(b) that the patented invention is not available to the public at a reasonably affordable price or

(c) that the patented invention is not worked in the territory of India.

Contd... CL Provisions

"For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied --

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced";

Royalty for CL

“the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors”;

Compulsory License in Special Circumstances

"If the Central Government is satisfied, in respect of any patent in force, in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to the effect, by notification in the Official Gazette, and thereupon the following provision shall have effect, that is to say.

(i) the Controller shall on application made any time after the notification by any person interested grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;

(ii) in settling the terms and conditions of a licence granted under this section; the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with patentees deriving a reasonable advantage from their patent rights".

Generic Manufacture and “mailbox”

- The time that the Patents office will take to examine the patents claim in the mailbox.

- Now provided: “…the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which comtinue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises.”

Exports from India to developing countries

Para 6 of Doha Declaration

- Solution to para 6 in the Doha Declaration in TRIPS Council
- Given the complexities now built into the process -- lack of interest in Indian companies
- Small size of the market in countries with no manufacturing facilities
- Their willingness to pledge resources to set up manufacturing facilities for an market that is plagued with uncertainty.
- Indian companies are looking to large generics market in the United States and possibly the EU.
- Indian companies to make use of 31(f) to export to other countries, Patented drugs that also have a large domestic market.
- Linked to their ability to obtain a CL to produce such drugs

CL -- Use of 31(f)
In the Indian Law:

The license is granted with a predominat purpose of supply in the domestic market and that the licensee may also export the patented product, if need be in accordance with Section 84(7) (a) (iii) (i.e. where an export market exists).

Use of Para 6:

"92A. (*1*) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided the importing country has by notification or otherwise allowed importation of the patented pharmaceutical product from India

(*2*) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

Indigenous Manufacturing Capability

New Trajectory for Generics Manufacture

- Domestic market will continue to be serviced by the generic manufacturers, at least in the immediate future.
- In addition the exports of generics will continue

Major Reasons:

- The existing large manufacturing base in the country and low costs
- Large unused manufacturing capacity -- 8,000 manufacturers, of which some 300 are major companies.
- The existing R&D capability in the country
- Ability to develop manufacturing processes in advance, thus allowing them to enter the generics market for a particular drug as soon as it goes off Patent.

New Trajectory – contd..

- Companies like Ranbaxy and Dr.Reddy's Laboratories are already working on this trajectory.
- In 2002 the North American market accounted for $123 million, or 32 percent of Dr. Reddy's total sales. Ranbaxy's revenues in the United States totalled $304 million, or 42 percent of the company's total sales.
- The relatively small Indian market in value terms makes the export market appear very lucrative for Indian companies.
- The perception in the Indian industry that, post-2005, they shall face competition in the domestic market from MNCs, and would need to find other markets to sustain them.

New Trajectory – contd..

- Large Indian companies having embraced the notion of a strong Patent regime, see their future in tie-ups with MNCs.
- Companies are looking for such tie-ups where domestic facilities will be used for outsourcing of both R&D and manufacture.
- Indian companies would leverage upon the advantages of cheap manufacturing and R&D costs to build such linkages with MNCs.
- In return they would expect accelerated entry into the large Northern markets.
- They would function as "junior partners" and would be subservient to the interests of big Pharma (in other words – if you cannot beat them, join them!).
- The thrust then is not of Indian generics reaching underserved markets but of Indian generics making a place for themselves in the lucrative Northern markets.
- Movement towards exports of Bulk drugs rather than finished formulations – shows exports are increasingly servicing the markets of developed countries.

TOP COUNTRIES OF EXPORTS (Rs.10 million)

USA	672
RUSSIA	493
GERMANY	325
HONG KONG	356
NIGERIA	258
U.K.	257
SINGAPORE	245
NETHERLANDS	219
IRAN	180
BRAZIL	163
VIETNAM	141
CHINA	137
ITALY	151
SPAIN	129
NEPAL	123
SRI LANKA	124
JAPAN	120
THAILAND	118
Total	6631

Exports from India

- Indian exports are still spread quite secularly over large segments of the industry
- Over a period the smaller manufacturers will get squeezed out and those who will survive will be the larger companies that tie up with MNCS.

Percent Share of Different Sectors in Drug Exports from India (Year: 1999-2000)	
Sector	**% of Exports**
Large Scale Sector	44.5%
Small Scale Sector	25.2%
Merchant Exporters	8.7%
Small Exporters (Others)	21.6%

Over the years the import content of bulk drug manufacture in the country has shown a rising trend and already stands at 50%.

Year	Avail. of Bulk Drugs	Total Imports	
1981	327	103	31%
1982	394	134	34%
1983	461	144	31%
1984	478	160	33%
1985	555	205	37%
1986	624	251	40%
1987	755	265	35%
1988	714	328	46%
1989	878	411	47%
1990	1066	597	56%
1991	1053	519	49%
1992	1359	712	52%
1993	1658	1017	61%
1994	1933	1028	53%
1995	2329	1195	51%
1996	3452	2135	62%
1997	3891	2261	58%
1998	4450	2438	55%
1999	5066	2588	51%
2000	5802	2761	48%

Price and Production Controls in India

Policy Changes since mid-1980s

- 1986 and 1994 Policies, reversed many positive features of the 1978 Policy.
- The span of price controls were reduced, and greater profitability was allowed,
- Imports were liberalised
- Various production control measures scrapped.
- Most manufacturers started vying for the up-market section of the Indian consumer
- Production of expensive drugs outstripped demand, less expensive drugs in short supply
- Industry fell into a self-destructive loop where 1000 manufacturers fight for the market for drugs among 5% of the population who can pay heavily.

No. of Drugs Under Price Control in Successive Policies

Policy	No. of Drugs under Price Control	% Market under price control
1978	378	80-85%
1986	166	60-65%
1994	73	30-35%
2002*	25-35	15-20%

* Not implemented yet due to Court stay order

Rise in Drug Prices (1998-2003)

Drug	Therapeutic Group	Pack	Price 1998	Price 2003	Change %
Evalon	Hormonal preparation	10 Tab	13.5	84.00	522.22
Loperamide	Anti Diarrhoeal	2mg	3.53	31.6	795.18
Ovral-L	Oral Contraceptive	21 Tab	14.20	30.00	111.27
Tixilyx	Cough syrup	60ml	9.27	29.12	214.13
Pyzina 300 mg	Anti TB	10 Tab	16.7	28.17	68.68
Augmentin	Anti infective	1 Tab	27.75	78.70	183.60
Euglucon	Anti diabetic	10 Tab	3.90	7.58	94.36
Avomine	Antiemitic	10 Tab	7.56	48.50	541.53
Angised	Cardiovascular	10 Tab	9.87	33.86	243.06
Enam	Anti hypertensive	10 Tab	8.11	14.04	73.12
Rcinex-Z	Anti TB	10 Tab	9.87	33.86	243.06

"Free" Market and Drug Prices

- Larger companies are showing less interes in producing drugs -- prefer to act as mere “traders” by concentrating on the Formulations market.
- Drugs are not purchased by the consumer on the basis of his choice or preference.
- Drug companies have built a market for their drugs through their extensive marketing network.
- Consumers have little or no choice in such a ‘rigged’ market and are forced to buy anything that Doctors are ‘induced’ to prescribe

Relative Cost of Top Selling Brands (Indian Rs.)

Brand	Price in Nov. 1997	Variation from Lowest Price (%)
SEPTRAN	7.72	14.88
CIFRAN	50.43	100.12
ALTHROCIN	35.69	35.04
BRUFEN	6.76	4.32
ZINETAC	17.39	0.12
NORFLOX	47.00	128.93
R-CIN	64.43	163.52
SPORIDEX	113.00	35.90

Myth of Low Drug Prices in India

- Drugs that are still Patent Protected are much cheaper in India due to 1970 Patent Act thyat promoted competition from generic manufacturers.
- Off-Patent drugs (approx. 80-85% of current sales) are not necessarily cheaper in India.
- Generally, drug prices for these Drugs are higher in India than those in Sri Lanka and Bangladesh.
- In fact prices of some top selling drugs are higher in India than those in Canada and the U.K.

Red Herring of R&D

- 2002 Policy has attempted to justify the price decontrol with the plea that this shall boost R&D expenditure in the pharmaceutical sector.
- Ministry of Chemicals and Fertilisers had consistently claimed that any rise in prices would be kept in check through mechanisms in the Drug Price Control Order (DPCO).
- In the past decade span of price controls has come down from in excess of 60% of the Industry's turnover to around 30%.
- If reduction in price controls is to spur R&D activity, why has there been no significant rise in R&D expenditure in the past decade?