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Marketing Beyond 2005: A study of the Indian Pharmaceutical Industry's Response to the TRIPS Regime

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Brands are good as long as they bolster a firm's marketing and financial bottom-line. Yet, it is common knowledge that today brand loyalty across a broad spectrum of products and services is dying a slow but certain death. The brave new world of marketing belongs to sound brands, i.e., strategic branding backed by intrinsically well performing products. More than them it belongs to the firms with the capacity and agility in creating, commercializing and protecting their intellectual property

They say about marketer, in a market place, that it is important to be the best but it is imperative to be the first. First to establish a unique selling proposition, first to carve out a niche, first to redefine a product category etc. The pressures of performance on businesses in a borderless world are intensifying. To create the cutting edge of consolidated brand equity, innovation in the marketing process and breakthrough in technology, product and ideas is getting increasingly difficult. To launch a sustainable marketing war on the above platforms is becoming elusive as well. Brands are good as long as they bolster a firm's marketing and financial bottom-line. Yet, it is common knowledge that today brand loyalty across a broad spectrum of products and services is dying a slow but certain death. The brave new world of marketing belongs to sound brands, i.e., strategic branding backed by intrinsically well performing products. More than them it belongs to the firms with the capacity and agility in creating, commercializing and protecting their intellectual property.

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INTELLECTUAL PROPERTY RIGHTS BASICS

Intellectual property is a public document issued by a government that grants to its owner for a limited period of time ***the right*** to exclude others from making, using or selling an invention, a brand name, a geographical indication, a plant variety, an industrial design etc. Patents, trademarks and copyrights are all forms of intellectual property rights (IPR). Japan leads the global tally for filing of patent applications, followed by USA and Europe. US courts saw 2,50,000 patent applications in 1999 out of which 1,60,000 were granted. In India during the same period 10,000 applications were filed. 80% of these were filed by Indian affiliates and subsidiaries of foreign firms.

IPRs grant the IPR holder the following rights:

I EXCLUSIVE RIGHTS:

The firm which is granted the IPR is at liberty to share or not share it with others. A firm may *Share with others,* **i.e., licensing, technology transfer in lieu of royalty, its IPR milestone payments etc. This royalty is prescribed not to exceed 5% of the licensee's annual sales turnover.**

Alternatively a firm may decide not to share, i.e., patent holder can deter others from using its IPR. It can seek legal redressal for infringement of its IPR with the authorization by relevant government.

The Marketing logic is that the cost of research should be recovered during the time period of exclusive or licensed commercial use, and the marketing implication is that IPR if stretched beyond a reasonable limit, can result in monopolistic prowess.

One can quote a recent case in point when Bayer, as patented manufacturer of ciprofloxacin (anti-anthrax drug) till year 2003, deterred the US F.D.A. to grant approval to Ranbaxy and Cipla for supplying its cheap generic versions.

Since 1999, when India agreed to adopt product patent in 2005, arrangement is on for granting **Exclusive Marketing Rights** to the patent applications filed between 2000 and 2005. These rights may or may not be eventually converted into patents.

II TEMPORAL RIGHTS:

A firm may continue to enjoy the exclusive rights on its intellectual property for a pre-specified time period. The maximum time durations for various IPRs are as follows:-

Patents: 20 years
Trademarks: 25 years
Copyright: 60 years
Meanwhile the firm can debar others from infringing on its IPR, that too with legal authorization.
The marketing logic is that from developing IP to commercializing it, there could be substantial time lapse. This coverage is to honour the innovators and give them the first right to commercial activity. The marketing implication is that it could result in underdevelopment and exploitation of markets against the consumer's interest.

III TERRITORIAL RIGHTS:

The boundaries to IPR are also getting eliminated. IPRs are granted by a relevant government for a pre-defined territorial coverage. Now, World Intellectual Property Rights Organization's (WIPO), Patent Co-operation Treaty (PCT), allows the inventor to file a single patent application in his home country (provided it is a signatory of the PCT) and get automatic territorial rights in other 108 countries, which are the signatories of the PCT. India became its a signatory in 1998. Yet even the PCT states that each country is free to apply its own laws in deciding on the patentability of an invention.

The marketing logic is that patent systems of various countries are not adequately harmonized. Therefore even in a borderless world territorial rights need to be protected. The marketing implication is that the government of another country can willfully allow exploitation of a foreign firm's IPR by its domestic industry or may ignore its IPR in national interest. This may lead to erosion of competitive advantage and loss of commercial activity for the innovator. We have a recent Case in point when 39 drug manufacturers took the South African government to task for allowing parallel import of cheap generic versions of their patented anti-AIDS drugs.

THE PHARMACEUTICAL INDUSTRY

I SIZE AND SEGMENTS

Global pharmaceutical industry is $300 billion in value currently and is expected to grow to $460 billion by 2004.

Major segments in this industry in terms of IPR can be defined as follows:

Generic Drugs

(Off- patent i.e. the patents on these have long since expired)

Segment size $20 billion (2001), expected to grow to $45 billion(2004)

New Drug Delivery Systems (NDDS)

i.e. newly patented or patentable drugs. These have long-term patent coverage.

Segment size: $24 billion (2001), expected to grow to $75 billion(2004)

Older patented products

The drugs, whose patents are likely to expire in the medium and short- term.
Segment size: $246billion(2001), expected to grow to $340billion(2004)

II THE INDIAN EDGE

India is 12th among drug producing countries in value terms and 5th largest in terms of volume. It is the only country that recognizes process patents. However, it agreed to convert to product patenting in 2005(i.e. not allowing reverse engineering of patented drugs thereafter). The cost advantage of drug manufacturing in India as compared with the USA for a new drug delivery (for 10-12 year time period from discovery to commercialization) is as follows:
India: Rs. 140-200 crores
USA: $ 200-500 million

III THE GREAT GENERICS OPPORTUNITY

The patents on 13 out of 35 leading molecules are expiring in next 10 years. The global market for generic drugs is expected to balloon to $45 billion in year 2004.The cost economies of production can create huge competitive advantage for Indian firms. Recently $500 million worth of opportunity arose for generics firms producing Ciprofloxacin (anti-anthrax drug) in USA. The original patent holder Bayer pleaded with FDA not to allow parallel imports from Indian firms. Yet when FDA finally gave the nod to Ranbaxy and Cipla to supply, Bayer as a quick reaction dropped its price from $4 to under $1. Similarly, Cipla created turmoil in the anti-AIDS segment by supplying generic version of anti-ritroviral (ARV) cocktail to various governments at $600(annual cost per patient) at a time when patent holders were charging between $10,000- $15,000. In retaliation, Glaxo-SKB, holding patents on some of these drugs marked down it's own prices by 90%, selling at cost price.

IV THE R&D AGENDA

Most Indian companies are refocusing themselves from low margin generic drugs to high margin branded formulations. The R&D allocations as such are also under review. Ranbaxy allocates its R&D budget to the twin heads of discovery research (NDDS) and generics (reverse engineering) in the following manner:

	Discovery Research	Generics Research
Year 2000	20%	80%
Year 2001	40%	60%
Year 2004	60%	40%

The trend indicates that the new growth engine for leading Indian pharmaceutical firms is indeed discovery research.

V THE HEALTH EMERGENCY AND WTO RULING ON TRIPS

In the recently concluded Doha summit India won a battle of sorts with the following ruling : 'Today a national government can determine without being challenged in a WTO dispute settlement forum, when a health emergency has arisen and patent rights need to be suspended. Epidemics suffice to suspend patent rights. Tuberculosis and malaria are explicitly recognized as epidemics that may warrant the suspension of patent rights and not just HIV-AIDS. Countries during such medical emergencies may import cheap drugs from countries like India even though the company supplying the drugs does not hold the patent on it and nor is licensed to produce them'.

Thus, parallel import of generic versions of patented drugs may be permissible now as also compulsory licensing. This gives Indian firms the vital flexibility as well as more market development opportunities.

VI THE DOMESTIC VS. MNC PHARMACEUTICAL COMPANIES' PERFORMANCE

On a rough estimate there are 2500 odd pharmaceutical companies in India. In the last six

years the market share of top 20 players has increased from 35% to 50%. This indicates that the industry concentration is increasing.

Speculations were rife about the fate of majority of Indian firms under the product patent regime. Yet much to the delight of us Indians, the market capitalization of the three large domestic companies namely, Dr. Reddy's, Ranbaxy and Cipla, has been higher last year than the capitalization of all the MNC's put together.

Dr. Reddy's Lab	Rs. 8415 cr
Ranbaxy	Rs.8400 cr
Cipla	Rs. 6521 cr
MNCs(combined)	Rs. 5,500 cr

A combination of factors, like, higher value addition, licensing deals with leading multinationals, and increasing focus on exports have enabled the domestic companies produce excellent bottom-lines.

THE STRATEGIC RESPONSE OF INDIAN PHARMACEUTICAL INDUSTRY TO POST 2005 SCENARIO

IPR Portfolio \ Brand Portfolio	SHALLOW	RICH
RICH	**CASE I** ☞ Licensing ☞ Contract Research ☞ Brand Acquisition ☞ Co-Marketing ☞ Discovery Research ☞ Reverse Engineering	**CASE 3** ☞ Licensing ☞ Cross Licensing ☞ Market Development ☞ Product Development (NDDS) ☞ Brand Development (Prescription Demand)
SHALLOW	**CASE 4** ☞ Contract Manufacturing Of Generics ☞ Acquisition Targets	**CASE 2** ☞ Outsource R&D ☞ Outsource Products ☞ Co-Marketing ☞ Acquisition And Takeover of Companies ☞ Acquisition of Brands

Case 1: The fact is that superior formulation alone may not generate good prescription demand. The mindset of doctors (primary customers for a pharmaceutical company) is difficult to change and most expensive too. Patent rights in absence of adequate commercialization lead nowhere. Therefore, co-marketing tie-ups, licensing and contract research can bolster the firm's financial bottom-line.

Case 2: Indian firms have flourished in the reverse engineering era. They have successfully built strong brands and are dominating market presence. But oflate, pressures are mounting on them to gear up for the IPR regime. Thanks to outsourcing and acquisitions, the task has become less cumbersome. Co-marketing arrangements between Indian and MNC firms are also going to increase.

Case 3: This is where majority of MNCs are perched internationally. It is the most enviable position in which a pharmaceutical company can find itself. While product development creates constant supply of Intellectual Property, market development generates additional cash flow from the already developed IPR. However, branding is also serious business in pharmaceutical marketing. Sound brand strategy results in automatic prescription demand. The firm at this stage may choose between the commercially viable and non-viable IPRs. The non-viable ones should be licensed out. Ranbaxy has made public its desire to move from case 2 position to case 3.

Case 4: Small and medium sized firms fall in this bracket. These firms were either violating another firm's IPR or were in engaged in reverse engineering permissible under process patent regime. Their size and skill set does not justify discovery research or active brand building and acquisition. The two routes for them are: becoming contract manufacturer for other Indian and MNC firms or divestment.

THE MODUS OPERANDI

Licensing

Develop technology and leave commercial aspects for someone else. Advantages for the firm are assured and steady revenue as royalty.

Dr Reddy's Lab has recently licensed insulin sensitiser DRF 4158 to Novartis with worldwide rights for development and commercialization. The deal has closed on the $55 million upfront payment and royalty rights later on.

Contract research

On a retainership basis (exclusive or shared), conduct customized research for the clients. Dr. Reddy's Lab is investing $10 million in one such research outfit to develop technology for global drug makers. It will enter into confidentiality agreement with each one of its customers.

Co-marketing

It may mean anything from sharing a brand to joint distribution and marketing-manufacturing type of tie-up. This leads to more channel power, cash flow and stronger market presence at marginally high cost. Recently Cipla and Ranbaxy entered in to one such arrangement to co-market Ranbaxy's once a day ciprofloxacin in India. While Ranbaxy will manufacture it for both the companies, each will market it under a separate brand name: Cifran OD (Ranbaxy) and Ciplox OD (Cipla). Together these brands are going to corner 30% market share.

Brand Acquisition

It is wiser and more uncomplicated in terms of both money and management. Zydus Cadilla recently acquired Kopran's Brand Aten, for Rs. 95 crores, which strengthens its cardiovascular franchise. Ranbaxy is planning to acquire three of ICI India's brands once again in the cardiovascular segment.

Contract Manufacturing

The manufacturing capacities of the existing firms can be utilized by MNCs as a cost effective source of supplies. As industry concentration increases the marginal Indian firms can find this as the only survival option.

Market development

An evolving generics market has created opportunities for Indian firms to look beyond the home turf. Torrent Pharma is developing three anti-AIDS drugs specifically for the Brazilian markets. Ranbaxy is planning to launch brand marketing in US market when it crosses $200 billion sales turnover mark there (expected in 2003). It has already crossed $100 billion mark.

Product development

It is critical to create IP on the regular basis to remain viable in the long term. Indian firms are active here too. Reliance Life Sciences' first product Relicord (antidote for leukemia) will be ready for trials next year. Dabur India has DCGI's approval for clinical trials on its NDDS for anti-cancer drug Paclitaxel.

Brand development

Indian firms must undertake the unavoidable journey from generics to brands. Brand allows the firm price flexibility to a certain extent. Ranbaxy is transitioning from a dominant generics company to a branded prescription one.

CONCLUSION

Pharmaceutical industry analysts and observers have long feared that process patenting based Indian pharmaceutical industry will vanish post 2005.This paper was an attempt to break the myth and to unravel the intelligent and scientific marketing strategies of those whose doom was predicted- a doom that shall never be.

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