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Battling with TRIPS: Emerging Firm Strategies of Indian Pharmaceutical Industry Post-TRIPS

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The full scale compliance of TRIPS Agreement essentially represents a big step in the opposite direction as it effectively ended more than three decades of protection for Indian companies and terminated legal 'reverse engineering'. The new patent regime throws a new challenge to the Indian pharmaceutical industry to maintain its competitiveness and profitability. This study investigates emerging firm strategies of the Indian pharmaceutical companies to overcome the challenge posed by new patent regime. The study concludes that the industry is witnessing a transition phase, and is undergoing consolidation and restructuring. The industry is adopting a mix of competitive and collaborative business and R&D strategies in the emerging business environment.

Keywords: TRIPS, Indian pharmaceutical industry, business strategies, R&D

The Indian pharmaceutical industry is one of the most vibrant knowledge driven industries in India. It has witnessed spectacular growth over the past three decades. Currently, over 90% of the modern medicine consumed in India is produced locally.[1] The industry manufactures almost entire range of therapeutic products and is capable of producing raw materials for manufacturing a wide range of bulk drugs. It was estimated to be worth $ 7 billion in the year 2003,[2] growing at about 6 to 7% annually. It is ranked 4th in terms of production volume (accounted for 8% of global output in terms of volume) and ranked 13th in terms of value in 2004.[2] The pharmaceutical exports were less than $600 million when India joined WTO in 1995.[3] By 2005, the exports had grown to $3.7 billion and accounted for more than 61% of industry turnover.[3] Currently, Indian pharmaceutical companies produce between 20 and 22% of the world's generic drugs (in value terms) and offer 60,000 finished medicines and nearly 400 bulk drugs used in formulations.[3]

Rapid growth in this sector has been largely due to three critical changes, mainly attributable to India's socialist vision in the 1960's and 1970's; firstly, setting-up of government-held companies to boost local pharmaceutical production of drugs[4], secondly, the Drug Price Control Order (DPCO)[4] and finally, the Indian Patents Act of 1970.[4] Besides, the government initiated other industrial policy instruments to augment these major changes, like restrictions on FDI, FERA Act, etc., also played a facilitating role. It imposed several investment and ownership restrictions on multi national companies (MNCs), some of which are now relaxed under the National Pharmaceutical Policy of 2002.[5] Although, public sector pharmaceutical companies were grossly inefficient, they showed that it was possible to produce drugs in India at competitive costs, developed human and physical capital, and spurred the existence of a network of support institutes, pharmacy colleges, and up and down stream businesses.

The Patents Act 1970 ended 'product' patent protection laws left over from the British colonial era and recognized the patent on 'processes.'[6] The stated objective of the Act was to foster development of an indigenous Indian pharmaceutical industry and to guarantee access to low-cost drugs to the Indian public. The Act enabled the Indian companies to legally produce drugs patented elsewhere through 'reverse-engineering' processes without paying the license fee, and cheaply sell copies of the world's best-selling patented drugs in India. Meanwhile, DPCO also acted disincentive to MNCs as it set a ceiling on the overall profits of the MNCs.[4] Later, even when the DPCO reduced its coverage, threat of 'reverse-engineering' kept subsidiaries of MNCs operating in India from introducing new products in the Indian market.[7]

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These policy interventions brought radical transformations in the foreign *versus* local firm ratio in the Indian market gradually, bringing it from 85:15 in 1970 to 61:39 in 1999.[8] Of the top 10 firms in 2001, eight were Indian firms and only two were subsidiaries of MNCs.[9] Over the period of time, the market share of indigenous firms has also increased in comparison to MNCs.[3]

The rules of the game, however, have completely changed for the Indian pharmaceutical industry with the implementation of TRIPS Agreement[10] which obligates the member countries to recognize and enforce product patents in all fields of technology, including pharmaceuticals.[10] To meet its obligations under the TRIPS Agreement, India has amended its patent law in 2005, abolishing its 'process' patents law and reintroduced 'product' patents for pharmaceuticals, food, and chemicals. With the end of transition period in January 2005, the pharmaceutical firms have now obtained full scale patent protection on their products in major markets in developing countries, such as, India, and prevent local firms from manufacturing generic copies of their patented products.

The emergent situation brings three very important questions to the forefront: capability of the generic pharmaceutical industry in the developing countries to compete with the global pharmaceutical majors, impact of new patent regime on accessibility and affordability to medicines to the poor in developing and least developed countries, and the extent to which compulsory license can actually ensure control of prices of drugs. There are several studies predicting the effect of the strong patent regime on Indian pharmaceutical industry, but they are not conclusive. While, some fear that the post-TRIPS regime will discriminate against local firms in favour of MNCs who can afford enormous funding required for R&D, and will harm the domestic industry, others argue that it will result in the rapid development of local industry.

While it may be too early to predict the direction in which the Indian pharmaceutical industry is heading in post-TRIPS regime, it is certain that the obligations imposed on India under TRIPS Agreement are going to have a significant impact on India's successful bulk and formulation-oriented pharmaceutical industry. The Indian pharmaceutical industry is currently going through a churning process and is modifying its firm strategies to address formidable challenge, and also to exploit opportunities thrown by the new patent regime.

The present study analyses how the local industry is gearing itself in terms of firm strategies to maintain their competitiveness and profitability *vis-à-vis* MNCs in the product patent regime. Since, the issue of affordability and accessibility to medicine to poor is a closely linked issue, the study proposes to identify key growth drivers for industry and offer policy suggestions to the Government to create an enabling business environment for local industry.

TRIPS and Indian Pharma Sector: The Existing Evidence

The extensive literatures on studies[11] have examined various aspects of impact of product patent protection on Indian pharmaceutical industry such as, incentives for R&D of local firms, FDI, technology transfer through foreign collaborations, market demand, prices of drugs in market, etc. Here, only the studies dealing with the impact of TRIPS on the emerging firm strategies are discussed.

The impact of introduction of product patents in India shows that, the profits of Indian firms from producing generic drugs will decrease, as they will probably have to pay some royalty to original innovators. Secondly, stronger IPR would not augment R&D activity of MNCs in India, since R&D is a highly centralized process, where cost is not the paramount concern. Thirdly, the incentives for investment in R&D in diseases prevalent in developing countries, as well as in creation of innovations in general, are likely to increase because the strategy of imitation will no longer be available.[7] The behaviour of pharmaceutical multinationals and the market structure in India also changes due to product patent protection. In case, new on-patent drugs and newer varieties of off-patented products are in the same therapeutic class, it will not have a major impact on prices of drugs. But if they are altogether new products, of which off-patent generic versions are not available, rise in price associated with such products may be high.[12]

India has reached such a stage in pharmaceutical production where stronger IPRs would induce greater innovation by local firms (the benefits of which would have to be set-off against the closure of other firms). TRIPS is also likely to induce greater innovation, more R&D expenditure, and more patents by both Indian and MNCs in the biopharmaceutical sector.[13-15] The potential adverse welfare effects of the TRIPS Agreement on the Indian industry shows that in the absence of any price regulation or compulsory

licensing, total welfare losses to the Indian economy would be enormous.[16]

The field survey of 103 firms combined with case studies and other secondary data on emerging business and R&D strategies of the Indian pharmaceutical industry shows that the product patent regime will be a decisive factor in determining access to medicines, both in India and third world countries in Africa. The Indian firms will face severe challenges to adapt new patent regime and cope with the losses induced by the restrictions placed on them by the new regime.[4] Very few studies have focused solely on the emerging firm strategies of Indian pharmaceutical industry to address the challenges as well as to harness opportunities presented by new product patent regime. Moreover, previous studies were conducted during transition period when the TRIPS was not yet in place in the country, and therefore, findings were based mostly on perceptions or simulated models which were based on assumptions. This study differs in three major ways from the preceding works. First one is a survey of Indian pharmaceutical firms for emerging strategies in the pharmaceutical industry. Secondly, investigation of whether the subsidiaries of MNCs operating in India are also modifying their strategies in view of new product patent regime. Thirdly, investigation of whether the strategies adopted by one group of industries are different *vis-à-vis* the other group and what are the dominant strategies adopted by various groups?

The Analytical Framework

Two methods were adopted for this study; firstly, industry survey questionnaire was used to investigate emerging firm strategies, and secondly, in-depth interviews of business executives handling IPRs and corporate affairs were conducted to understand reasons for preferring a particular set of strategies *vis-à-vis* others. In order to assess emerging firm strategies, data collected in the survey was mostly for a time period of 2000 to 2006. The study was initiated in May 2006 and completed in January 2007. As compared to previous studies, more robust statistical tools are used for the analysis of the data (Table 1).

The study relied upon semi-structured interviews with experts, government officials and representatives of industry to clarify the structure and content of the study framework. Thereafter, based on the secondary research and semi-structured interviews, a structured questionnaire was prepared to conduct interviews with experts, government officials and selected companies that participated in the survey. Having identified the constructs and variables, questionnaire was prepared and tested for its content validity. The questionnaire was sent to industry for pre-test survey and after receiving few responses, it was suitably modified. Mail survey method was used for data collection from the industry because of ease of administration to firms that are scattered all over the country. Secondary data regarding acquisitions & mergers, joint ventures, in-licensing, out-licensing agreements, marketing alliances, etc. was collected from a variety of sources, e.g., websites of the companies, business magazines, etc. The data for the R&D expenditure was collected from the Prowess Release 2 databases of the CMIE.[17]

Description of Population and Sampling Frame

The Indian pharmaceutical industry is highly fragmented, split between organized and unorganized sectors.[18] Its major constituents are subsidiaries of large MNCs and a large Indian industry comprising of large, medium and small-sized firms. Though, it is commonly quoted that there are more than 20,000 manufacturing units, but the number of active units engaged in production of both bulk-drugs and formulations is not more than 5877.[19] Of these, around 300 companies account for over 95% of the total domestic market, the rest are marginal players.

Based on the annual sales turnovers, the industry was divided into four categories: Group 1 comprised of subsidiaries of MNCs, irrespective of their turnover, Group 2 comprised of large-scale pharmaceutical firms having annual sale turnover of more than Rs 300 crores, Group 3 comprised of medium-sized firms having annual sales turnover between Rs 100-300 crores. In Group 4 were those firms having annual sales turnover less than Rs 100 crores. The members of the three main associations, namely, IDMA, OPPI and IPA were used as a sampling frame (Table 2).

The sample for the study was selected through purposive probability sampling (PPS) technique so that key representatives (Group 2) of the industry were taken into account in the survey completely (purposive) and rest of the population was chosen at random. Questionnaire was mailed to more than 400 companies. Though for mail survey, likely response rate is 10-12%, a response rate of around 22% was received.

Statistical Analysis

Descriptive, univariate and inferential procedures were used to analyse the data. All data were entered on SPSS. Frequencies were run for all items and data

Table 1 — Information needs and data source

Constructs	Variables	Data source
Competitive strategies	Specialty generics Innovation Development of non-infringing processes Novel drug delivery system, Research on new chemical entities Positive patenting Defensive patenting Biopharmaceutical research	Questionnaire Secondary sources Interviews
Collaborative strategies	In-licensing arrangements Collaborative R&D Contract research Contract manufacturing	Questionnaire Secondary sources Interviews
Business strategies	In-licensing alliances Out-licensing alliances Co-marketing alliances Generics Herbal medicines Contract R&D Access to TK International acquisitions Setting up of production facilities Entering into marketing alliances abroad	Questionnaire Secondary sources Interviews
R&D strategies	Collaborative research Custom synthesis and drug development In-licensing Clinical trials Generic More basic research API supply Contract manufacturing More innovations	Questionnaire Secondary sources Interviews
Overall corporate growth strategy	Joint ventures Acquisition and mergers Acquisition of products Creation of new production facilities	Secondary sources Interviews

Table 2 — Group-wise representation of Indian pharmaceutical industry

Firm break-up	Formulations (No of firms)	API Production (No of firms)
Group 1	25	100
Group 2	275	200
Group 3	5700	5700
Total	6000	6000[19]

Source: Sampath (2005)

was cleaned before doing the analysis. Since data was collected on large number of variables, there could be some redundancy in those variables, i.e. some of the variables are correlated with one another, and possibly they are measuring the same construct. Thus Principal Component Analysis (PCA) was chosen to transform a number of (possibly) correlated variables into a (smaller) number of uncorrelated variables called principal components (artificial variables) that were then used as predictor or criterion variables in subsequent analyses. Principal Factor Analysis (PFA) was conducted for scale validation and to assess dimensionality of scale. Thereafter, reliability of data was tested by using Cronbach's Alpha[20] methodology. The data collected for competitive, collaborative, R&D and business strategies on the rating scale of 1 to 5 was treated as interval data (nominal) for statistical analysis. Descriptive and inferential techniques, *viz.*, Co-relation test, Partial co-relation, ANOVA test, Post-hoc test, etc. were used to do the statistical analysis. SPSS 13.0 was used for basic descriptive, reliability, factor, co-relational analysis, etc.

Sample

Total number of 94 pharmaceutical firms participated in this study, including 10 in Group 1, 31 in Group 2, 25 in Group 3 and 28 in Group 4 (Table 3).

Data Analysis

Strategic Choices for Indian Pharmaceutical Industry post-TRIPS

In pre-TRIPS era, the Indian pharmaceutical companies were primarily engaged in development of new processes for manufacturing drugs. They mostly concentrated on Indian domestic market and unregulated markets in east-Europe, African countries, etc. for their growth. Most of the Indian companies in commodity generics, where apart from regulatory barriers, there were practically no other entry barriers. These markets were characterized by intense competition among large number of companies, with low prices and profit margins. Indian companies in fact competed a lot among themselves. The success of one Indian company in a field often induced the entry of other Indian companies in the same field. Traditionally, Indian pharmaceutical industry spent very little on R&D. In early 1990s, its R&D expenditures amounted to only about 1.5% of sales.[21] Even larger companies, such as, Ranbaxy and Dr Reddy's Laboratories (DRL) spent only 2-3% of their sales on R&D in 1992-93.[17] Since MNCs were also reluctant to expose their IP, they limited their exposure to India.[7]

However, full scale compliance of TRIPS Agreement has significant implications for both Indian and MNCs competing in Indian market. On one hand, leading companies are moving away from the reliance on domestic market for the development of new drugs, exports to regulated markets, and cooperative agreements with MNCs. The companies have also increased their expenditure on R&D and now they are also involved in R&D for new chemical entities (NCEs) and modifications of existing chemical entities to develop new formulations and compositions, combinations (incrementally modified drugs) and development of generics (development of processes for manufacturing active pharmaceutical ingredients (APIs) and development of formulations to satisfy quality and regulatory requirements for marketing patent-expired drugs. On the other hand, many MNCs lagging in sales of patented drugs in their home markets, declining R&D revenues, and rising costs, have turned to contract manufacturing and research services (CRAMS), co-marketing alliances, outsourcing of research and clinical trials to reduce costs, increase development capacity, and trim the 'time to market' for new drugs. India's competitive advantage lies in its lower production and research costs, its large pool of low cost technical and scientifically trained personnel, and the large number of US FDA certified plants. Other important factors include popularity of outsourcing non-critical business functions to India by MNCs, reintroduction of product patents for pharmaceuticals, growing importance of R&D related to drug discovery by Indian drug companies, and growing demand for generic drugs in developed markets. It is estimated that manufacturing costs in India are between 30 and 40% lower than those in US and Western Europe and labour costs are one-seventh of that in US.[7]

In this context, Indian pharmaceutical firms have two basic options, either compete with MNCs for vanilla generics and NCEs, or co-operate.[21] For the purpose of this study; the options available to the Indian pharmaceutical firms are classified into five different constructs, i.e., competitive, collaborative, R&D, business, and overall corporate growth strategies. Factor analysis was carried out using PCA for each strategy and reliability test was conducted using Cronbach's Alpha methodology (Table 4).

Competitive Strategy

The factor analysis using PCA showed KMO sample adequacy and Bartlett's test[22] as 0.835 and significant, respectively. All the extracted communalities were above 0.5. Two factors emerged

Table 3 — Descriptive statistics of the sample

Company type	Sales turnover (in Rs crores)		Mean	Median	SD	Range	%
	Min	Max					
Group 1	150.00	1520.00	460.35	336.75	431.58	1370.00	10.6
Group 2	305.00	4500.00	1028.48	700.00	896.82	4195.00	33.0
Group 3	100.30	300.00	166.1232	157.00	57.50	199.70	26.6
Group 4	1.15	90.00	26.2193	19.38	23.01	88.85	29.8

Table 4 — Factor analysis of firm strategies

Items	Components		
	1	2	3
Competitive strategies			
Speciality generics		0.934	
Non-infringing processes		0.596	
NDDS		0.757	
Innovation	0.730		
Research on NCE	0.994		
Positive patenting	0.812		
Defensive patenting	0.752		
Biopharmaceutical research	0.721		
Collaborative strategies			
In-licensing arrangements	0.667		
Collaborative R&D	0.881		
Contract research	0.834		
Contract manufacturing	0.446		
R&D strategies			
Collaborative R&D	0.745		
Custom synthesis & drug development	0.491	0.537	
In-licensing	0.847		
Clinical trial	0.816		
Focus on basic research	0.703		
Focus on innovation	0.806		
Focus on generics		0.816	
Focus on API supply		0.755	
Contract research & manufacturing services			0.924
Business strategies			
In-licensing alliances	0.936		
Out-licensing alliances	0.844		
Co-marketing alliances	0.741		
Focus on generics		0.754	
Focus on international acquisition		0.702	
Setting up production facilities abroad		0.794	
Marketing alliances abroad		0.921	
Focus on herbal medicines			0.936
Focus on traditional knowledge			0.849
Focus on contract R&D	0.368		0.383

(Only loading above 0.4 are presented)

which had initial eigen values of more than 1. These two factors cumulatively explained 69.25% of variance. Principal component factor analysis showed that mainly two separate sets of strategies are adopted by pharmaceutical firms i.e., High End Competitive Strategies (HECS) and Low End Competitive Strategies (LECS). HECS included focus on innovation, research on NCE, positive patenting, defensive patenting and biopharmaceutical research. LECS included focus on speciality generics, non-infringing processes and Novel Drug Delivery Systems (NDDS). HECS require higher investments, and technological knowledge and skills as compared to LECS. The Cronbach's Alpha of the components LECS and HECS was 0.701 and 0.879, respectively.

Collaborative Strategy

The factor analysis using PCA showed the KMO sample adequacy and Bartlett's test as 0.581 and significant, respectively. Only one factor emerged that had initial eigen value of more than 1. This factor explained 52.89% of variance. The Cronbach's Alpha was 0.680.

R&D Strategy

The factor analysis using PCA showed KMO sample adequacy and Bartlett's test as 0.824 and significant, respectively. All the extracted communalities were above 0.5. While two components factors emerged which had initial eigen values of more than 1 which explained cumulative variance of 58.25%, one component had eigen value very close to 1 (0.987) and explained cumulative variance of approx 11%. Moreover, since loadings were also not clearly loaded on any component, PCA was carried out for three components to see whether factors can be clearly loaded on separate components. But, the issue could not be resolved and focus on custom synthesis & drug development loaded on two factors.

Custom synthesis & drug development having loading of 0.491 and 0.537 on two components signified that it is not a unique R&D strategy adopted by the particular group of firm in industry. Custom synthesis & drug development is used for the production of organic drug compounds to the specification of the client for their specific development and research needs. This strategy is being increasingly adopted by the major pharmaceutical companies including MNCs for various reasons even if some of these major pharmaceutical companies have huge in-house capabilities. This is mainly because of two factors, firstly, increasing demand of more NCEs, and secondly, pressure of reducing cost of development. Therefore, focus on custom synthesis and drug development was included in Component 2 for the purpose of further analysis of R&D strategies because it included focus on API supply and focus on generics which are main domain of Indian pharmaceutical firms.

The Principal component factor analysis showed that pharmaceuticals have predominantly adopted three sets of strategies. High End R&D Strategies (HER&DS) included focus on collaborative research, in-licensing, clinical trial, more basic research and more innovation; Low End R&D Strategies (LER&DS) included focus on generics, API supply

and custom synthesis and drug development; and Component 3 included only focus on contract research & manufacturing services. Strategies like clinical trial, focus on more basic research, etc. involve huge financial outlays. Thus, these are adopted mainly by Group 1, few Group 2 firms and some other niche players. LER&DS involve comparatively less financial outlays and, are generally adopted by generic drug manufactures and API suppliers. CRAMS are adopted by firms who do not have financial muscle power to invest in huge R&D expenditure but have technical skills and knowledge base. The Cronbach's Alpha of HER&DS and LER&DS was 0.834 and 0.534, respectively.

Business Strategy

The factor analysis using PCA showed KMO sample adequacy and Bartlett's test as 0.785 and significant, respectively. All the extracted communalities were above 0.5. Three components emerged having initial eigen values more than 1. These three components cumulatively explained 70.13% of variance. The promax rotation provided clear loadings for all the variables except contract R&D strategy which loaded on two factors. Therefore, outsourcing was dropped from the business strategies for analysis. Moreover, contract R&D has been covered in collaborative strategies as well as R&D strategies. Principal component factor showed that there are three separate sets of business strategies adopted by pharmaceutical firms. Business strategies (alliances) [BS(All)], comprised of in-licensing, out-licensing and co-marketing alliances. These business strategies are adopted by those firms who have branded products but do not have adequate sales network. By entering into such alliances they leverage the already existing sales net-work of alliance companies. Business strategies (expansion & diversification) [(BS(E & D)] comprised of generics, international acquisition, creation of production facilities abroad and marketing alliance abroad. These business strategies are predominantly followed by firms who are endeavouring to increase their market share and expanding into regulated markets. Business strategies (traditional) [BS(Trad)] comprised of traditional knowledge and herbal medicines. This strategy is predominantly followed by few firms who are niche player in this field. The Cronbach's Alpha for [BS(All)], [(BS(E & D)] and [BS(Trad)] are 0.825, 0.793 and 0.809, respectively.

Emerging Firm Strategies

The participating firms were asked to rank each strategy on the scale of 1 (rarely), 2 (occasionally), 3 (average), 4 (quite often) and 5 (frequently) depending upon the frequency of their usage. ANOVA test and Welch and Brown-Forsythe statistics[23] were carried out to examine the difference between frequencies of usage of strategies by various groups of firms. Post-hoc test was also carried out for pair-wise comparisons of the groups.

Emerging Competitive Strategies

The mean of the usage of the individual competitive strategies by various groups of firms is given in Table 5.

The dominant competitive strategies of Group 1 firms are positive patenting, research on NCE, innovation, biopharmaceutical research and NDDS. The focus of Group 2 firms is high on non-infringing processes, innovations, positive patenting and speciality generics. The focus of these firms on research on NCE and biopharmaceutical research is comparatively low. Interviews with the industry revealed that biopharmaceutical research is an area where niche players like Biocon, Bharat Serums,

Table 5 — Emerging competitive strategies

Company type	Focus areas							
	Speciality generics	Innovation	Non-infringing process	NDDS	Research on NCE	Positive patenting	Defensive patenting	Biopharmaceutical research
Group 1	2.75	4.38	3.80	3.88	4.29	4.83	2.86	3.86
Group 2	3.55	3.83	4.55	3.68	2.61	3.87	3.43	3.00
Group 3	2.71	3.16	3.40	3.09	1.39	2.35	2.38	1.61
Group 4	2.63	2.14	2.43	2.27	1.37	1.57	1.39	1.46
Total	2.98	3.17	3.52	3.13	2.05	2.81	2.46	2.20

Shantha Biotechnics, etc. focus. In addition, some Group 2 firms like DRL, Ranbaxy have started focusing on research on NCE but they do not have finances to carry this research to the last stage. The Group 3 firms focus on non-infringing process and innovations. It is interesting to note that their focus on defensive patenting is more than positive patenting. Discussions with the industry revealed that it was mainly to prevent others from disrupting their research work. Their focus on research on NCE is almost negligible which is not counter intuitive as they do not have financial lay out to carry research in this area. The Group 4 firms do not have any dominating competitive strategy. They, however, focus more on non-infringing processes and speciality generics than any other competitive strategy. Hence, it is evident from the industry response that firms of groups 1, 2, 3 and 4 adopted mixed competitive strategies. While Group 1 and 2 firms were more frequently using HECS and, Group 3 and 4 were more frequently using LECS. The result of the ANOVA test for HECS ($p<0.05$) indicated that at least one of the group significantly differed from others. Similarly, the result of Welch and Brown-Forsythe for LECS ($p<0.05$) also indicated that at least one of the group significantly differed from others. The result of the Post-hoc test indicated that while there is no significant difference between Group 1 and Group 2 firms; Group 1 firms significantly differed from the Group 3 and 4 firms; Group 2 firms significantly differed from Group 3 and 4 firms, and Group 3 firms significantly differed from the Group 4 firms with regard to HECS. It further indicated that while there is no significant difference between Group 1 and 2, Group 3 and 4 firms; Group 2 firms significantly differed from Group 3 and 4 firms; and Group 3 firms significantly differed from Group 4 firms with regard to LECS (Table 6). The competitive strategies adopted by Indian firms are exhibited in Table 7.

Emerging Collaborative Strategies

The mean usage of the individual collaborative strategies by various groups of firms is given in Table 8.

Table 6 — Frequency of usage of competitive strategies

Category of firm	HECS	LECS
Group 1	3.97	3.200
Group 2	3.31	3.925
Group 3	2.19	3.101
Group 4	1.51	2.359

The contract manufacturing is the most dominating collaborative strategy adopted by all groups of firms. Group 1 adopted this strategy because of cost advantage offered by India. Group 1 and Group 2 also adopted collaborative R&D quite regularly. The result of ANOVA Test [$p = .082$ (>0.05)] indicated that various groups did not differ significantly from each other. The result of the Post-hoc test indicated that there was no significant difference between various groups (Table 9).

Though there may not be any significant difference between various groups of firms, Group 2 followed by Group 1 most frequently used collaborative strategies. The collaborative strategies adopted by Indian firms are exhibited in Table 10.

Emerging R&D Strategies

The mean usage of individual R&D strategies by various groups of firms is given in Table 11.

While clinical trials and innovations are the dominant R&D strategies of Group 1, Group 2 focuses more on generics, supply of API and contract manufacturing. The Group 2 is also focusing more on regulated markets of US and Europe where profit margins are high. The dominant R&D strategy of Group 3 is on generics followed by contract manufacturing (70%). Group 3 rarely focused on clinical research and basic research. The dominant R&D strategy of Group 4 is contract manufacturing and generics. The result of ANOVA test for LER&DS ($p<0.05$) indicated that at least one group significantly differed from others. Similarly, while the result of Welch and Brown-Forsythe for HER&DS ($P<0.05$) indicated that at least one group significantly differed from others, the result for CRAMS ($p>0.05$) indicated that there was no significant difference between various groups. The result of Post-hoc test indicated that with regard to HER&DS, while there is no significant difference between Group 1 and Group 2, 3 & 4, the Group 2 significantly differed from Group 3 and 4. The Post-hoc test also indicated that with regard to LER&DS, while there is no significant difference between Group 1 and 2; Group 2 significantly differed from Group 3 and 4. Similarly, Group 3 differed significantly from Group 4. The result further indicated that there is no significant difference between various groups with respect to CRAMS (Table 12).

The HER&DS are most frequently used by Group 1 followed by Group 2 and LER&DS are most frequently used by Group 2 followed by Group 3 and Group 1, and CRAMS is most frequently used by

Table 7 — Competitive strategies adopted by Indian firms

Strategy	Examples
Speciality Generics An innovator company not only obtains a patent on active ingredient involved in the new drug, but also have secondary patents relating to the same active ingredient, such as, new formulations and compositions, e.g., new dosage forms or routes of administration; new salts, esters, etc. of existing ingredients, i.e., chemical derivatives of active ingredient; (iii) new use for treatment of disease; and new process of manufacturing the active ingredient. These secondary patents are obtained later and hence typically expire after the basic patent on NCE.	Glenmark has reorganized its business into generics and speciality. Cipla and DRL are actively focusing on the development of specialty generics to gain drug discovery abilities.
Non infringing Processes Process patents are not required to be listed by the originator companies with US FDA and hence, when a generic company applies for an ANDA, no certification is required for such patents. But originator companies usually have patents for a large number of processes which help them to delay generic entry.[24] In such cases, a generic player can develop a non-infringing process and enter the market with higher price and margin.	Matrix Laboratories was the first company to develop a non-infringing process for manufacturing citalopram. With restricted competition it was able to reap huge benefits with sales of Rs 5600 million till 2005-06. Another commercially successful example is the cefotaxime process developed by Lupin. Ranbaxy's non-infringing process on Cefuroxime Axetil enabled Ranbaxy to be its sole seller for almost one and a half years in US market.
NDDS Several Indian companies are increasingly focusing on R&D for modifications of existing drugs so as to develop new formulations, get patents on them and sell at a higher price. The new formulations include novel drug delivery systems (NDDS), such as, developing a controlled or extended release formulation of existing oral therapies to reduce side effects or increase patient compliance; developing alternative delivery routes, including oral as opposed to injectables, to increase patient convenience and compliance; and enhancing purification of product to reduce dosing and side effects.	NDDS developed by Ranbaxy for ciprofloxacin. Dabur Pharma has introduced Nanoxel, an NDDS to enter clinical trials in Europe and US for use with anti-cancer drug paclitaxel. Alembic has entered into a license with UCB to apply company's NDDS for a once-a-day version of UCB's market leading epilepsy drug levetiracetam
New Chemical Entities The Indian pharmaceutical companies began investing in R&D for NCEs when TRIPS came into effect in the mid-1990s. But none of these companies is engaged in the entire process of drug development because they are not yet ready for a start-to-finish model in NCE research as they do not yet have all the skills and funds required for the development and marketing of drug. The model adopted by Indian companies has, rather, is to develop new molecules up to a certain stage and then license out to partners from developed countries, primarily to MNCs.	Lupin has licensed out its NCE, LL3348, to US and European pharma firms Ranbaxy licensed out its NCE RBx 2258 for treatment of cancer to Schwarz Pharma AG. DRL had licensed out its molecule for treatment of diabetes (Balaglitazone) to Novo Nordisk in 1997, for carrying out toxicology studies as a part of phase II clinical trials. This molecule had to be dropped from clinical trials due to toxicity issues.
Patenting Strategy Most Indian firms which perform innovative R&D are following a mixed strategy of both positive and defensive patenting.	Indian companies like Cipla, DRL and Ranbaxy use patent system to secure their own products which are presently based on NDDS, polymorphs or novel combinations Matrix Laboratories has filed 38 patents involving 36 inventions in the last three years. Their positive patenting strategy is to secure their proprietary rights on the innovative processes they create worldwide. Their defensive patenting strategy, on the other hand, has been motivated by their experience to abandon research at the commercialization stage because their process had been filed by someone else.

Source: Sampath (2005); Field interviews and web pages of individual firms

Table 8 — Emerging collaborative strategies

Company type	Focus			
	In-licensing arrangements	Collaborative R&D	Contract research	Contract manufacturing
Group 1	2.80	3.10	2.78	3.50
Group 2	2.63	3.13	3.00	3.55
Group 3	2.04	2.52	2.88	3.92
Group 4	2.07	2.19	1.93	3.75
Total	2.32	2.69	2.63	3.70

Table 9 — Frequency of usage of collaborative strategies

Group of firms	Collaborative strategy
Group 1	2.944
Group 2	3.042
Group 3	2.840
Group 4	2.442

Group 3. The results of the empirical survey and interviews conducted with a cross-section of the firms showed that each one of the three categories of the indigenous Indian firms are driven by different factors and are using a combination of R&D strategies to deal with pressures imposed by India's full scale TRIPS compliance (Table 13).

Shifting R&D Investment Model

The model of R&D investment by Indian firms is shifting from core process research to new drug development and new drug delivery system (Fig. 1). The major R&D expenditure on new drug discovery and development are conducted by a limited number of companies, with Dr Reddy's and Ranbaxy at the forefront.

Emerging R&D Business Models

Despite severe weakness in supporting scientific disciplines like medicinal chemistry and biology, and lack of collaborative web of networks of research institutes, academia and industry due in part to lack of trust because of weak regulatory and enforcement structure, India is emerging as an alliance and outsourcing destination for global majors because Indian pharmaceutical companies are extremely strong in chemistry driven drug discovery research activities such as, organic synthesis, process and analytical chemistry. India combines these strengths with low cost of operations, competent scientific workforce and expertise in IT to offer a strong value proposition to global pharmaceutical companies. Because of these advantages, companies such as, Roche, Bayer, Aventis and Chiron are making India

Before patent protection implementation

After patent protection implementation

Fig. 1 — Model of R&D investment by Indian pharmaceutical companies

the regional hub for APIs and supplies of bulk drugs. GSK is making India a global hub for their clinical research activities. Indian companies are adopting a combination of the following alternative R&D business models to navigate competition and opportunity:

(i) Out-licensing of innovations
(ii) Services model
(iii) Collaborative R&D

Out-Licensing of Innovations

With increase in R&D, some Indian firms have enhanced focus on NCE development in addition to generic filings, but it is in early stages and has not yet reached the critical mass. Given their limited balance-sheet sizes, Indian R&D is not yet ready for a start-to-finish model for NCE research. Therefore, Indian companies are out-licensing molecules to MNCs for milestone payments and rights for certain markets after conducting pre-clinical and phase-I trials on their own (Table 14).

Services Model

The services model has on account certain players specializing in niche activities like clinical trial monitoring, regulatory affairs and data management. Many small-sized companies and scientist-driven organizations called as Contract Research Organizations which focus on research and not marketing are following this model. The margins in this business depend upon on the criticality of the service being provided and are in the range of 20-40% (Table 15).

Table 10 — Main collaborative strategies adopted by Indian firms

Strategy	Examples
In-Licensing Arrangements Since, Indian firms do not have enough new drugs for the domestic market and they can no longer rip off drugs from MNCs, they are increasingly looking to forge in-licensing arrangements with the MNCs to launch their products in India. The arrangement varies from pure marketing relationships (including JVs) to more elaborate ones where the Indian company makes the product locally and shares a portion of the profit with MNC. In addition to building up the innovative product portfolio, the in- licensing arrangements are cheaper and less risky way of securing products rather than buying companies or doing R&D, which is far more expensive.[25] The in-licensing strategy also helps Indian companies to bring novel medications to the country at reasonable prices. Besides, regulatory procedures are also easier and faster, as they directly undergo a bio-equivalence study and phase-III trials since these products are already approved for marketing in other countries,[25]	In-licensing agreement of Elder Pharmaceutical with GNOSIS S.p.A. to market SAMe, an anti-osteoarthritic nutritional supplement. Glenmark has in-licensed Crofelemer, Napo's proprietary anti-diarrheal compound in over 140 countries, including India.[26] Wockhardt's in-licensing deal with Syrio Pharma SpA for dermatology products.[25] Nicholas Piramal's agreement with Roche for launching products of Roche dealing with cancer, epilepsy and AIDS.[27] Ranbaxy's agreement with KS Biomedix Ltd for EMRs to market Trans MID in India with an option to expand to China and other South East Asian countries.[2]
Collaborative R&D	Agreement between Zydus Cadilla and Fermenta Biotech Ltd to process technologies to manufacture Lisinopril and Benazepril exclusively, within India. Ranbaxy has entered into many collaborative research programmes, e.g. with MMV, Geneva for an anti-malarial molecule, Rbx 11160; with GlaxoSmithKline for drug discovery and clinical development, covering a wide range of therapeutic areas;[28] with University of Strathclyde, UK in NDDS; with Vectura, a drug delivery company for development of platform technologies in the area of oral controlled release system.[29] Cipla has established an R&D deal with Avestagen Laboratories to produce biogeneric drug for Artritis, *N-Bril*.[4] Avesthagen has an ongoing collaborative approach with Nestle, BioMérieux, France and other companies.[30]
CRAMS It is emerging as one of the most important collaborative strategy. Currently, India accounts for between 6-7% of global market and many expect India will command at least 15% of the market by 2009-10.[31] CRAMS market in India was valued at US$ 532.10 million in 2005, of which contract manufacturing accounted for 84% of the total market, while remaining 16% was accounted by contract research excluding clinical trials. Both the segments of CRAMS have registered a robust growth of over 40% in 2005 in comparison to 2004.[32] The industry experts maintain that Indian companies have the capacity to gain between 35-40% of the global CRAMS market.[33] It is estimated that contract manufacturing market for global companies in India would touch $900 million by 2010.[2] Pharmaceutical companies involved in contract manufacturing can be divided in to three broad categories:	Syngene has tied up with BMS to operate about 400-scientist R&D centre for it. Eli Lilly has licensed a patented drug that has yet to be launched in US or anywhere else to Nicholas Piramal. GlaxoSmithKline has tied up with Ranbaxy to work on lead compounds until second round of clinical trials are completed. Avestagen Laboratories, biotechnology firm, performs R&D for many European pharmaceutical companies.[34]
Contract manufacturing for patent drugs (very few players; margins are high)	Patent drugs, custom synthesis and scale ups: Dishman Pharma, Divis's Laboratories
Contract manufacturing for specialized generics (some players; margins are comparatively low)	Specialized generics: Nicholas Piramal, Matrix Laboratories, Shasun Drugs & Chemicals
Contract manufacturing for old generic molecules (most players; opportunities huge but margins low due to increased competition)	Old generics/old molecules: IPCA labs, Morepan Laboratories, Jubilant Organsys, Torrent Pharma, Shasun Drugs & Chemicals

Source: Field interviews and web pages of individual firms

Table 11 — Emerging R&D strategies

Company type	Collaborative research	Custom synthesis & drug development	In-licensing	Clinical trials	Generics	Basic research	API supply	Contract manufacturing	More innovations
Group 1	3.20	3.20	3.00	4.00	2.25	3.00	2.80	3.00	3.50
Group 2	3.23	3.55	2.52	2.77	4.63	2.79	3.97	3.52	3.86
Group 3	2.24	2.60	1.96	1.84	3.96	1.44	3.12	4.00	3.24
Group 4	2.07	1.68	1.79	1.96	3.41	1.68	2.11	3.96	2.57
Total	2.58	2.66	2.15	2.32	3.94	2.06	3.06	3.78	3.24

Table 12 — Frequency of usage of R&D strategies

Group of firms	HER&DS	LER&DS	CRAMS
Group 1	3.20	2.917	3.00
Group 2	2.993	4.046	3.517
Group 3	2.144	3.227	4.00
Group 4	2.022	2.37	3.964

Collaborative R&D

It is a risk-sharing model which involves joint venture/collaboration with another pharmaceutical company or a research house in order to develop and commercialize the drug (Table 16).

Clinical Trials

The depleting bottom line and the need to cut costs is persuading US and Western European firms to seek alternative destinations. India presents a good option for outsourcing because of cost advantages offered by *vis-à-vis* western countries. The cost of phase I, II and III trials in India is 50%, 60% and 60% respectively, less than average cost in US. In addition, India offers other kinds of advantages in critical trail domain. In 2006, the global clinical trials sector was estimated to be about $10 billion and has the potential for considerable growth over the next few years.[35] The Assocham projects the demand for contract clinical trials to grow from $100 million in 2005 to $200 million in 2007 and to $1 billion by 2010.[36] According to India's Chemical Pharmaceutical Generic Association, the domestic contract research market is growing between 20-25% per year.[37] Clinical trials represent 65% of this market and new drug discovery makes up the remaining 35%.[38] The pharmaceutical companies have successfully used clinical trial data generated from India for US FDA new drug application.

Out-Licensing Alliances

The MNCs out-licenses their molecules to Indian firms as this arrangement brings about regular royalty at minimum investments with a wider geographical coverage for their products. For example, Strides Arcolab Ltd entered into a number of out-licensing and supply agreements with companies in US, UK, Australia Japan, South Africa and Europe.

Co-Marketing Alliances

These are alliances where two drug firms market the same product using a distinct brand name, in order to build up brand identity and loyalty and capture a larger share of the market. For example, Lupin has launched injectible Ceftriaxone with the help of Baxter, Glenmark has purchased a leading hormonal brand, Uno-Ciclo, from Instituto Biochimico Industria Farmaceutica Ltd with exclusive manufacturing and global marketing rights, Dabur has entered into alliance with Abbott where Abbott's would market the oncologics generics produced by Dabur from its UK-based facility in the regulated markets of EU and USA.

Outsourcing

Clinical outsourcing has become a lucrative strategy for the Indian firms. For example, Lupin's entered into development and licensing agreement with Cornerstone Bio Pharma Inc for clinical development of NDDS for an anti-infective product, Cadila Healthcare has entered into alliances with Altana Pharma, Schering AG, and Boehringer Ingelheim.

Production Facilities

Several Indian companies have set up production facilities abroad. For example, Ranbaxy has set up new production facilities at New Brunswick, USA;

Table 13 — Emerging R&D strategies & drivers

Firm group	Drivers	R&D strategies	Relative risk & returns
Group 2	Need to strengthen product and IP portfolios to compete in global market Entry in regulated markets as gains are higher than the entry barrier	Greater investment into R&D Higher innovation in generics, NDDS, new products and processes and bulk drugs.	High
Group 3	Need to strengthen the competitive advantage to leverage CRAM opportunities Fill the gap created by the Group 2 by the shift in focus of Group 2 companies to regulated markets	Establish as niche players in selected areas, e.g., clinical research, contract research Supply of off-patent generics to the semi-regulated and unregulated markets Moving up the industry's value chain gradually.	Medium
Group 4	Survival in the light of India's full fledged TRIPS compliance Schedule M of the Drugs and Cosmetics Act	Upgrading facilities for contract manufacturing for Group 2 and 3.	Low

Source: Sampath (2005)

Table 14 — R&D licensing deals by Indian companies

Indian firm	Partner	Molecule
Dr Reddy's Lab	Nova Nordisk	DRF 2593 (diabetes)
	Novartis	DRF 4158 (diabetes)
	Nova Nordisk	DRF 2725 (diabetes)
Ranbaxy	Bayer	Cipro XR (NDDS) RBx 2258 (BPH)
Torrent	Novartis	Advanced Glycosylation age breaker (diabetic)
Glenmark	Forest (North America)	GRC 3886 (asthma/COPD)
	Tejin (Japan)	GRC 3886 (asthma/COPD)

Source: Interviews, web page of individual companies

Table 15 — R&D service agreements by Indian companies

Indian firm	MNC partner	Purpose
Orchid Chemicals	Bexel	Drug discovery research in metabolic diseases
Biocon	BMS Pfizer AstraZeneca	Contract research for bulk drugs
Jubliant Organosys	Eli Lily	New Chemical Entities: CVS, CNS, diabetes and oncology
Divi	Merck Abbot GSK	Custom chemical synthesis
Shasun Chemicals	Aventis Boots Eli Lilly GSK Teva	Contract research and custom synthesis services
Syngene	AstraZeneca	Drug discovery
Strides Arcolabs	AstraZeneca	Drug discovery

Source: Interviews, web page of individual companies

Table 16 — Collaborative R&D agreements by Indian companies

MNC company	Indian company	Purpose
GSK	Ranbaxy	Drug discovery and clinical development tie-up covering a wide range of therapeutic areas
Novartis	Ranbaxy	Drug discovery
Eli Lily	Ranbaxy	Drug discovery
Pfizer	Ranbaxy	Drug discovery
AstraZeneca	Torrent	Discovering a drug for the treatment of hypertension
Bexel Lab	Orchid Pharmaceutical	Development of anti-diabetic molecule

Source: Interviews, web page of individual companies

Sao Gonzalo, Brazil; Guangzhou in China; Malaysia; Cashel, Ireland; DRL has set up two plants in UK, one in China and one in US; Sunpharma has setup its plant at Caraco, US; Aurbindo Pharma Ltd has setup manufacturing facilities in USA, Brazil and China; Wockhardt has setup manufacturing facilities at Wrexham, UK; Cadila Healthcare has entered into agreement with Mayne Pharma of Australia to set up integrated facilities for oncology injectables (50:50 JV).

Marketing Alliances

Several firms rely on marketing alliances abroad instead of setting up subsidiaries or production facilities. For example, Lupin's marketing alliance with Cornerstone to market Suprax; DRL's alliance with Pliva, for development and marketing of oncology products in Europe; muli-product agreement with Pharmascience Group for development and marketing of generic products in Canada; Glenmark's supply and marketing agreement with Lehigh Valley

Technologies Inc (LVT) to make and market liquid generic pharma products in the US.

Herbal Medicines and Access to Traditional Knowledge

Some of the Indian companies are focusing on herbal medicines and access to traditional knowledge to capture the international market. For example, Ranbaxy has launched its 'New Age Herbals' range with a basket of 3 new herbal products in US; Himalaya Drugs has entered in to market alliance in Malasiya, US and Europe for its herbal products; Dabur Pharma and Ajantha Pharma are focusing to develop new drugs through access to traditional knowledge.

Overall Corporate Growth Strategies

Last few years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances in Indian pharmaceutical industry. The motive behind these acquisitions and mergers is to penetrate overseas markets and widen their global network, strengthen geographic reach, diversify and enhance their product and IP portfolios, improve their custom manufacturing, packing, R&D capabilities and gain access to the highly regulated US and European market in order to survive in the post-TRIPS era. Indian firms without significant R&D capabilities for drug discovery are also purchasing Western drug discovery firms.

In 2005-06, 18 Indian companies spent approximately $1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico.[39] These companies included Ranbaxy, Dr Reddy's Labs, Nicholas Piramal, Sun Pharmaceutical, and Jubilant Organosys.[40] Although, eleven of these transactions were for medium-and-small sized companies valued between $5 million and $30 million, several have significant acquisitions valued in excess of $500 million. To date, Dr Reddy's purchase of Betapharm Arzneimittel of Germany for $572 million is the industry's largest overseas acquisition. Many Indian firms are now on the lookout for consolidations in the European market which is among the largest pharmaceutical markets in the world after the US and are available at reasonable valuations.[41]

The new patent regime is also forcing Indian pharmaceutical market to consolidate, and only firms with a global presence and significant R&D capabilities for drug discovery, drug delivery systems, etc. will prosper in the future. Since 2000, a number of smaller Indian pharmaceutical companies have been acquired by larger companies including Wockhardt's acquisition of Merind and Tata Pharma; Ranbaxy's purchase of Crosland; Nicholas Piramal's acquisition of Roche, Boehringer, and Sumitra Pharma, and Glaxo-Wellcome's merger with Ciba-Sandoz. Matrix, one of India's and the world's leading producers of APIs, was acquired by Mylan (US) in January 2007 for $546 million. Mylan, one of the largest generic drug producers in the US, acquired Matrix to expand its manufacturing capabilities, gain a foothold in key markets, and gain access to Matrix's technical and scientific expertise.[3] Major acquisitions of Indian firms in 2005-06 are given in Table 17.

Table 17 — Major acquisitions of Indian firms in 2005-06

Acquirer	Target	Value US$ million	Year
Generics			
Dr Reddy's	Betapharm (Germany)	574	2006
Ranbaxy	Terapia (Romania)	324	2006
Ranbaxy	Ethimed NV (Spain)	-	2006
Ranbaxy	Allen Spa (Italy)	-	2006
Aurobindo	Milpharma (UK)	13	2006
Jubilant Organosys	Target Research Associates(US)	34	2005
Branded formulation			
Sun Pharma	Able Laboratories (US)	24	2005
Valeant Pharma	(2 facilities) (Hungary, US)	10	2005
Glenmark	Uno-Ciclo (Brazil)	4.6	2005
API			
Dr Reddy's	Roche's API Business (Mexico)	59	2005
Matrix	Docpharma (Belgium)	263	2005
Sun Pharma	Two units from Valeant Pharma	10	2005
CRAMS			
Jubilant Organosys	Trinity Laboratories (US)	20	2005
Dishman	Solutia's Pharma services (US)	75	2006
Nicholas Piramal	Avecia Pharma (UK)	17	2005
Nicholas Piramal	Biosyntech (Canada)	6	2005

Source: IBEF, Ernst & Young, The Economic Times, individual company web pages

Conclusions and Policy Suggestions

It has been a long journey for the Indian pharmaceutical industry from being merely an import dependent to emerge as self-reliant producer and an innovation driven developing country competitor in the global market. The government of India has employed a variety of policy tools to develop domestic pharmaceutical sector and to protect it from large multinational firms operating in and dominating the industry. While the Indian policy regime has succeeded in bringing out its pharmaceutical sector

among the fastest growing in the world, it has also created its own limitations in pushing forward its productivity and technological activities. The fragmented nature of policy that encouraged a large number of small and medium-sized pharmaceutical firms appears to have placed a constraint on the scale of production and capabilities to further upgrade technological strength. The shift towards a strong patent regime postulated by TRIPS coupled with policy liberalization of the past decade or so like liberalization of foreign investment, trade and industrial policy has opened up new competitive challenges for the Indian pharmaceutical sector.

The study brings out two important aspects. First, global market is witnessing a slowdown in growth, which has exerted pressure on the profitability of global pharmaceutical majors. The growth model adopted in the past (high dependence on blockbuster drugs) has become unsustainable because of falling numbers of global launches and approval, and increase in R&D cost and other miscellaneous expenses,[42] which compelled global players in building cost-efficient business model to improve their waning productivity and profitability. Thus, outsourcing has emerged as an alternative model enabling them to focus on their core competence, i.e. keeping in-house intellectual capital i.e., vital to competitive advantage and outsourcing the rest through contracts and strategic alliances in the developing countries. Second, the industrial and regulatory climate is still not fully geared up to the need of indigenous industry, the medium and small scale firms are facing severe challenges in adapting to emerging patent regime. They are finding it difficult to cope with the losses induced by restrictions placed on them by new patent regime. This is in line with earlier studies on the topic.[4,12,16] Hence, emerging firm strategies of the local firms will continue to be dictated by survival needs.

In the above context, when major global players are looking for destinations for off-shoring activities like manufacturing and a part or the entire R&D process, India's inherent strengths makes it a lucrative destination for them. The mutual need has led to emergence of Networked Pharma Model[43] through which the major players in the Indian pharmaceutical industry are all set to leverage its strength and exploit the opportunities provided by the emerging business environment. Many pharmaceutical firms are adopting new internationalization strategies for meeting such challenges and achieving their goal for global growth. They are strengthening their geographical presence by starting their own subsidiaries and affiliates in different strategic overseas markets. They are aggressively acquiring overseas business enterprises, brands and research facilities. Strategic alliances with and contract manufacturing, R&D and marketing for pharmaceutical companies from developed countries are also being employed by Indian pharmaceutical companies.

The Indian government can take several policy measures for enhancing the nation's competitiveness in the pharmaceutical sectors. A fragmented domestic market marked by a lower degree of domestic competition is not conducive for global competitiveness. Hence, policy measures are needed to encourage mergers and acquisitions among domestic firms to offset the scale disadvantage and to overcome the trap of low R&D intensity. Increase in average firm size through M&A until the concentration index of the industry rises significantly, may result in improving India's competitive advantages in the pharmaceutical sector. Government policies that encourage overseas acquisitions by the Indian companies for brands, technology and market access can also be important for strengthening firms' technological capabilities.

Incentives and facilitation policies for encouraging global pharmaceutical companies to outsource their production and R&D works to Indian firms should be put in place e.g. investment and tax allowances for the outsourced production, R&D works and setting up of USFDA-compliant plants. The government should encourage setting up of USFDA-compliant plants by providing tax holidays for a specified period (as given in regions like Baddi), so that Indian companies can exploit the opportunity arising out of patented drugs and take up marketing of generics in developed countries like USA. The provision of low cost finance for research with subsidy facilities for indigenous research activities continues to be a key to competitive strategy. The government should initiate more public R&D programmes that utilize the strengths of the industry. The government has earmarked 150 crores for R&D. This is just not enough and should be augmented to at least 2000 crores.

In addition, policies for an enabling legal and regulatory framework are urgently required. The government needs to invest extensively in strengthening existing institutions such as local

competition enforcement agencies, an informed judiciary which is more attuned to new patent law, public health and local industry needs. There is also an urgent need to strengthen information management tools to scan total IP landscape by improving Patent's office and quality of patent examiners. Further, rationalization of DPCO is urgently required in the fast changing business environment. The objective of the price control was to ensure adequate availability of quality medicines at affordable prices. The product patent regime will make it obligatory for Indian companies to compete in R&D if they want to survive. Similarly, WTO led global trading system will result in import tariffs coming down. The Indian companies, to compete with cheap imports, will have to invest in cost effective technology and processes. Therefore, it is imperative that the pharmaceutical industry has surplus for investment. In this context, a liberalized price control regime becomes more important in order to promote access to medicines in the local market and other LDCs.

Academic–industrial relationship needs to be strengthened, on the lines of the US model, where the universities are the sites of innovation and the industry commercializes the product. The universities are permitted to own the IPR and get the share out of profits. Academic institutions will then become the engines of entrepreneurship. India should exploit its know-how in herbal medicines as these medicines do not come under the purview of the TRIPS regime and research in NCEs involves millions of dollars of investment, the Indian companies should engage in R&D of herbal medicine. These policy measures will help the Indian pharmaceutical industry to harness its strength, mitigate the weaknesses, ward off the threats and cash in on the opportunities.

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