TRIPS and Its Implications on Indian Pharmaceutical Industry: A Firm Wise Analysis of North West India

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Abstract-In recent years, the Indian pharmaceutical industry has been witnessing tremendous growth. Not only did the industry improve its performance in the last few decades, the industry has turned into a rising phase and has left its footprints in the pharmaceutical market all over the world. The objective of the present study is to examine the relation between firm size and technology management factors. The study also examines the status of patents, trademark, Copyrights, etc. On this basis the performance indicators are analysed. The study has been taken for 152 pharmaceutical firms selected from North-West region of India. Mean and ANOVA have been used to analyses the results of study. The results indicate a focus on cultural factors to induce firms to adopt IPR conducive culture, reliance on Govt, assistance is still high. Size of firm and cultural factors emerge as important predictors of sales.

 $\label{local_index_to_index_to_index} \emph{Index} \ \textit{Terms} - \emph{IPR}, \ technological \ adoption, \ product \ and \\ process innovation, SWOT$

I. INTRODUCTION

After the industrial policy 1991, pharmaceutical industry has been a favorite sector for policy makers in the developed as well in many developing countries, including India. The Indian pharmaceutical market is one of the fastest growing in the world. The Pharmaceutical industry has shown tremendous improvement in their growth and development, especially after TRIPS. The policies towards protecting Intellectual Property Rights (IPRs) have reflected a positive phase of the enhancement and growth of pharmaceuticals. The industry has shown their strongest performance during post-TRIPS period. India has acknowledged and made a commitment to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, and keeping with this commitment, implemented the Patent (Amendment) Act in 2005. Domestic and global Pharma companies are showing an increased assurance in the patent laws and is expected an increase in the number of inventions and innovations of patented products in the Indian market in the future.

With the introduction of the industrial revolution and the innovation of new technology it became apparent that ideas, thoughts as well as material property required to be protected [1]. Jefferson, in particular, shielded patent

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protection because it encourages the pace of inventions and inspires creativity by protecting possession of ownership of new ideas, and authorize the inventor or creator to gather benefits from it. The Indian Pharma Industry comprise of small scale, medium scaled, large scaled players, which totals nearly 300 different companies.

TABLE I. INDIAN PHARMACEUTICAL EVOLUTION

Phase-I	Phase-II	Phase-III	Phase-IV	Phase-V	
Early Years	Early Years Government control		Growth Phase	Research & Innovation	
Market share is dominated by Foreign Com.	Indian Patent Act – 1970 Drug prices capped	Process dev. Prod. Infrastructure creation	Rapid expansion of domestic market	New IP law Discovery	
Absence of organized Indian Companies	Local companies begin to make an impact	Export initiatives	International market development Research orientation	Research Convergence	

Table I shows the evolution of Pharmaceutical Industry. It has been categorized in five different phases. In Phase-I, Early years, (1950s–60s), Foreign companies grabs more market share as compare to domestic industries and the Indian companies are not organized as well. With the intervention of Indian government, pharmaceuticals industry improved it position and moved to Phase-II (1970s). In this phase Indian Patent Act-1970 was introduced, the Act did not provide for monopoly rights in the area of drugs and agro-chemicals as only process patents and not product patents were recognized, which encouraged the SMEs to innovate new products. This improvises the quality of the product as well as capping the price to grab more market share and enjoy profit.

SMEs took initiatives and became the essential part of the supply chain for the bigger players in the country. This encouragement leads to the development of the pharmaceutical industries and move on to Phase-III, i.e. Development Phase (1980s). During this phase new processes are invented for R&D, more emphasis is laid on development of infrastructure and exports are also encouraged. Phase-IV (1990-2000), Growth Phase, express the expansion of domestic market and development of International market, via. FDI and MNC. Now the Pharma industry reached on Phase-V (2000), where Patent laws, Trademarks, Industrial design, Trade secret, schedule M etc. are introduced. New inventions take place. Now SMEs are recognized as the strong pillar of the pharmaceutical industry.

A. Objectives of the Study

- To determine the firm-wise status of IPRs
- To examine the firm-wise status of Sales, Turnover, Market share, Productivity, competitiveness, Technological skills.
- To examine technology management status in terms of Product and Process innovation, R&D intensity and New Technology Adoption and Adaptation.

II. REVIEW OF LITERATURE

With the advancement of relative measures taken for [the growth and development of SMEs, Pharmaceuticals in India and Government of India the pharmaceutical industry has witnessed several changes. Though, enough literature is not available on the growth of Indian Pharmaceutical industry as limited research has been done on firm wise patent, Copyright, Trademarks, Schedule M, ANDA filings and approvals, DMF filings and approvals with USFDA. Whatever literature is available is in the form of papers/articles published in pharma magazines and studies showing growth of Indian pharmaceutical industry by taking a few parameters only. Further the review of literature is divided into two sections:

- Firm Size and Pharma Industry
- Status of IPRs in Indian Pharmaceutical Sector

A. Firm Size and Pharma Industry

The study by Kiran and Mishra [2] focuses on the impact of India's economic reforms on economic structure in less than 15 years; India has transformed itself as a hottest emerging market and even being preferred by many foreign countries for investment. Goldman Sach's BRIC (Brazil, Russia, India and China) report (2006) places India is ahead of Japan and placed third rank in the global pecking order of economies by 2050. Due to growth and advancement of small and medium enterprises in countries like India, China and Japan the significance of US slowdown comparatively. India has shown that the boundaries separating nations into the first, second and third worlds can easily be lapsed. As per the results of Census of India 2001, about 39.1% of the total population was in the workforce, out of which male contributes about 51.7% while female contributes about 25.6%. Female in rural areas contribute more (30.8%) as compared to female work force o in urban areas (11.9%). Whereas Male work force in rural areas counted 52.1% and the same in urban areas was

contribute only 50.6%. Further, India is lacking because of inadequate infrastructure, poor coastal development and untapped rural markets etc. that ceases the opportunity to invest the capital by foreign countries. India interested in going global subsequently showing interest in strengthening economic and commercial relations with foreign countries.

Chadha [3] opined that Indian firms are spending maximum resources to secure non-infringing process patents in foreign countries especially of the growth of SME. Developing countries emphasize more emphasis on drug master filings (DMFs) for bulk actives supply and abbreviated new drug applications (ANDAs) for formulations. According to FICCI Report [4] Intellectual property rights contributes to economic growth in both developed as well as developing countries by invigorating innovation and adopting new technology as part of a better policy framework.

Shivanand [5] and Pandey and Dixit [6] explain the performance of SMEs Pharmaceuticals in Indian economy in terms of absolute growth in number of enterprises, employment, production and exports both in the TRIPs period Reddy [7]. The SMEs require small investment, so the entrepreneurs can afford to take risks. The Government of India and financial institutions have played an important role in the Indian economy in the development of SSIs.

According to Salazar [8] the growth in R&D for SME pharmaceuticals is greater than the growth for the general pharmaceutical sector. Pharmaceuticals have huge resources to devote more investment for R&D and can afford to think about the future. Chaudhuri [9] reveals that With a view to enhance the competitiveness in Indian, SIDBI has initiated project to provide demand driven and need-based Business Development Services (BDS) to, improve MSME recover to finance and market oriented BDS, thereby encouragement MSME growth, competitiveness and employment creation.

B. Status of IPRs in Indian Pharmaceutical Sector

Grace [10] tried to show the increased push for IPR protection for the research institutions and also developing the means of protection and commercialization of their technologies and products. Dhar and Gopakumar [11] explores drastic shift in the structure of R&D activities of the Indian pharmaceutical industry after TRIPS came into effect. Primarily the SMEs industries were primarily engaged with the development of new processes for manufacturing drugs, now they are also involved in R&D for new chemical entities (NCE).

The study by Gupta [12] reveals that the prospects of changing intellectual property on pharmaceutical industry are extremely positive for the future of the Indian industry. The study shows that one third of all FDA applications came from India in 2003 and this number is expected to be one half in 2004. MNCs have been interested in working with Indian firms for some time, attracted by lower cost structure.

Sunil [13] provides analysis to indicate the performance of the firms in the Indian pharmaceutical

industry following the changes in the patent regime necessitated by the "Agreement on TRIPS". The study shows that the R&D spending of some of the leading firms has shown increase in Post- TRIPS period and hence R&D intensities of the firms have improved significantly. According to EXIM Report [14] Indian Pharmaceutical Industry has Stimulating Opportunities in Post- TRIPS period. Indian companies are accelerating their rate of DMF filings every quarter. Indian generic players are also increasing their participation in the advanced markets, particularly the US. Intellectual property right has protected the innovation and products of the pharmaceuticals and ANDA filings with USFDA are also increasing in Post- TRIPS period.

Lalitha [15] undertakes a detailed mapping out of the sectoral system of innovation of India's pharmaceutical industry. The study shows that the TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both research budget and patenting. Favorable Government policies along with industry/firm level initiative have helped the industry to upward the growth rates over the years [16]. Many Indian pharmaceutical companies showed their good performance in domestic market as well as in overseas markets. Despite of many confronts posed by the WTO regime, the growth momentum has continued in this sector.

Kiran and Mishra [17] highlight that Indian firms are adapting to the changing environment. R&D is recognized as the 'survival kit' in the post-TRIPs scenario. The paper observed that Indian firms are investing in R&D not only for new drug discovery but for developing capabilities to assimilate and exploit knowledge available externally. They are also positioning themselves as a partner of choice for technology savvy national and multinational firms.

India is now rising as a preferred supplier of Active Pharmaceutical Ingredients (APIs) to many global companies beyond costs. It is today the third largest API player after China and Italy [18]. India is way ahead of its competitors in Drug Master File (DMF) filings. The proportion of DMF filings by Indian players has gone up more than three times in the last few years. India has the largest (being outside the US) US FDA approved facilities.

Nair [19] reports, industrial Drugs and Chemical increased their share in global exports; therefore, the observed decline in value added and employment remains unexplained. Small and medium enterprises employ more than 100 employers and generate employment. Pradhan [20] shows the importance of TRIPS on Pharmaceutical industry. The study emphasizes on the significance of IP that helps in fulfillment of the obligation to comply with TRIPS as well as enforcement of new IP regimes to protect the innovation. The study elaborates the significance of Patents, trademarks, Trade secret, Industrial design, etc. He explains the impact of Post-TRIPS in Indian Pharmaceutical industries with specific reference to International operations.

Indian pharmaceuticals are expected to grow over the next five years which is driven by increase in disposable income, an aging population and by improved medical infrastructure [21]. He referred in his study that India is going through major shift in its business model in last few years. He further explains that because of the government intervention Indian pharmaceuticals deliberately indulge into promotion and encouragement of the domestic healthcare industry in producing cheap and affordable drugs. Now Indian pharmaceuticals establish their own standards in pharmaceutical markets.

SWOT analysis of the Indian pharmaceutical industry in the WTO period reveals that the much applauded IPI's expertise in process development skills were achieved by positive amendments made to the Indian Patents Act 1970. This strength should be utilized to the get to the benefit from opportunities that arise from vertical disintegration of research, clinical trials manufacturing by the multinationals. IPI faces threats in the form of competition from other Asian giants, particularly China. The IPI should adopt various strategies like producing off-patented products, new patented products by acquiring compulsory licensing or cross licensing, collaborate with multinationals not only in R&D and manufacturing, but also in marketing new patented products and improving the standards of production to widen the export market.

III. RESEARCH METHODOLOGY

The present study is descriptive in approach based upon primary data. The data has been collected through the stratified random sampling. A self-structured questionnaire has been used for collecting the data from pharmaceutical industries of Punjab, Harvana and Himachal Pradesh. The questionnaire has been tested for the reliability of the respective factors which are used in this study. The overall reliability of the questionnaire depicted is 0.704. Questionnaire was distributed among 250 pharmaceutical firms on the basis of the type of the firm i.e. Small, Medium and Large scale. The data has been collected from the approached 141 pharmaceutical firms from major cities of Punjab, Haryana and Himachal Pradesh. This study considered few attribute such as Patent, Copyright, Trademarks, Market competitiveness, Technological skills, Product and Process innovation, R&D intensity etc. Mean and ANOVA have been used for analyzing the data.

TABLE II. RELIABILITY OF QUESTIONNAIRE

Reliability Statistics							
Item Name	Cronbach's Alpha	No of Items					
Performance Indicators	.882	10					
IPR Scenario	.804	04					
IPR Culture	.814	14					
Total	.912	28					

The overall reliability of the Questionnaire is .912. for different sections also the reliability ranges between .804 to .882. Thus, the questionnaire is reliable. Validation

IV. RESULTS AND ANALYSIS

A. Performance Indicators

It is important to study and analyse the size-wise average rate of performance indicators. Initially descriptive statistics are taken and then firm-wise ANOVA analysis has been used. The details of sample size have been indicated through Table III.

TABLE III. SIZE OF THE SAMPLE FIRM

Firm size	Frequency	Percent	Valid Percent	
Small	72	51.1	51.1	
Medium 56		39.7	39.7	
Large	13	9.2	9.2	
Total	141	100.0	100.0	

Size wise break up of firm depicts that there are 72 small firms, 56 medium scale and 13 large scale firms.

Firm-wise results of performance indicators have been presented through Fig. 1.

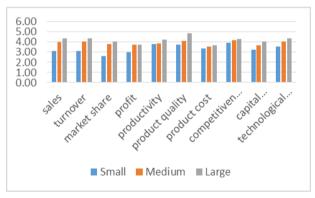


Figure 1. Firm size and performance indicators

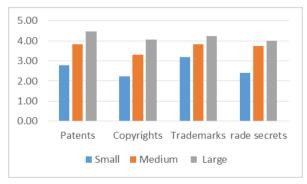
As shown through Fig. 1 the performance indicators are highest for large scale, be it turnover, sales or capital intensity and technological performance, but what is surprising is that even small scale firms are trying to catch up with medium and large scale in terms of product quality and competitiveness. One reason for this could be that mostly they are into contract manufacturing and have to maintain quality to remain competitive.

ANOVA results (Table IV) indicate that there is a significant difference in firm size for Sales; Turnover; Market share; Profit; Product quality; capital investment and technological skills. The results are not significant for remaining indicators, viz. product cost; productivity and competitiveness.

TABLE IV. ANOVA RESULTS FOR SIZE OF FIRM

		Sum of Squares	Df	Mean Square	F	Sig.		
	Bet. Gp	33.298	2	16.649	21.846	.000		
Sales	Within Gp	105.170	138	.762				
	Total	138.468	140					
	Bet. Gp	34.878	2	17.439	22.946	.000		
Turnover	Within Gp	104.880	138	.760				
	Total	139.759	140					
	Bet. Gp	56.535	2	28.268	16.048	.000		
Market share	Within Gp	243.082	138	1.761				
	Total	299.617	140					
	Bet. Gp	20.737	2	10.369	10.427	.000		
Profit	Within Gp	137.234	138	.994				
	Total	157.972	140					
	Bet. Gp	1.739	2	.870	1.038	.357		
Productivity	Within Gp	115.665	138	.838				
	Total	117.404	140					
	Bet. Gp	15.189	2	7.595	8.466	.000		
Product quality	Within Gp	123.803	138	.897				
4	Total	138.993	140					
	Bet. Gp	2.068	2	1.034	1.179	.311		
Product cost	Within Gp	121.095	138	.877				
	Total	123.163	140					
	Bet. Gp.	3.029	2	1.515	1.656	.195		
Competitive- ness	Within Gp.	126.261	138	.915				
	Total	129.291	140					
	Bet. Gp	9.785	2	4.893	4.912	.009		
Capital investment	Within Gp	137.463	138	.996				
III . Commont	Total	147.248	140					
	Bet. Gp	12.325	2	6.163	7.035	.001		
Technological skills	Within Gp	120.880	138	.876				
SKIIIS	Total	133.206	140					

IPR Scenario of sample firms has been depicted through Fig. 2. Results highlight that



 $Figure\ 2.\quad IPR\ status\ of\ small,\ medium\ and\ large\ firms.$

The results indicate that performance is better for large scale firms for all forms of IPRS, which is obvious also as they can afford more money and have better technical expertise for filing IPRs. At the same time results are also indicating that even small scale firms are into patent filing and they are competing with others in trademarks. This is a perceived change which predicts new hope. One reason could be that survival without IPRs is becoming impossible in the competitive global environment.

B. Factors Enhancing IPR Conducive Environment

The next step of research was to identify factors for enhancing IPR environment. This was achieved through factor analysis. The results are shown through Table V.

This section consisted of 12 items for understanding which factors are important for enhancing copyright environment in pharmaceutical firms. Factor analysis helped to classify these items into three factors, viz. cultural, economic and legal factors. These three factors explain 67.335 % of variation.

In Cultural factors Association with R & D centers, Expanding R& D Budget and franching are having higher item loading and are considered more relevant than other items in this factor.

In case of economic factors Govt. Assistance, Increased Global presence and Pool patenting- all these three items have item loading more than 0. 70, but as Govt. assistance still predominates. Thus, Indian firms are still relying on Govt. support for filing IPRs.

In case of legal factors there is still strong reliance on reduction in taxes and fee for IPR filings and registration. Collaboration with IPR facilitation centres is having low item loading and requires increased impetus.

TABLE V. FACTORS ENHANCING IPR CONDUCIVE ENVIRONMENT

Factors	Items	Components				
ractors	Items	1	2	3		
Cultural	Association with R & D centres	.867				
Factors Eigen	Expanding R& D Budget	.818				
Value:	Franchising	.811				
4.074 % of Variation:	Increased Filing of IPRs	.734				
33.947	Internal Training	.669				
	Reward IPRs	.652				
Economic Factors	Govt. Assistance		.788			
Eigen Value :	Increased Global presence		.755			
2.635 % of Variation: 21.958	Pool patenting		.722			
Legal Factors	Reduction in taxes & fee			.731		
Eigen Value :	Faster Registration			.583		
1.372 % of Variation: 11.430	Enhanced collaboration with IPR Facilitation Centres			.514		
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.						
	a. Rotation converged i	n 8 iteratio	ns.			

The last step was to regress these IPR factors along with size of the firm and age of the firm on Performance indicator. We took sales as the performance indicator and the results of regression model are depicted through Table VI.

TABLE VI. RELATIONSHIP, BETWEEN SALES AND FACTORS INFLUENCING IPR CULTURE, SIZE AND AGE OF FIRMS

Model Summary ^a											
Model R		R		R quare	Adjuste d R Square	Std. Error of the Estimat e		Durbin- Watson			
	1	.60	7a		.368	.363	.797	17			
	2	.68	1b		.464	.456	.737	10			
	3	.71	1c		.506	.495	.709	98			
a.	Predicto	ors: (C	Consta	nt),	yr. of e	st.					
b.	Predicte	ors: (C	Consta	ınt),	yr. of e	st., Cultura	l Facto	rs			
c.	Predicto	ors: (C	Consta	ınt),	Yr. of	est., Cultura	l facto	rs, si	ze of f	ïrm	
d.	Depend	lent V	ariabl	e: S	ales						
					Coef	ficients ^a					
Model Standardized Unstand. t Si Coefficients Coefficients t								Sig			
			В		Std. Error	Beta	Beta				
	Const	tant	4.23	34	.347			12	2.20	.000	
3	Estab	ear of ablish .50 nent		9	.098	.377		5	.21	.000	
	Cultu Facto	ors	.32	4	.064	.325	5.		.07	.000	
	Size the fi	-	.36	1	.105	.237		3	.43	.001	
a. Dependent Variable: Sales b. F: 46.785 p: <.001											

The results of step wise regression depict that the model explains 49.5 % of variation. The predictors of sales are Age of the firm, size of the firm and cultural factors. The most important predictor is age of the firm with highest B value. Of the three factors influencing IPR environment only cultural factors are selected by the model. Size of the firm is another predictor chosen by the model. F value for model is 46.785 and is significant. This depicts that the model is acceptable.

V. CONCLUSION

The basic objective of research was to determine the firm-wise status of IPRs. The results indicate that performance is better for large scale firms for all forms of IPRS, which is obvious also as they can afford more money and have better technical expertise for filing IPRs. At the same time results are also indicating that even small scale firms are into patent filing and they are competing with others in trademarks. These results are corroborated by Kiran and Mishra (2010); Nair (2008).

The next objective was to examine the firm-wise status of Sales, Turnover, Market share, Productivity, competitiveness, Technological skills. This was tested through ANOVA. The results indicate that there is a significant difference in firm size w.r.t. most performance indicators, viz. Sales; Turnover; Market share; Profit; Product quality; capital investment and technological

skills. Earlier literature supports this as is eminent from studies by (Grace, 2004; Chaudhuri, 2007).

The last objective was to examine technology management status in terms of Product and Process innovation, R&D intensity and New Technology Adoption and Adaptation. In Cultural factors Association with R & D centers, Expanding R& D Budget and franching are chosen as more important. In case of economic factors Govt. Assistance, Increased Global presence and Pool patenting- are important but Govt. assistance is valued more. This is new area and results are not directly supported by literature. Although indirectly supported by Lalitha (2002).

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