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Innovation and Intellectual Property Laws: The Case of Indian Pharma Industry

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Article Info Volume 83
Page Number: 3401 - 3408
Publication Issue:
July - August 2020

Abstract:
The pharmaceutical industry is stimulated with a culture of radical innovation. However, the Indian pharma firms frequently accede to the internal and external pressures that often coerce them to pursue immediate profit arenas rather than investing in radical innovation. The paper reflects on the importance of stringent intellectual property laws and their impact on innovation and firm profitability. The authors seek to determine the relationship between R&D expenditure and innovation in the pharmaceutical firms.

The study gathers significance as over the last two decades India's IPR and FDI regime have become favourable to foreign players with huge capital. In the pre-TRIPS era, innovation in the pharma industry was predominantly limited to incremental innovation and there was increased emphasis on generic drugs rather than on developing new drugs and molecules.

Vital amendments in the normative framework of the Indian pharmaceutical industry have elicited the firms in India to make far-reaching changes pertinent to their outlook on innovation which is echoed in their R&D budgets. This is also reflected in the fact that international firms are conducting their clinical trials for COVID-19 vaccine in India without any apprehension of patent infringement.

The results of the study show that an increase in R&D activity has a positive impact on innovation. Moreover, this relationship is strengthened in presence of a stricter IPR Regime. The results also confirmed that increase in innovation activity enhances the firm's profitability. Thus, in view of the stringent patent laws, the pharmaceutical firms operating in India should invest their resources in innovation. This will have a positive impact on the profitability of the firms and help them be in a position where they can sustain their competitive advantage in the industry.

Article History
Article Received: *25 April 2020*
Revised: *29 May 2020*
Accepted: *20 June 2020*
Publication: *10 August 2020*

Keywords: *Innovation, Patents, Pharmaceutical Industry, IPR Regime*

I. INTRODUCTION

Innovation is the key driving force in the pharmaceutical industry (Arrow,1962). Competition in this industry is predominantly driven by innovation and the companies that are more innovative have an edge and a sustained competitive advantage.

Ever since the Indian economy has allowed FDI in the pharmaceutical sector, the Indian pharmaceutical firms have encountered immense competition from foreign multinational firms (Bhaumik et al., 2010). This was made possible in 1995 when India adopted the agreement on trade-related aspects of intellectual property rights (TRIPS) which was eventually implemented in 2005 (Watal, 2000). Consequently, many pharmaceutical firms operating in India had to significantly change their modus operandi to comply with the provisions of the amended Intellectual Property Rights (IPR). These changes included alterations in the organization structure, health and safety standards, compositions, manufacturing, research & development, patent policies, etc. (Watal, 2000). The rigorous implementation of TRIPS by the Indian government was an impetus to the foreign pharmaceutical firms (Adelman and Bauldia, 1996). Many international pharmaceutical firms now felt safe to enter and establish their presence in the Indian sub-continent and invest more in manufacturing and research & development.

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Moreover, the cost of setting up and operating in India is drastically less than in other foreign countries.

The Indian pharmaceutical sector has gained importance, not just domestically, but internationally as well. It has become even more evident considering the COVID-19 scenario. The whole world looks up to India to supply the drugs and vaccines as it has a huge capacity to manufacture the same (Kamath, 2008). Even the clinical trials for many foreign companies are conducted in India.

A report by the Indian Brand Equity Foundation (2019) claims that the Indian pharmaceutical industry supplies over 50% of global demand for vaccines. 40% of the generic demand in the US and about 25% of the total medicine demand in the UK is catered by the Indian pharma industry (IBEF, 2019). A huge highly talented and skilled workforce in the pharmaceutical sector has helped the sector grow successfully and enjoy such an important and prominent position globally. It is one of the fastest growing industries in our country and is expected to grow to US$ 100 billion by 2025 (IBEF, 2019). This reflects on the industry's colossal size and market potential. It is one of the leading producers of generic drugs and is also a leading filer of abbreviated new drug applications (ANDA) in the USA, receiving 336 ANDA approvals from the US FDA in 2019 (IBEF, 2019).

The Indian pharmaceutical sector is primarily dominated by the generic drug segment. The share of patented drug segment in India is very low. It is slowly progressing over the years; however, it is yet to make a significant presence (Gokhale & Kannan, 2017). Consequently, the industry requires rapid innovation that can be achieved through sizable investments in R&D activities. This will play an important role in survival of Indian pharmaceutical firms considering the increasing competition from its foreign counterparts (Solow, 1957).

Previous studies have extensively reviewed innovation in the pharmaceutical industry. However, majority of these studies have presented innovation as a theoretical concept driving out of an organization's culture (Ling, 2003; Schein, 1990; Khazanchi et al., 2007). These studies have overlooked the external factors in the firm's environment that could force a firm to innovate and invest more in research and development. Furthermore, researches analysing the pharmaceutical industry performance post the implementation of TRIPS in India are scarce.

This paper analyses the critical outputs of innovation, that is patents, and their relationship to the R&D expenditure by firms in the pharmaceutical industry. The authors also examine the performance of the Indian pharmaceutical industry that is measured through profitability, especially in the post TRIPS era.

LITERATURE REVIEW

Intellectual Property Rights is not a novel concept for India. Britishers introduced Patent Laws in India in 1856 on the same lines as the British Patent Law of 1852 with the objective to stimulate inventions and to induce the inventors to reveal their inventions to stir up scientific research, new technology and industrial progress (Kochhar, 2008). Gradually, over time, this law was amended and more laws catering to various other intellectual properties got introduced. Indian Patents & Designs Protection Act 1872, Indian Inventions and Designs Act 1888, and Indian Patents and Designs Act 1911 were introduced (Haley and Haley, 2012).

When India gained independence in 1947, its pharmaceutical industry was modestly sized at around US$ 28.5 million (Haley and Haley, 2012). Various foreign multinational companies dominated the pharma sector and there was high dependency on imported drugs. To lessen this dependency, the government of India invested in establishing public sector pharmaceutical enterprises such as Hindustan Antibiotics Limited and Indian Drugs and Pharmaceuticals Limited and introduced the 'drug price control' to control the prices of various drugs (Rao, 2008). Consequently, many foreign pharmaceutical companies decreased their investment and gradually started to withdraw from India. Thereafter, the government decided to introduce amendments in the patent laws.

The first set of significant changes in the intellectual property laws were made in 1972 when the Indian Patents Act came into force and introduced the process patent regime. It was only in 1994, i.e., after India signed the TRIPS agreement that an ordinance was issued to bring changes in the extant patent law (Godinho and Ferreira, 2012) and the inventors or their assignees were granted restrictive Exclusive Marketing Rights to sell or distribute their products

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in the country (Tripathi, 2007).

Now the firms could patent the process by means of which a product is manufactured. Ergo, from 1972 to 2004, India's pharmaceutical industry became the fourth largest in the world and recorded a growth rate of 21.9% (Haley and Haley, 2012). However, the Indian pharmaceutical companies exploited the loophole in the legislation wherein only the manufacturing process of a drug was patented and not the drug itself. To avoid infringing the law of the land, Indian pharmaceutical companies used to conduct an in-depth analysis of the molecular structure of the product whose process was patented and then introduce a similar product with the same impact and potency as the drug by closely altering the process (Chaudhury and Das, 2006). Because of this they could easily keep away from any legal complication while manufacturing a similar product whose manufacturing process was patented. This amendment proved to be profitable to the Indian pharmaceutical companies as their capital expenditures dropped drastically balanced against the capital cost of discovering a new molecule. They were manufacturing a low-priced product of the same efficacy in a very short span of time and at the same time, investing very little resources.

India became a signatory to the TRIPS agreement in 1994. The agreement required its signatories to establish a product as well as the process patent regime in their respective countries (Sahu, 2014). For this purpose, India was given a period of 10 years to introduce the product patent regime by 2005 in the country. For a decade (1995-2005), India witnessed a drastic remodelling of its Patent laws to comply with the TRIPS agreement. In 2003, another significant amendment was made in the Patents Act wherein the term of protection granted by way of patents was increased from 7 years to 20 years (Kiran and Mishra, 2011). Moreover, to deal with the matters falling within the purview of the Indian Patents Act, an Appellate Board was established. The final major amendment to the patent laws was in January 2005 when the product patent regime was also established (Sahu, 2014). Now in addition to the process of manufacturing a product, the final product itself could also be patented for 20 years (Law Commission of India, 1999). These reforms were brought into force with the motive to encourage domestic firms to invest in R&D in case of patented drugs.

Whereas a number of researches have been conducted on the issues relating to the trends in the R&D activity, innovation led exports growth pattern, and patenting activity in the Indian pharmaceutical industry (Department of Pharmaceuticals, 2018; Thomas et al., 2014; Achilladelis & Antonakis, 2001), however, the impact of increased research and development on the patenting activity and firm profitability is not comprehensively explored.

HYPOTHESIS DEVELOPMENT

Innovation in Pharmaceutical Industry

Innovation has often been interpreted as a function of research and development. Schwartzman (1976) in his research concluded that to understand the behaviour of the pharma industry, it is imperative to understand that pharmaceutical companies compete in the market predominantly for product sales primarily through developing new drugs. In this innovation led industry, firms are required to devote specialized resources for new drug discovery to achieve a sustained competitive advantage in the industry (Schwartzman, 1976). Therefore, innovation should be perceived as outcome oriented construct that can be assessed either through new product/process launch (Dewar & Dutton, 1986) or tempering an extant product/process that could considerably enhance the strategic position of a company (Menguc & Auh, 2006).

In this study, the authors view innovation as an outcome variable that enables firms to launch new products and processes and acquire patents. The authors have used R&D intensity to predict innovation as firms spend a lot of resources on new drug discoveries (Simanjutak & Tjandrawinata, 2011). Previous researches have also established a strong positive correlation between investments in research and development, products and process discovery and increase in productivity.

Hence, the authors propose the following hypothesis:

H1: Increase in investment in R&D positively impacts innovation.

Innovation and IPR Regime

The agreement on trade related aspects of intellectual property rights changed the strategic perspectives of firms. The industry swiftly

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transformed itself from a process protectionist regime to a rigorous product patent edict wherein firms needed to ascertain themselves by way of innovative R&D rather than imitative R&D to sweep through the cutthroat competition especially from foreign firms (Saranga, 2007).

Many countries across the globe have now implemented stricter intellectual property protection and that gives an incentive to the pharma firms to invest in such countries, especially if other conditions (such as cheap labour, favourable laws, stable government, good market demand, etc.) are also conducive for the industry. Without significant protection, drugs can be reverse engineered, manufactured, and marketed by competing firms (Popper & Nason, 1994).

Many previous researches have established that innovation would be the key to deal with turbulence in the dynamic business environment in the pharmaceutical industry (Tellis et al., 2009; Baker & Sinkula, 2002; Bean, 1995). Therefore, in such dynamic environments, innovation is considered as an obligation that the environment imposes on pharma firms and that in turn improves their performance (Miller & Friesen, 1983).

Although patents do not confer complete monopoly over a product or process, however, the inventor or his assignee are granted exclusionary rights for a limited time. In exchange, the inventor is required to disclose the invention. Granting patents encourages the firms to innovate as it guarantees them the exclusionary right over their product or process and thereby a protected income. In a way, patents may be regarded as a reward for a new discovery which motivates them to innovate more (Acemoglu and Linn, 2004).

The post TRIPS era has seen firms engaging robustly in R&D activity (Mahajan et al., 2014; Nauriyal & Sahoo, 2008; Majumdar & Feinberg, 2001). Therefore, it can be deduced that a country's IPR regulations influence a firm's policy on innovation.

Hence, the authors propose the following hypothesis:

H2: A highly regulated IPR Regime enhances the positive effect of R&D on innovation in the pharma industry.

Innovation and Firm Performance

Innovation plays a major role in the pharmaceutical industry. Firms that innovate more, launch new products and services faster. This helps firms acquire a significant market share. It is especially important for pharmaceutical firms to launch more effective drugs with least side effects. In such cases, the consumers switch their medication to better quality drugs and that in turn helps firms increase their sales and profitability. Innovative new products play a significant role in creating business value (Bakos and Treacy 1986; Dewan et al., 1998). The relationship between innovation and increase in firm performance has also been validated through numerous previous studies (Avlonitis and Gounaris, 1999; Atuahene-Gima, 1996; Capon et al., 1992; Deshpande et al., 1993; Li and Calantone, 1998; Manu and Sriram, 1996; Mavondo, 1999).

Therefore, the authors propose the following hypothesis:

H3: Increase in innovation positively affects firms' performance.

RESEARCH METHODOLOGY

The proposed hypotheses were tested using secondary data which has been extracted from the Center for Monitoring of Indian Economy (CMIE), Prowess Database and WIPO IP statistics Data Center from 1993 to 2016. To study industry level determinants of R&D and performance, the data set used for this study consists of 889 Indian Pharmaceutical firms.

The data collected was analysed using descriptive statistics, correlation and multiple hierarchical regressions. Descriptive statistics for each measure are included in Table 1.

Descriptive Statistics (Table 1)

	N	Minimum	Maximum	Mean	Std. Deviation
Year	24	1993	2016	2004.5	7.1
R&D Intensity	24	0.7	5.2	2.7	1.5
Profit	24	4912.8	282258.0	84561.1	86340.0
Patents	24	3	496	180.7	154.1

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Measures

Innovation

Innovation has been measured through patents filed by the Indian pharmaceutical firms during 1993 to 2016. This time period is representative of both the pre-TRIPS era (1993 to 2004); and the post-TRIPS era (2005 to 2016). The data for patents has been extracted from WIPO IP statistics Data Center. The mean and standard deviation have been computed as 180.7 and 154.1 respectively.

Firm Performance

Performance has been measured by way of profits after tax earned by 889 pharmaceutical firms during 1993 to 2016. To study the industry wide trends, the authors have summed up the annual profits earned by all the firms. The data has been extracted from CMIE-Prowess database. The mean and standard deviation have been computed as 84561.1 and 86340.0 respectively.

R&D Intensity

R&D intensity has been computed by taking the ratio of R&D expenditure over sales turnover. The data was extracted from CMIE-Prowess database for the period between 1993-2016. To study the industry wide trends, the authors have summed up the R&D intensity of all the firms at the end of each year. The mean and standard deviation for the same are 2.7 and 1.5 respectively.

Results

The first step was to determine whether there was any relationship between the constructs. To confirm the association between R&D, patents and profits, the authors computed Pearson correlation. The correlations (Table 2) were found to be highly significant ($p<0.01$) for all the three constructs. A strong positive correlation was found between the constructs that indicated that R&D intensity, innovation and performance are strongly related to one another.

Correlations (Table 2)

	RDIntensity	Profit	Patents
RDIntensity	1		
Profit	.863**	1	
Patents	.964**	.913**	1
**. Correlation is significant at the 0.01 level (2-tailed).			

The hypotheses were tested using regression analysis. The first two hypotheses were assessed using the ordinary least square regression. The third hypothesis was examined using moderated regression analysis suggested by Aiken and West (1991).

Hypothesis 1, increase in investment in R&D positively impacts innovation, was found to be true (Table 3). The relationship between R&D intensity and innovation was found to be highly significant (p-value< 0.001). The adjusted R^2 value for the hypothesis was found to be 0.926 which indicates that 92.6% of the variation in patents is explained by R&D intensity. This indicates that an increased R&D activity leads to more innovation for pharmaceutical firms.

Hypothesis 2, a highly regulated IPR Regime enhances the positive effect of R&D on innovation in the pharma industry, was also found to be true (Table 3). The relationship between R&D intensity and innovation before the implementation of TRIPS (1993-2004) was found to be significant ($p<0.001$). The relationship between R&D intensity and innovation was found to be significant ($p<0.001$) in the post-TRIPS era (2005-2016) as well. Moreover, looking at the results, we can see that the post-TRIPS relationship between R&D intensity and innovation was stronger than in the pre-TRIPS era.

Regression Analysis (Table 3)

	(1)	(2)	(3)
	Patents	Pre-TRIPS	Post-TRIPS
RDIntensity	100.0***		
	(5.285)		
prerdi		73.26***	
		(5.636)	
postrdi			138.1***
			(18.66)
constant	-88.39***	-54.62***	-236.8*
	(10.43)	(6.853)	(85.70)
N	24	12	12
R^2	0.930	0.969	0.639
adj. R^2	0.926	0.966	0.603
F	358.3	169.0	54.80

Standard errors in parentheses

$^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

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Regression Analysis (Table 4)

	(1)
	Profitability
Patents	647.6***
	(106.8)
_cons	6982.1
	(12949.0)
N	24
R^2	0.838
adj. R^2	0.822
F	70.38

Standard errors in parentheses

$^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

The third hypothesis, increase in innovation positively affects firms' performance, was also proved to be true (Table 4). The relationship between innovation and firm performance was found to be significant at 0.001 level. The adjusted R-square value explained 82.2% of variation in performance brought about by innovation. Thus, innovation, indeed, enhances firm performance.

CONCLUSION

There is ample evidence in the literature that Indian pharmaceutical industry has predominantly been driven by imitation rather than innovation (Banerji & Suri, 2017). This has been primarily due to lackadaisical intellectual property laws. However, since India has made its patent laws more stringent, we have seen a change in this trend. Post 2005 (post-TRIPS era), India started granting patents to both the products and the process. As a result, only new discoveries would be patentable and slight modifications of existing drugs will not be granted patents. This has turned the tables in favour of large pharmaceutical firms, especially the ones with exorbitant capital budgets. These companies can now invest a huge capital in research and development without any apprehension as the patent granted would ensure exclusive manufacturing and selling rights to the company.

This study enhances the understanding of innovation as an outcome based construct that is being determined by the patenting activity in the industry. The results in the study indicate that innovation in the Indian pharmaceutical industry has strongly been driven by research and development, both in the pre- and post- TRIPS era. However, it can be noted that this approach has been considerably stronger in the post-TRIPS era, that is after the implementation of stringent intellectual property laws. The study also indicates that with greater R&D activity, there has been a significant increase in the patenting activity which indicates the firms' inclination for innovation.

Hence it is verifiable that TRIPS has changed firms' perspective on innovation and research & development. Firms are increasingly engaging in discovering new drugs and processes. This has also had a positive impact on the firm performance. However, considering the competition and growth exhibited by foreign big budget pharma companies, the Indian companies still have a lot of ground to cover.

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