



Innovation in Indian Pharmaceutical Industry: Impact of Changing Regulatory Regime

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The Pharmaceutical industry has always been fostered with a culture of radical innovation. Nevertheless, the significance of radical innovation is yet unrealized by the Indian pharmaceutical firms.

Introduction: The Indian pharma companies often seek immediate profit avenues rather than investing in radical innovation. They lead by imitation than innovation. This has been majorly due to the lax intellectual property laws in the country.

Objectives: This paper ruminates on the significance of a stringent intellectual property regime and its impact on profitability and innovation.

Result: The findings of the study indicate that increased R&D intensity enhances innovation. Furthermore, this relationship is bolstered in the presence of a stringent intellectual property regime. The findings also indicate that enhanced innovation activity increases the profitability of the firms.

Conclusion: Innovation activity is enhanced in presence of a stricter intellectual property regime, and this indeed has a positive impact on the firm profitability as well. Hence, as the results of the study indicate, the pharmaceutical firms in India should be encouraged to invest in research and development, especially considering the stricter patent laws. It will help firms bolster their profitability and have a sustained competitive advantage in the industry.

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1. INTRODUCTION

Pharmaceutical industry thrives on innovation [1]. It is what drives sales and profits in this industry. Competition in the pharmaceutical industry is largely determined through innovation [2] Tajpour et al., 2000; [3] [4]. Such companies that are driven by innovation are able to gain and sustain a competitive advantage in the industry. As a result, the top management is usually keen to develop innovative new products and enhance their product development process [5].

The Indian pharma companies face immense competition from their foreign counterparts. This has become even more significant considering Indian economy easing the pathways for international pharma companies to enter and establish themselves in India [6]. This has been mostly a result of India signing the TRIPs (trade-related aspects of intellectual property rights) agreement in 1995 that came to full force by 2005 [7]. Prior to implementation of TRIPs agreement, India did not have very stringent Intellectual Property Laws [8]. However, post TRIPs, India had to strengthen its intellectual property regime. As a result, several pharma companies had to alter the ways in which they used to function to comply with the now amended and stringent intellectual property laws [7]. The companies had to adjust their structure, production, research & development (R&D) activities, patent guidelines, etc [7].

However, the implementation of TRIPs and the consequent changes acted as an incentive to draw in the international pharmaceutical companies [9]. These changes instilled confidence in the international pharma firms to invest in India and establish themselves in the Indian sub-continent [10]. India has always been a lucrative destination for the foreign firms since the operating cost in India is significantly less than the western countries.

Over time, the Indian pharma sector has established a significant presence globally. India is a leading producer and supplier of drugs, active pharmaceutical ingredients and vaccines

[11]. It is also one of the preferred destinations for conducting clinical trials owing to low costs

and availability of manpower and other specialized resources.

The Indian pharma industry caters to more than 50 per cent of global vaccine demand. Worldwide, India ranks third in terms of pharmaceutical production by volume and fourteenth by value [12]. The ready availability of skilled labour has aided this industry to prosper and have a dominant global presence. It is one of the fastest growing sectors and is expected to reach \$130 billion by 2030 [13].

The generic drug segment dominates the Indian pharma industry. India contributes to 20 per cent of the world's generic exports [13]. However, the patented drug segment is still in its nascent stages. There are very few indigenous pharma companies that do drug discovery and new drug development. Their contribution is increasing over the years, but they still have a long way to go [14]. These firms need to increase their investments in research and development and innovate to survive in light of increasing competition from the international pharma firms [15] [16]

Pharmaceutical industry is very tightly controlled. Various regulatory authorities worldwide keep a check on this industry [17]. In India, Central Drug Standard Control Organization (CDSCO) acts as the primary regulatory authority [17]. These authorities ensure that the drugs that are launched in market are safe and effective for human use.

There exists extant literature on pharma industry and innovation. However, most of it is theoretical in nature [18-21] [10]. Moreover, these studies do not account for the influence of the environment in which the firm operates. This study seeks to analyse the relationship between innovation and research & development in the pharma industry specifically in light of the TRIPs agreement being enacted in India. The paper also studies the performance of the Indian pharma industry across the years.

This is a key research area, especially considering the current scenario. Most of the pharmaceutical firms are investing their resources heavily in developing and launching new products, thereby increasing their profitability [22] [23]. It has now become very crucial to comprehend the impact of a stringent

intellectual property regime on innovation in the pharmaceutical sector.

2. REVIEW OF LITERATURE

Intellectual Property Rights is not a contemporary idea for India. Patent Laws were promulgated in India in 1856 by Britishers. The said laws were in the same spirit as the British Patent Law, 1852 and were enacted with the objective to stir up inventions and to promote the investors to reveal their inventions to trigger scientific research, novel technology and industrial advancement [24]. Over a stretch of time, this law was amended and more laws concerning other intellectual properties were enforced. Ergo Indian Patents & Designs Protection Act 1872, Indian Inventions and Designs Act 1888, and Indian Patents and Designs Act 1911 were enacted [25].

Upon independence in 1947, India's pharmaceutical industry was moderately sized at around US\$ 28.5 million [26]. Numerous foreign multinational companies influenced the pharma sector. Indian pharmaceutical sector was highly reliant on imported drugs. To minimize this reliance, Indian government invested in setting up public sector pharmaceutical enterprises such as Hindustan Antibiotics Limited and Indian Drugs and Pharmaceuticals Limited and launched 'drug price control' to regulate the prices of various drugs [27] [28]. Ergo many foreign pharmaceutical companies curtailed their investment and steadily withdrew themselves from India. This compelled the government to amend the then existing patent laws.

With the advent of Indian Patent Act in 1972, India witnessed the first segment of important modifications in the intellectual property sector with the introduction of process patent regime. The next significant changes in the extant patent laws occurred only in 1994 with the promulgation of an ordinance when India signed the TRIPS agreement [29] [30]. and the inventors or their representatives were accorded restrictive Exclusive Marketing Rights to sell or distribute their works in the country [31]

Subsequent to the amendment, the process by means of which a product is manufactured could also be patented. Consequently, from 1972 to 2004, Indian pharmaceutical industries recorded a growth rate of 21.9% and became the fourth largest in the world [26]. Since only the

manufacturing process and not the final product was patented, the Indian pharmaceutical industries made the most of this flaw in the law. The industries used to exhaustively analyse the molecular structure of the product whose process was patented and then used to produce a similar drug with the same efficacy by making subtle modifications in the process, thereby successfully evading the law [32]. Thus, while manufacturing a similar product whose process was patented, the India pharmaceutical industries could comfortably dodge the law of the land. The capital expenditures of the industries as weighed against the capital cost of discovering a new molecule dropped substantially and hence, this amendment proved to be beneficial to the Indian pharmaceutical industries which could manufacture a low-priced product of the same potency in a short stretch of time at once without investing considerable resources.

India signed the TRIPs agreement in 1994. As per the agreement, signatories were obligated to set up a product as well as process patent regime in their states [33] [30]. India was granted 10 years to establish the product patent regime by 2005. Consequently, to comply with the TRIPs agreement, Indian patent laws underwent radical amendments from 1995 to 2005. Duration of patents was increased to 20 years from 7 years by way of amendment in the year 2003 [34-35] An Appellate Board was also constituted to cater to the appeals filed under the Patents law. Finally, in January 2005, the product patent regime was established in India [33]. Now besides the process of manufacturing a product, the final product could also be patented for 20 years [36]. Object of these reforms was to push the domestic industries to invest in R&D in case of patented drugs.

Albeit several research have been carried out on the themes of trends in the R&D activity, innovation led exports growth pattern, and patenting activity in the Indian pharmaceutical industry [37-40] however, no extensive research has been performed to explore the influence of increased research and development on the patenting activity and firm profitability.

3. HYPOTHESIS DEVELOPMENT

As discussed above, innovation is pertinent for the growth of pharma companies and is one of the key factors that lend the pharma firms a sustained competitive advantage in the market.

Innovation in the pharmaceutical industry can be gauged through number of patents filed or launch of new products or processes [41-42] or even when a firm modifies its existing product or process in such a manner that it lends it a competitive edge in the industry [43-44]

In this industry, firms have to allocate specialized resources for developing new drugs. New drug discovery and innovation is not possible unless the companies spend considerable resources on research and development [45-46]. Therefore, the authors propose the following hypothesis:

H1: Increase in R&D intensity has a positive impact on innovation.

Intellectual property law has gained more importance in the recent past due to an unprecedented development in science and technology particularly in the field of information technology [47]. In the age of satellites and internet, any development that takes place in one corner of the world gets communicated across the globe in no time. This gives rise to enormous possibility of unauthorized working of inventions or piracy of industrial designs, infringement or passing off the trademarks, etc. at the international level [48]. In such situations, rights of a person with respect to his intellectual property require more protection by way of stringent intellectual property law [49-52]. Unauthorized working of inventions or piracy of industrial designs affects adversely not only the individual commercial interest of the owner of the intellectual property, but also affects the economy of a nation to which the owner of intellectual property belongs [49-52].

By changing the intellectual property law so that it conforms to the international standard, India has given protection to companies that have research potential to conduct research and development so the companies can develop new drugs/molecules etc. without fearing for unauthorized copying or piracy [53] [54]. And in case, there are offenders, there is a well-established legal mechanism through which the patentees can seek adequate compensation [53] [55]

After the implementation of TRIPs, the pharmaceutical firms are engaging more in research and development [56-58] [10]. Therefore, it can be inferred that a country's IPR regime does have an influence on a firm's approach to innovation.

Hence, the authors propose the following hypothesis:

H2: Strengthening of intellectual property law will increase the positive impact of research and development on innovation in the industry.

Pharmaceutical sector is driven by innovation. Innovative pharmaceutical firms launch more new products and services [59] [60] [61]. Consequently, such firms dominate the market and are able to gain substantial market share [62] and [63] Pharma companies continuously strive to launch modified form of existing drugs that have more efficacy and lesser of side effects [64] [65] [66] [61]. This prompts the consumer to change their medicine and consume drugs that are more efficacious and also at the same time cause least side effect. This results in company's acquiring an increased consumer base which affects the firm's profitability positively and creates business value for the firms [67] [68]. Hence, the authors propose the following hypothesis:

H3: Increased innovation enhances firms' performance.

4. RESEARCH METHODOLOGY

The authors have tested the proposed hypotheses primarily by using secondary data. The data was mined from CMIE database, that is, Center for Monitoring of Indian Economy, WIPO IP Statistics and Prowess. The data was taken spanning across 23 years, that is, from 1993 to 2016. This data captures the essence of both the periods, i.e., before TRIPs was implemented in India (pre-2005) and after TRIPs came into effect (post 2005). Data for about 890 India pharma firms has been collected by the authors and was analysed using multiple hierarchical regression.

Descriptive statistics for the measures are given in Table 1.

5. MEASURES

Patents filed by the Indian pharma companies from 1993 to 2016 have been used to measure innovation. Patents are a function of innovation. More the innovation, more the patents. This data has been taken from the WIPO IP statistics Data Center.

Performance of the firm has been measured through profits after tax gained by 889 pharma companies from 1993 to 2016. Annual profits gained by the companies have been added to analyse the industry trends. This data has been taken from CMIE Prowess database.

Data for R&D intensity (ratio of expenditure on R&D and sales) has been again extracted from the CMIE Prowess database for the same time period, i.e., from 1993 to 2016. R&D intensity of all the firms have been added annually to analyse the industry wide trends.

6. FINDINGS

The authors first ascertained if there was any relationship among the various variables. To determine the link between R&D intensity, profits and patents, Pearson correlation was computed (Table 2). The correlations were found to be significant with a p value of less than 0.01 for all the three variables.

Thereafter, the authors tested the hypothesis using regression analysis via SPSS software. Hypothesis 1 and hypothesis 2 were tested using OLS regression and hypothesis 3 was assessed using moderated regression [69]. The results of the analysis are depicted in Table 3.

The first hypothesis, increase in R&D intensity has a positive impact on innovation, held true. The association between innovation and R&D intensity was found to be significant with p-value less than 0.001 (Table 3). This implies that when pharmaceutical firms invest more in research and development, it leads to an increase in their innovative activities.

The second hypothesis, strengthening of intellectual property law will increase the positive impact of research and development on innovation in the industry, also held true. The association between innovation and R&D intensity was found to be significant in

Table 1. Descriptive statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Year	24	1993	2016	2004.5	7.1
R&D Intensity	24	1.7	5.2	2.7	1.5
Profit	24	4912.8	282258.0	84561.1	86340.0
Patents	24	3	496	180.7	154.1

Table 2. Correlations

	RD Intensity	Profit	Patents
RD Intensity	1		
Profit	.863"	1	
Patents	.964"	.913"	1

** . Correlation is significant at the 0.01 level (2-tailed).

Table 3. Regression Analysis

	(1) Patents	(2) Pre-TRIPS	(3) Post-TRIPS
RD Intensity	100.0 (5.285)		
prerdi		73.26" (5.636)	
postrdi			138.1" (18.66)
constant	-88,39" (10,43)	-54.62" (6.853)	-236.8" (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

Table 4. Regression Analysis

	(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 pre-TRIPs era ($p < 0.001$) as well as the post-TRIPs era ($p < 0.001$). However, it was found that the relationship between innovation and R&D intensity was stronger after the implementation of TRIPs in India. Hence, hypothesis 2 is also supported.

The third hypothesis, increased innovation enhances firms' performance, also held true. The association between firm performance and innovation was found to be significant with p -value less than 0.001 (Table 4). Hence, firm performance is indeed enhanced through increased innovation.

5. CONCLUSION

The extant literature provides that the Indian pharma sector has erstwhile majorly been driven by way of imitation [70] [71]. One of the major reasons contributing to this fact has been the lack of a stringent intellectual property regime. However, as a result of the change in intellectual property laws after the implementation of TRIPs agreement in 2005, this landscape is changing [72] [73] Chattopadhyay & Bercovitz, 2020). Now India has both process and product patents with a longer duration of patent protection and a severe penalty for any infringement [74]. This has acted as a catalyst and India has seen an influx of international pharmaceutical firms establishing their operations in India and increasing their investment in research development.

The results from this study indicate that innovation and R&D have indeed increased after the implementation of TRIPs agreement. Hence, once the intellectual property regime was strengthened in India, it led to an increase in investment in research and development by the Indian pharmaceutical firms that in turn led to an increase in the number of patents filed by

the pharma companies which indicates an increase in innovation in the firms, thereby increasing the firm's performance.

Hence, the managers in the pharmaceutical firms should ensure to create a culture that fosters creativity and innovation [75] [76] [77]. Pharmaceutical firms should increase their R&D budgets and encourage more breakthrough and radical innovations in the organization. This will ensure that the firms sustain their competitive advantage in the market.

Therefore, it can be stated that the implementation of TRIPs has indeed increased innovation in the Indian pharmaceutical industry and thus helped increase the firm performance as well. Pharmaceutical companies are now engaging in launching new and better drugs in the market.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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