

R & D Performance in Indian Drugs & Pharmaceutical Industry in the Post-TRIPs Period



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Abstract

During the first two decades of planning period, growth of Indian drugs & pharmaceutical industry was very slow and industry was dominated by Foreign Companies. With a view to develop a self-reliant indigenous industry, Government took various protective steps in 1970s. One such a step was the adoption of Patent Act 1970. But, after the formation of WTO, the industry has witnessed a dramatic change with respect to policy environment. India, being a signatory member of WTO, formulated its Patent Act in accordance with the TRIPs Agreement of WTO. The New Patent Act is likely to pose some certain serious challenges for the industry. The new framework may affect the R&D performance of the industry. The results of this paper reflect that TRIPs has induced more R&D expenditure in Indian pharmaceutical industry as both R&D expenditure and R&D intensity for post-TRIPs period are more than the values for pre-TRIPs period. Data on numbers of patent applications also reflect the increasing intention of pharmaceutical firms towards R&D activity during post-TRIPs period.

Keywords: Drugs, Pharmaceutical, TRIPs, Patent.

Introduction

During the first two decades of the planning period (1950 to 1970), growth of Indian drugs & pharmaceutical industry was very slow and industry was dominated by Foreign Companies. With a view to develop a self-reliant indigenous industry, Government took various protective steps in 1970s. One such a step was the adoption of Patent Act 1970. But, after the formation of WTO, the industry has witnessed a dramatic change with respect to policy environment. India, being a signatory member of WTO, formulated its Patent Act in accordance with the TRIPs Agreement of WTO. The New Patent Act is likely to pose some certain serious challenges for the industry. In this background, this paper presents the analysis of R&D performance of Indian pharmaceutical industry in post -TRIPs period.

Review of Literature

Various studies suggest that the new framework may affect the R&D performance of the industry. Ganguli (2003) and Lalitha (2002) in their study concluded that TRIPs is likely to induce greater innovation creation, more R&D expenditure and more patents by both Indian and foreign firms in bio-pharmaceutical sector. Similarly, analyzing the impact of TRIPs on R&D activity, the study by Kiran and Mishra (2009) found that growth in R&D of the industry as a whole was more in the post-TRIPs period (6.56) when compared to pre-TRIPs period (4.89). The same result was seen at firm level (top 9 Indian Pharmaceutical firms). The study by Joseph K Reji (2011) concluded that TRIPs is not likely to have a significant impact on incentives for innovation creation in pharmaceutical segment of India as the study observed a trend in the growth of R&D intensity, which began to decline after reaching its peak in 2005-06. Analyzing the patent holding pattern, study of Mainak et al (2009) showed that the patents in drugs and pharmaceutical industry have grown at a higher rate of 6.06 (2005-2008) percent per annum as against the 5.57 (1994-2008) percent growth of total patents granted.

Methodology of the Study

R&D performance was examined on the basis of two variables – expenditure on research & development, and numbers of patent application filed and patent granted from the Indian patent office. Expenditure on research & development was analysed by using firm level data for 543 firms which were accessed from CMIE Prowess Database covering the period from 1998 to 2015. Information regarding Patent application filed

and granted to the firms or institution was gathered from the Annual Report from 1998 to 2015 published by the Office of Controller General of Patents, Designs, and Trademark and Geographical Indication, Ministry of Commerce & Industry. Keeping in view the significance of study, the entire period was divided into two sub-periods – 1998 to 2004 (considered as pre- TRIPs period) and 2004 to 2015 (considered as post- TRIPs period)¹.

Analysis of R&D performance was carried out by classifying the pharmaceutical firms into AGE GROUP and OWNERSHIP GROUP. Accordingly, selected firms were classified as OLD firms (incorporated before 1970), MODERATE firms (incorporated between 1970 and 2005), and NEW firms (incorporated after 2004). Similarly, on the basis of ownership group, firms were classified as Indian owned firms, Foreign owned firms and Govt. owned firms. After these classifications, R&D expenditure of all these firms was analyzed both in absolute as well as in relative terms. In absolute term, firm's absolute figure of R&D expenditure was calculated. In relative terms, firm's R&D intensity was calculated. Numbers

of patent application filed as well as granted from the Indian patent office to the firms were also analyzed in both absolute as well as in relative terms. In absolute term, absolute figures of status of patent application were analyzed. In relative term, year wise growth rate as well as patent granted as a percentage of application filed was calculated. Findings and results of the analysis are presented below.

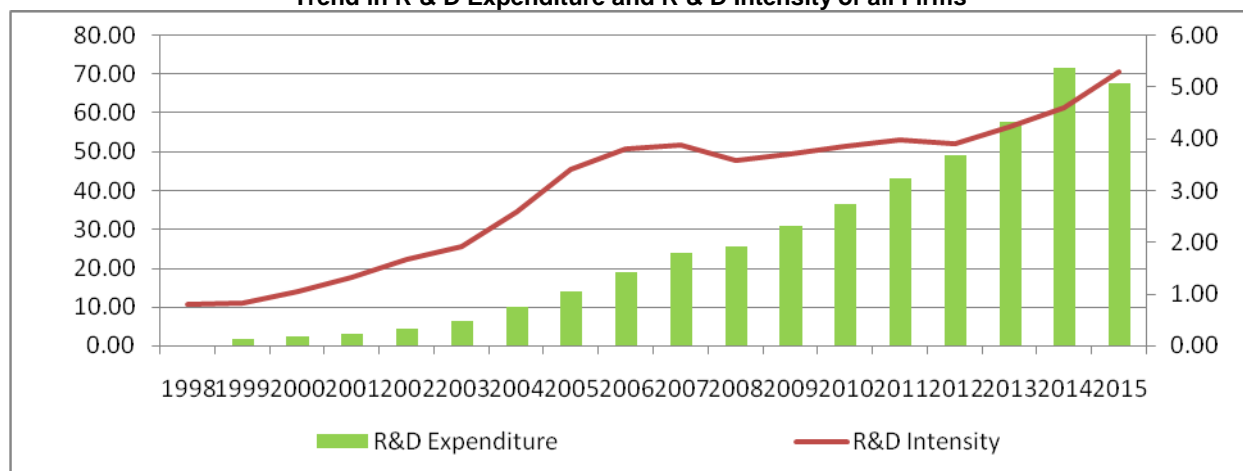
Analysis of R & D Expenditure

Trend in R & D Expenditure

On the basis of collected data for 543 firms, average R&D expenditure and R&D intensities (R&D expenditure as percentage of sales) were computed for different years and thereafter a trend was observed on these two parameters. The observed trends on average R&D expenditure and R&D intensities are depicted in figure-1. This figure clearly shows the increasing trend in both R&D expenditure as well as R&D intensity. It is evident from figure that average R&D expenditure has increased from Rs .023 billion in 1998 to Rs 67.81 billion in 2015 while average R&D intensity has increased by 0.81 percent in 1998 to 5.29 percent in 2015.

Figure-1

Trend in R & D Expenditure and R & D Intensity of all Firms



Source: Computed from PROWESS database

A comparative analysis of R&D performance of all firms was done by computing the average R&D expenditure and R&D intensity for two sub periods— pre- TRIPs and post- TRIPs period. Computed values are presented in table-1. This table clearly shows that both R&D expenditure and R&D intensity for post-TRIPs period are more than the values for pre-TRIPs

period. The corresponding values of t-statistics show that the difference between the R&D performances of two periods is statistically significant. This finding reflects that TRIPs has induced more R&D expenditure in Indian pharmaceutical industry. These findings are consistent with the findings of Ganguli (2003) and Lalitha (2002).

TABLE-1

Comparative analysis of R & D Performance of all Firms

(Values are in Rs. billions)

Indicator	Pre TRIPs Period	Post TRIPs Period	t-statistic [#]
	(1998-2004)	(2005-2015)	
R&D Expenditure	4.14	40.07	-5.9351008 [*]
R&D Intensity	1.46 (%)	4.02 (%)	-8.7646504 [*]

Source: Computed from PROWESS database

Ownership wise R&D Performance

Ownership wise of R&D performance are presented in table-2. This table clearly shows that both R&D expenditure and R&D intensities of Indian firms for post-TRIPs period are more than the values

for pre-TRIPs period. It is evident from the table that R&D expenditure and R&D intensity of Indian pharmaceutical firms in post TRIPs period (Rs 33.06 billion and 3.98 percent) are greater than the values of pre TRIPs period (Rs 2.98 billion and 1.45percent).

The computed values of R&D expenditure and R&D intensity for Foreign MNCs firms shows that both R&D expenditure and R&D intensities of Foreign MNCs firms for post-TRIPs period are also more than the values for pre-TRIPs period. It is evident from the table that R&D expenditure and R&D intensity of Foreign MNCs firms in post TRIPS period (Rs 4.10 billion and 6.93 percent) are greater than the values of

pre TRIPs period (Rs 1.63 billion and 1.38 percent). The corresponding values of t-statistics show that the difference between the R&D performances of two periods is statistically significant. Table – 2 also shows that R&D performance of Indian firms are far better than foreign firms in both the periods as in both period R&D expenditure as well as R&D intensity of Indian firms are greater than foreign firms.

Table –2
Ownership Wise R&D Performance
(Values are in Rs. billion)

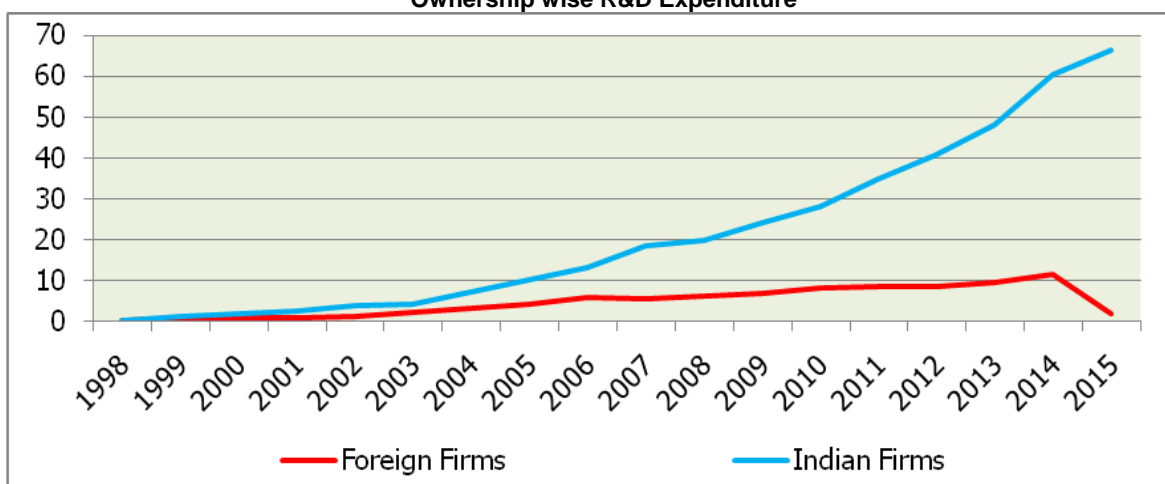
Indicator	Pre TRIPs Period	Post TRIPs Period	t-statistic [#]
	(1998-2004)	(2005-2015)	
Indian Firms			
Expenditure	2.98	33.06	-5.2367116
Intensity	1.45 (%)	3.98 (%)	-7.6686043
Foreign MNCs			
Expenditure	1.63	4.10	-5.820034
Intensity	1.38 %	6.93 %	-6.117361

Source: Computed from PROWESS database.

The comparative values of R&D expenditure and R&D intensity of foreign firms and Indian firms are also exhibited in figure – 2 and figure – 3 respectively. Though figure – 3 does not show any clear difference between R&D performances, figure – 2 clearly shows

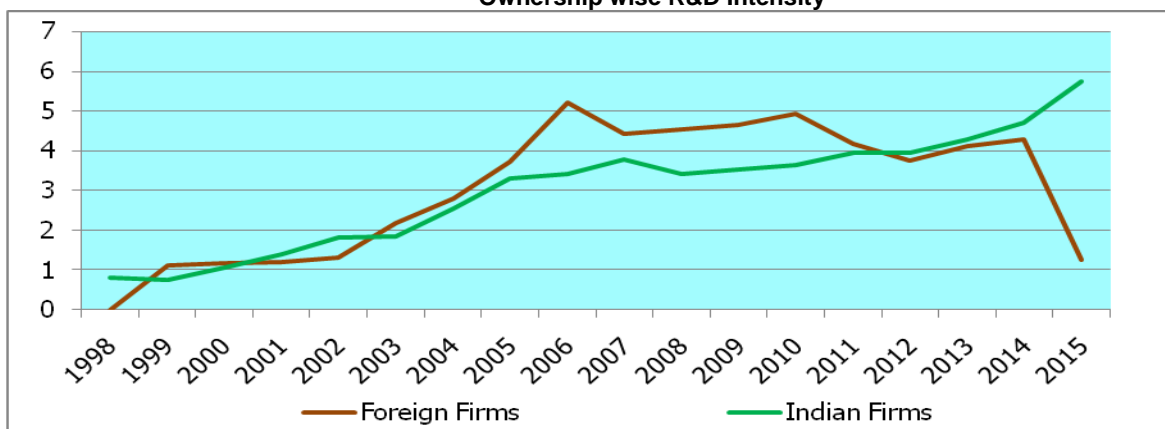
that during the post-TRIPs period, R&D activity of Indian firms are far better than the foreign firms as gap between the R&D expenditure of the two group of firms kept on increasing over the period of 2005-15.

Figure- 2
Ownership wise R&D Expenditure



Source: Computed from PROWESS database.

Figure- 3
Ownership wise R&D Intensity



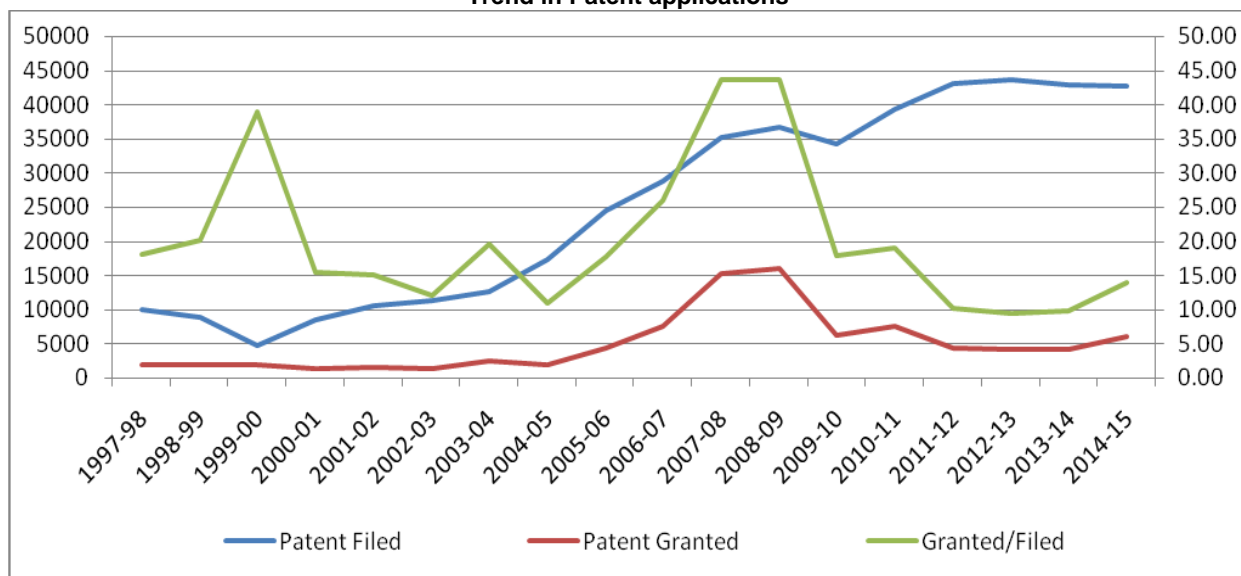
Source: Computed from PROWESS database.

**Analysis of Patent Application
Trend in Patent Application**

Data on numbers of patent application for the period 1997-98 to 2014-15 are depicted in figure -4 through three different trend curves. This figure shows that there is clear trend emerge for patent granted and patent granted/filled. But for patent filled, clearly an increasing trend is observed which reflect that number

of patent application kept on increasing throughout the entire period particularly in post-TRIPs period. Figure shows that number of patent application filed at Indian patent office has increased from 10155 in 1997-98 to 42763 in 2014-15. This trend reflects the increasing intention of pharmaceutical firms towards R&D activity during post-TRIPs period. These findings are consistent with the findings of Mainak (2009).

**Figure- 4
Trend in Patent applications**



Source: Computed from the Annual Reports of Office of Controller General of Patents

Comparative figures of numbers of patent applications of pharmaceutical firms in pre and post-TRIPs period are depicted in table - 3. This table clearly shows that both filled number of patent applications and granted number of patent applications of these firms for post-TRIPs period are far greater than the values for pre-TRIPs period. It is evident from the table that in post TRIPs period filled number of patent applications and granted number of

patent applications (37174.70 and 7567) are greater than the numbers in pre TRIPs period (10571.62 and 1774.12). The corresponding values of t-statistics show that the difference between the R&D performances of two periods is statistically significant. These results also reflect the increasing intention of pharmaceutical firms towards R&D activity during post-TRIPs period.

**Table- 3
Comparative analysis of Trends in Patent Applications
(Values are in Numbers)**

Indicator	Pre TRIPs Period	Post TRIPs Period	t-statistic [#]
	(1997-98 to 2004-05)	(2005-06 to 2014-15)	
Filed	10571.62	37174.70	-10.88573417
Granted	1774.12	7567.00	-4.067549218
Granted / Filed	18.78977	21.13839	-0.457542913

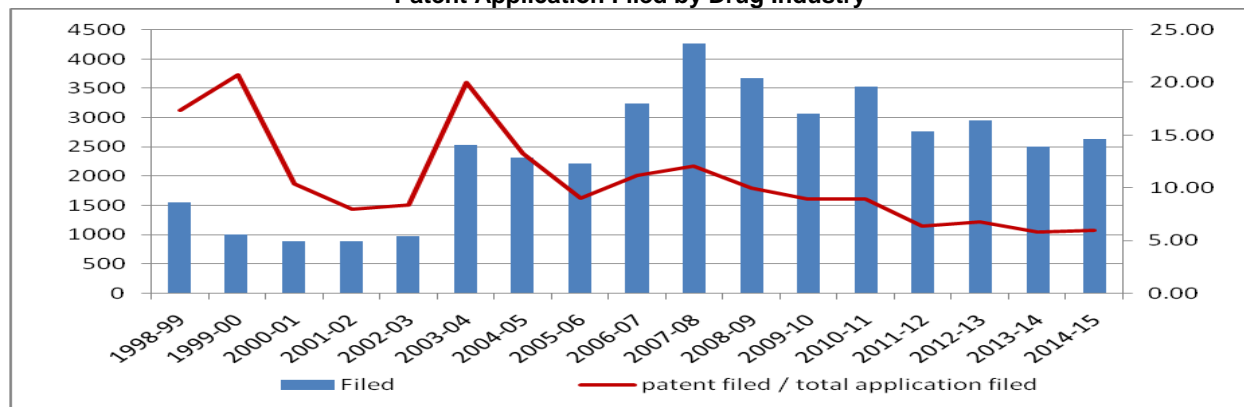
Source: Computed from the Annual Reports of Office of Controller General of Patents

Patent Application Filed by Drug Industry (Other than PCT National Phase)

Status of patent application analyzed earlier was the general analysis; in particular, the patent application status filed by drug industry other than PCT route is compiled from the annual reports to access the performance of pharmaceutical firms. The

observed data are depicted in figure-5. This figure shows that though the number of patent application filed by the drugs industry has been increasing throughout the period 1998-99 to 2014-15, but the share of patent application filed in total application filed has been declining during the period. Particularly, decline is sharp in post TRIPs period.

Figure- 5
Patent Application Filed by Drug Industry



Source: Computed from the Annual Reports of Office of Controller General of Patents

Comparative figures of patent application filled by drug industry are presented in table-4. This table also exhibits that though the number of patent application filed by the drugs industry has increased but the share of patent application in total application filed has declined in post- TRIPs period. It is evident

from the table that share of patent application in total application filed was 14.03 percent in pre TRIPs period which came down to 8.52 percent in post TRIPs period. The corresponding value of t-statistics shows that difference is statistically significant.

Table-4
Comparative Analysis Trends in Patent Applications
(Values are in Percentage)

Indicator	Pre TRIPs Period	Post TRIPs Period	t-statistic [#]
	(1997-98 to 2004-05)	(2005-06 to 2014-15)	
Filed	1446.29	3084.80	-4.96345668
Granted	282.29	632.80	-2.62207373
Filed/Total Filed	14.03	8.52	2.56010119

Source: Computed from the Annual Reports of Office of Controller General of Patents

Conclusion

The results of paper reflect that TRIPs has no adverse effect rather it induced more R&D expenditure in Indian pharmaceutical industry as both R&D expenditure and R&D intensity for post-TRIPs period are more than the values for pre-TRIPs period. The obtained results also show that both R&D expenditure and R&D intensities for post-TRIPs period are more than the values for pre-TRIPs period for both groups of firms (Indian firms and foreign firms). However, R&D performance of Indian firms are far better than foreign firms in both the periods as in both period R&D expenditure as well as R&D intensity of Indian firms are greater than foreign firms. Data on numbers of patent application also reflects the increasing intention of pharmaceutical firms towards R&D activity during post-TRIPs period. However, the share of patent application filed in total application filed has been declining during the period. Particularly, decline is sharp in post TRIPs period.

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Endnotes

1. The justification for this subdivision lies in the fact that it was the year 1999 in which the New Patent Act was introduced by the Government of India. But it was finally passed in the year 2005.