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# Research and Development, Patenting and Performance: Evidence from Indian Pharmaceutical Industry

Ishita G. Tripathy, Surendra S. Yadav and Seema Sharma

*Indian Institute of Technology, Hauz Khas, New Delhi-110 016*
*E-mail: ishita.tripathy@nic.in*

**ABSTRACT**

The Indian pharmaceutical industry (IPI) has been largely influenced by the changes in the patent regimes in India. This paper, besides reviewing the evolution of IPI, studies the trends of research and development (R&D) and patenting of pharmaceutical firms and identifies the determinants of R&D. It examines the interdependence between R&D and patenting, and firms' overall performance. Secondary data analysis indicates that the product patent regime has impacted the R&D intensity of IPI firms. The analysis of primary data collected from 64 pharmaceutical firms identifies three distinct clusters of firms of IPI. The firms' performance, measured by the rate of capital employed by the three groups of firms, indicates that superior R&D and a large number of patent filings need not necessarily imply a better performance. The paper adds to the extant literature on IPI by bringing forth implications which are important for formulating appropriate action plans to enable pharmaceutical firms to efficiently employ their resources in the product patent era.

**Keywords**: Indian pharmaceutical industry, patents, patent regime, Tobit, ROCE, cluster analysis, return on capital employed

## 1. INTRODUCTION

In recent times, technological innovation, low production and research and development (R&D) costs and availability of a huge skilled, well-educated, English-speaking manpower have propelled India's economic growth and competitiveness[1]. Technology-intensive sectors, like the pharmaceutical industry, have put India onto the global business atlas, with the Indian pharmaceutical industry (IPI) accounting for 10 per cent of world's production by volume and 1.5 per cent in terms of value[2]. The evolution of IPI can be broadly divided into four phases, in congruence with the changes in patenting regimes followed in the country. The first phase (1911 - 1970) was that of the product patent regime, established by the Patents and Designs Act, 1911. The regime helped multi-national companies (MNCs) to rule the Indian market by importing bulk drugs and processing these into formulations. Indigenous firms, in contrast, had to produce the corresponding bulk drugs for their formulations. The second phase (1970-1995) started with the replacement of product patents by process patents, introduced by Indian Patents Act, 1970. This phase enabled Indian firms to manufacture drugs using less expensive processes than those developed by the innovators, thereby boosting the growth of the indigenous firms vis-à-vis that of MNCs[3]. During the third phase (1995-2005), Patents (Amendment) Act, 1999, and Patents (Amendment) Act, 2002, were enacted, which provided for the implementation of the 'mail box', 'exclusive marketing rights' facilities and 'compulsory licensing', in conformance with the provisions of World Trade Organisation's Trade Related Aspects of Intellectual Property Rights[4].

With the establishment of a product patent regime by the enactment of Patents (Amendment) Act, 2005, drugs patented after 1995 were not allowed to be produced through reverse engineering[5]. Since 1995, the operational environment of the firms of IPI has undergone a tremendous transformation. The changed environment of patenting in India witnessed rapid alterations in the firms' operational and growth strategies[6]. Firms have resorted to setting up R&D units, demerger of R&D units from manufacturing set-ups, strong collaborations with research laboratories and separation of generics segment[4,7]. MNCs have viewed this changed patent era as an opportunity to expand their pharmaceutical business and acquired large firms[8]. In the new regime, the two-pronged strategy of MNCs has been to target the mass

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market through 'product localisation and India specific pricing' to capture the branded generics segment; and 'launch globally patented products in niche segments at a premium'[9,10]. In this backdrop, this paper examines the trend of R&D and patenting of firms of IPI and identifies the determinants of R&D. It tests the underlying hypothesis that distinct groups of firms, identified according to the R&D activities and patenting trends, have performance differentials.

## 2. METHODOLOGY AND DATA USED

This study relies on both secondary and primary data and covers all large firms of IPI. Large firms are those firms which have a minimum investment of Rs. 10 crore on plant and machinery[1]. The reference period of this study is from 2001-02 to 2008-09, i.e. the last four years of the process patent regime and the first four years of the product patent regime. As per data available from the Prowess database of Centre for Monitoring Indian Economy (CMIE), during the year 2008-09 there were 183 such pharmaceutical firms.

### 2.1 Secondary Data

Secondary data analysis covers data of all 183 large firms for the years 2001-02 to 2008-09. To understand the R&D behaviour of IPI, the R&D intensity of pharmaceutical firms was estimated, using a Tobit model. The Tobit model was found to be appropriate for the analysis because the dependent variable, R&D intensity, is continuous, but its range is constrained[11] since a large number of firms in the sample do not have R&D activities, rendering a null value for the dependent variable. The description of the independent variables and their expected relationship with the dependent variable is given in Table 1. The relationship between the dependent and independent variables in the Tobit model used in this study can be presented in the following form:

$$RDI=\beta_1 PRdum+\beta_2 Odum+\beta_3 A+\beta_4 S+\beta_5 S^2+\beta_6 KM+ \beta_7 X+\beta_8 FDI+\beta_9 PR+\beta_{10} IA \quad \text{if } X_{it}\beta + u_{it} > 0 \qquad (1)$$

$$= 0 \quad \text{if } X_{it}\beta + u_{it} \leq 0$$

where, RDI is the dependent variable; $\beta$ is the vector of unknown parameters which determine the relationship between the independent variables and the latent variable; and $X_i$ is the vector of explanatory variables.

$$u \sim N(0, \sigma^2)$$

Due to some missing data, an unbalanced panel data of 173 firms for eight years was used. The firm-year observations were 1,243.

### 2.2 Primary Data

The primary data was collected at two levels, expert level and firm level, between September 2009 and October 2010. Based on discussions held with experts drawn from the industry, Government of India and academia, on important aspects of IPI, a questionnaire for the firm-level survey was prepared and administered to the pharmaceutical firms. The questionnaire was of closed type and included questions regarding R&D and patents. The firms were asked to indicate their perception on a five point Likert scale. A pre-testing of the questionnaire was done on a sample of 21 pharmaceutical firms through personal interviews and e-mails. Changes, wherever necessary, were made according to the feedback received from the pre-testing.

Thereafter, the final questionnaire was e-mailed to all the firms. This was followed up by telephone calls and personal interviews. Sixty four responses were found suitable for analysis. Keeping in view the multivariate nature of the factors/variables incorporated into the questionnaire, cluster analysis was found to be the suitable statistical tool for analysis[12]. The responses received were subjected to a cluster analysis with the help of Statistical Package for Social Sciences. Initially, the number of clusters was found out by running a hierarchical cluster analysis of the responses. Agglomeration schedule and dendrograms were used to group the firms according to the similarity in their R&D and patenting characteristics. With the help of Euclidean measure of distance, the firms with similarities (which were a short distance apart), and those with

**Table 1. Variables used for Tobit Model**

| Dependent variable for tobit estimation: R&D intensity, 'Y' | | |
|---|---|---|
| **Independent variables** | **Description** | **Expected relationship** |
| Patent regime, 'PRdum' | PRdum = 1 for 2005-06 to 2008-09<br>= 0 for 2001-02 to 2004-05 | + |
| Ownership, 'Odum' | Odum = 1 if domestic ownership;<br>= 0, otherwise | + |
| Age, 'A' | Age of the firm in number of years. | + |
| Firm size, 'S' | Sales of the firm | + |
| Square of firm size, $S^2$ | Square of the sales of the firm | +/- |
| Intensity of capital imports, KM | Ratio of capital imports to sales | +/- |
| Intensity of goods exported, X | Ratio of export of goods to sales | + |
| Intensity of foreign direct investment | Ratio of FDI to sales | + |
| Profit rate, PR | Ratio of profit to sales | + |
| Ratio of intangible assets to sales, IA | Ratio of intangible assets to sales | + |

dissimilarities (which were a long distance apart), were found to form three distinct groups, with firms within the groups showing similar characteristics. The number of clusters was identified by the distances between the clusters and by a sudden gap in the distance coefficients. Having identified the number of clusters as three, a *k*-means cluster option was run on the data. The final cluster centres were obtained for each variable. From the final cluster centres, the average values of each variable for a cluster were interpreted. Return on capital employed (ROCE) is a popular performance measure and relates the profits of a firm to the capital employed by it[13]. Capital employed refers to long-term funds supplied by the lenders and owners of the firm. ROCE is calculated as:

A high ROCE indicates an efficient use of the capital employed. To estimate performance differentials across the three different groups of firms identified by the cluster analysis, ROCE was used.

$$\text{ROCE} = \frac{\text{Profit before interest and tax}}{\text{Average total capital employed}} \times 100 \qquad (2)$$

## 3. ANALYSIS AND DISCUSSIONS

### 3.1 Secondary Data

For the pharmaceutical industry, the number of patent applications recorded an annual quantum jump of 161.4 per cent during 2003-04, a year prior to the introduction of the product patent regime (Table 2).

As a proportion of total patent applications in the country, the IPI recorded its largest share (20 %) during 2003-04. Thereafter, although there have been some fluctuations in the share of IPI in total patent applications in the country, the IPI maintained a minimum share of 9 per cent in the subsequent years (2004-05 to 2008-09) and the absolute number of applications continued to remain high.

There were 71 large firms which had filed applications for patents either in India or abroad during 2001-02 to 2008-09[15, 16]. Of these, 29 firms applied for Indian patents, 10 filed for patents outside the country and 32 filed for patents both within India and outside. Between 2001-02 and 2008-09, within India, 3,241 patents had been filed by 61 firms. Outside India, 43 firms had applied for 1,667 patents during the same period. There is a heavy concentration of firms which have less than five patent applications in both India and abroad (Table 3). On the other end of the spectrum, there are very few firms with more than 100 applications. There are eight firms with applications of more than 100 within the country and four have more than 100 filings outside the country. Each of the 14 firms which had patent filings of more than 50 in India, also had filings outside the country. The 24 firms which had less than five patents in India, had not filed for any patents outside the country.

The focus of IPI is shifting towards R&D, with more and more firms spending larger shares of their sales on R&D (Table 4). Between 2001-02 and 2008-09, the

**Table 2. Number of applications for patents under various fields of inventions**

| Year | Total | 2001-2002 to 2008-2009 | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Chemicals | Pharmaceuticals | Food | Electrical | Mechanical | Electronics | Biotechnology |
| 2001-02 | 10,592 | 778<br>(7.3) | 879<br>(8.3) | 110<br>(1.0) | 731<br>(6.9) | 1,174<br>(11.1) | 0<br>(0.00) | 2<br>(0.02) |
| 2002-03 | 11,466 | 776<br>(6.8) | 966<br>(8.4); {9.9} | 119<br>(1.0) | 690<br>(6.0) | 1,257<br>(11.0) | 0<br>(0.00) | 46<br>(0.4) |
| 2003-04 | 12,613 | 2,952<br>(23.4) | 2,525<br>(20.0); {161.4} | 123<br>(1.0) | 2,125<br>(16.8) | 2,717<br>(21.5) | 0<br>(0.00) | 23<br>(0.2) |
| 2004-05 | 17,466 | 3,916<br>(22.4) | 2,316<br>(13.3); {-8.3} | 190<br>(1.1) | 1,079<br>(6.2) | 3,304<br>(18.9) | 2,787<br>(16.0) | 1,214<br>(7.0) |
| 2005-06 | 24,505 | 5,810<br>(23.7) | 2,211<br>(9.0); {-4.5} | 101<br>(0.4) | 1,274<br>(5.2) | 4,734<br>(19.3) | 5,700<br>(23.3) | 1,525<br>(6.2) |
| 2006-07 | 28,940 | 6354<br>(22.0) | 3,239<br>(11.2); {46.5} | 1223<br>(4.2) | 2,371<br>(8.2) | 5,536<br>(19.1) | 5,822<br>(20.1) | 2,774<br>(9.6) |
| 2007-08 | 35,218 | 6,375<br>(18.1) | 4,267<br>(12.1); {31.7} | 233<br>(0.7) | 2,210<br>(6.3) | 6,424<br>(18.2) | 4,842<br>(13.7) | 1,950<br>(5.5) |
| 2008-09 | 36,812 | 5,884<br>(16.0) | 3,672<br>(10.0); {13.9} | 340<br>(0.9) | 2,319<br>(6.3) | 6,360<br>(17.3) | 7,063<br>(19.2) | 1,844<br>(5.0) |

Note*: Figures in round parentheses are percentage of total patent applications.*
*Figures in curly parentheses are percentage growth over the previous year.*
*Source: Adapted from Tripathy*[14]

Table 3. Number of firms which filed applications for patents: 2001-2002 to 2008-2009

| Patents filed | In India | Outside India |
|---|---|---|
| More than 100 | 08 | 04 |
| 50 to 100 | 06 | 05 |
| 25 to 50 | 06 | 03 |
| 10 to 25 | 08 | 03 |
| 5 to 10 | 09 | 05 |
| Less than 5 | 24 | 22 |
| Total | 61 | 42 |

Table 4. R&D expenditure by large pharmaceutical firms: 2001-02 to 2008-09

| Year | R&D (in Crore) | Proportion of firms with more than 3 % R&D intensity (%) | R&D intensity (%) |
|---|---|---|---|
| 2001-02 | 674.37 | 14.5 | 3.2 |
| 2002-03 | 882.07 | 09.8 | 3.6 |
| 2003-04 | 1,415.69 | 18.2 | 3.9 |
| 2004-05 | 1,742.67 | 23.0 | 4.7 |
| 2005-06 | 2,424.74 | 25.8 | 5.2 |
| 2006-07 | 2,612.99 | 29.4 | 4.5 |
| 2007-08 | 3,124.58 | 25.0 | 4.6 |
| 2008-09 | 4,248.25 | 23.8 | 5.4 |

*Source: Prowess Database, CMIE*

proportion of firms investing more than 3 per cent of their sales in R&D activities grew from 14.5 per cent to 23.8 per cent. Despite an increase in the number of firms incurring R&D expenses, a large proportion (66.4 per cent) of the firms either did not invest at all or invested less than 1 per cent of their total sales on R&D in 2008-09.

The determinants of R&D intensity of firms of IPI were identified using a Tobit model. The coefficients of the dummies for patent regime, 'PRdum', and ownership 'Odum', were significant, implying that the new patent regime and domestic ownership were likely to contribute significantly to R&D intensity (Table 5).

The variables, size, measured by sales, '*S*', and the square of size, '$S^2$', were significant and indicated an inverted 'U' shaped relationship with the dependent variable. The coefficient of the intensity of imports of capital goods, 'KM', was positive and significant, indicating a complementary relationship with in-house R&D.

The coefficient of profit rate, 'PR', was significant and positively related to the dependent variable. The coefficients of other independent variables did not have a significant impact on the dependent variable. Thus, the patent regime was found to be an important determinant of R&D intensity, along with domestic ownership, size of firms, intensity of capital imports, and profit rate.

Table 5. Results of Tobit estimation: N = 1,243 (unbalanced panel data of 173 firms)

| Dependent variable independent variables | R&D Intensity Coefficients | |
|---|---|---|
| PRdum | 7.19265 | * |
| Odum | 25.28886 | * |
| A | -0.0834039 | |
| S | 0.0061551 | *** |
| $S^2$ | -0.000003 | *** |
| KM | 8.261369 | * |
| XG | 0.1019723 | |
| FDI | -3.649337 | |
| PR | 0.6353571 | *** |
| IA | 1.090348 | |
| Constant | -47.54288 | |
| $\chi^2(10)$ | 851.24 | |
| Log Likelihood | -5953.0685 | |
| Prob>$\chi^2$ | 0.0000 | |

**: Significant at 10%. ***: Significant at 1 %*

## 3.2 Primary Data

Out of the 64 firms which participated in the primary survey, there were 60 indigenous respondents and four MNCs. Each of the respondents had their own in-house R&D units, within India. On an average, a firm invested Rs. 1,971 crore on plant and machinery. During the reference period, 2001-02 to 2008-09, the firms reported annual average domestic sales of Rs. 4,315 crore and annual average exports of Rs. 1,495 crore.

The annual average R&D investment during the reference period was Rs. 241 crore, with an intensity of 5.6 per cent. Besides these quantitative variables, respondents were asked to indicate their preferences on other parameters like nature of R&D activities, R&D laboratories, R&D personnel, IPR, collaboration with research institutes, R&D strategy and patents.

The responses of these firms were subjected to cluster analysis. From the analysis, three groups emerged (Table 6). The first group consisted of six firms, the second and third groups had 17 and 39 firms, respectively. Amongst the three groups of firms, some of the firms of the first group were found to be investing on R&D related to new products. All the remaining firms were engaged in R&D entailing new processes and modifications in existing products and processes. The first group had the highest mean number of patent applications both in India and outside the country. Besides, it had the highest mean R&D intensity.

The mean ROCE of the first group was the lowest and that of the second group was the highest. One-way ANOVA procedure showed that the ROCE means of the three groups were significantly different from each other at

Table 6. Means of variables for the three groups

| Parameters | Measurement scale/unit | Means | | |
|---|---|---|---|---|
| | | Group 1 | Group 2 | Group 3 |
| Members | Number | 006.0 | 17 | 41 |
| Mean number of patents applied for in India | Number | 197.3 | 59 | 10 |
| Mean number of patents applied for outside India | Number | 225.7 | 80 | 02 |
| Mean R&D intensity | per cent | 007.1 | 4.3 | 2.4 |
| ROCE | per cent | 017.7 | 27.1 | 21.3 |

5 per cent level of significance. Thus, a large number of patent applications and R&D for new products may not necessarily translate into a higher ROCE. This reiterates the fact that higher-end R&D is expensive.

## 4. CONCLUSIONS

The focus of IPI is shifting towards R&D, with more and more firms spending larger shares of their sales on R&D. The number of patent applications of IPI has continued to remain high since 2003-04. The product patent regime has impacted the R&D intensity of IPI firms. The patent regime is an important determinant of R&D intensity, along with domestic ownership, size of firms, intensity of capital imports and profit rate. An analysis of performance differentials between firms of IPI indicated that superior R&D and a large number of patents need not necessarily imply a better performance of firms.

The policy implications of this study are important for the pharmaceutical industry for formulating appropriate action plans to enable firms to efficiently employ their resources in the new patent era. In-house R&D conducted by pharmaceutical firms would get a further boost if their research is backed by industry-academia collaborations. Indian firms need to revisit the spectrum of activities involved in their R&D, so that these culminate in patents.

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