Challenges and Prospects of Indian Pharmaceutical Sector:
R&D, Innovation and Profitability Perspectives

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1. Introduction
Innovative strategy is central to a firm’s competitive advantage as they help to develop superior new products/technologies with a well-defined competitive advantage (Bhagwat and De Bruin 2011, Ettlie 1998, Lev and Sougiannis 1996), especially in knowledge intensive areas such as drug and pharmaceutical industry. In this industry, the firms need to continuously innovate by developing and marketing new products, drug delivery systems, and product attributes, based on cutting-edge scientific advances, as part of survival and growth strategies at national and global levels. Understanding that product life cycles have become shorter and numerous regulatory challenges are emerging faster, this industry spends far more on R&D, relative to its sales revenue, as compared to almost all other industries. The pharmaceutical industry is seen as analogous to drilling for oil which involves many dry holes and a very few gushers (U.S. Congress 1993).

2. R&D and Patenting Scenario in Indian Drug and Pharmaceutical Industry
Low R&D intensity in Indian D&P industry can be attributed to the fact that until 2005 Indian leading pharmaceutical firms were into production of generic drugs through non-infringing processes which required a low level of investment as compared to development, testing, producing and marketing of new drugs and novel drug delivery systems (NDDS) (Joseph 2011, Ray 2010, Chaudhary 2005, Kumar 2005). Since 1999, a noticeable shift in the attitude towards The most remarkable change, nevertheless, is evident during 2004-09 when the firms started investing far more resources towards R&D activities, as part of the strategic shift, induced by changed business environment. Some of the firms, especially large sized, started focusing on Novel Drug
Delivery Systems (NDDS), and expanding production facilities by importing latest capital goods and it appears that these firms have focused on generating patents before the amendment of the Indian Patent Act as per the TRIPS obligations in 2005, in order to have ‘knowledge stock’ as bargaining leverage. The fact that the acquisitions of these patents did not lead to any indication of the appropriation of the same towards successful patent applications, the significance of these patents in generating private/social value addition stands uncertain. In such cases, the patent counts remain a ‘noisy indicator’ of R&D productivity. Interestingly, the decline in the patent yield was accompanied by an exceptional rise in the R&D intensity. Interestingly, while the international pharma majors are into novel drug discovery research, Indian pharmaceutical firms have been investing in development of bioequivalent copies of existing and patent expired blockbusters and me-too drugs targeted for ever-greening the molecule (Ray 2010, Ray and Bhaduri 2004). The patents, so far executed by Indian pharma / biotech companies, are mostly derivative compounds and that is the reason for much lower R&D expenditure and intensity of Indian pharmaceutical firms, as there was any evidence of any research involving New Chemical Entities (NCE) and clinical trials.

3. Database, Methodology, and Conceptual Framework

3 (a). The Database:
The study uses inflation adjusted financial data at industry level for Indian Drugs and Pharmaceutical (D&P) industry time period from 1995 to 2011, drawn from Prowess Database of Centre for Monitoring Indian Economy (CMIE). Patent data has been taken from website of office of the patent controller of India.

3 (b). The Methodology:
The dependent variable for the study is a count one following the Poisson distribution. PTN is having a Poisson distribution with parameter μ as it takes integer values 0; 1; 2; ... Since the mean is equal to the variance, any factor that affects one will also affect the other. Thus, the usual assumption of homoscedasticity would not be appropriate for Poisson data.

3 (c). Conceptual Framework:
Table 2 presents and defines the list of independent variables that are postulated to be affecting the innovation output in Indian pharmaceutical firms.

Table 2: Determinants of Patenting Activity in ID&PI.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Symbols</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patents counts</td>
<td>PTN</td>
<td>Total patents granted to ID&amp;PI in the year of study</td>
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Independent Variables

<table>
<thead>
<tr>
<th>Past R&amp;D Intensity</th>
<th>LRDI&lt;sup&gt;t-3&lt;/sup&gt;</th>
<th>Ratio of aggregate R&amp;D expenditure of ID&amp;PI to aggregate total sales revenue (in %) at time t-3</th>
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<tbody>
<tr>
<td>Past Marketing and Advertising Intensity</td>
<td>LMAI&lt;sup&gt;t-3&lt;/sup&gt;</td>
<td>Ratio of aggregate Marketing and advertising expenditure of ID&amp;PI to aggregate total sales revenue (in %) at time t-3</td>
</tr>
<tr>
<td>Past Profitability</td>
<td>(LPI&lt;sup&gt;t-3&lt;/sup&gt;)</td>
<td>Ratio of aggregate profit after tax of ID&amp;PI to aggregate total sales revenue (in %) at time t-3</td>
</tr>
<tr>
<td>Patent Protection Regime</td>
<td>(PPDUM)</td>
<td>Taken as dummy variable; assume 1 if product patent regime, 0 otherwise</td>
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Considering the abovementioned determinants, the basic econometric specification can be expressed as given below

\[
PTN = \beta_0 + \beta_1 LRDI_{t-3} + \beta_2 LPI_{t-3} + \beta_3 LMAI_{t-3} + \beta_4 PPDUM + \varepsilon_t \quad (1)
\]

This conceptual framework allows formulating a set of empirically testable hypotheses.

4. Results and Discussion

The results of the Poisson regression model are displayed in Table 3. Standardized coefficients of independent variables have been provided which are, by construction, scale free and appropriate for comparing the relative strengths of the independent variables in terms of effect on the dependent variable. Results of post-estimated tests of skewness, kurtosis and heteroskedasticity suggest that selected sample is non-skewed and homoscedastic.

Table 3: Determinants of Patents: Poisson regression model.

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Coefficients</th>
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<tbody>
<tr>
<td>LPI&lt;sup&gt;t-3&lt;/sup&gt;</td>
<td>0.0907456</td>
</tr>
<tr>
<td>LMAI&lt;sup&gt;t-3&lt;/sup&gt;</td>
<td>1.051646</td>
</tr>
<tr>
<td>LRDI&lt;sup&gt;t-3&lt;/sup&gt;</td>
<td>0.3787175</td>
</tr>
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</table>
Profit intensity lagged by three years bears a positive and statistically significant impact on the total patent counts of ID&PI. One percent increase in profit intensity increase total patent counts by 0.09 per cent. This finding is consistent with earlier research findings.

Past marketing and advertising intensity emerged as the most dominating variable. This finding turned out to be as expected one because theoretical underpinnings suggest that with an emphasis on alternative strategy of increasing marketing and advertising expenditure firms in ID&PI tends to move ahead with patents filing so that they can capture market gradually.

Past R&D intensity also depicts the positive a significant relationship with patent counts. The literature has implicitly or explicitly assumed that the patent-to-R&D ratio is driven by a research productivity stage (the extent to which additional units of R&D generate additional inventions) and a propensity-to-patent stage.

Patent Protection Regime as a dichotomous variable also exhibits a strongly significant and inverse relationship with patent counts. It implies that after the introduction of product patent regime in 2005 industry started to go for less patent filings and patent counts also declined and this is expected from a generic and imitative industry like ours. In stronger patent regime firm could not evergreen their patents and go for copy a different process for patents.

5. Conclusion
In this paper, we reviewed the most relevant determinants of patent counts. What has emerged is that innovation is a complex and multifaceted phenomenon and that a large amount of factors tends to influence it. The presence of many difficulties in studying patent counts is confirmed by the fact that diverse theoretical approaches coexist in the economic literature and, in fact, to present the analysis of the determinants of innovation, it has been necessary to consider all these different perspectives. However, to increase R&D spending is not sufficient. We discussed the analysis of the economics of intellectual property right protection showing how there is no general agreement on which is the best patent policy to promote innovation. We showed also that there are differences among industries concerning the effects of patents on technological change patterns. A better understanding of these issues is an obvious goal for future research. A promising field of enquiry is to analyze the effects of alliances, mergers and acquisitions and other forms of collaboration on innovation from an antitrust perspective.
References


