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Domestic market competitiveness of Indian drug and pharmaceutical industry

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Abstract

This paper attempts to analyse the competitiveness of Indian drug and pharmaceutical industry in the domestic market where multinational pharma companies are entering and expanding in a big way, especially after enforcement of product patent regime in 2005. The study applied data envelopment analysis model to estimate relative efficiency and productivity changes in 141 Indian pharmaceutical firms during 2000–2001 to 2012–2013 which encompass pre- and post-product patent regimes. The present study found negative impact of Product Patent Act on the efficiency scores. The technological change factor is found to have played positive role in the growth of productivity, whereas technical efficiency change depicts the judicious utilization of input resources for improving performance. A sensitivity analysis with the inclusion of R&D expenditure in input variables, confirmed the validity of our selected variables. It found marginal bearing of new patent regime on the efficiency of R&D active firms, though it was found to have significantly impacted efficiency scores of large firms, R&D intensive firms, and group-owned firms. The study reported that large size, R&D intensive, private-foreign owned and those engaged in drug formulations exhibit better performance. Further, it is found that ownership, capital imports intensity and size have a positive and significant relationship with efficiency scores, whereas the age, time dummy and size square variables are inversely related. The results suggest that Indian firms need substantive improvements in efficiency by adopting best managerial practices, ensuring optimum utilization of resources, and investing significantly in the technology and products innovation.

Keywords India · Pharmaceutical industry · Efficiency · Productivity · Data envelopment analysis · R&D · Size · Ownership · TRIPS · Product patent

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1 Introduction

The Indian Drug and Pharmaceutical industry (ID&PI) is considered to be one of the most dynamic and vibrant industries for being the largest producers and exporters of the generic drugs[1] across the globe. It certainly has achieved a significant scale and levels of products and technological capability for manufacturing drugs cost-effectively to emerge as a major competitor in the world market for generic drugs.

It may be mentioned here that the structure of ID&PI has undergone major changes over time. The introduction of process patent regime in 70s, provided a great fillip to ID&PI, which certainly made rapid strides and emerged as world's one of the leading drug and pharmaceutical industry. However, with rising proactive actions on the part of governments across the world in terms of medical products' safety, practices adopted by the producers, the market has become far more demanding. The pharmaceutical firms have not only to adhere to the best management and production practices, meet stringent requirements of the regulating agencies, but also have to become far more efficient and norms-compliant. This study primarily focusses on the efficiency and productivity of Indian drug and pharmaceutical firms in the domestic market during pre- and post-product patent regimes. It also analyses factors affecting their performance.

For analyzing efficiency and productivity, the instrument of Data Envelopment Analysis (DEA) has been consciously preferred as it is driven by its intrinsic advantages over other techniques for measuring the relative efficiency and productivity of producing firms. First, in DEA, there is no need to specify any explicit functional form for the production function and mathematical programming techniques can be used to get pointwise estimates of the production function. In case of parametric stochastic frontier analysis (SFA), on the other hand, there is need to impose an explicit parametric form for the underlying technology and an explicit distributional assumption for the inefficiency term (Coelli et al. 2005). Second, multiple inputs and multiple outputs can be analyzed simultaneously in DEA. Third, DEA identifies the inefficiency in a particular firm by comparing it to similar firms regarded as efficient, rather than trying to associate a firm's performance with statistical averages (Avkiran 2006). Nevertheless, DEA also suffers from some limitations. First, it is an extreme point technique; therefore, errors in measurement can cause significant problems in the results. Second, the selection of input and output variables is an important task in DEA analysis. The inappropriate selection of input and output variables may lead to misleading results. The results are also influenced by the number of observations. In order to address these problems, the appropriateness of selected input and output variables in terms of discriminatory power of the model has been checked on the basis of a sensitivity analysis. Further, the issue of measurement error has been addressed by scrutinizing data for outliers. The notable contribution of this study lies in the fact that the time, the impacts of pre and post-product regimes are being accounted for. Precisely, this study takes four objectives:

[1] Generic drugs: Copies of off-patent brand-name drugs that come in the same dosage, safety, strength, and quality and for the same intended use. These drugs have received market approval based on proof of bio-equivalence to the originator's product (Grace 2004).

1. to analyze the efficiency and productivity in pre and post-product patent regimes.
2. to examine the impact of R&D variable on efficiency & productivity of ID&P firms and evaluate the performance of R&D active firms.
3. To analyze domestic market competitiveness across different categories of firms.
4. To identify the factors that determines efficiency of ID&PI.

The remainder of the paper is organized in the following ways. The next section briefly discusses the evolution and structure of ID&PI. The following section reviews the literature on the efficiency and productivity of ID&PI. The subsequent section describes the methodology of DEA models used in the present study. The description of the data and variable construct are reported in the succeeding section. The penultimate section presents the empirical results of efficiency, productivity, R&D active firms and their performance, domestic market competitiveness across different categories of firms, and determinants of efficiency. Finally, the last section presents the conclusions and policy suggestions.

1.1 Evolution and structural changes in ID&PI in product patent regime

Table 1 highlights the key features of the evolution of ID&PI which brings to the fore that the structure of ID&PI has undergone major changes over the period of time. The most notable change that can be discerned from Table 1 is that shift from process to product patent regime in 2005 under Trade Related Intellectual Property Rights agreement (TRIPS[2]) posed a major challenge to the ID&PI that had flourished under the process patent regime of 1970, almost forcing them to reorient themselves to initiate their own R&D and also to look for contract manufacturing and research. Consequently, the number of patents filed and acquired in the industry went up rapidly during 1990s. Larger firms have also ventured out offshore locations to capitalize upon local production and distribution networks, technology and new products (Lanjouw 1998; Grace 2004; Jha 2007; Rao 2008; Tyagi et al. 2014; GOI 2014).

There has been drastic structural changes in ID&PI in new patent regime especially in R&D, mergers and acquisitions, ownership and concentration ratio. The ID&PI is highly fragmented with top twenty firms claiming for majority of the market share which demonstrates the oligopoly nature of the industry. The Concentration Ratios for top firms have been increasing which suggest an increase in the market power of larger firms especially after 2009, probably because of increasing mergers and acquisitions activities. Nearly about 70% of the market

[2] According to this agreement, all the member countries had to grant 20-year patents on pharmaceutical products since January 1, 2005. This new product patent regime, outlawed the generic production of new patented medicines. It provided the freedom that all the approved generic drugs of India could still be sold in the market, after paying for the license fees. Under this Act, generic manufacturer after paying a reasonable royalty can apply to copy a patented drug, but only after it has been marketed for 3 years (Dhar and Gopakumar 2011).

Table 1 Key features of the evolution of the Pharmaceutical Industry of India. *Source*: Adapted from Pradhan 2010

Phase	Period	Key features
I	1850–1945	British India introduced allopathic form of medicine on a larger scale. Initially, the drug production was low in the country but increased with the entry of new firms
II	1945–1970	Establishment of public sector units (PSUs). MNCs were importing bulk drugs and processing and selling them into final products or formulations in India. Domination of MNCs increased. Share of indigenous companies reduced from 62 to 32% in 1970
III	1970–1995	Indian Patents Act, 1970 was modified in favour of Process Patent. Large numbers of generic version of patented drugs were introduced, which led to significant fall in the prices of medicines. Unprecedented growth of indigenous firms
IV	1995–2005	WTO came into effect. Compulsory to introduce product patents from 2005 onward. Phase of liberalisation, de-control and transition period from process patent regime to product patent regime. Export led growth and increase in domestic consumption
V	Since 2005	Shift from process-based patenting to product patents. R&D expenditure rose rapidly. Rise in the number of cases of mergers and acquisitions

share, in terms of net sales revenue, was captured by top 50 firms in 2012–2013 (Mahajan et al. 2014). This phenomenon is characterized by the dominance of Indian companies owning almost 80% of the market, though the share of foreign firms has started registering rising trend in recent years. Further, the impact of product patent was largely felt on R&D behavior of firms. Interestingly, there has been a phenomenal escalation in the R&D expenditure incurred by Indian companies, especially after the signing of TRIPs in 1995, although a rising trend is discernible even before that. It picked up momentum by 2000 and attained peak in 2006 after which it stabilized. The R&D intensity of the industry has risen to around 5% by 2013 from negligible percent in 1990. However, increased R&D investment is not all pervasive in the ID&PI, but is limited to small number of larger companies (Tyagi et al. 2016).

Exports have been the mainstay of most of the Indian firms in the organised sector. The export of formulation has shown remarkable growth in the recent decade to developed markets such as US. Foreign trade in bulk drugs, on the other hand, exhibit trade deficit. The exports of bulk drugs grew faster than the export of formulations, while growth rate of formulations imports exceeded that of the imports of bulk drugs in the post-modified India Patent Act era (Kallummal and Bugalya 2012; Mahajan et al. 2015).

There have also been vigorous efforts on the part of MNCs to acquire the on-going concern in order to deeply penetrate the large Indian branded generic market, and also to use these acquisitions to strengthen their product and supply chain pipe lines. A strong and growing domestic market, strong generics portfolio of Indian firms with presence in high growth/high margin therapeutic categories such as acute and chronic disease segments, manufacturing prowess (highest number of USFDA approved plants outside US), cost competitiveness of Indian companies, and their outreach have made them as one of the most sought-after in the M&A space. As a result, this industry has witnessed mergers, acquisitions and consolidation in recent years which not only encouraged MNCs to improve access to the domestic market but also gain foothold in the target global market (IMAP Industry Report 2015; CII-PwC 2013).

Table 2 provides information on the recent acquisitions of and by Indian pharmaceutical firms. MNCs are also forming alliances and partnership with Indian pharma companies for contract manufacturing and supply of drugs and formulations, to the advantage of both the parties involved. Indian companies, on the other hand, have also acquired overseas firms in order to move up the value chain, expand footprints into under-explored/unexplored geographical territories, and diversify their business models. Although, the coverage of drugs under price controls has enlarged, yet overall regulatory climate supports growth and development of the industry. It has significantly moved up from a tight control to much more liberalised regime. The industry has many challenges ahead and opportunities for future growth. The challenges come from R&D intensity, growing competition from Israel, low brand value of India in global market, tightening of safety and efficacy testing requirements (Sharma et al. 2010).

Table 2 Recent acquisitions of and by Indian pharmaceutical firms. *Source*: CII-PwC (2013); ICRA Limited, 2012; KPMG, 2011 and Annual Reports of the companies

Recent acquisitions of IP firms by MNCs			Recent acquisitions of overseas firms by IP firms		
Year	Target company	Acquirer	Year	Target company	Acquirer
2008	Dabur Pharma	Fresenius Kabi (Germany)	2005	Docpharma NV (Belgium)	Matrix Lab.
			2006	BetapharmArzneimittel GmbH (Germany)	Dr. Reddy's Lab
2008	Ranbaxy Lab	Daiichi Sankyo (Japan)	2006	Terapia (Romania)	Ranbaxy Lab
2009	Shantha Biotech	Sanofi Aventis (France)	2007	NegmaLerads (France)	Wockhardt Ltd.
2009	Orchid	Hospira (US)	2007	Morton Grove Pharmaceuticals (US)	Wockhardt Ltd.
2010	Paras Pharma	Reckitt Benckiser (UK)	2007	Hollister-Stier Labs (US)	Jubilant Organosys Ltd.
2010	Piramal Healthcare	Abbott Laboratories (US)	2008	Draxix Health Inc. (Canada)	Jubilant Organosys Ltd.
2011	Wockhardt	Danone (France)	2008	Axicorp (German)	Biocon
2013	Elder Pharma	Sanofi Aventis (France)	2011	I'rom Pharmaceuticals (Japan)	Lupin
2014	Ranbaxy	Sun Pharmaceuticals (India)	2011	Nesher Pharma (US)	ZydusCadila
			2011	GSK's Penicillin manufacturing facility (US)	Dr Reddy's Labs.
			2011	Onyx Research Chemicals	IPCA Labs
			2012	DUSA (US)	Sun Pharmaceuticals
			2013	OctoPlus (Netherlands)	Dr Reddy's Labs.
			2014	Natrol Inc. (US)	Aurobindo Pharma

2 Review of literature

The change in the policy to move to the product patent, sparked considerable debate much of which was centered on the future prospects of Indian pharmaceutical firms. Performance of ID&PI during the product patent regime has been a subject of a debate among empirical analysts over the last decade. Interestingly, there have been a number of studies on India's pharmaceutical sector reflecting upon issues such as R&D intensity, export competitiveness, efficiency and productivity. The studies on efficiency and productivity related issues of the ID&PI are, nonetheless, very few and most of them reported that firms with low efficiency and productivity were not able to survive in the business and were compelled to make exit or merge with larger efficient firms.

It may be mentioned here that various deterministic and stochastic production frontier models (Coelli et al. 2005) have been developed to estimate efficiency and productivity of decision making units (DMUs[3]), including drug and pharmaceutical units. Notably, while the stochastic frontier approach is parametric in nature, the deterministic frontier can either be parametric or non-parametric. Some of the studies have applied SFA in ID&PI (Pradhan 2004; Chaudhuri and Das 2006; Ghose and Chakraborty 2012; Neogi et al. 2012; Pattnayak and Chadha 2013; Sharma 2016). These studies have largely reported that technical efficiency has registered improvement during the process patent regime and that R&D intensive firms were more efficient than their counterparts (Pattnayak and Chadha 2013; Pradhan 2004). Chaudhuri and Das (2006) found that large firms have reduced their inefficiency. Pradhan (2004) and Pattnayak and Chadha (2013) reported that R&D intensity and imports of technology exercise positive impact on efficiency. They reported that technical efficiency has moved up during the process patent regime. Ghose and Chakraborty (2012) and Neogi et al. (2012) also showed that productivity has increased during process patent regime and firm's size stood out to be the significant determinant of productivity. Recently, Sharma (2016) analysed R&D, technology transfer and productivity in the ID&PI for the period 1994–2010. His growth accounting analysis found that R&D intensity has exercised negative impact on TFP growth of firms. He indicates that technological spillover could be the crucial source of technology and productivity enhancement in regard of Indian pharmaceutical firms. Interestingly, a fairly good number of studies have applied non-parametric Data Envelopment Approach (DEA) to measure efficiency and productivity of the ID&PI (Majumdar 1994; Saranga and Phani 2009; Saranga 2007; Mazumdar et al. 2009; Mazumdar and Rajeev 2009; Saranga and Banker 2010; Pannu et al. 2011; Tripathy et al. 2013; Mahajan et al. 2014, 2015; Gascón et al. 2017). The technical efficiency was also analyzed in the context of R&D expenditure, ownership, size of the firm and different product groups (Mazumdar and Rajeev 2009; Pannu et al. 2011). Some of the studies reported that large firms and MNCs are more efficient than their counterparts (Mazumdar and Rajeev 2009; Mazumdar et al. 2009). Further, they found that high R&D expenditure did not improve output efficiency of the firms. Nevertheless, some of the studies have reported that R&D intensive firms were more efficient than non-R&D intensive firms (Saranga and Banker 2010; Pannu et al. 2011; Tripathy et al. 2013) Other studies on the similar subject in

[3] DMUs are usually defined as entities responsible for turning input(s) into output(s), such as firms and production units. In the present study, DMUs refer to the Indian pharmaceutical firms.

regard of pharmaceutical industries in Sweden, Spain, Japan, Korea, Egypt, Puerto Rico and China (Färe et al. 1995; Lothgren and Tambour 1999; Gonzalez and Gascon 2004; Hashimoto and Haneda 2008; Shinnawy 2010; You et al. 2010; Ramcharran 2011; Mao et al. 2014) have also reported mixed findings. The direction of relationship between R&D expenditure and efficiency, therefore, remains inconclusive.

As pointed out earlier, most of studies on ID&PI have examined the aforementioned issues in the setting of pre-product patent regime which do not the account for possible changes in technical efficiency in the era thereafter. Interestingly, product patent regime created a new competitive environment that was far fiercer and efficiency oriented. In this context, it is important to understand whether the internal efficiencies of individual pharmaceutical firms have undergone any change over the period of time especially after signing of TRIPS. This necessitates a deeper investigation into the efficiency and productivity gains/losses with the appropriate tools and techniques. Thus, given the importance of this dynamic industry from both the political-economic and the ethical-healthcare points of view, the present study analyses the issue of differences in efficiency in the context of various categories viz., R&D intensity, size, type of ownership and product-wise and the impact of Product Patent Act on these categories. Further, this study also examines the determinants of efficiency.

3 Methodology

The present study applies non-parametric approach of data envelopment analysis (DEA)[4] introduced by Charnes et al. (1978) and further generalized by Banker et al. (1984) to compute the technical efficiency[5] of IP firms.

DEA is based on and restricted by certain assumptions. One of these is the assumption of homogeneity, which asserts that all decision making units must have the same inputs and outputs. In DEA, homogeneity in DMUs means that all DMUs under evaluation are under the same operating environment; pursue the same target with the same processes. Although there is heterogeneity in the ID&PI, yet all these firms are in the same business of medicine (whether in bulk drugs or formulations or both) and, therefore, face the similar types of market and input–output variables.

The CCR DEA model assumes that the size of a DMU does not affect the efficiency of a firm. Since this assumption may not always hold good in practice, Banker et al. (1984) developed a DEA model called the BCC model that measures 'pure technical efficiency'. The Input Oriented BCC (envelopment) model is given as:

$$Min\, Z_k = \theta_k - \varepsilon\left(\sum_{i=1}^{m} s_{ik}^{+} + \sum_{j=1}^{s} s_{jk}^{-}\right) \tag{1}$$

[4] Other popular techniques for measuring relative efficiency of DMUs are Stochastic Frontier Analysis (SFA), Thick Frontier Analysis (TFA), Distribution Free Approach (DFA) and Free Disposal Hull (FDH).

[5] Koopmans (1951; p. 60) defined technical efficiency as 'an input–output vector is technically efficient if, and only if, increasing any output or decreasing any input is possible only by decreasing some other output or increasing some other input'. This definition in economics is treated as a Pareto–Koopmans condition of technical efficiency.

Subject to:

$$\sum_{r=1}^{n} \lambda_{rk} y_{ir} - s_{ik}^{+} = y_{ik} \quad \forall i = 1, \ldots m,$$

$$\sum_{r=1}^{n} \lambda_{rk} x_{ji} + s_{jk}^{-} = \theta_k x_{jk} \quad \forall j = 1, \ldots s,$$

$$\sum_{r=1}^{n} \lambda_{rk} = 1 \quad \forall r = 1, 2, \ldots, n,$$

θ_k is unrestricted in sign, and

$$\lambda_{rk},\ s_{jk}^{-},\ s_{ik}^{+} \geq 0 \quad \forall\, r, j, i,$$

where s_{ik}^{+} is slack in ith output of the kth DMU; s_{jk}^{-} is slack in the jth input of the kth DMU. $\lambda'_{rk}s$ are the dual variables, known as intensity variables. θ_k(Scalar) is the (proportional) reduction applied simultaneously to all inputs and results in a radial movement towards the envelopment surface.

3.1 Malmquist productivity index: Ray and Desli decomposition

We supplement the efficiency analysis results by computing the productivity change and its components. Productivity is a descriptive measure of performance; on the other hand, efficiency is a normative measure (Ray 2004). Productivity is commonly defined as a ratio of output to input. Malmquist (1953) suggested this as a quantity index for use in the analysis of consumption of inputs. Originally, Caves (1982) defined the productivity change and after that Färe et al. (1992) extended the model. Productivity is measured by three approaches i.e., growth accounting (GAA), stochastic frontier analysis (SFA), and Malmquist productivity index (MPI). Growth Accounting is based on unrealistic assumptions of constant returns to scale (CRS) and perfect competition, and requires prior specification of production function.

The Färe et al. decomposition (1994) has been criticized by Ray and Desli (1997) by contending that there may be confusion in the simultaneous use of CRS and VRS technologies within the same decomposition of the MPI. Since then, there have been hosts of proposed alternate decompositions of the MPI under VRS assumption, including Ray and Desli (1997), Simar and Wilson (1998), Grifell-Tatjé and Lovell (1999), Balk (2001), Pastor and Lovell (2005) and Pastor et al. (2011). Ray and Desli (1997) proposed a decomposition using a VRS frontier as the benchmark. Lovell (2003) supported the Ray and Desli's decomposition by holding that it was theoretically correct and concluded that Ray and Desli decomposition is preferable to Färe et al. decomposition.

Ray and Desli decomposed the Malmquist index into three components viz., pure technical efficiency change (PTECH), technical change (TCH) and scale change factor (SCF). Their decomposition is given as:

$$M(x_{t+1}, y_{t+1}; x_t, y_t) = \left[\frac{D^v_{t+1}(x_{t+1}, y_{t+1})}{D^v_t(x_t, y_t)}\right]\left[\frac{D^v_t(x_t, y_t)}{D^v_{t+1}(x_t, y_t)} \cdot \frac{D^v_t(x_{t+1}, y_{t+1})}{D^v_{t+1}(x_{t+1}, y_{t+1})}\right]^{1/2}$$
$$\left[\frac{SE_t(x_{t+1}, y_{t+1})}{SE_t(x_t, y_t)} \frac{SE_{t+1}(x_{t+1}, y_{t+1})}{SE_{t+1}(x_t, y_t)}\right]^{1/2} \quad (2)$$
$$M(x_{t+1}, y_{t+1}; x_t, y_t) = PTECH * TCH(v) * SCF$$

3.1.1 DEA methodology for measuring the MPI

Let $y^t_j = (y^t_{1j}, y^t_{2j}, \ldots, y^t_{mj})$ be the output bundle and $x^t_j = (x^t_{1j}, x^t_{2j}, \ldots, x^t_{nj})$ input bundle for firm j (j = 1, 2,…, N) in period(t = t, t + 1). The same period (VRS) distance function is as follows:

$$D^t(x^t_k, y^t_k) = \frac{1}{\theta^*_k}; \quad where \quad \theta^*_k = \max \theta$$

$$subject\ to:$$
$$\sum_{j=1}^{N} \lambda_j y^t_j \geq \quad \theta y^t_k;$$
$$\sum_{j=1}^{N} \lambda_j x^t_j \leq x^t_k; \quad (3)$$
$$\sum_{j=1}^{N} \lambda_j = 1;$$
$$\lambda_j \geq 0; \ (j = 1, 2, \ldots, N)$$

This is the standard BCC model. The other same period (VRS) distance function $D^{t+1}(x^{t+1}_k, y^{t+1}_k)$ can be computed in an analogous manner. Cross-period efficiency score[6] is measured by comparing actual output of a firm in period t (or t + 1) with the maximum producible output from period t + 1 (or t) input set.

We have applied input-oriented[7] DEA models to measure the technical and scale efficiencies of individual firms under the standard CRS and VRS models. Input variables considered in this study are relatively more flexible as compared to the

[6] Estimation of cross-period efficiency scores under a VRS technology may result in linear programming infeasibilities for some observations (Ray and Mukherjee 1996).

[7] There are two orientations of DEA models viz., input-orientation and outputorientation. In an input-orientated model (input minimization), desired output is produced with minimum inputs. This model is preferred when inputs are more flexible than output. On the other hand, in an output-orientated model (output maximization), efforts are made to maximize the output with input level held fixed. The choice of orientation depends on the available flexibility either with the inputs or outputs (Coelli et al. 2005; Ramanathan 2003).

output. The output variable 'net sales revenue' is dependent on external factors such as demand, exports etc. which are not in the control of management. For calculating the Ray and Desli decomposition, programming in the MATLAB has been used for calculating the technical change and scale change factor.

4 Description of data and variable construct

Section 4.1 provides information on data used for this study. Section 4.2 describes variables and relevant details of the firms.

4.1 Description of data

The main data source is Prowess[8] of Centre for Monitoring Indian Economy (CMIE). Our sample consists of firm-level data of 141 firms of ID&PI for the period from 2000–2001 to 2012–2013. DEA results are influenced by the size of the sample. The first rule is that the number of DMUs must be greater than the product of inputs and output. The second rule as stated by Cooper et al. (2000) is that number of DMUs should be at least three times the sum of inputs and output variables. Therefore, our size of the sample is more than adequate according to the thumb rules of DEA literature. The year 2000–2001 has been considered as starting year owing to the fact that sufficient data for firms are available in the Prowess database only after 1999–2000. Although, in the Prowess database, 596 ID&P firms' data are available, we have considered balanced panel data for only 141 firms due to non-availability of data for other firms for some years. The main reason for choosing this sample is the fact that we have continuous availability of data for a common sample, which enables measurement of various performance characteristics of those pharmaceutical companies that have survived for at least 13 years or more. These 141 firms together account for about 80% of the total sales revenue and 85% of the input usage in the industry for almost all the years.[9] It includes most of the market leaders on the top and the companies that are struggling to make ends meet at the bottom. Thus, we hope that the sample is representative enough to include all kinds of firms with a history of 13 years or more, except for the ones, which have started after 2000–2001, and the ones that have closed down or got merged before 2012–2013.

The key limitation of DEA is that the efficiency results are very sensitive to the presence of outliers. To overcome this limitation of DEA methodology, we first identified outliers among the initial sample firms. The DEA analysis was run, after

[8] Prowess of CMIE provides data on a large number of manufacturing firms, including pharmaceutical ones. It is an online database provided by the CMIE and covers financial data for over 23,000 companies operating in India. Most of the companies covered in the database are listed on stock exchanges, and the financial data include all those information that operating companies require to disclose in their annual reports.

[9] The figures have been arrived at by taking the ratio of the output manufacturing by the registered Indian pharmaceutical companies (provided by the CMIE Prowess database) to the total value of output produced by the sector (provided by the Department of Chemicals & Petrochemicals, Ministry of Chemicals & Fertilisers).

dropping out the most efficient firm with the highest peer count one at a time, in order to test the presence of extreme outliers which may have affected the frontier and efficiency scores. The procedure is known as Jackknifing test for the robustness of DEA results with regard to outliers (Mostafa 2007; Ramanathan 2003). Initially, there were 145 firms in this sample set, but after the four firms, namely Biddle Sawyer Ltd, Martin and Harris Lab, Phaarmasia Ltd. and Concord Drugs Ltd. were found to be outliers, the sample was restricted to 141 firms.

Since the Prowess database provides data on current prices, therefore, they had to be converted to constant prices (at 2000–2001 prices). The net sales revenue is deflated by WPI for industrial workers taken from the RBI monthly bulletins. Salaries & wages and advertisement & marketing expenditure are deflated by the CPI for both the manual and non-manual workers. The raw material is deflated by average price index for chemical and chemical products from the Annual Survey of Industry database. Capital cost is deflated by price index for machinery and transport equipment.

The DEA analysis in this sample would give relative efficiencies of these 141 firms with respect to each other and not with respect to all the companies of ID&PI. This means, there might be other efficient/inefficient companies, with better/worse practices in the larger population, that are not included in this sample, and whose inclusion might reduce/increase the respective efficiencies of the firms in the present sample. The unbalanced panel might have given a different picture. The advantage of balanced panel data is that we can analyse relative performance of sample firms and suggest policies for improving the efficiency of inefficient firms. However, for now, we restrict ourselves to the present sample and focus on their best practices and analyse emerging trends in ID&PI.

4.2 Variable construct

The selection of inputs and outputs of the model is a key part of DEA. The larger the number of inputs and outputs, the less discriminatory the model becomes. Hence, there should be a balance between relevant inputs and outputs so as to differentiate between efficient and inefficient firms. The ideal way of computing the efficiency is to use the physical volume of output and inputs. However, in the absence of non-availability of physical data, the present study has used data in monetary terms only. Such an approach can be useful particularly when firms produce differentiated products and products varieties differ across firms (Katayama et al. 2009). In our case, ID&PI firms produce differentiated products (bulk drugs, formulations or both). Therefore, it is appropriate to apply DEA with monetary values of input and outputs. Further, the condition that is required for DEA is that the function relating inputs and outputs should possess the monotonicity property, which essentially means that an increase in the inputs will increase the output. This relation is observed in the inputs and outputs which have been considered for analysis in the study.

The pharmaceutical industry is characterized by low fixed asset intensity and high working capital intensity with the material cost, manpower cost, marketing and selling cost and capital usage cost constituting the four major cost elements for the ID&PI, accounting for close to 80% of the operating income. There are market

related variables which also affect the technical efficiency but our study focusses on analysing efficiency of individual firm rather than the whole industry. Therefore, the following variables have been considered for the study.

4.2.1 Output variable

- Net Sales Revenue (NS): It is the amount of sales generated by a company after the deduction of returns, allowances for damaged or missing goods and any discount allowed. In case of ID&PI, a fair number of studies (Pannu et al. 2011; Saranga and Phani 2009; Saranga and Banker 2010; Tripathy et al. 2013) have made use of sales revenue to examine the progress of the industry. Since the data on output in physical terms are not reported in the balance sheets, net sales revenue, as an output variable becomes a rational choice.

4.2.2 Input variables

- Raw Material Cost (RM): It includes the cost of all raw materials, spares and packaging.

This accounts for 49% of the total cost incurred by 141 sample firms during the period under study.

- Salary and Wages (SW) representing employment cost or factor payment to human capital employed: It includes total annual expenses incurred by a firm on all its employees, including management. These expenses also take account of payment of bonus, contribution to employee's provident fund and staff welfare related expenses, including staff training costs. This comprises 11% of the total cost incurred by sample firms.
- Advertising and Marketing (AM) Cost: It includes the cost of advertising, marketing, distribution, travel and communication. Advertising & Marketing plays a crucial role in a pharmaceutical market, in which both clinical and cost issues are important to prescribing and purchasing medicines. The Indian pharmaceutical firms generally incur large expenditure on advertising & marketing. Cost of AM accounts for around 11% of the total cost of the sample firms. Therefore, AM is an important part of total cost as it helps to increase revenue by improving customers' awareness regarding the availability and efficacy of the product.
- Capital Usage Cost (CUC): It includes rent, interest, depreciation, repairs and maintenance of plant and machinery. It is used as proxy variable for capital. This comprises 1/4th of the total cost incurred by sample firms.

In case of ID&PI, a large number of studies (Pannu et al. 2011; Saranga and Phani 2009; Saranga and Banker 2010; Tripathy et al. 2013) have made use of these input variables to examine DEA results. Similar output and input variables have also been used by the earlier studies (Saranga 2007; Saranga and Banker 2010; Pannu et al. 2011) (Table 3).

Table 3 Data description and variables used in the previous studies on efficiency and productivity of ID&PI by using DEA methodology. *Source*: Authors' compilation

S.N.	Author (s)	Firms size	Study period	Input	Output
1.	Majumdar (1994)	9 firms	1987–1990	Gross fixed capital, net working capital, total no. of employees	Value added by operations
2.	Saranga (2007)	44 firms	1992–2002	Cost of production, cost of material, cost of man-power	Net sales, profit margin
3.	Saranga and Phani (2009)	44 firms	1992–2002	Cost of production and selling, cost of material, cost of manpower	Profit margin, net sales, exports
4.	a. Mazumdar and Rajeev (2009) b. Mazumdar et al. (2009) c. Mazumdar and Rajeev (2012)	70–289 (unbalanced data)	1991–2005	Wages and salaries, raw material cost, energy input, capital	Output (total sales plus change in the stock of output)
5.	Saranga and Banker (2010)	76 firms	1993–2003	Raw material, wages and salary, capital (interest, depreciation, rent and repairs), marketing cost	Net sales
6.	Pannu et al. (2011)	146	1998–2007	Cost of material, cost of manpower, capital cost	Sales
7.	Tripathy et al. (2013)	90 firms	2001–2008	Raw material, wages and salaries, advertisement and marketing cost, energy input	Net sales revenue and exports
8.	Singh and Singh (2014)	Firms: 30 (balanced data)	1991–2011	Net fixed assets, raw material and total expenses	Net sales
9.	Gascón et al. (2017)	37 firms	2008–2013	Size of the workforce, total assets, investment in R&D	Net profit market capitalization

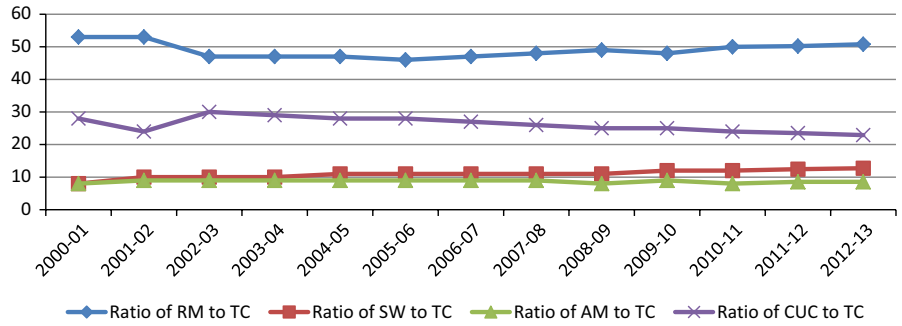


Fig. 1 Trend in the ratio of inputs cost to total cost. *Source*: Authors' computation based on CMIE Prowess database

Figure 1 explains the share of selected inputs in total cost from 2000–2001 to 2012–2013. It shows that the ratio of raw material cost has remained around 50% of total cost (TC). The share of capital cost has declined over a period and it is around 1/4th of the TC. There is significant share of marketing and advertisement expenditure of around 9% in total cost due to the emphasis of firms on sales of formulations.

Further, the sample is sub-divided into four categories on the basis of ownership, R&D intensity, firm-size, and product-group in order to assess the performance of the firms in different categories in terms of efficiency scores. It may be noted that IP firms exhibit wide heterogeneity in terms of ownership, product portfolios, R&D intensity, and market concentration. This variation in sample firms helps in identifying the impact of different characteristics on the performance of firms (Fig. 2).

Table 4 provides descriptive statistics of inputs and output for the period from 2000–2001 to 2012–2013. The descriptive statistics (mean, SD, ranges, etc.) indicate that the firms in our sample vary significantly in terms of magnitude of their output and input variables.

In order to test validity of the selected variables, adjusted R^2 and F-statistics have been calculated. These estimates are based on multiple regression analysis

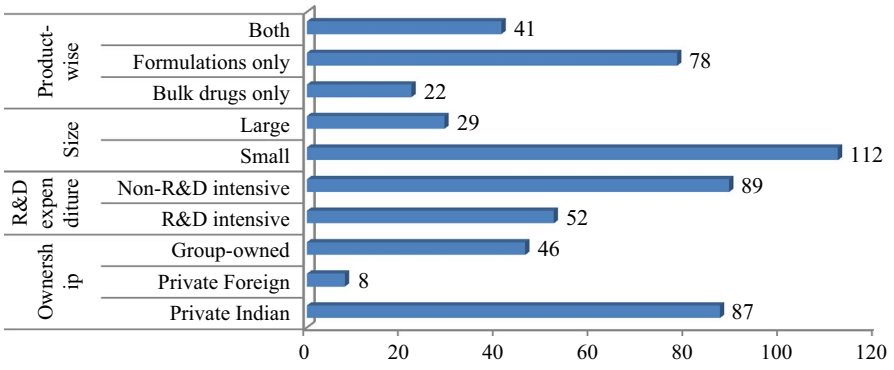


Fig. 2 Details of the sample Indian pharmaceutical firms

Table 4 Average descriptive statistics of inputs and output for the period 2000–2001 to 2012–2013 (Rs. Million at 2000–2001 prices). *Source*: Computed from Prowess Database

Statistics	Net sales	Raw material	Salary and wages	Advertising and marketing	Capital cost
Mean	1969.31	578.16	148.90	121.20	101.41
Std. deviation	3996.29	1062.11	307.82	324.68	215.85
Range	36,683.46	8363.92	3546.37	3861.28	2268.21
Minimum	0.13	0.05	0.16	0.05	0.08
Maximum	36,683.59	8363.96	3546.53	3861.28	2268.20

with net sales revenue as a dependent variable and raw material, salaries and wages, advertising and marketing expenditure and capital usage cost as independent variables. The value of adjusted R^2 was found to be 0.952, suggesting that the four input variables together explain 95.2% of variations in net sales revenue. The F-statistics is found to be statistically significant at 1% level. These two tests suggest that there exists a best-fit between output and input variables.

4.3 Appropriateness of selected input and output variables: sensitivity analysis

In DEA, the distribution of efficiency scores is very sensitive to the choice of input and output vectors. Thus, the selection of input and output variables for the DEA study requires a careful thought as the distribution of efficiency scores and rank order of DMUs are likely to be affected by the selection of variables and their number. Therefore, we checked whether our choice of inputs and outputs in the above-selected model was appropriate and yields robust inferences. For this purpose, we carried out a sensitivity analysis by considering an additional model with different input and output vectors. In case of model II, the output vector includes net sales and profit, with profit as an additional output variable, and the input vector contains one more energy variable. This model is constructed after reviewing the existing literature (Saranga 2007; Saranga and Phani 2009; Mazumdar and Rajeev 2009, 2012; Mazumdar et al. 2009 and Tripathy et al. 2013). It was found that both the models have very high and statistically significant correlation. Therefore, according to Chen and Yeh's (1999) criteria, we can infer that our choice of input and output variables was appropriate and results are quite robust.

5 Empirical results and interpretations

The summary statistics of efficiency and productivity scores, empirical results and their interpretations are discussed in this section. Sections 5.1 and 5.2 analyze efficiency and productivity in pre and post-patent regimes while Sects. 5.3

and 5.4 deal with performance of R&D active firms and domestic competitiveness across different categories of firms.

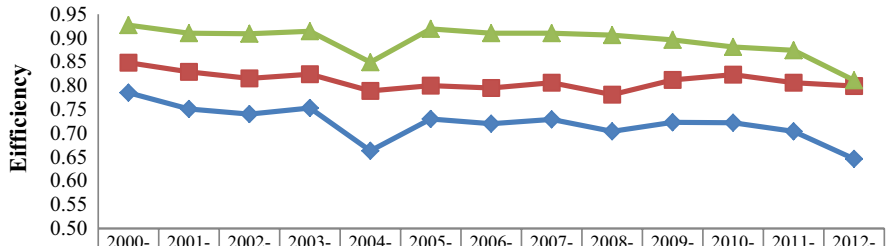
The present study has estimated the efficiency and productivity of 141 Indian pharmaceutical firms for the period from 2000–2001 to 2012–2013. The empirical analysis is based on the data for 13 years has been further divided into two sub-periods on the basis of introduction of Product Patent regime in the ID&PI: (1) Pre-Product Patent Regime (2000–2001 to 2004–2005) and (2) Post-Product Patent Regime (for rest of the period). This bifurcation was done in order to examine the impact of Product Patent Act of 2005 on the efficiency and productivity of ID&PI.

5.1 Efficiency trend in pre and post product patent regime

Figure 3 depicts that the mean OTE score has declined from 0.785 in 2000–2001 to 0.663 in 2004–2005. In the product patent regime, the mean OTE has not shown any perceptible trend up to 2010–2011 but after that, it has declined continuously.

It is evident from Figure that the mean PTE score has declined to 0.789 in 2004–2005 from 0.848 in 2000–2001. The year 2004–2005 saw the maximum decline in efficiency scores. The mean PTE score was around 0.810, indicating thereby that the firms were 19% pure technical inefficient, which partly could be attributed to the infrastructural bottlenecks i.e., mainly frequent power cuts, inadequate road transport infrastructure leading to delays and productivity losses (Perlitz et al. 2008). It can also be inferred from the above analysis that overall inefficiency in the industry during the entire study period could be attributed to both pure technical inefficiency and scale inefficiency.

Table 5 brings to the fore that mean efficiency has recorded a declining trend in the post-patent period. There is negative growth of OTE, PTE, and SE in the post-product patent regime as compared to the previous period. The K–W Test suggests a significant change at 10% in OTE and PTE. This study finds a negative impact of Product Patent Act of 2005 on the efficiency scores (OTE and PTE).The accelerated input cost of the industry can also be attributed to the part of the decline in efficiency. It was believed that with this new patent regime, Indian generic firms would face difficulties in reverse engineering and imitation of drugs. Many studies predicted that this changing scenario might not be conducive for the growth and development of this industry (Lanjouw 1998; Grace 2004; Chaudhuri 2005; Nauriyal 2006). Abrol (2004) also criticised the introduction of strong IPRs and points out that it has neither led to transfer of technology to Indian firms nor has it benefited the Indian population. Interestingly, the new regime has led to increase in R&D intensity of Indian firms significantly, as industry is learning to develop capabilities in innovative R&D. However, over the period of time, Indian firms have adopted a mix of competitive and collaborative business and technology strategies to deal with TRIPS related challenges (Chadha 2009; Goldar et al. 2010; Rai 2008; Tyagi et al. 2016). As a result of changes in patent law, the industry is learning to develop capabilities in innovative R&D. Further, ID&P firms also began to internationalize



	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13
OTE	0.785	0.751	0.74	0.753	0.663	0.73	0.72	0.729	0.704	0.723	0.722	0.704	0.646
PTE	0.848	0.829	0.815	0.824	0.789	0.8	0.795	0.806	0.781	0.812	0.823	0.806	0.799
SE	0.927	0.91	0.909	0.914	0.849	0.919	0.91	0.91	0.906	0.896	0.881	0.874	0.811

Fig. 3 Average OTE, PTE, and SE across year (2000–2001 to 2012–2013)

Table 5 Mean OTE, PTE and SE during 2000–2001 to 2012–2013. *Source*: Authors' calculations

Year	OTE	PTE	SE
Entire period mean	0.721	0.810	0.894
Pre-patent period	0.738	0.821	0.902
Post-patent period	0.710	0.803	0.888
Percentage change	− 3.880	− 2.223	− 1.489
Kruskal–Wallis test	3.631 (0.057)*	3.094 (0.079)*	1.062 (0.303)

(1) Percentage change represents percentage change of average efficiency during post-product patent period in comparison to pre-product patent period (2) values in parenthesis represents level of significance (* represents level of significance at 10%)

through acquisitions of foreign assets that were to help them to gain access to new markets and expand their product portfolios to overcome their limited product development competencies (Pradhan 2010).

5.2 Productivity in pre and post product patent regime

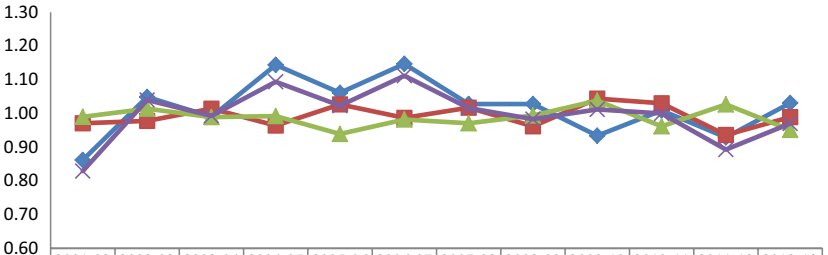
The present study has applied Ray and Desli's Malmquist Productivity Index and its decomposition to measure TFP change, pure technical efficiency change, scale efficiency change and technical change under VRS technology assumption for the same 141 IP firms during 2000–2001 to 2012–2013. Figure 4 exhibits the TFP growth and its decomposition into technical change (frontier shift), pure technical efficiency change (catching up effect) and scale efficiency change over the period of study.

The MPI indices show that during the entire time period, ID&P firms experienced an average regress of 0.6% in TFP change indices. This study found marginal decline in TFP during product patent regime. The marginal regress in TFP over the study period is attributable to PTECH. On the other hand, there is progress in TCH by 1.5%. Interestingly, when we compare the pre and post-patent regime, the regress

in TFP in post patent regime was lesser than the pre-patent regime. Thus, new patent regime has introduced some improvement in PTECH, although there is regress in this index.

The frontier shift or technical progress could be due to new technological investment or adoption of superior technology by existing frontier firms. The industry has experienced some technological improvement in the study period but most of the firms could not realize these technology-related benefits, probably owing to improper utilization of inputs which added up to the decline in productivity. There was also not much of the compulsion on the firms to improve input utilization for the fact that their well-entrenched competitive advantage did not demand any downward movement in the cost. The continuance of input use inefficiency by itself also appears to emerge from the fact that ID&PI is broadly operating in the generic market and is already producing and marketing drugs, as usual, at the most competitive prices. With the increasing integration of this industry with the global market, the focus is more on creating facilities that conform to the norms of FDA and other western and East Asian regulatory agencies. There has also been an increasing interest in carrying out R&D though precisely not to carry out drug discovery but utility models. These two factors, then bettering the input utilization efficiency, appear to have engrossed the major attention, energy, and investment of ID&PI.

From Table 6 it is clear that there is no statistically significant difference that exists in TFP and its components between pre and post product periods. The study observes marginal improvement in TFPCH index and its components during the product patent regime. It is generally believed that this change in scenario would have long-term impact than the short-term impact. It can be observed that, on an average, there was marginal regress in PTECH for the industry, as average value estimated to be less than one during the study period. The estimated results indicate that, on an average, TE has a regress of 0.7% and SE of 1.3%. Further, the analysis shows positive growth in TECH during the product patent regime as compared to the pre-patent regime.



	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13
TCH	0.862	1.049	0.99	1.144	1.061	1.147	1.028	1.028	0.934	1.009	0.929	1.031
PTECH	0.971	0.978	1.014	0.964	1.027	0.987	1.017	0.962	1.044	1.03	0.936	0.989
SECH	0.99	1.014	0.989	0.992	0.939	0.982	0.971	0.994	1.038	0.962	1.027	0.951
TFPCH	0.829	1.04	0.993	1.094	1.023	1.112	1.016	0.983	1.012	1	0.893	0.97

Fig. 4 Year-wise TFP change, TCH, PTECH and SE change

Table 6 Average TFP Change, TCH, PTECH and SE change. *Source*: Authors' calculations

Year	TCH	PTECH	SECH	TFPCH
Entire period mean	1.015	0.993	0.987	0.994
Pre-patent period	1.006	0.982	0.996	0.984
Post-patent period	1.019	0.998	0.982	0.999
Percentage change	1.301 (0.895)	1.714 (0.308)	− 1.395 (0.832)	1.599 (0.865)

(1) Mean is the geometric mean (2) Percentage change represents percentage change of average productivity during post-product patent period as compared to pre-product patent period (3) values in parentheses represent level of significance

5.3 Efficiency and productivity of R&D active firms

In this section, the efficiency and productivity of R&D active is analysed. It may be noted that R&D active firms are those which are actively participating in R&D expenditure from 2001–2002 to 2012–2013. We have constructed the balanced panel of 52 R&D active firms and then both, efficiency and productivity, were calculated.

5.3.1 R&D expenditure in new patent regime

The literature review clearly predicts that the impact of the change in the patent regime would be felt largely on a firm's R&D behaviour (Lanjouw 1998; Nauriyal 2006; Nauriyal and Sahoo 2008; Pradhan 2010; Sharma 2012; Tyagi et al. 2016). There has been a phenomenal rise in the R&D expenditure, especially after the signing of TRIPs in 1995, although a rising trend was visible even before that. It picked up momentum by 2000 and attained peak in 2006 after which it stabilized. After India became TRIPS compliant in 2005, it went for appreciable upgradation of the patent infrastructure and digitization of records which provided enough stimuli to invest in R&D activities, as is revealed by the rising R&D intensity (R&D expenditure as percentage of sales revenue) from 0.10% in 1995 to 5.14% in 2014 (Fig. 5).

It may be pointed out that prior to 1992, new drug discovery and development has never been on the agenda of the Indian pharmaceutical firms, as reflected in their output and from the fact that there was almost marginal investment in R&D with some larger firms investing, on an average, around 2% of their sales revenue on R&D as compared to 15–20% in regard of the western firms (Grace 2004). This large difference in the R&D intensity can be attributed to the different priorities and the macroeconomic environment in which Indian and foreign firms had to operate. For instance, while Indian firms had been operating in a protected environment where replication and marketing of a drug/formulation were possible, albeit through a different route, at a much cheaper price. The subsidiaries of MNCs, on the other hand, had to operate in a far more competitive environment where inventions and innovations were at the premium. The onset of liberalization era in 1991, exposed Indian firms to the stark reality that R&D was imperative for survival and existence and it became far more visible after the signing of TRIPs agreement. The larger

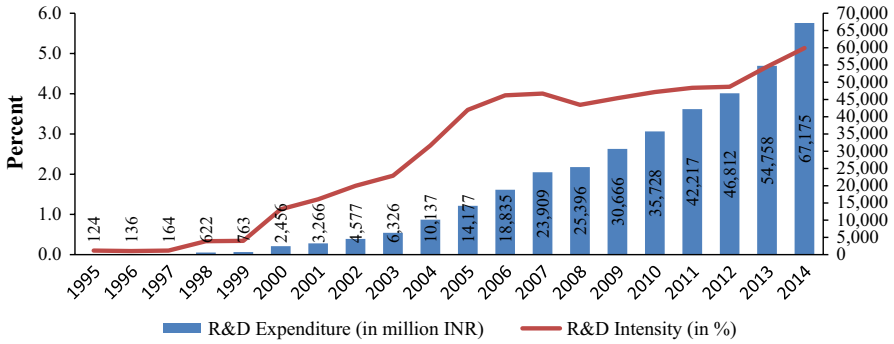


Fig. 5 R&D intensity and expenditure in Indian Drugs and Pharmaceutical Industry. *Source* CMIE Prowess Database 2016

firms, also mopping up a substantial part of their revenue from exports, also realized that R&D is compulsory if competition in the domestic as well as international markets is to withstand.

The R&D intensity has increased to around 5% by 2013 from negligible percent in 1990. However, increased R&D investment is not all pervasive in the Indian pharmaceutical industry, but limited to a small number of larger companies. Post-2006, firms started moving to higher R&D intensity bracket due to TRIPS implementation probably for the realization on the part of the firms that they needed to put more efforts to increase R&D investment so that global expansion goals could be reached. Apart from that, another major incentive for increasing R&D intensity came via R&D taxation benefits scheme of Government of India. Table 7 clearly shows only a few firms are actively participating in R&D activities. Around 85% of the R&D is being undertaken by top 52 firms. Therefore, the sample size selected for R&D active firms can be a true representative of whole industry R&D expenditure.

Table 8 highlights the classification of R&D active (the firms which have reported R&D activity during the given period) firms in ID&PI. From the classification of 52 R&D active firms of ID&PI, it is revealed that all the large firms were R&D intensive firms. It was probably for the facts that while the large companies could afford the resources and R&D initiatives. Most of the R&D is been done by domestic firms. It is found that the percentage of small companies reporting R&D expenditure is 20.5% (23 out of 112). The small companies had also been forced to undertake R&D in order to stay in the competition. The large firms are focused mainly on advanced processes, bio-pharmaceuticals, and novel products. It may be pointed out here that the nature of Indian pharmaceutical R&D is very different from the MNCs. The Indian firms have achieved a decisive edge over their multinational counterparts in this regard. The lower growth of R&D expenditure in regard of the MNCs' subsidiaries can be attributed to the fact that these companies had already established a strong base for R&D; therefore, any dramatic rise in their R&D expenditure could not be expected. Further R&D activities of MNCs' subsidiaries are part of their global network which would

Table 7 R&D expenditure and intensity of Indian pharmaceutical industry (1990–2014). *Source*: Authors' compilation from CMIE Prowess Database, 2016

Year	All listed ID&P firms		Top 52 ID&P firms		
	Aggregate R&D expenditure (INR in billions)	Average R&D intensity	Aggregate R&D expenditure (INR in billions)	Average R&D intensity	Share in R&D expenditure of all listed firms (%)
1999–2004	37.99	1.24	32.05	2.14	84.36
2004–2009	250.3	2.61	221.41	4.27	88.46
2009–2014	462.07	4.67	384.14	5.75	83.13

Table 8 Classification of R&D active firms in ID&PI. *Source*: Authors' computation from CMIE Prowess, 2014

Categories of the firms	Number	Share (%)
Ownership type		
Foreign	7	13.46
Domestic	45	86.54
Size		
Large	29	55.77
Small	23	44.23

The firms which together capture about 75% of the market share and have net sales revenue more than Rs. 5000 million, have been classified as large firms, and others as small firms

distribute the costs among various subsidiaries, which is not a case with Indian pharmaceutical firms. Indian pharmaceutical companies are spending more than their foreign counterparts in India (Department of Pharmaceuticals, 2012).

5.3.2 Efficiency analysis of R&D active firms

To analyze the impact of R&D on the efficiency of IP firms, R&D expenditure is taken as input variable in the DEA analysis. With the inclusion of this new variable, our sample size has drastically reduced, as few firms are actively participating in R&D. When we take only the R&D firms then it is found that efficiency scores of R&D active firms are higher than the efficiency scores in case of whole sample. Therefore, when we restrict our sample to R&D firms only or R&D variable is taken as input then there is significant improvement in efficiency scores. This improvement in efficiency may be the result of reduction in sample firms or inclusion of R&D expenditure in input variables. There is negative growth of OTE, PTE and SE in post-patent regime as compared to the previous period. K–W test suggested insignificant change in all the efficiency scores. The impact of product patent was found to be inverse on R&D firms as well as on the entire set of sample firms, although latter were significantly affected by this policy change. The present study finds marginal impact of Product Patent Act 2005 on the efficiency of R&D active firms owing to the fact that patents probably did not result in remarkably better products which could have boosted up the sale, consequently profitability, and as outcome, the efficiency. Although increased R&D

Table 9 Mean OTE, PTE and SE of R&D firms during 2000–2001 to 2012–2013. *Source*: Authors' calculations

Year	OTE	PTE	SE
Entire period mean	0.817	0.886	0.923
Pre-patent period	0.829	0.894	0.928
Post-patent period	0.811	0.881	0.920
Percentage change	−2.184	−1.482	−0.822
Kruskal–Wallis test	0.910 (0.340)	0.908 (0.341)	0.539 (0.463)

(1) Mean is the geometric mean (2) Percentage change represents percentage change of average productivity during post-product patent period as compared to pre-product patent period (3) values in parentheses represent level of significance

might have broadened the product portfolios of some of the leading Indian pharmaceutical firms, it might have not resulted in the optimum scale operations as each firm might have a small slice of the market in that particular therapeutic segment. Further, the inherent weakness of Indian firms to carry out basic research resulting in commercially viable products, owing to their limited internal research capabilities and for the probability that R&D could be part of strategic patenting; the shift to stronger patent regime might not have exercised any significant improvement in efficiency of the firms. The emphasis on meeting the demands of changing global regulatory environment also appeared to have shifted focus of the firms from improving internal efficiencies to match up with the best manufacturing practices which might have had their own teething problems (Table 9).

5.3.3 Model III: sensitivity analysis with inclusion of R&D in input variables

The results of DEA analysis have given the efficiencies of 52 firms with respect to each other and not with respect to all the companies of ID&PI. This means that when we reduce our sample size so as to include R&D variable then there might be a possibility that we have excluded some inefficient firms which have increase the efficiency scores. There is also the possibility that R&D variable has an impact on efficiency scores. For analysing the impact of R&D variable, we have further conducted the sensitivity analysis on 52 R&D active firms. In one model, we have included the R&D variable and in the other model, we have excluded this variable. The results of sensitivity analysis confirm the validity of our selected variables. The results of both the models were highly correlated which signifies that there is negligible impact of the inclusion of R&D variable in inputs. The possible reason could be that the share of R&D expenditure in total cost is very less and major share around 85–95% is occupied by other inputs (raw material, salary & wages, advertisement cost and capital usage cost) which are selected as inputs in our study. Further, R&D expenditure has long gestation period and, therefore, might not have an impact on output variable in immediate future. To capture the impact of R&D expenditure on efficiency of ID&P firms, one of the variables as lagged R&D variable is used by applying fixed effect model in Sect. 5.5.

5.3.4 Productivity analysis of R&D active firms

The MPI indices show that during the entire time period, R&D active firms experienced an average regress of 2.6% in TFP change indices. The marginal regress in TFP over the study period is attributable to both technical efficiency change and technical change factors. The regress in TFP growth was probably due to improper utilization of resources and less investment in technological advancement. No statistically significant difference was found in TFP and its components during pre and post-product patent periods. The study observes marginal improvement in TFPCH index and its components during the product patent regime. It is generally believed that this change in scenario would have long term rather than the short-term impact (Table 10).

Both the pre and post-patent regime have witnessed regress in productivity, although in pre-patent regime the regress was comparatively more. One interesting finding is that productivity regress in product patent regime is the consequence of TCH and SECH rather than PTECH. On the other hand, in pre-patent regime, ID&PI experienced productivity decline of 3.9% because of both PTECH and TCH. In entire period mean and pre-patent period, PTECH and TCH are found to be less one. PTECH less than one indicate that ID&PI has become less pure technical efficient in this period as compared to other period. In case of TCH value less than one indicates a negative shift in the frontier or technical regress. In Ray and Desli methodology, scale change factor is a geometric mean of the ratios of scale efficiencies of the two bundles using in turn the VRS technologies from the two periods as the benchmark. The SECH is found to be less than one except in pre-patent regime indicating that ID&PI is less scale efficient in period $t+1$ compared to period t. This represents a negative impact on its productivity attributable to changes to its scale size. In other words, it indicates that scale of production had contributed negatively towards productivity change. SECH is around one in pre-patent regime that means scale efficiency is same in period t and period $t+1$ and so ID&PI has no impact to its productivity attributable to changes in its scale size.

Table 10 Average TFP change, TCH, PTECH and SE change of R&D active firms during 2000–2001 to 2012–2013. *Source*: Authors' calculations

Year	TCH	PTECH	SECH	TFPCH
Entire period mean	0.989	0.994	0.991	0.974
Pre-patent period	0.978	0.981	1.003	0.961
Post-patent period	0.996	1.003	0.984	0.983
Percentage change	1.840	2.231	−1.881	2.188
Kruskal–Wallis test	0.409 (0.522)	1.136 (0.286)	0.736 (0.391)	0.045 (0.831)

(1) Mean is the geometric mean (2) Percentage change represents percentage change of average productivity during post-product patent period as compared to pre-product patent period (3) values in parentheses represent level of significance

New patent regime has introduced some improvement in PTECH, TCH and TFPCH although there is regress in this index in the entire period. But this positive change was found to be insignificant as shown by K–W test results. It is generally believed that this change in scenario would have long-term impact than the short-term impact. The productivity results are more or less similar as compared to the whole sample which excludes R&D variable in input. The inclusion of R&D variable in the data and with the significant reduction in sample size, there was no major change in the results of productivity change. In case of TCH, the whole sample has shown progress whereas R&D active firms have shown regress. The technical regress in R&D active firms could be due to less technological investment by existing frontier firms. Such a case may arise for the ID&P firms because a large number of firms (mainly small firms) in this industry came into business due to the absence of Product Patent Act and most of these firms were not engaged in R&D expenditure and new technological investment. This technological regress as well as improper utilization of resources is responsible for decline in productivity. It was predicted that R&D firms may have more productivity as compared to all the firms, as it was seen in case of efficiency scores. The study by Sharma (2016) finds R&D firms to be more productive than other firms. Our results are contrary to his study. The choice of estimation technique could be the reason for diversion of results. He applied parametric technique for estimation whereas our efficiency and productivity analysis is based non-parametric DEA technique. In several studies, application of different econometric techniques has yielded wide variation in the results with the same data (e.g. see O'Mahony and Vecchi 2009).

5.4 Domestic competitiveness across different categories of firms

5.4.1 Size and efficiency

It may be mentioned here that although ID&PI has more than 20,000 registered units, yet top few firms share an overwhelming chunk of the market. The share of top four firms is around 25% in the product patent regime. The concentration ratio has been escalating which shows the dominance of major players. There is wide heterogeneity in size of IP firms, with most of the firms are smaller. Therefore, it would be interesting to examine if size displays any definite relationship with efficiency scores.

Hypothesis 1 In the ID&PI, large firms, on an average, are associated with higher efficiencies in comparison with small firms during the study period 2000–2001 to 2012–2013.

The firms which together capture around 75% of the market share and have net sales revenue more than Rs. 5000 million, have been classified as large firms, and others as small firms (Mazumdar and Rajeev 2009; Pannu et al. 2011; Mazumdar and Rajeev 2012). Table 11 depicts that large firms are more efficient than the small

Table 11 Mean OTE, PTE and SE scores according to size. *Source*: Authors' calculations

Year	Small firms			Large firms		
	Mean OTE	Mean PTE	Mean SE	Mean OTE	Mean PTE	Mean SE
Entire period mean	0.716	0.794	0.905	0.755	0.871	0.869
Pre-patent period	0.731	0.801	0.914	0.766	0.897	0.854
Post-patent period	0.707↓	0.789↓	0.898↓	0.749↓	0.854↓	0.878↑
Percentage change	−3.205 (0.079)*	−1.467 (0.143)	−1.753 (0.304)	−2.336 (0.079)*	−4.766 (0.013)**	2.728 (1.000)
t-test	Mean OTE		Mean PTE		Mean SE	
	−2.923***		−7.550***		2.431**	

(1) The arrows ↑ and ↓ indicate that mean efficiency has increased or decreased respectively during post-product patent period in comparison to pre-product patent period. (2) Percentage change represents percentage change of average efficiency during post-product patent period in comparison to pre-product patent period (3) values in parentheses represent level of significance (*, **, *** represents 10, 5 and 1% level of significance respectively)

firms in both OTE and PTE scores. Other studies carried out in India on this aspect also support a positive impact of size on the efficiency of the firms citing added advantages of larger firms in terms of better technology, R&D facility and efficient human specialisation(Mazumdar and Rajeev 2009; Neogi et al. 2012; Pannu et al. 2011). These large firms were focused on Novel Drug Delivery Systems (NDDS), and expanding production facilities by importing the latest capital goods and seeking technology transfer (Chaturvedi and Chataway 2006). As a corollary to this, it can be presumed that smaller firms are likely to be less efficient due to lesser division of labour, absence of R&D owing to resource constraints, high capacity utilization ratio, low value of working to fixed capital and limited market reach for their products.

Further, around 41% large firms have more than 0.90 average PTE score, while only around 27% small firms have more than 0.90 average PTE score.[10] The difference between the mean OTE, mean PTE and mean SE scores of both small and large firms is statistically significant, as indicated by t-values. Both types of firms have registered a significant decline in the TE growth in the product patent regime as compared to the pre-product patent regime. Interestingly, larger firms comparatively have recorded significant decline in PTE during the post-patent era.

5.4.2 R&D and efficiency

Prior to 1992, new drug discovery and development has never been on the agenda of IP firms. The onset of liberalization era in 1991, exposed Indian firms to the stark reality that R&D is imperative for survival and existence and it became far more visible after the signing of TRIPS agreement. Thereafter, R&D expenditure has been increasing significantly. With this drastic change in ID&PI, it would be interesting to analyze the impact of R&D on performance of IP firms.

[10] These results are not reported here to conserve the space however will be made available on a request.

Hypothesis 2 In the ID&PI, R&D intensive firms, on an average, are associated with higher efficiencies in comparison to their non-R&D counterparts during the study period from 2000–2001 to 2012–2013.

The sample of 141 firms was categorized as R&D and non-R&D firms. Table 12 compares the mean OTE, PTE and SE scores according to R&D. There are 68 firms having R&D expenditure while rest of the 73 firms do not incur any notable expenditure on R&D. The mean OTE scores for the study period of both groups are 0.748 and 0.709 respectively, indicating that 25.2 and 29.1% of inputs can be reduced without altering the output. Table 12 brings to the fore that there is difference between R&D and non-R&D firms in regard of the efficiency scores. It can be seen that the efficiency score (OTE and PTE) of R&D firms is higher than the non-R&D firms for all the years. Many empirical studies have reported that technical progress and R&D may help to significantly improve performance of the firm (Solow 1957; Griliches 1980). In a pioneer study, Solow (1957) well documented that technological change is one of the key driving factors of growth of a firm. Klette and Griliches (1996) further supported that R&D investment and innovation activities are the engine of growth. The results suggest that R&D intensive firms have benefited more from technological progress than other firms.

The results reported in Table 12 also indicate that both R&D and non-R&D firms have shown pessimistic growth in the product patent regime as compared to the pre-product patent regime. Interestingly, R&D intensive firms have witnessed higher decline in efficiency scores as compared to non-R&D intensive firms in the product patent regime. It may be probably attributed to the considerable rise in the input costs due to increased R&D expenditure during the new patent regime. Besides, it appeared that the disappointing results of the molecules identified and out-licensed by Dr. Reddy Lab and Ranbaxy to MNC majors in recent years discouraged R&D intensive firms about the gains expected of R&D activities despite their putting high stress on the firm's resources. The onset of patent cliff in recent years and growing

Table 12 Mean OTE, PTE and SE scores according to R&D. *Source*: Authors' calculations

Year	R&D intensive firms			Non-R&D firms		
	Mean OTE	Mean PTE	Mean SE	Mean OTE	Mean PTE	Mean SE
Entire period mean	0.748	0.831	0.898	0.709	0.798	0.892
Pre-patent period	0.766	0.846	0.907	0.716	0.799	0.899
Post-patent period	0.736↓	0.822↓	0.892↓	0.704↓	0.798↓	0.887↓
Percentage change	−3.950 (0.079)*	−2.837 (0.079)*	−1.689 (0.188)	−1.776 (0.410)	−0.206 (0.768)	−1.293 (0.769)
t-test	Mean OTE		Mean PTE		Mean SE	
	2.742**		4.120***		0.435	

(1) The arrows ↓ indicates that mean efficiency has decreased respectively during post-product patent period in comparison to pre-product patent period. (2) Percentage change represents percentage change of average efficiency during post-product patent period in comparison to pre-product patent period (3) values in parentheses represents level of significance (*, **, *** represents 10, 5 and 1% level of significance)

emphasis on generic drugs world over probably have also put the Indian R&D intensive firms almost at par with the non-R&D intensive firms. It may be further pointed out that the resources pumped by Indian R&D intensive firms are a small fraction of what exactly is being done by world pharma majors and they are largely inadequate to sustain formidable expenses incurred on drug discovery, testing and marketing by any standard.

5.4.3 Ownership and efficiency

The percentage share of foreign companies in the market share has been declining since the exemption of pharmaceutical products from product patent in India since 1971. It dwindled from around 70% in 1970 to 21% in 2013. The share of Indian companies, on the other hand, registered a phenomenal rise due to their skill in reverse engineering process. But interestingly after Product Patent Act, the share of foreign companies has shown rising trend. With this structural change in ID&PI, it would be interesting to analyze the impact of product patent on different ownership categories' performance.

Hypothesis 3 In the ID&PI, private foreign firms, on an average, are associated with higher efficiencies in comparison to counterparts.

Table 13 compares the mean OTE, PTE and SE scores according to ownership. In the overall sample of 141 firms, 87, 8, 46 are private Indian (PI), private foreign (PF) and group owned (GO) firmsrespectively. A group-owned company may be owned by an Indian or foreign group. The PTE scores highlight that the inefficiency levels in the PI, PF and GO firms were 19.0, 9.7 and 19.7% respectively, thereby suggesting that there were inefficiencies across all firms yet private foreign firms appeared to be performing better on efficiency front than the other two categories.[11] Many studies have reported that the efficiency of MNCs is higher than the domestic Indian firms. There are also studies that found significant spillovers, especially among the international drug majors (Cohen and Levinthal 1989; Feinberg and Majumdar 2001; Epifani 2003; Shrivastava et al. 2012). It appears to be plausible to assume that technical spillovers, superior technology, intangible know-how and wide networking, sourcing and marketing make foreign firms far more efficient than their domestic counterparts (Aitken and Harrison 1999; Djankov and Peter 2002). Interestingly, many studies on the ID&PI have also found MNC subsidiaries to be more efficient than the domestic firms (Mazumdar and Rajeev 2009; Pannu et al. 2011) citing specific reasons of their branded product portfolios, exclusive marketing rights, allocation of more

[11] PI firms having more than 0.90 mean PTE scores are: Ankur Drugs & Pharma Ltd., Divi'S Laboratories Ltd., Anuh Pharma Ltd., Hetero Drugs Ltd.and Arvind Remedies Ltd. PF category includes Novartis India Ltd., Martin & Harris Lab. Ltd., Merck Ltd. and Wyeth Ltd. In GO category, firms such as Elder Health Care Ltd., Aurubindo Pharma Ltd., Cipla Ltd., Ranbaxy Lab. Ltd. and Glaxosmithkline Pharma Ltd. have more than 0.95 mean efficiency scores.

Table 13 Mean OTE, PTE and SE scores according to ownership. *Source*: Authors' calculations

Year	Private Indian			Private Foreign			Group-owned		
	Mean OTE	Mean PTE	Mean SE	Mean OTE	Mean PTE	Mean SE	Mean OTE	Mean PTE	Mean SE
Entire period mean	0.722	0.81	0.896	0.822	0.903	0.909	0.708	0.803	0.885
Pre-patent period	0.727	0.808	0.904	0.817	0.902	0.907	0.748	0.838	0.896
Post-patent period	0.719↓	0.811↑	0.89↓	0.825↑	0.905↑	0.911↑	0.684↓	0.781↓	0.878↓
Percentage change	−1.162 (0.463)	0.346 (0.770)	−1.551 (0.380)	0.943 (0.558)	0.061 (0.941)	0.378 (0.558)	−8.647 (0.040)**	−6.735 (0.003)***	−2.001 (0.464)
F-value	Mean OTE			Mean PTE			Mean SE		
	41.304***			52.009***			1.765		

(1) The arrows ↑ and ↓ indicate that mean efficiency has increased and decreased respectively during post-product patent period in comparison to pre-product patent period. (2) Percentage change represents percentage change of average efficiency during post-product patent period in comparison to pre-product patent period (3) values in parentheses represent level of significance

resources towards marketing activities, and superior technologies. On the other hand, private Indian firms and group-owned firms have to operate in an intensely competitive environment for the markets for the branded and non-branded generic products and, at the same time, allocate more resources towards advertising and marketing so as to compete for maintaining/earning greater share of the same pie.

The study finds that there is negative percentage change in the efficiency of group-owned firms in product patent regime as compared to the pre-product patent period. Incidentally, GO firms appeared to have suffered the most in terms of efficiency loss, whereas PF firms have gained some efficiency in the product patent regime. The F-statistics which has been applied in order to examine differences in the mean scores of efficiencies according to ownership categories, demonstrate statistically significant difference in the mean OTE, PTE and SE scores for various ownership categories. It is probably, the efficiency issues that forced the MNCs and domestic companies to start working together, utilizing each other's strengths for mutual gains. For the foreign firms, this includes not only the Indian companies' research and manufacturing capabilities and their much lower operational cost levels, but also comprehensive marketing and distribution networks operating throughout India's vast territories (KPMG Report 2011). Consequently, MNCs have been able to further improve their performance by outsourcing production of drugs; applying newer methods for employee costs reduction, and rationalizing the workforce and manufacturing facilities (ICRA 2012). Many subsidiaries of MNCs majors, of late, have also set up R&D facilities in India so as to conduct innovation, especially after granting of EMR (Electronic Medical Record) to patent holders from the starting of 1995 year for the development of new drugs by Govt. of India.

5.4.4 Product-wise categories and efficiency

Hypothesis 4 In the ID&PI, firms in formulations section are, on an average, associated with higher efficiencies in comparison to their counterparts during the study period from 2000–2001 to 2012–2013.

In order to examine efficiency across the product categories, the sample firms have also been rearranged product-wise.[12] It may be mentioned that the sample comprises 22 producers of bulk drugs,[13] 78 of formulations exclusively, while remaining 41 firms were found to be operating in both the domains. The relationship between market segments (bulk and formulation), and the efficiency have also been examined. It

[12] Drug manufacturing in India has two important vertically linked processes: (1) production of bulk drug; and (2) the production of formulation. The Bulk drug production is essentially the production of the raw materials or active pharmaceutical ingredients (API) for drugs, whereas formulations are end-products of the medicine manufacturing process, and can take the form of tablets, capsules, injectables or syrups, and can be administered directly to patients (Greene 2007).

[13] Most of the bulk drugs are imported from China due to cost advantage. The significant dependence of India on China is found to be in case of 12 essential drugs namely; Paracetamol, Metformin, Ranitidine, Amoxicillin, Ciprofloxacin, Cefixime, Acetyl salicylic acid, Ascorbic acid, Ofloxacin, Ibuprofen, Metronidazole and Ampicillin. The phenomenal growth of China as a bulk producer has already led to closer of many companies in India (Kallummal and Bugalya 2012).

may be noted that this industry manufactures about 400 bulk drugs belonging to various therapeutic segments, though a fairly large proportion of Indian companies (around 45%) are producing formulations only probably for the fact that formulations are considered to be the high end of value chain of the market as compared to bulk drugs (Liebler 1976).

Table 14 shows that firms engaged in both (bulk and formulation) have recorded highest PTE score. The combinational category of the bulk and formulations has also been found to be quite tempting to the prospective investors due to better profit margins. The customer base being large, these two categories of firms are generally broad product based and have entered into many therapeutic segments. The results demonstrate that there is negative growth in PTE scores of bulk drugs firms both in the post-product patent as compared to pre-product patent regime, whereas formulations have registered positive growth. The decline in efficiency, nevertheless, was far more conspicuous in regard of bulk drug companies, whereas firms in formulations segment have shown some semblance of stability and improvement during the product patent regime. The ANOVA results also indicate that there exists a statistically significant difference in the mean PTE and mean SE scores among the three categories. The mean OTE scores for all the three categories of firms reached at their respective highest points in the year 2000–2001 and minimum in the year 2012–2013. There has been decreasing trend in mean OTE scores from 2000–2001 to 2004–2005 and after that the scores have been more or less stable up to 2010–2011 but again they demonstrate declining trend in recent years. The firms engaged in formulations have shown stable and increasing trend in the mean PTE scores over the study period. It may be due to the fact that most of the private foreign firms are in this segment. The Indian companies are undergoing a transition from active pharmaceutical ingredients (API) to high margin generic formulations and from unregulated to regulated markets.

5.5 Determinants of efficiency

After estimating efficiency levels, it was interesting to examine the factors affecting the efficiency scores of the firms. From the literature (Ray 1991; Simar and Wilson 2007; Banker and Natarajan 2008; McDonald 2009), it is clear that there is no consensus on how a second stage analysis following the DEA should be carried out. With this ambiguity in mind, the study applies simple OLS method in order to identify determinants of efficiency in the Indian pharmaceutical industry. It may be noted here that several studies have been undertaken to identify the determinants of efficiency, with the most notable contribution from Caves (1982).

In the present study, we have considered seven important factors which may exert influence on the efficiency score of IP firm. Table 15 provides the description of the factors and their expected effect on the efficiency of the IP firms.

We hypothesize that all the selected variables (ownership, R&D intensity, age, export intensity, intensity of capital imports and size) except for time dummy, have positive effect on the efficiency of IP firm.

Table 14 Mean OTE, PTE and SE scores according to product-wise. *Source*: Authors' calculations

Year	Bulk drugs			Formulations			Both		
	Mean OTE	Mean PTE	Mean SE	Mean OTE	Mean PTE	Mean SE	Mean OTE	Mean PTE	Mean SE
Entire period mean	0.732	0.79	0.925	0.722	0.818	0.887	0.734	0.823	0.895
Pre-patent period	0.774	0.834	0.928	0.718	0.806	0.894	0.766	0.851	0.904
Post-patent period	0.706↓	0.762↓	0.924↓	0.724↑	0.826↑	0.883↓	0.714↓	0.805↓	0.889↓
Percentage change	− 8.817 (0.040)**	− 8.64 (0.013)**	− 0.506 (0.714)	0.86 (0.608)	2.486 (0.048)**	− 1.286 (0.464)	− 6.788 (0.057)*	− 5.346 (0.010)**	− 1.651 (0.378)
F-test	Mean OTE			Mean PTE			Mean SE		
	0.27			3.436**			4.682**		

(1) The arrows ↑ and ↓ indicate that mean efficiency has increased/decreased respectively during post-product patent period in comparison to pre-product patent period. (2) Percentage change represents percentage change of average efficiency during post-product patent period in comparison to pre-product patent period (3) values in parentheses represent level of significance (*, ** represents 10, 5 and 1% level of significance)

Table 15 Description of independent variables used for fixed effect regression. *Source*: Authors' elaboration

Variables	Description	Hypothesis or expected sign
Ownership (dummy)	Ownership dummy = 1, if foreign firm = 0, otherwise	Foreign ownership has positive impact on efficiency
R&D intensity (t-4)	Ratio of R&D expenditure to sales of firms. Lag of 4 years in R&D is taken in the study	Positive
Age	Age of firms in years	Positive
Export intensity	Ratio of exports to total sales of firms	Positive
Intensity of capital imports	Ratio of capital imports to total sales of firms	Positive
Size	Total fixed assets of firm (Rs. Million)	Positive
Time dummy	T dummy = 1 for the years 2005–2006 to 2012–2013 = 0 for the years 2000–2001 to 2004–2005	Positive or negative

Positive indicates a positive influence of the explanatory variable on the dependent variable (efficiency scores)

5.6 The model

Given the panel data, the OLS regression model is specified as

$$\mathrm{Ln}\left(\mathrm{TE_{jt}}\right) = \mathrm{x_{jt}}\beta + \mu_{it}$$

where j represents the jth firm j (= 1, 2,…, N); the subscript t denotes time (from 2000–2001 to 2012–2013). Utilising a one-way error component model for the disturbance terms to account for the unobservable firm-specific effect[14] we can write $\mu_{it} = \mu_i + \nu_{it}$, where μ_i is the unobservable firm specific effect that is independent of x_{jt}.

The independent variable in our model is x_{jt} which is a vector of k factors that explains variations of the efficiency of the jth firm in the t-th time period (t = 2000–2001 to 2012–2013). In the study, data for all 141 firms are available for all the years and, therefore, there is balanced panel of 1833 firm observations for 13 years.

The exact specification of the fitted model was:

$$\begin{aligned}\mathrm{Ln(PTE)} = {} & \beta_0 + \beta_1\, \mathit{Ownership\ (dummy)} + \beta_2\, \mathit{R\&D\ intensity} + \beta_3\, \mathrm{Age} + \beta_4\, \mathit{Export\ Intensity} \\ & + \beta_5\, \mathit{Intensity\ of\ Capital\ imports} + \beta_6\, \mathit{Size} + \beta_7\, \mathit{Size} * \mathit{R\&D} + \beta_8\, \mathit{Export} * \mathit{Size} \\ & + \beta_9\, \mathit{Square\ Firm\ Size} + \beta_{10}\, \mathit{Time\ Dummy} + \mu_i + \nu_{it}\end{aligned}$$

Here μ_i are the unobserved firm-specific effects and ν_{it} are stochastic terms which are assumed to be identically and independently distributed, IID $(0, \sigma^2)$. It is assumed that the independent variables are independent of ν_{it} for all I and t.

[14] The advantage of panel data is its ability to account for the unobservable firm-specific individual effects, like managerial skill, firm-specific capabilities and others. Not accounting for the firm-specific individual effects can actually lead to bias in the resulting estimates (see Baltagi 2005).

Hausman's specification test was applied for a choice between a fixed effect (FE) and a random effect (RE) model. The value of the relevant Chi square was 36.73 with a p value 0.0000 and rejected the null-hypothesis of no fixed effects.

Apart from correcting heteroscedasticity in the variance matrix, the study has also checked for problems of multicollinearity that can inflate standard errors of the estimates. Tests such as variance inflating factor (VIF) and condition index (CI) reveal that a moderate level of colinearity exists among independent variables not serious enough to mislead the estimated standard errors.

Table 16 presents the results of the fixed effect model wherein LnPTE and LnOTE are the dependent variables. It is observed that the coefficients of ownership, age, capital imports intensity, the time dummy, size, and size square are significant. Ownership, capital imports intensity and size has a positive and significant relationship with efficiency scores, whereas the age, time dummy and size square variables are inversely related. Private foreign firms appeared to be more efficient due to their business in branded drugs which have a higher margin than generic drugs, their superior organizational structure, better experience in management, and higher resource allocations on marketing activities which strengthen their brand and product imageresulting in higher revenue and in turn enhanced efficiency. Our result related to ownership and efficiency is similar to that of Mazumdar and Rajeev 2009; Pannu et al. 2011; Cohen and Levinthal 1989; Feinberg and Majumdar 2001).

This study examines the 4-year gestation period of R&D expenditure due to the incremental nature of the Indian pharmaceutical sector's R&D and the processes involved in marketing the output. The coefficient of R&D intensity is found to be negative and insignificant in case of efficiency scores, possibly because R&D investment increases input costs, but its percentage of return is low and it has a long gestation period. The most plausible reason could be that efficiency is more directly affected by investment in fixed assets rather than in R&D which focuses on incremental value additions in a largely branded/plain generic products market. Sharma (2016) found that R&D data in ID&PI also suffer from non-reporting and measurement problems which often lead to estimation of small or insignificant impact of R&D efforts. He proved that the sunk cost of R&D is high and policy should be designed to decrease it. Arrow (1962) also believes that R&D intensity cannot be related to a firm's monopoly power. The age of the firm is statistically significant with a negative coefficient, indicating that young and new firms are more efficient than old firms. Generally, young firms tend to use advanced technology, which results in higher efficiency. The product patent regime has also provided new business opportunities to firms and the outsourcing business has dramatically increased.

The time dummy was found to be negative and significant with respect to efficiency, indicating that the product patent regime negatively affected the efficiency of firms. The accelerated input cost of the industry coupled with the compulsion to introduce best manufacturing practices can also be attributed in part to the decline in efficiency. It is believed that with this new patent regime Indian generic firms would face difficulties in reverse engineering and imitation of drugs. This changing scenario might not be conducive for the development of this industry (Lanjouw 1998; Grace 2004; Chaudhuri 2005; Nauriyal 2006). Further, as expected, our analysis reveals that the use of advanced imported foreign technology improves

Table 16 Results from fixed effect model. *Source*: Authors' calculation

Number of observations: 1833						
Variables	Model I			Model II		
Dependent Variable	LnPTE			LnOTE		
Independent Variables	Coefficient	t-values	*p* values	Coefficient	t-values	*p* values
Ownership	0.235429**	2.51	0.012	0.1134328**	2.05	0.045
Age	−0.0066107**	−2.21	0.027	−0.0212912***	−5.24	0.000
R&D intensity (t-4)	−0.0014438	−0.56	0.572	−0.0035339	−1.06	0.294
Export intensity	−0.0002488	−1.03	0.305	−0.0002465	−0.75	0.454
Capital imports intensity	0.0019563*	1.73	0.083	0.0030505**	1.99	0.047
Size	0.00001**	2.10	0.036	0.00001**	2.42	0.016
Time dummy	−0.000001*	−1.77	0.075	−0.0674493**	2.18	0.029
Size Square	−1.92e−11*	−1.77	0.076	−3.56e−11**	−2.03	0.043
Size*R&D intensity	−5.30e−08	−0.57	0.568	1.43e−08	0.11	0.909
Size*Export intensity	1.71e−08	0.91	0.363	1.31e−08	0.51	0.609
Constant	−0.0734247	−1.05	0.292	0.1623196*	1.72	0.086
R square (overall)	0.250	F Statistic	10.38	0.23	F Statistic	9.47

***, **, * significant at 1%, 5% and 10% level

the efficiency of firms. Indian pharmaceutical firms have tried to adapt and learn innovated processes of production in the new patent regime, through the import of technology. These developments have significantly and positively affected their performance. This finding is in conformity with the findings of earlier studies (Tybout 2000; Bas and Berthou 2012). The relationship between export intensity and efficiency was found to be negative and insignificant, which was contrary to our expectations. The interaction between the size of the firm and export intensity is positive but insignificant. Similarly, the interaction between size and R&D was also found to be insignificant.

The coefficient of size is positive and significant which implies that with an increase in the size of the firm, its efficiency increases. Large firms are more efficient than small firms due to their scale economies, better technology and efficient human specialization. This indicates that there is better capacity utilization and economies of scale in larger firms. This finding is consistent with the existing studies on ID&PI (Mazumdar and Rajeev 2009; Neogi et al. 2012; Pannu et al. 2011). In such an environment, small firms may either merge to form bigger entities or manufacture pharmaceutical products for other companies as well, to raise the size of their operational scale and improve their capacity utilization. To capture the non-linear relationship between size and efficiency, the square of the size is included in the regression. However, the relationship between the square of size and efficiency

scores was found to be negative and significant. This may be due to X-inefficiency[15] (Leibenstein 1966 and Jovanovic 1982). This implies that diseconomies of scale in production emerge beyond a certain threshold limit, and therefore, the efficiency of the firm falls.

6 Conclusion and policy suggestions

The study estimated the efficiency and productivity of 141 IP firms using Prowess database on from 2000–2001 to 2012–2013 and further divided into two sub-periods on the basis of the threshold for the introduction of Product Patent Regime. The overall inefficiency in the industry during the entire study period could be attributed to both pure technical inefficiency and scale inefficiency. The present study found negative impact of Product Patent Act of 2005 on the efficiency scores. The technological change has played a positive role in the growth of productivity, whereas technical efficiency change depicts the judicious utilization of resources for improving performance.

For analyzing the impact of other variables, a sensitivity analysis was done and it confirms the validity of our selected variables. There is negligible impact of the inclusion of R&D variable in inputs. The possible reason could be that the share of R&D expenditure in total cost is very less and major share around 85–95% is occupied by other inputs which are selected as inputs in our study. With the inclusion of R&D expenditure in input variables, it is found that efficiency scores of R&D active firms are higher than the efficiency scores in case of the whole sample. The present study finds the marginal impact of Product Patent Act of 2005 on efficiency of R&D active firms owing to the fact that patents probably did not result in remarkably better efficiency. The results of productivity were contrary to our expectation due to the choice of estimation technique, as there was no major change in the results of productivity with the inclusion of R&D variable. The regress in TFP growth was probably due to improper utilization of resources and less investment in technological advancement.

The comparative analysis of efficiency results seems to suggest that the efficiency scores varied across sizes, R&D, ownership, and product-groups. On an average, large size firms, R&D intensive firms, private foreign owned, and those engaged in drug and formulations segments have relatively performed better than their counterparts. Further, R&D intensive and large size firms have witnessed a greater decline in efficiency scores in the post-patent regime as compared to their counterparts. The differences among the mean OTE, mean PTE and mean SE scores across almost all the categories are found statistically significant. Private Foreign firms have

[15] X-inefficiency was introduced by Leibenstein (1966). It is the difference between efficient behavior of businesses assumed or implied by economic theory and their observed behavior in practice caused by a lack of competitive pressure. The sources of X-inefficiency have been ascribed to things such as over-investment and empire building by managers, lack of motivation stemming from a lack of competition, and pressure by labor unionsto pay above-market wages.

demonstrated growth in efficiency scores and firms in formulations suggest stability and improvement in the post-patent regime. Thus, the study finds a significant impact of product patent regime on the efficiency scores of large firms, R&D firms, GO firms and all product-wise firms. Further, it is found that ownership, capital imports intensity, and size have a positive and significant relationship with efficiency scores, whereas the age, time dummy and size square variables are inversely related.

6.1 Policy implications

The present research will help in analyzing the impact of the new patent regime on the performance of different categories of IP firms. The study seems to suggest that ID&P firms need to speed up their movement towards diversifying operations, augmenting their product pipeline, considerable improvements in efficiency and gradually shifting to the biopharmaceutical end. Given the fact that the generic market pie is expanding at a reasonably faster rate, more efficient and innovative Indian firms are likely to take advantage of being part of the early birds. The ID&P firms for whom the value of efficiency score has been less than one, improvement in efficiency could result from an improvement in managerial practices, better utilization of existing resources, and investment in innovation and technology. These inefficient firms should identify an optimum sales and marketing mix so as to yield desired profits, as many firms spend a significant amount of their revenue on sales promotion, training of medical representatives and building of brands.

Further, in this competitive environment, the small firms may either merge together to form bigger entities or may manufacture pharma products for other companies in order to raise the size of operational scale and improve the capacity utilization. The mergers and consequent growth in size, nevertheless, need to be supplemented with further investment in the technologically upgraded production facilities that meet the global production and quality standards, along with the adoption of Good Manufacturing Practices (GMPs) as per the requirements of the regulatory agencies. The challenges posed by drug price control, quality management, infrastructure development and conformance to global standards may prove to be insurmountable for relatively smaller Indian firms which may opt to become a feeder line for medium and large firms. Therefore, there are possibilities of further consolidation of the ID&PI.

A possible extension of the present research would be to analysis productivity across different categories of firms which could be undertaken for further research.

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