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Impact of patent (Amendment) act, 2005 on Indian pharmaceutical industry with reference to R&D expenditure, profit, export and sales

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***Abstract*---**The Indian pharmaceutical business is the world's third-largest pharmaceutical sector in terms of volume, but it ranks 14th in terms of value. The lower position in terms of value might be due to the fact that Indian pharmaceutical enterprises are mostly focused on low-cost generic pharmaceuticals, with a broad range of company sizes and product mix. Because of Trade Related Intellectual Property Rights (TRIPS) restrictions, the Indian pharmaceutical business has undergone significant transformation since 1995. TRIPS ratification has had a considerable effect on Indian pharmaceutical industries. The effect of TRIPS on the Indian pharmaceutical industry's R&D Expenditure, profit, export and sales is examined using a dummy variable in this research. Various industrial performance drivers, such as knowledge-based resources and property-based resources, are considered. The research considers a sample of 25 Indian pharmaceutical enterprises over a twenty-five year period (1996-2020). The results show that the Indian pharmaceutical industry is significantly impacted by TRIPS compliance. The findings of this study also emphasize the relative impact of various company resources on the performance of Indian pharmaceutical enterprises. The results of this study will add to the expanding body of knowledge addressing the factors that influence the success of the Indian pharmaceutical sector in developing countries.

***Keywords*---**Indian pharmaceutical industry, R&D expenditure, profit, export.

Introduction

The pharmaceutical sector contributes to humanity's wellbeing and delivers significant socioeconomic benefits to society via employment creation, supply chain development, and community enhancement. The pharmaceutical business in India is one of the biggest and most sophisticated in the world. India is third in terms of volume and fourteenth in terms of value (IBEF, 2021). The Indian pharmaceutical industry contributes roughly 2% to GDP and over 8% to total goods exports (Department of Pharmaceuticals, 2019). India's over 18% rise in pharmaceutical exports during 2020-21, a pandemic year, when world production and trade dropped, demonstrates the sector's resilience. Even throughout the 2008 global recession, the Asian pharmaceutical sector remained largely unaffected with India having negligible impact (Bhatt and Panigrahi 2014).

Aside from that, the pharmaceutical industry's linked industries, such as healthcare, medical technology, and biotechnology, provide a significant amount of employment across the nation. The pharmaceutical export market had a total turnover of US$24.4 billion in 2020-21, representing an increase of 18.1% year on year. It is anticipated that India's domestic pharmaceutical business would be worth US$65 billion by 2024, and that it will expand even further to US$130 billion by 2030. Over the years, the nation has established itself as a significant producer and exporter of not just bulk pharmaceuticals and formulations, but also other medical supplies and provisions (Export–Import Bank, 2016). The pharmaceutical sector's performance has improved significantly as a result of a series of policy reforms, including TRIPS ratification, facilitation of sector-specific infrastructure development, skill development, and foreign direct investment (FDI) inflows, on the one hand, and ease of doing business on the other (Government of India [GoI], 2017).

Against this backdrop, the purpose of this paper is to study the peculiarities of the Indian Pharmaceutical Industry's changing dynamics over the previous two decades, as well as the role of firm specific variables that continue to impact the sector's performance. More precisely, the R&D Expenditure, profit, export and sales analyzed in order to identify potential for India's pharmaceutical exports to grow. The remaining paper is divided into five parts. The second portion contains an overview of the literature, while the third section contains conceptual framework. The fourth portion explains the data sources and technique used to conduct the empirical study, while the fifth section analyses the empirical results. Lastly, policy implications are discussed.

Conceptual framework

Indian pharmaceutical industry and Patent

The Indian pharmaceutical industry (IPI) is the world's largest provider of low-cost generic pharmaceuticals. The spectacular growth in this sector is primarily due to various legislative reforms implemented by the Indian government to protect its domestic pharmaceutical industry and reduce foreign dominance, as well as other changes such as reverse engineering of patented drug molecules and the implementation of Trade Related Intellectual Property Rights (TRIPS). Patents are

intellectual property right (IPR) in the pharmaceutical sector. India's patent system underwent significant modifications after India's 1995 signing of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. India, as a party to the TRIPS agreement, was legally obligated to alter its patent legislation to conform to the agreement's rules. The first in this series was the Patents (Amendment) Act, 1999, which provided pipeline protection[1]until the government began granting product patents for pharmaceutical discoveries. It established regulations for the filing of product patent applications in the fields of medicines and agrochemicals as mailbox applications with effect from 1st January 1995 and for the granting of Exclusive Marketing Rights (EMRs) on such patents. India revised the Patents Act, 1970 by the Patents (Amendment) Act, 2002 to meet with the second set of TRIPS commitments. This amendment provided a consistent 20-year patent term[2] for all kinds of inventions, i.e. patents have a restricted period of 20 years commencing from the filing date of the patent application.

Historically, India has pursued numerous patent regimes at various times. The emergence of the World Trade Organization has led several countries to amend their domestic patent laws in order to encourage international trade in accordance with the terms of the new Trade Related Intellectual Property Rights (TRIPS). India became a signatory to World Trade Organization regulations on January 1, 1995, and has been allowed a 10-year window time beginning January 1, 2005, to completely transition from a process-patent system to a product patent regime. In this study, the process-patent regime (1995-2004) was referred to as the transitory-TRIPS period, and the product-patent regime after 2005 was referred to as the post-TRIPS period, following the convention established by previous researchers (Gupta & Manchikanti, 2010; Rentala, Anand & Vutukuri, 2015).

Earlier researchers highlighted that institutional reforms result in significant changes to a country's economic and competitive situations. Institutional changes have a range of effects across nations and sectors within a country (Chari & Banalieva, 2015). Prior empirical research on the relationship between institutional changes and company performance has mostly come from China (Park, Li, & Tse, 2006) and Latin America (Bruton, Ahlstrom & Puky, 2009; Cuervo-Cazurra & Dau, 2009). Thus, India provides a novel scenario for examining the predicted link between institutional changes and business export success (Aulakh & Kotabe, 2008)

Profit

Earnings are a fundamental notion in industrial growth plans because profits influence investment decisions, industry growth, and trade orientation, and so have a significant impact on capacity, productivity, and efficiency (Uctum, 1995).
The Indian pharmaceutical industry has had rapid growth in recent years, and it now has tremendous prospects to build a highly diverse branded generics portfolio. Several blockbuster medications will soon lose their patent protection. The year 2000 appears to be a tipping point after which profit and profit intensity appear to be steadily increasing (Tyagi and Nauriyal, 2016). The most intriguing aspect of ID&PI is that the pharmaceutical industry is heavily concentrated within the top 20 companies, which share over half of the earnings earned. Profit

intensities (profit after taxes as a percentage of total sales revenue) of the top 91 and 20 companies are significantly higher than those of all listed companies, implying that successful Indian pharmaceutical companies are the leading profit earners. This can be linked to the comparably larger and wiser players' robust growth through global expansion, which resulted in increasing profit intensity up until 2009. As a result, globalization and the reduction of trade restrictions appear to have ushered in a slew of positive improvements in the Indian pharmaceutical industry. One such change was the increased investment in drug development and generics to combat the threat of MNCs in the global market (Govindaraj and Chellaraj, 2002).

Although profit intensities for all listed firms remained comparatively greater in 2009-2013 than in 2004-2009, the top 91 and 20 enterprises only showed a modest improvement. Larger pharma businesses' slower growth rate can be ascribed to factors such as growing production costs, failed R&D projects, and stringent regulatory requirements, among others. Because profitability is crucial to any industry's survival and growth, it would be interesting to look at the determinants of profitability in ID&PI from 1995 to 2020, when the signs of a shift in the operating environment began to emerge and the transition really occurred.

R&D expenditure

R&D programmes are critical to a company's competitive advantage because they assist in the development of superior products/technologies with a well-defined competitive advantage (Lev and Sougiannis 1996; Ettlie 1998; Bhagwat and DeBruine 2011), particularly in knowledge-intensive industries like the drugs and pharmaceutical (D&P) industry. As part of their national and worldwide survival and growth plans, companies in this business must constantly innovate by inventing and promoting new goods, drug delivery systems, and product features based on cutting-edge scientific discoveries. The worldwide drug and pharmaceutical sector has seen a tremendous increase in R&D intensity during the previous two decades (R&D expenditure-to-sales revenue ratio). According to a report published by the European Federation of Pharmaceutical Industries and Associations in 2013, the top 1500 global pharmaceutical companies spent roughly 15% of their sales revenue on R&D operations in 2011. The Indian D&P industry's R&D investment has also changed dramatically.

Export

Indian pharmaceuticals are exported to more than 200 countries around the world, with the United States being the largest market. India's 'Pharma Vision 2020,' according to the Department of Pharmaceuticals, wants to become a major centre for end-to-end pharmaceutical innovation. Export performance is one of the most extensively researched yet most ambiguous domain in international business study (Katsikeas, Leonidou & Morgan, 2000). In the international business realm, determining the factors that affect a firm's export competitiveness has long been a major study objective (Peng, 2004). The study of the determinants of export success gives an ideal opportunity for a variety and mix of empirical experiments in a range of scenarios (McKinley, Mone & Moon, 1999).

Sales

The goal of the pharmaceutical industry is to maximize financial return on investments through sales.

Review of literature

Kiran and Mishra (2009) looked at patenting activity, R&D, and exports to assess the performance of the Indian pharmaceutical business in the post-TRIPS era. Patent filings and patent granted in medications and pharmaceuticals increased after TRIPS, as did sales, exports, and R&D spending, according to the study. TRIPS compliance benefited India's pharmaceutical industry by encouraging innovation and increasing R&D spending. The foreign penetration of the Indian pharmaceutical business was explored in terms of mergers and acquisitions (M&A). The results of panel data regression suggest that export and M&A have a favourable link. 2017 (Mishra & Jaiswal). The impact of TRIPS and Regional Trade Agreements (RTAs) on Indian pharmaceutical product exports was investigated using the Gravity Model. RTAs have a favourable influence on exports, whereas TRIPS has a negative impact (Loitongbam, 2016).

Despite the fact that the product patent regime has made life difficult for Indian companies, an examination of pharmaceutical patents granted in India and at the USPTO (United States Patent and Trademark Office) has revealed that the number of applications and patents granted is steadily increasing. However, in comparison to the entire number of pharmaceutical companies, the number of applications submitted is lower (Rau, Nair & Appaji, 2012).

Even if India does not fully utilise the compulsory licencing options, generic manufacturers in India may be able to enter the market once the patent expires. Prior to the creation of the product patent system, it favoured non-patent holders; but, post TRIPs compliance, it clearly favours patent holders (Chaudhuri, 2005). According to study (Chaudhuri, 2011) on post-TRIPS pharmaceutical MNC behaviour, MNCs have been pushing new patented medications at exorbitant prices, importing expensive formulations, and boosting their market share of formulations by acquiring select Indian firms. MNCs are apprehensive to expand R&D in India following TRIPS. Manufacturing patent medications in India is a risky business for multinational corporations. They prefer to import those from other countries. MNCs wanted patents to prevent generic competition from Indian enterprises, rather than for true innovation.

Duperon and Cinar evaluated the relative impacts of policies related to Intellectual Property Rights on the Indian domestic pharmaceutical industry (2010). According to the study, India provides the finest environment for developing KPO (knowledge process outsourcing) operations, and as a result, several U.S. pharmaceutical companies have clinical testing units in India. During the transitional TRIPs era, the impact of various enterprise resources (internal, marketing, and capital) on the export performance of the Indian pharmaceutical industry was stronger than after TRIPs (Rentala, Nandru, Vutukuri & Anand, 2015).

The impact of issued patents, regulatory filings, and R&D spending on Indian pharmaceutical exports was investigated using the paired Granger causality test (Banerji & Suri, 2017). According to study, patents lead to export and R&D spending leads to regulatory filing. Additionally, the Autoregressive Distributed Lag (ARDL) model demonstrated that both patent issuance and regulatory filing had a positive impact on pharmaceutical export. The impact of regulatory submission, on the other hand, is bigger. In light of this, research models have been developed to evaluate the influence of patents on R&D expenditure, profit, export, and sales in the Indian pharmaceutical business.

The Indian pharmaceutical business, which has undergone many institutional changes in the last two decades, is the subject of this study. The framework for this investigation was developed from a previous study (Tseng et al, 2007). This method divides firm resources into knowledge-based and property-based categories. Resources are only beneficial when they allow organisations to implement approaches that improve efficiency and effectiveness (Barney, 1991). As a result, businesses must evaluate the efficacy and efficiency of their resource allocation. As a result, several international business scholars have looked into the impact of internal company resources on firm success.Objectives of Study. To study the impact of TRIPS on pharmaceutical industry's R&D expenditure, profit, exports an sales of India using knowledge based and property based resources as determinants.

Data

The data for this study was taken from the PROWESS database, which was created by the Centre for Monitoring Indian Economy (CMIE) for a twenty-five-year period from March 1995 to March 2020. To analyse the performance of the Indian pharmaceutical industry, a dummy variable is used. The time period before Patent (amendment)Act, 2005) is referred to as the transitory-TRIPS phase, and it covers the years 1995 to 2004. The time period after Patent (Amendment Act, 2005) is referred to as the post-TRIPS phase, and it covers the years 2005 through 2020. These two time periods were selected to align with the institutional developments that influenced the Indian pharmaceutical business after India became a signatory to the WTO regulations on January 1, 1995. India has been allowed a ten-year grace period to fully comply with the TRIPS requirements, and as a result, India has begun to accept product patents as of January 1, 2005.

As a result, this study examines the performance of the Indian pharmaceutical industry's exports throughout the transitory-TRIPS (1995-2004) and post-TRIPS (2005-2020) eras. The Prowess database contains information on almost 908 companies in the Indian pharmaceutical business. A total of 25 companies were included in the study's final sample. These companies were chosen based on the assumption that they all had export sales during both the transitory-TRIPS and post-TRIPS eras. As a result, the final sample is an unbalanced panel of 25 companies spanning 25 years.

Research methodology

The present research uses panel data to examine the effect of Patent (Amendment) Act, 2005) on Indian pharmaceutical exports. Because it involves double subscript, a panel regression differs from conventional time series and cross sectional regression models. Another benefit of panel regression is that it aids in the control of unobserved variables that vary over time but not across entities. Furthermore, the temporal effect is incorporated in panel model estimation, which aids in managing individual heterogeneity by enabling firm specific random or fixed effect components (Baltagi, 2008).

In the current study, panel data estimation is used for a variety of reasons. For instance, companies are considered heterogeneous in panel models, although this is not the case in time and cross-sectional data series, resulting in biases. As a result, the capacity to manage heterogeneity is the primary cause. Second, the panel data technique gives greater variance in datasets, high information data, reduced multi-collinearity, and a large degree of freedom with a high efficiency (Gujrati, 2009). The model utilised in this study has n cross sectional units, n = 1,....., N, which are observed at each t time period, t = 1,....., T. The dataset has a total of n x t observations. The panel regression model that follows is based on the same panel dataset structure as the above-mentioned researchers.

Where ynt stands for regressand, is the intercept term, is the K x 1 vector of the parameter to be estimated, and xnt stands for the nth observation on the K regressors, which is 1 x k, t = 1,....., T, n = 1,.....,N.
The above-mentioned model's operational form is:

$$Y_{it} = \alpha + X_{it1}\beta_1 + X_{it2}\beta_2 + X_{it3}\beta_3 + \ldots\ldots\ldots\ldots + X_{itk}\beta_k + \varepsilon_{it}$$

Six regression equation model for the study are as follows:

1st model: RDINT is a dependent variable, whereas knowledge-based resources(EXPINT, ICGINT, IRMINT, MKTINT, MKTSHR) and property-based resources (CAPINT, PINT, DER) are independent variables for the Pharmaceutical Industry and AGE & SIZE of the firm are control variables.

$$RDINT_{it} = \alpha + \beta_1 EXPINT_{it1} + \beta_2 ICGINT_{it2} + \beta_3 IRMINT_{it3} + \beta_4 MKTINT_{it4} + \beta_5 MKTSHR_{it5} + \beta_6 CAPINT_{it6} + \beta_7 PINT_{it7} + \beta_8 DER_{it8} + \beta_9 SIZE_{it9} + \beta_{10} AGE_{it10} + \varepsilon_{it}$$

2nd model: PINT is a dependent variable, whereas knowledge-based resources (EXPINT, RDINT, ICGINT, IRMINT, MKTINT, MKTSHR) and property-based resources (CAPINT, DER) are independent variables for the Pharmaceutical Industry and AGE & SIZE of the firm are control variables.

$$PINT_{it} = \alpha + \beta_1 EXPINT_{it1} + \beta_2 ICGINT_{it2} + \beta_3 IRMINT_{it3} + \beta_4 MKTINT_{it4} + \beta_5 MKTSHR_{it5} + \beta_6 CAPINT_{it6} + \beta_7 RDINT_{it7} + \beta_8 DER_{it8} + \beta_9 SIZE_{it9} + \beta_{10} AGE_{it10} + \beta_{11} \mathrm{SPR}_{it11} + \varepsilon_{it}$$

3rd model: EXPINT is a dependent variable, whereas knowledge-based resources (RDINT, ICGINT, IRMINT, MKTINT, MKTSHR) and property-based resources

(CAPINT, PINT, DER) are independent variables for the Pharmaceutical Industry and AGE & SIZE of the firm are control variables.

$$EXPINT_{it} = a + \beta_1 RDINT_{it1} + \beta_2 ICGINT_{it2} + \beta_3 IRMINT_{it3} + \beta_4 MKTINT_{it4} + \beta_5 MKTSHR_{it5} + \beta_6 CAPINT_{it6} + \beta_7 PINT_{it7} + \beta_8 DER_{it8} + \beta_9 SIZE_{it9} + \beta_{10} AGE_{it10} + \varepsilon_{it}$$

4th model: SALES is a dependent variable, whereas knowledge-based resources (EXPINT, RDINT, ICGINT, IRMINT, MKTINT, MKTSHR) and property-based resources (CAPINT, PINT, DER) are independent variables for the Pharmaceutical Industry and AGE & SIZE of the firm are control variables.

$$LSALES_{it} = a + \beta_1 EXPINT_{it1} + \beta_2 ICGINT_{it2} + \beta_3 IRMINT_{it3} + \beta_4 MKTINT_{it4} + \beta_5 MKTSHR_{it5} + \beta_6 CAPINT_{it6} + \beta_7 RDINT_{it7} + \beta_8 DER_{it8} + \beta_9 SIZE_{it9} + \beta_{10} AGE_{it10} + \beta_{11} \mathrm{SPR}_{it11} + PINT_{it12} + \varepsilon_{it}$$

In all the proposed models, i.e. model 1, model 2, model 3 and model 4 the meaning of different symbols is as follows:
a = intercept,
i = company name,
t = time period (year)
β_1, ,…, β_{12} = Co-efficient of the respective regressor,
ε = Error term, assume to be uncorrelated with mean zero.

Variables and their definition

The details of the various variables used in previously proposed models and their definitions are described in table 1.

Table 1: List of Variables and Their Description

S. No.	Variable Name	Proxy	Description
1.	Export Intensity	EXPINT	Export/Total Sales
2.	R&D Intensity	RDINT	Research & Development Expenses / Total
3.	Import of Capital Goods Intensity	ICGINT	Import of Capital Goods Expenses /Total Sales
4.	Import of Raw Materials Intensity	IRMINT	Import of Raw Materials Expenses / Total Sales
5.	Marketing Intensity	MKTINT	(Advertising + Distribution + Promotion Expenses) / Total Sales
6.	Market Share	MKTSHR	Firm's sales / Total sales
7.	Profitability Intensity	PINT	Profit after Tax / Total Sales
8.	Capital Intensity	CAPINT	Net Assets / Total Sales
9.	Debt-Equity Ratio	DER	Borrowings / Net worth
10.	Size of the firm	SIZE	Natural Logarithm of Total Sales
11.	Age of the firm	AGE	No. of Years since Incorporation
12.	Dummy (for stronger patent regime)	SPR	It is taken as dichotomous variables, i.e., attributing the value of *1* for a period after *2004*, otherwise *0*.

Empirical results and Discussion

This study is an attempt to investigate impact of TRIPS on pharmaceutical export of India using firm specific variables as control variable through Panel Data regression analysis.

Descriptive Statistics

Table 2 and 3 give a summary of all variables for the pre and post Patent (amendment) Act, 2005 periods. It is seen that the Research & Development intensity (RDINT) has increased more than 2 times from 1.22, before amendment to 2.68 after amendment, this shows that post 2005 amendment Research and development activities got a push. The mean value of Profit intensity (PINT) has significantly increased from -9.998 to 5.93, whish shows that the industry is more profitable post amendment. The export intensity (EXPINT) has also increased from 33.45 to 41.21. Moreover, the standard deviation show variation in dataset. Which in RDINT and PINT is reported more in post Patent (amendment) Act, 2005 when compared with before amendment period. However, EXPINT is reported more for before the amendment period. This can be clear through the maximum and minimum value of RDINT, PINT and EXPINT. Finally, it can also be noticed that minimum value of PINT and DER are negative which indicates that firms are incurring losses and have more liabilities than assets, which is considered as a risky situation. Further, other variables indicate a variation in the average value and standard deviation. Mean value and standard deviation of marketing intensity (MKTGINT) and sales (SALES) are greater for post amendment period in comparison to pre-amendment period. Whereas, the mean value of Capital Intensity (CAPINT) is less for post amendment period in comparison to pre-amendment. This is a good indicator as it indicates how well a company can use its resources to maximize revenue with minimum operating cost. Hence, it can be concluded that in post amendment period companies have greater sales with lesser investment.

On the other hand, the mean value of import of raw material intensity (IRMINT) is lesser in post amendment period and the import of capital goods intensity (ICGINT) is more in post amendment period which means more investment in fixed assets which could result into exports. The mean value of market share (MKTSHR) for post amendment period is lesser in comparison to pre amendment. There is an improvement in pharmaceutical industry in post amendment period in comparison to pre amendment. The total asset size of companies post amendment are greater than pre amendment. However, based on the above result a concrete conclusion cannot be formulated as it fails to divulge the relationship among different factors affecting pharmaceutical industry.

Table 2: Descriptive Statistics of Pre-TRIPS period

Variable	Obs	Mean	Std. Dev.	Min	Max
RDINT	106	1.223	1.278	.07	8.55
MKTGINT	225	5.426	3.384	-1.33	19.3
PINT	225	-9.987	76.315	-871.429	70.968

EXPINT	221	33.452	30.711	.089	223.077
IRMINT	146	19.376	17.113	.416	90.847
ICGINT	35	2.043	8.714	.007	51.939
DER	223	67.263	507.765	-6773.077	2281.25
CAPINT	225	93.557	243.372	1.892	2253.846
MKTSHR	225	1.017	1.674	.001	7.544
AGE	225	44.88	18.221	28	98
SIZE	225	2.686	.763	1.417	4.417
SALES	225	1778.058	3456.618	1.4	24011.7

Table 3: Descriptive Statistics of Post-TRIPS period

Variable	Obs	Mean	Std. Dev.	Min	Max
RDINT	276	2.685	5.931	.04	83.18
MKTGINT	401	5.551	3.786	.16	26.7
PINT	401	5.938	81.691	-315.686	1564.423
EXPINT	398	41.211	28.77	0	121.569
IRMINT	270	17.26	15.15	.052	78.054
ICGINT	106	1.501	6.469	.006	64.715
DER	388	113.418	236.627	-933.964	2200.457
CAPINT	401	63.134	91.001	3.129	801.25
MKTSHR	401	.684	1.459	.001	8.277
AGE	401	45.451	18.365	28	98
SIZE	401	3.396	.839	1.846	5.368
SALES	401	10104.092	24524.967	8	158236.8

Unit-root test

Stationary time series are used in the concept of Autoregressive Moving Average (ARMA) estimation (Graupe et al. 1975). If the mean vales and autocovariance of a sequence do not vary on time, it is designated as (weakly or covariance) stationary. Non-stationary series are those that are not stationary. All the variables were found to be stationary at level.

Table 4: Result of Unit Root Test

	ADF Test Statistic		PP Test Statistic	
Variable	Inverse chi-squared P	Inverse normal Z	Inverse chi-squared P	Inverse normal Z
RDINT	175.2305***	-5.8789***	175.2305***	-5.8789***
MKTINT	152.9046***	-7.0481***	152.9046***	-7.0481***
PINT	238.1078***	-10.0860***	238.1078***	-10.0860***
EXPINT	141.4541***	-5.4660***	141.4541***	-5.4660***
IRMINT	53.9273***	-1.9353***	53.9273***	-1.9353***
ICGINT	147.8846***	-7.7614***	147.8846***	-7.7614***
DER	267.2553***	-8.5862***	267.2553***	-8.5862***
CAPINT	138.9155***	-5.2767***	138.9155***	-5.2767***
MKTSHR	171.9270***	-3.7166***	171.9270***	-3.7166***

LSALES	167.7475***	-7.9372***	167.7475***	-7.9372***
SIZE	154.9655***	-2.4087***	154.9655***	-2.4087***

*** p<.01, ** p<.05, * p<.1

Pearson Correlation Analysis

Table 5,6,7 and 8 shows the Pearson Correlation Analysis for the chosen variables. No two variables are substantially correlated, according to the correlation finding. All variables have lower than the 0.80 cutoff value (Hair et al., 1995).

Table 5: correlation matrix for model 1

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
(1) RDINT	1.000											
(2) MKTGINT	0.068	1.000										
(3) PINT	-0.008	0.050	1.000									
(4) EXPINT	0.298	-0.145	-0.062	1.000								
(5) IRMINT	0.157	-0.373	0.041	0.563	1.000							
(6) ICGINT	-0.015	-0.040	0.027	-0.108	-0.016	1.000						
(7) SPR	0.129	0.018	0.095	0.127	-0.063	-0.032	1.000					
(8) DER	0.038	0.023	0.017	0.027	-0.014	0.062	0.062	1.000				
(9) CAPINT	0.298	0.109	-0.337	0.236	0.144	0.130	-0.089	0.014	1.000			
(10) MKTSHR	0.158	0.026	0.065	0.123	0.160	-0.080	-0.103	-0.025	-0.106	1.000		
(11) AGE	-0.013	0.258	0.056	-0.245	-0.252	-0.199	0.013	0.005	-0.207	0.339	1.000	
(12) SIZE	0.369	0.041	0.085	0.145	0.175	-0.107	0.387	0.035	-0.117	0.612	0.221	1.000

Table 6: correlation matrix for model 2

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
1) PINT	1.000											
(2) RDINT	-0.008	1.000										
(3) MKTGINT	0.050	0.068	1.000									
(4) EXPINT	-0.062	0.298	-0.145	1.000								
(5) IRMINT	0.041	0.157	-0.373	0.563	1.000							
(6) ICGINT	0.027	-0.015	-0.040	-0.108	-0.016	1.000						
(7) SPR	0.095	0.129	0.018	0.127	-0.063	-0.032	1.000					
(8) DER	0.017	0.038	0.023	0.027	-0.014	0.062	0.062	1.000				
(9) CAPINT	-0.337	0.298	0.109	0.236	0.144	0.130	-0.089	0.014	1.000			
(10) MKTSHR	0.065	0.158	0.026	0.123	0.160	-0.080	-0.103	-0.025	-0.106	1.000		
(11) AGE	0.056	-0.013	0.258	-0.245	-0.252	-0.199	0.013	0.005	-0.207	0.339	1.000	
(12) SIZE	0.085	0.369	0.041	0.145	0.175	-0.107	0.387	0.035	-0.117	0.612	0.221	1.000

Table 7: Correlation matrix for model 3

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
(1) EXPINT	1.000											
(2) RDINT	0.298	1.000										
(3) MKTGINT	-0.145	0.068	1.000									
(4) PINT	-0.062	-0.008	0.050	1.000								
(5) IRMINT	0.563	0.157	-0.373	0.041	1.000							
(6) ICGINT	-0.108	-0.015	-0.040	0.027	-0.016	1.000						
(7) SPR	0.127	0.129	0.018	0.095	-0.063	-0.032	1.000					
(8) DER	0.027	0.038	0.023	0.017	-0.014	0.062	0.062	1.000				
(9) CAPINT	0.236	0.298	0.109	-0.337	0.144	0.130	-0.089	0.014	1.000			
(10) MKTSHR	0.123	0.158	0.026	0.065	0.160	-0.080	-0.103	-0.025	-0.106	1.000		
(11) AGE	-0.245	-0.013	0.258	0.056	-0.252	-0.199	0.013	0.005	-0.207	0.339	1.000	
(12) SIZE	0.145	0.369	0.041	0.085	0.175	-0.107	0.387	0.035	-0.117	0.612	0.221	1.000

Table 8: Correlation matrix for model 4

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
(1) SALES	1.000												
(2) RDINT	0.239	1.000											
(3) MKTGINT	0.056	0.068	1.000										
(4) PINT	0.043	-0.008	0.050	1.000									
(5) EXPINT	0.193	0.298	-0.145	-0.062	1.000								
(6) IRMINT	0.047	0.157	-0.373	0.041	0.563	1.000							
(7) ICGINT	-0.059	-0.015	-0.040	0.027	-0.108	-0.016	1.000						
(8) SPR	0.199	0.129	0.018	0.095	0.127	-0.063	-0.032	1.000					
(9) DER	-0.019	0.038	0.023	0.017	0.027	-0.014	0.062	0.062	1.000				
(10) CAPINT	-0.073	0.298	0.109	-0.337	0.236	0.144	0.130	-0.089	0.014	1.000			
(11) MKTSHR	0.618	0.158	0.026	0.065	0.123	0.160	-0.080	-0.103	-0.025	-0.106	1.000		
(12) AGE	0.238	-0.013	0.258	0.056	-0.245	-0.252	-0.199	0.013	0.005	-0.207	0.339	1.000	
(13) SIZE	0.625	0.369	0.041	0.085	0.145	0.175	-0.107	0.387	0.035	-0.117	0.612	0.221	1.000

Analysis of Multicollinearity

Table 9,10,11 and 12 demonstrates how the variance inflation factor (VIF) and tolerance test may be used to diagnose multicollinearity in all variables. Before performing the regression, the VIF is utilised to quantify the relationship between

all independent variables. Panel regression's most important assumption is that it estimates the amount of variation in the coefficient owing to multicollinearity. When it comes to multicollinearity, the common guideline is that VIF should be smaller than 10. (Gujrati, 2009). All of the variables in this research had values that are lower than the permissible level.

Table 9: Results of multicollinearity test for model 1

	VIF	1/VIF
SIZE	3.378	.296
MKTSHR	3.205	.312
MKTGINT	3.005	.333
AGE	2.223	.45
CAPINT	2.118	.472
SPR	2.106	.475
IRMINT	1.866	.536
PINT	1.799	.556
EXPINT	1.511	.662
DER	1.168	.856
ICGINT	1.131	.885
Mean VIF	2.137	.

Table 10: Results of multicollinearity test for model 2

	VIF	1/VIF
SIZE	3.415	.293
MKTSHR	3.358	.298
MKTGINT	2.917	.343
AGE	2.504	.399
RDINT	2.469	.405
CAPINT	2.425	.412
SPR	2.146	.466
IRMINT	2.051	.487
EXPINT	1.897	.527
DER	1.166	.858
ICGINT	1.089	.918
Mean VIF	2.312	.

Table 11: Results of multicollinearity test for model 3

	VIF	1/VIF
CAPINT	5.31	.188
SIZE	3.366	.297
MKTGINT	3.362	.297
RDINT	3.202	.312
MKTSHR	2.936	.341
PINT	2.928	.341
IRMINT	2.034	.492

AGE	2.015	.496
SPR	1.897	.527
ICGINT	1.245	.803
DER	1.147	.872
Mean VIF	2.676	.

Table 12: Results of multicollinearity test for model 4

	VIF	1/VIF
CAPINT	5.882	.17
RDINT	4.368	.229
MKTSHR	3.714	.269
SIZE	3.446	.29
MKTGINT	3.363	.297
PINT	3.183	.314
AGE	2.547	.393
SPR	2.226	.449
IRMINT	2.218	.451
EXPINT	2.061	.485
ICGINT	1.246	.802
DER	1.171	.854
Mean VIF	2.952	.

Heteroscedasticity analysis

Heteroscedasticity is a kind of error term in which the error term's variances are not constant (Gujarati, 2009). Variance is used to assess spread in economics, while heteroscedasticity is uneven spread. The Breusch-Pagan (BP-LM) test is used to determine if the residuals have an unequal distribution (Greene, 2003). To summarize, model exhibit heteroscedasticity, as shown by p-values less than 0.05, as seen in Table 13.

Table 13: Breusch-Pagan Test for Heteroscedasticity

Models	Chi-square	P-value
Model-1 RDINT	chi2(1) = 326.08	Prob > chi2 = 0.0000
Model-2 PINT	chi2(1) = 150.18	Prob > chi2 = 0.0000
Model-3 EXPINT	chi2(1) = 7.82	Prob > chi2 = 0.0052
Model-4 SALES	chi2(1) = 67.44	Prob > chi2 = 0.0000

Auto-Correlation Analysis

Serial correlation occurs only when error terms from distinct periods are correlated. The Wooldridge autocorrelation test is used to determine the existence of serial correlation (Wooldridge, 2002). The null hypothesis is that there is no serial correlation between the data, whereas the alternative hypothesis is that there is serial correlation between the data. As seen in Table 14, all models have auto correlation. When heteroscedasticity and autocorrelation are present in the data, robust standard errors are used to estimate the outcomes.

Null hypothesis: No first-order autocorrelation
Alternate hypothesis: Null is not true.

Table 14: Wooldridge Test for Autocorrelation in Panel Data

Models	F-statistics	P-value
Model-1 RDINT	F(1, 6) = 11.114	Prob > F = 0.0157
Model-2 PINT	F(1, 6) = 9.527	Prob > F = 0.0215
Model-3 EXPINT	F(1, 6) = 323.494	Prob > F = 0.0000
Model-4 SALES	F(1, 6) = 774.836	Prob > F = 0.0000

Static panel regression analysis

In this section, results of panel regression analysis are presented. We have computed fixed effect and random effect model for the dependent variables RDINT, PINT, EXPINT and LSALES separately and adopted robust regression technique as the model has the presence of heteroscedasticity. Table 15,16,17 and 18 presents the regression result. Firstly, both FEM and REM results are calculated. Then, hausman test is conducted to select between FEM and REM. In this case, FEM was selected. So finally, robust technique was conducted on FEM basis and results are interpreted accordingly

Table 15: Prais-Winsten regression, heteroskedastic panels corrected standard errors (model 1)

RDINT	Coef.	St.Err.	t-value	p-value	[95% Conf	Interval]	Sig
MKTGINT	.723	.168	4.30	0	.393	1.053	***
PINT	.277	.037	7.48	0	.204	.349	***
EXPINT	.113	.036	3.11	.002	.042	.184	***
IRMINT	.075	.079	0.95	.341	-.079	.23	
ICGINT	-.212	.069	-3.08	.002	-.346	-.077	***
SPR	-3.064	1.926	-1.59	.112	-6.839	.712	
DER	0	.002	0.29	.775	-.003	.004	
CAPINT	.096	.012	8.00	0	.072	.119	***
MKTSHR	-2.007	.746	-2.69	.007	-3.469	-.544	***
AGE	.095	.061	1.54	.123	-.026	.215	
SIZE	1.646	1.507	1.09	.275	-1.307	4.6	
Constant	-19.302	5.339	-3.62	0	-29.767	-8.838	***

Mean dependent var	3.777	SD dependent var	8.992
R-squared	0.710	Number of obs	108
Chi-square	110.967	Prob > chi2	0.000

*** p<.01, ** p<.05, * p<.1

Table 16: Prais-Winsten regression, heteroskedastic panels corrected standard errors (model 2)

PINT	Coef.	St.Err.	t-value	p-value	[95% Conf	Interval]	Sig
RDINT	1.987	.252	7.88	0	1.492	2.481	***
MKTGINT	-2.436	.428	-5.69	0	-3.275	-1.597	***
EXPINT	-.184	.09	-2.05	.04	-.359	-.008	**
IRMINT	-.35	.179	-1.95	.051	-.702	.001	*
ICGINT	.622	.199	3.12	.002	.231	1.012	***
SPR	6.498	5.021	1.29	.196	-3.343	16.339	
DER	-.002	.005	-0.49	.627	-.012	.007	
CAPINT	-.252	.03	-8.28	0	-.311	-.192	***
MKTSHR	5.489	2.042	2.69	.007	1.487	9.492	***
AGE	-.115	.161	-0.71	.477	-.431	.201	
SIZE	-1.62	4.023	-0.40	.687	-9.506	6.266	
Constant	39.941	14.436	2.77	.006	11.647	68.236	***

Mean dependent var	2.773	SD dependent var	21.372
R-squared	0.692	Number of obs	108
Chi-square	143.741	Prob > chi2	0.000

*** p<.01, ** p<.05, * p<.1

Table 17: Prais-Winsten regression, heteroskedastic panels corrected standard errors (model 3)

EXPINT	Coef.	St.Err.	t-value	p-value	[95% Conf	Interval]	Sig
RDINT	.781	.318	2.45	.014	.157	1.405	**
MKTGINT	.214	.478	0.45	.654	-.723	1.151	
PINT	-.155	.111	-1.39	.163	-.374	.063	
IRMINT	.123	.195	0.63	.527	-.258	.505	
ICGINT	.167	.156	1.07	.283	-.138	.473	
SPR	15.484	5.127	3.02	.003	5.436	25.532	***
DER	-.002	.003	-0.61	.539	-.009	.005	
CAPINT	-.033	.04	-0.84	.401	-.111	.044	
MKTSHR	8.771	2.05	4.28	0	4.752	12.789	***
AGE	-.534	.15	-3.56	0	-.828	-.24	***
SIZE	-5.119	5.574	-0.92	.358	-16.043	5.806	
Constant	54.275	21.111	2.57	.01	12.898	95.651	**

Mean dependent var	35.186	SD dependent var	24.179
R-squared	0.244	Number of obs	108
Chi-square	60.282	Prob > chi2	0.000

*** p<.01, ** p<.05, * p<.1

Table 18: Prais-Winsten regression, heteroskedastic panels corrected standard errors (model 4)

SALES	Coef.	St.Err.	t-value	p-value	[95% Conf	Interval]	Sig
RDINT	32.683	68.154	0.48	.632	-100.897	166.262	
MKTGINT	428.921	232.221	1.85	.065	-26.224	884.065	*
PINT	-18.188	28.925	-0.63	.529	-74.88	38.504	
EXPINT	71.938	30.954	2.32	.02	11.269	132.606	**
IRMINT	-44.561	39.242	-1.14	.256	-121.475	32.352	
ICGINT	5.073	21.058	0.24	.81	-36.201	46.347	
SPR	2792.91	1653.542	1.69	.091	-447.973	6033.793	*
DER	.342	.388	0.88	.377	-.417	1.102	
CAPINT	-27.299	8.684	-3.14	.002	-44.32	-10.278	***
MKTSHR	3126.743	1477.651	2.12	.034	230.601	6022.885	**
AGE	19.402	53.642	0.36	.718	-85.735	124.539	
SIZE	11807.29	2391.432	4.94	0	7120.17	16494.411	***
Constant	-44029.5	9201.448	-4.79	0	-62064.007	-25994.994	***

Mean dependent var	9780.637	SD dependent var	14621.983
R-squared	0.483	Number of obs	108
Chi-square	68.783	Prob > chi2	0.000

**** p<.01, ** p<.05, * p<.1*

Findings

The empirical findings show that firm's marketing intensity, market share, export intensity, profitability and import of goods intensity and capital intensity are all essential factors that impact a firm's R&D activities, while their direction and level of effect varied. The market share and import of technology/capital goods intensity is shown to have a detrimental influence on R&D intensity and marketing intensity, capital intensity, profit and export orientation seem to be affecting Indian pharmaceutical enterprises' R&D activities positively.

Export intensity, marketing intensity, market share, R&D intensity, raw material import intensity, capital intensity and import of capital goods intensity are all essential characteristics that impact a firm's profit earnings, however their direction and level of effect varies. The negative and statistically significant impact of leverage ratio indicates that enterprises must increase fund management efficiency and cost containment. While external variables like as exports and economic situations are outside the firm's control, it can always improve its revenue-generating ability by focusing more strategically on research and development. However, if the company has a strong market share, technology transfer and R&D emphasis, it will certainly benefit more in the long run. marketing intensity, export, Raw material imports and capital intensity have a negative and statistically significant impact on profitability, indicating the need for better and more strategic resource allocation.

Strong patent regime, age of the firm, market share, R&D intensity and raw material import intensity are all important factors that influence a company's exports, although their direction and magnitude of effect differ. All of these elements are crucial drivers because they provide businesses with significant tools to improve their performance and revenue by expanding into new markets across the globe. The study reveals that the patent regime has proven to be beneficial for exports as with the advent of TRIPS regime India explored new unregulated markets for its generic medicines. Strong patent regime , market share, R&D intensity and raw material import intensity all have positive and significant impact on exports, while age of the firm was found to have negative impact on exports.

The empirical findings reveal that a firm's profit intensity, market share, size and capital intensity are all important variables that influence sales of the company, while the direction and magnitude of the effect differ. capital intensity demonstrated to have a negative impact on sales, indicating a need for effective and efficient asset management practice. Market share, size and profit, seem to be impacting Indian pharmaceutical companies in a systematic way. The firm can generate more sales revenue by focusing and improving upon these factors.

Conclusion and policy implications

Improving technical skills will assist Indian pharmaceutical companies in introducing novel research compounds into worldwide markets, hence increasing the industry's global competitiveness. The Indian pharmaceutical sector's significant import reliance and unexpectedly low R&D intensity of exports need prompt diversification of source nations for importing raw materials in order to avoid possible supply-side bottlenecks. In addition to safeguarding its domestic supply chain, the nation may exploit the pandemic to strengthen the pharmaceutical sector's position in the global supply chain by establishing itself as a trustworthy supplier of medications.

Government policies should promote enterprises' outward orientation by encouraging joint ventures overseas and liberalizing the laws that govern them. Because the rate of profit has a systematic impact on enterprises' R&D activities, the government must assure competitive pressure in the sector via institutional mechanisms. The negative and statistically significant impact of the debt-to-equity ratio highlights the need for companies to increase fund management efficiency and cost containment. It should be noted that, although external variables such as exports and economic situations are outside the firm's control, it can always improve its revenue-generating ability by focusing more strategically on MKTINT and debts. As a result, a liberal foreign trade policy aimed at promoting pharmaceutical exports would assist to boost profit margins. In addition to export orientation and market power, advertising and marketing tactics must be prioritized since they provide a competitive advantage in the near term and assist develop a brand value that aids in market capture, which leads to increased profitability. A rigorous price restriction approach for vital medications, for example, might result in the unintended downfall of various products owing to lower profitability. The government should find a way to strike a balance between viability and affordability, and policy measures such as insurance and public-

private partnerships might be used. Indian local enterprises must gradually improve their industrial skills. This will allow them to remain competitive and gain a larger portion of the global pharmaceutical industry. According to previous study on the Indian pharmaceutical business, to transition to the product-patent system after 1995, Indian pharmaceutical companies used both exploitative and exploratory strategies (Kale & Wield, 2008). This study's results are consistent with previous conclusions.

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