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**Pharmaceutical Exports and Patents in India - An
Empirical Investigation**

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Pharmaceutical Exports and Patents in India – An Empirical Investigation

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ABSTRACT:

The Indian pharma industry are faced with challenges like slowing exports and rising costs. This has impacted their ability to capture a larger share of global pharmaceutical market. Sustaining the profitability and market share in this sector requires the ability on the part of the firms to obtain patents. Such activity involves huge investments in R&D and knowledge building. Hence it is of utmost importance to ascertain whether obtaining a patent enhance exports of pharma products especially since it is a significant revenue generator. The paper attempts to answer this question through a simultaneous equation approach. The results show that after controlling for the relevant variables impacting the export of pharma products, patents have a significant positive impact on pharma exports.

JEL Codes: F14, C3, L65

Key Words: Exports, Empirical, Simultaneous Equation, Pharmaceutical.

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Pharmaceutical Exports and Patents in India - An Empirical Investigation

1. Introduction

With its unlimited natural resources India has a long history of medical and pharmaceutical activities. Indian Pharmaceutical Industry has faced massive changes (especially in case of foreign trade) after formation of WTO, specifically after implementation of international patent law. Not only has it established itself as one of the major suppliers of generics but it developed new formulas as well. After meeting the domestic medicine requirements, it is now in a position to export significant amount of pharmaceutical product to the rest of the world including the developed markets of U.S.A, U.K, South Africa, Russia, Nigeria, E.U and Japan.

The allopathic form of medicine was introduced by the British Government in the country. In pre-independence period there were no production units in the country. The foreign companies imported raw materials from India in their home country to process them into finished products. Those finished products were again exported back to India. Primarily this kind of production peaked up in India to supply the necessary medicines to the British Army who were suffering from tropical diseases. Indian Pharmaceutical Industry had started its journey in true sense with the establishment of Calcutta-based Bengal Chemical and Pharmaceuticals Works' and Baroda-based Alembic Chemicals in 1910. Earlier Multinational Companies (MNCs) set up their subsidiaries in India and through those subsidiaries they dominated the Indian Pharmaceutical market. These subsidiaries used to import bulk drugs from their origin countries and processed them to make formulations by using easily available cheap Indian resources. Between the years 1947-57, 99%⁵ of the drug and pharmaceuticals patent in India were held by the MNCs. MNCs' monopoly status allowed them to sell formulations at a high price in India. High prices

⁵Aradhna Aggarwal, Strengthening the Export Competitiveness of firms in the Indian Pharmaceutical Industry



prevented majority of the Indians from accessing necessary medicines. Along with the MNCs there were a number of indigenous companies who also entered the Indian drug market with their ayurvedic formulations like tonics, cough syrups etc. After the 2nd World War with new development in therapeutics in western countries many new drugs like vitamins, hormones, antibiotics, tranquilizers etc. were invented. These new drugs eliminated the existing drugs from the market. During this transitional phase of new drug development indigenous drug companies faced the problem of product obsolescence and were under pressure to upgrade their technology so that the new inventions in the field could be leveraged. As a result many new companies were established. In 1947, USD 1.6 million⁶ worth Pharmaceutical industry was inherited by independent India. Post-independence there was a significant change in industrial policies. During that time importance of research and development was realized particularly in this industry. In 1948, because of therapeutic revolution in the global pharmaceutical industry the need for manufacturing and the importance of foreign technology was comprehended by the Indian Government. As a result India embarked on an inward looking expansion strategy of import surrogating industrialisation based on centralised planning. Additionally, foreign companies got the permission to establish plant without any licensing agreement in India. With the inflow of foreign capital within the country the pharma industry grew approximately four times in the next six years. As per directive of Government of India, it was mandated to manufacture drugs from the basic stage in the year 1956. During this time period for overall development in manufacturing sector Indian government adopted different trade and industrial policies, which were particularly important for the pharmaceutical industry. Both public and private sector companies were allowed to participate in the pharmaceutical industry it being part of schedule B of the Industrial Policy Resolution Act 1956. The first drug manufacturing public sector company, The Hindustan Antibiotic Limited was incorporated in 1954. Hindustan Organic

⁶[shodhganga.inflibnet.ac.in/bitstream/10603/99743/14/14_chapter% 204.pdf](http://shodhganga.inflibnet.ac.in/bitstream/10603/99743/14/14_chapter%204.pdf), retrieved on 12/12/2017



Chemicals (HOC), another public sector company started its operation in the same year. With the help of Soviet technical know-how Indian Drugs and Pharmaceuticals Limited (IDPL) commenced its operation in 1962. Apart from this during that time period with assistance from WHO and UNICEF the Indian government had set up a number of public sector units and research institutes to promote and encourage research. By 1962, the Indian pharmaceutical industry was valued at USD 16 million⁷. Indian companies were facing a strong competition though from foreign pharma companies. For the private pharmaceutical companies it became so difficult to survive amidst strong competition that many of them were compelled to close down. Indian pharmaceutical industry was literally dominated by MNCs and their subsidiaries. This market monopoly of foreign companies continued till seventies. The Reserve Bank of India (RBI) undertook a survey during the phase 1964-1970, which showed that the dominance of foreign firms was much higher in the Indian pharmaceutical sector than others. There were 197 companies operating with more than 50 percent foreign equity out of which 38 were from the pharmaceutical sector. Moreover, out of 17, wholly owned foreign subsidiaries, 8 were from pharmaceutical sector. These companies concentrated more on formulations than bulk drugs and procured bulk drugs from their parent companies abroad. A new era in pharmaceutical industry ushered in from 1970 in terms of attaining self-reliance in production and technology. In 1970 Indian Patent Act was framed. With the revised government policy Indian firms could produce the patented drugs by applying reverse engineering. The patented drugs could be produced by a different or a new process on which no patent exists. The foreign equity participation was restricted to 40%⁸ to discourage MNCs' participation in the Indian market. During eighties and nineties Indian pharmaceutical industry witnessed noticeable growth because of introduction of several

⁷shodhganga.inflibnet.ac.in/bitstream/10603/99743/14/14_chapter%204.pdf, retrieved on 12/12/2017

⁸Aas Mohammad and Bandi Kamaiah, The Indian Pharmaceutical Industry in Post-TRIPS and Post-Product Patent Regime: A Group-wise Analysis of Relative Efficiency Using Nonparametric Approach



generics. As a part of liberalisation initiated in early 1990s, in 1994 licensing was eradicated for producing bulk drugs and formulations. FDI policy was also modified. Foreign equity limit was extended to 74%⁹. Slowly India got recognised as one of the key suppliers in generics as well as new formulae. In the global market India got recognized as a cost-effective but high quality producer of pharmaceutical products. After catering to the domestic requirements, export has increased significantly which reaches over 200 countries including U.S.A, U.K, China, South Africa, Russia, E.U and Japan. Currently Indian Pharmaceutical Industry is ranked third in terms of volume by producing 10 percent of the world's pharmaceutical output¹⁰. On the other hand with 2.4 percent share in global pharmaceutical industry India is ranked among the top 14¹¹ in terms of value. In Financial Year 2015-16, India exported pharmaceutical products worth USD16.89 billion, which is expected to reach USD40¹²billion by 2020. The country's pharmaceutical industry is expected to expand at a CAGR of 12.89 percent over 2015–20 to reach USD55¹³ billion. Apart from growth in demand for Indian drugs within the country as well as from rest of the world, the industry has developed significantly in terms of infrastructure, technology and in range of products manufactured.

To comply with TRIPs India has amended its 1970's Patent Act three times, in 1999, 2002 and finally in 2005 (Jha, 2007). India has gone through several industrial and trade reforms to establish itself as a global player. R&D expenditures, by the domestic and foreign pharmaceutical companies, merger and

⁹<https://economictimes.indiatimes.com › News › Economy › Policy>, retrieved on 10/07/2017

¹⁰https://www.taxmanagementindia.com/visitor/detail_article.asp?ArticleID=6854&kw=growth-pharmaceutical-industry-india, retrieved on 11/09/2017

¹¹<https://www.ibef.org/download/Pharmaceutical-March-2017.pdf>

¹²<https://www.ibef.org/download/Pharmaceutical-March-2017.pdf>

¹³<https://www.ibef.org/download/Pharmaceutical-March-2017.pdf>



acquisitions (M&A), and patent activity and patent filings by Indian pharmaceutical firms, have significantly increased. The consumption of medications in India is increasing due to the increase in basic healthcare infrastructure, ease of access and due to booming medical insurance market. A dramatic increase in export growth has also contributed to the industry growth. This growth has been achieved mainly due to development in the generic market. Especially since the regulated market has swung to formulation export from usual export of bulk drugs.¹⁴ This shows that bulk drugs exports don't enjoy a comparative advantage any longer. In global market, India is having a tough competition from developing countries due to the global meltdown. So it is crucial to analyse the issues relating to India's global competitiveness in the world pharmaceutical market in this changed environment. As the IPR (Intellectual Property Right) provisions at WTO had to be honoured India had to move to a product patent regime. Survival in the World market depended on innovation. Large firms could successfully innovate and brought new products in the market. Medium and Small firms who survived mainly had done so by concentrating on generics, contract research and contract manufacturing. Given the survival of the firms in the long run one needs to check the impact of patents obtained by pharma companies on exportability. Exports have been one of the major drivers of the sector. Hence it has to be ascertained as to whether patents enhanced the firms' ability to export. From policy point of view a positive relationship would point out to the need of incentivising R&D. Firms on the other hand would not spend too much on R&D and try to collaborate with foreign counterparts if it is found that the patents did not impact exports from the sector. While testing this relationship other relevant variables impacting exports have also been considered.

¹⁴https://mpra.ub.uni-muenchen.de/75764/1/MPRA_paper_75764.pdf



Under TRIPS regime, countries were allowed to protect the existing investments made by generic manufacturers. As a result, if a generic firm in India before 2005 made a significant investment in products which contain a newly patented molecule and continues to manufacture that patented molecule on the date of the patent being granted, it cannot be forced to halt production. Instead, the firm pays a “reasonable royalty” to the patent holding firm and continues its commercial activity (Hason and Shimotake, 2006). The future of pharmaceutical industry depends on export growth through innovations and price control.

The paper is structured as follows. Section 2 discusses the existing work. The data and methods are elaborated in Section 3. Section 4 discusses the results. Finally, conclusions and policy implications are spelt out in Section 5.

2. Literature review

Foreign entry by Indian Pharmaceutical Industry was examined with regards to Merger and Acquisition (M&A). Panel data regression results reveals positive relationship between export and M&A (Mishra & Jaiswal, 2017). Kiran & Mishra (2009) considers the patenting activity, R&D and Exports of Indian Pharmaceutical industry to analyse the performance in the post-TRIPS period. The study shows that patent filing and patent granted in Drugs and pharmaceuticals has increased in the Post-TRIPs period and concomitantly sales, exports and R&D expenditures also grew. Impact of TRIPS compliance on the pharmaceutical industry in India was found to be positive as it encouraged innovation and greater investment in R&D.

An analysis of influence of TRIPS and Regional Trade Agreements (RTAs) on Indian pharmaceutical product exports using the Gravity Model has revealed that TRIPS negatively affects the export, whereas RTAs increase the export of such products (Loitongbam, 2016).



An in-depth study about pharmaceutical patents granted in India and at USPTO (United States Patent and Trademark Office) has revealed that though the situation has become challenging for Indian companies under the product patent regime, in spite of that the number of applications and grant of patents are gradually increasing. But the number of companies filing applications are less in comparison to the total number of pharmaceutical companies (Rau, Nair & Appaji, 2012).

Though India fails to take full advantage of the compulsory licensing provisions, even then the generic producers of the country could enter the market as soon as the patent expires by incorporating the Bolar provision¹⁵. Before the product patent regime was introduced, the provision was in favour of the non-patentees, whereas after TRIPs compliance it is clearly in favour of the patentees (Chaudhuri, 2005). The study (Chaudhuri, 2011) concerned with the behaviour of the pharmaceutical MNCs in the post-TRIPs era reveals that the MNCs have started marketing new patented drugs at very high prices along with importing high priced formulations and there is a drastic increase in the formulation market share of the MNCs with the help of some Indian companies which had been taken over by them. After implementation of TRIPs MNCs are reluctant to increase their R&D activities in India. MNCs are reluctant to manufacture patented drugs in India. They are more comfortable in importing those from outside. MNCs have tried to get patents for preventing generic competition coming from Indian players rather than having patent rights for genuine innovation. (Chaudhuri, 2014).

The study conducted by Centre for Trade and Development (Centad), New Delhi (2010), concluded that with the advent of the product patent regime, major concerns are generic entry and prices

¹⁵ Section 107A(a) of the Patents Act, 1970, commonly referred to as the "Bolar" provision exempts certain acts related to the development and submission of information required under Indian law or the law of any other country from being considered as infringement of the patent.



of drugs. Anti-competitive practices may arise due to information asymmetries and exercise of passive market power. It is also expected that CCI (Competition Commission of India) may actively play a role in ensuring healthy and competitive markets from a health care perspective which will go a long way in fulfilment of the objectives laid in the Competition Act, 2002.

Duperon & Cinar, (2010) studied the relative effects of policies related to Intellectual Property Rights on Indian domestic pharmaceutical industry. The paper has shown that India provides the most conducive environment to establish KPO (knowledge process outsourcing) operations and as a result of that U.S. pharmaceutical companies have their clinical testing departments in this country as part of their KPO operations.

Export performance of Indian Pharmaceutical Industry was impacted by firms' various resources (internal, marketing, and capital) more significantly in the transitory TRIPs period than the post-TRIPs scenario (Rentala, Nandru, Vutukuri & Anand, 2015).

The impact of patent granted, regulatory filing and R&D expenditure on Indian pharmaceutical export was examined through the pairwise Granger causality test (Banerji & Suri, 2017). It was revealed that patent granted causes export and R&D expenditure causes regulatory filling. Additionally, the result of Autoregressive Distributed Lag (ARDL) model showed that the patent granted and the regulatory filing both have positive impacts on pharmaceutical export. Regulatory filing has a stronger impact though.

In this backdrop we have developed our research model to study the impact of patents granted on the Indian pharmaceutical exports.



3. Methodology and Data

3.1 Research model

Following Goldstein and Khan (1978) we have hypothesised a simultaneous system of equations as follows

$$X_P^D = \alpha + \beta_1 \frac{P_X}{P_D} + \beta_2 WGDP + \beta_3 T + \varepsilon \dots\dots\dots(1)$$

$$X_P^S = \gamma + \beta_4 \frac{P_X}{P_D} + \beta_5 GVA + \vartheta \dots\dots\dots(2)$$

$$X_P^D = X_P^S \dots\dots\dots(3)$$

This is the base specification. Equation (1) is the export demand specification for Pharma exports (X_P^D) which depends on $\frac{P_X}{P_D}$ the ratio of export price to domestic price of Pharma products, adjusted World GDP (WGDP) and average Tariffs (T) on Pharma products in destination countries. Export supply equation (Equation 2) postulates that supply of pharma exports (X_P^S) on the other hand depends on the price ratio and industrial capacity in pharma sector approximated by Gross Value Added (GVA) of the sector. ε and ϑ are the respective error terms. Equation (3) depicts the equilibrium condition. In order to obtain the impact of number of patents granted to Indian Pharma companies in the next specification we alter the supply equation (2) as follows:

$$X_P^S = \gamma + \beta_4 \frac{P_X}{P_D} + \beta_5 GVA + \beta_6 P + \vartheta \dots\dots\dots(2.1)$$

where P is the number of patents granted to Indian Pharma companies.

Finally, to test for the dependence of number of patents on change in IPR regime we have considered the following additional specification of supply equation (2):

$$X_P^S = \gamma + \beta_4 \frac{P_X}{P_D} + \beta_5 GVA + \beta_6 P + \beta_7 R + \vartheta \dots\dots\dots(2.2)$$

R is a dummy variable taking a value of 1 for years 2005 onwards, otherwise considered as 0. India embraced the IPR provisions in WTO after becoming its member in 1995 but the new regime



became operational from 2005. In this paper we are trying to estimate the relationship between patents granted and export of pharma products. Hence we are basically trying to estimate the supply equation but accounting for endogeneity of $\frac{P_X}{P_D}$ and P. The endogeneity of the price ratio emanates from its presence in both equations and the fact that it is simultaneously determined with the quantity of exports. Studies have shown that the change in IPR regime had significant impact on the number of patents filed by Indian Pharma companies. Hence this relationship is estimated through a systems approach by considering a 3SLS structure more suited for multiple endogenous variables. It gives a more efficient outcome than 2SLS approach.

After estimating the base specifications (1-3), we estimate equations (1, 2.1 and 3). Finally, we estimate equations (1, 2.2 and 3). While estimating the final set of equations we have used the Reg3 command in STATA to allow for use of two instruments to tackle endogeneity in both the price ratio and patents. The Reg3 command along with 2sls specification estimates the system equation by equation.

3.2 Data

In order to conduct our research, the secondary data for the Indian Pharmaceutical export along with drug patent granted gross value added, world GDP, world average tariff and exchange rate have been collected for the period 1997 to 2016 from various sources as mentioned in table 1.

**Variable description***Table1*

Variable	Description	Source
Export	<p>Dependent variable of the study. Due to ambiguity in considering pharmaceutical HS codes during the study we have taken SITC codes for division 54 according to their basic headings as SITC division 54 sub-groups 541 and 542 are all about Medicinal and pharmaceutical products. After that all the HS codes at six digit level in corresponding to those SITC codes are taken into consideration for the study. Here a concordance is made between SITC revision four with different amendments of HS codes. Due to obsolescence, amalgamation or restructure of codes in different amendments HS codes may vary from period to period according to the introduction of new amendments to the</p>	<p>Import –Export data bank of Indian government. Website: www.commerce.nic.in</p>



	<p>HS codes. We have taken six digit level code wise exports of all the codes included in chapter 30, 60 codes from chapter 29 and a single code from chapter 13 for a period from 1997 to 2016. All these codes represent medicinal and pharmaceutical products.</p>	
<p>World Average Tariff</p>	<p>It is one of the independent variables of the study. For computation of World Average Tariff we have collected average tariff of all available countries for the period 1997 to 2016. Then we have separated year wise all countries average tariff for each six digit level HS codes considered for the study. Finally we have calculated year wise average of all available countries average tariff for each six digit level HS codes. This average is considered as World Average Tariff.</p>	<p>IIFT</p>
<p>World GDP</p>	<p>World GDP is an independent variable for the study. We have gathered world</p>	<p>World bank Website :</p>



	GDP for the said study period at constant price of 2010.	https://data.worldbank.org/indicator/NY.GDP.MKTP.KD
Gross Value Added	It is the instrumental variable considered for the study. We have taken India's pharmaceutical value added.	ASI (Annual Survey of Industries) data. Collected from Indian Statistical Institute, Kolkata.
WPI	Wholesale Price Index of Indian pharmaceuticals is another independent variable considered for the study. We have taken pharmaceutical WPI for different years starting from 1997 to 2016.	Website : http://eaindustry.nic.in
Patent Granted	It is another independent variable. We have taken number of pharmaceutical patent granted for the period 1997 to 2016.	Patent office, Kolkata.
Exchange Rate	It is also act as an independent variable for the study. We have gathered dollar rupee average exchange rate for the study period.	RBI (Reserve Bank of India)



Pharma Export

The pharmaceutical industry in India ranks 3rd in the world terms of volume and 14th in terms of value. As India is having higher rank in volume of pharmaceutical export we have taken it as our dependant variable to gauge the export performance. Figure 1: Pharmaceutical Exports



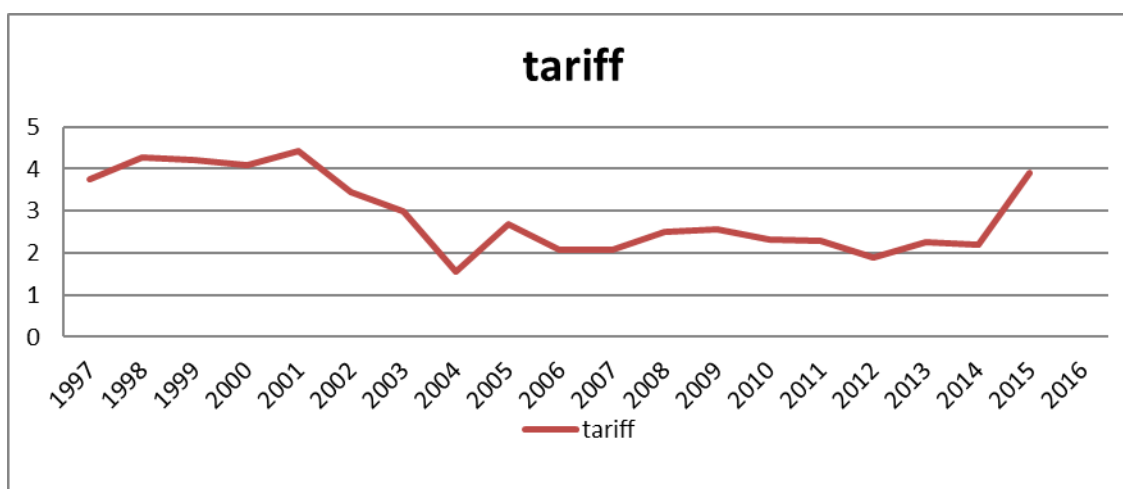
Here export is taken at US \$ million. Pharmaceutical export shows an increasing trend. India became one of the largest exporters of pharma products with many companies getting more than 50% revenue from international sales. The growth somewhat muted in recent years due to strong regulations in advanced countries and pricing pressures. The major markets for Indian pharma exports are US, UK, South Africa, and Russia. US alone accounts for around 25% of Indian exports. More than 55% of the country's exports go to highly regulated markets. Hence regulation and pricing pressure due to competition from countries like China are the major challenges that are hindering the growth prospects of exports of this sector currently.



World Average Tariff

Tariff is an important factor on which export depends. If world tariff increases then price of the export goods in the target country also increases impacting its demand adversely. A negative relationship between world average tariff and export is expected. The average tariff for each of the HS 6 digit codes have been meticulously calculated by first identifying the export destinations. Then for each of these codes the average tariffs have been calculated on the basis of the tariffs imposed by the destination countries on imports of the product from India.

Figure 2: Average Tariff on Pharmaceutical Exports from India



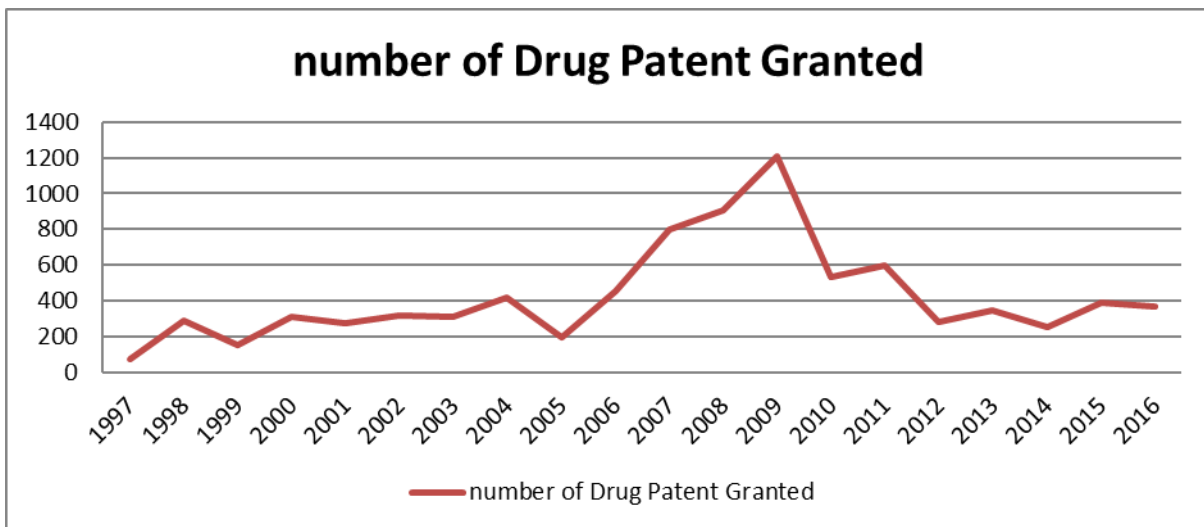
World average tariff had shown a decreasing trend from 2000 to 2004. There was clear hike in 2005. Thereafter it was more or less steady with little fluctuations till 2014. But from 2015 again it has started to rise. The probable reason being hike in tariffs by US and India losing GSP benefits.

Number of Drug Patent Granted

In India drug patent is very much important because of change in paradigm from process patent to product patent after TRIP's compliances.



Figure 3: Patents granted to Companies in India



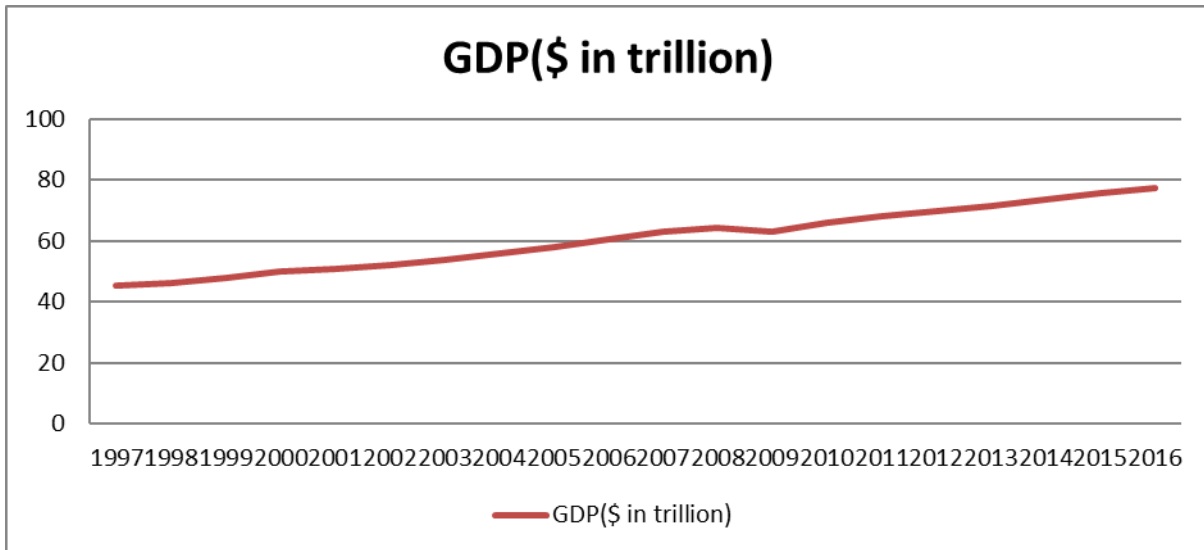
In India drug patent increases very slowly in initial years of the study. But after compliance with TRIP's in 2005 diagram shows an instant spike in drug patent granted and that continues for the following four to five years. Looking at the filings it seems that the major reason for increase was to protect application, formulation and devices rather than new molecules. The latter requires substantial capability and finances which may be the reason for decrease in patent filings (Gokhale and Kannan, 2017).



World Gross Domestic Product (WGDP)

World GDP shows a steady increase over the years.

Figure 4: World GDP



This variable have been transformed to reflect the realised demand for Pharma products in the World market. WGDP used for estimation purpose have been calculated as follows:

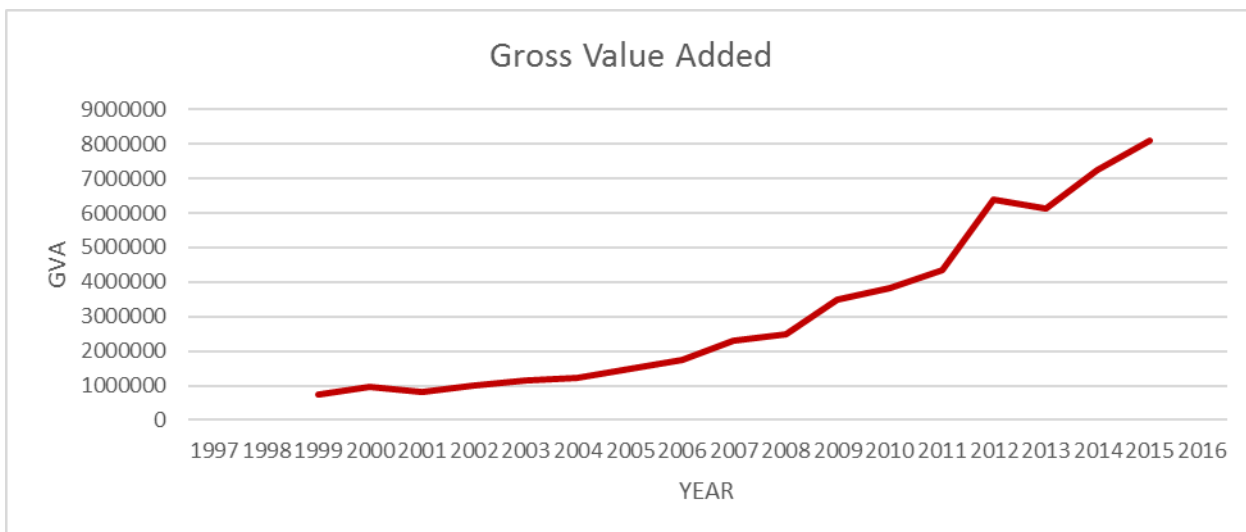
$WGDP = \frac{X_{Pt}}{\sum P X_{Pt}} GDP_t^W$ where X_{Pt} is the export of pharma product P in period t and $\sum P X_{Pt}$ is the total pharma exports from India in period t. GDP_t^W is the World GDP in period t.

Gross value Added of Pharmaceutical (GVAD)

We have taken GVA of pharmaceutical industry which is indicating the production capacity of the industry. If production increases significantly then a country can export that product after meeting the local needs. Gross value added throughout the study period shows an increasing trend except a slight decrease in 2013 after continous growth till 2012.



Figure 5: Gross Value Added for Pharmaceutical Industry in India



Wholesale Price Index (WPI)

The price index shows an increasing trend. This may partly explain the fall in exports in recent years given competitors like China.

Figure 6: Wholesale Price Index for Pharmaceutical Sector

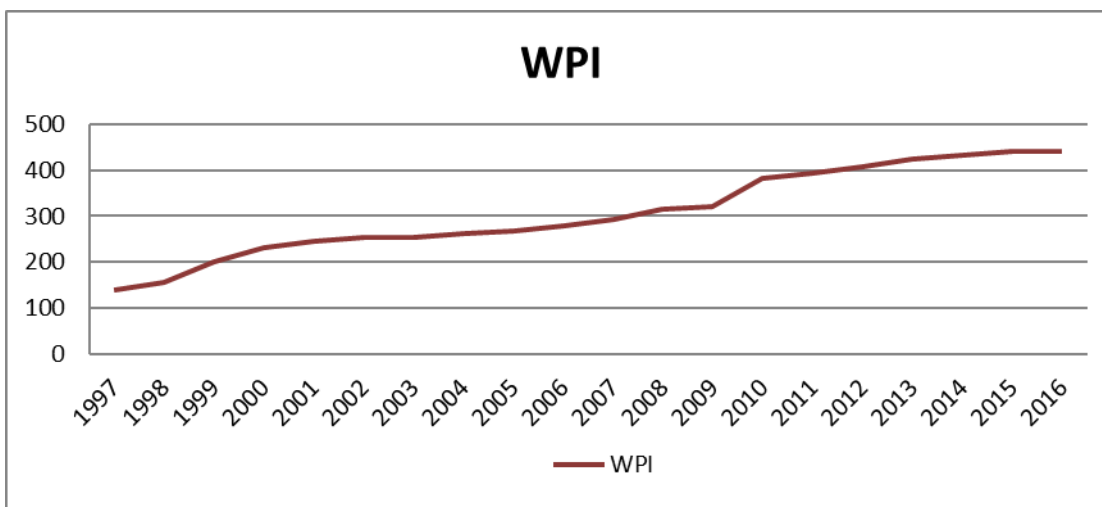




Table 2: Descriptive Statistics

Variable		Mean	Std. Dev.	Min	Max	Observations
px	overall	0.197898	1.266867	0	39.07954	N = 1435
	between		0.725275	0.0032431	5.67366	n = 97
	within		1.096228	-4.666471	33.60378	T-bar = 14.7938
wgdp	overall	0.835947	4.221877	0	49.24246	N = 1450
	between		3.554084	0.0000262	34.39133	n = 97
	within		1.11482	-11.68944	15.68708	T-bar = 14.9485
patent	overall	422.3123	264.1032	71	1207	N = 1473
	between		81.69325	246.7143	554.2	n = 97
	within		257.3093	41.49979	1205.712	T-bar = 15.1856
tariff	overall	2.909559	1.686382	0.1	11.2857	N = 1390
	between		1.422797	1.041271	8.3508	n = 97
	within		1.132676	-2.341242	6.638506	T-bar = 14.3299
gvad	overall	59725.46	37920.74	17283.62	123723.6	N = 1253
	between		21032.87	19115.82	114982	n = 97
	within		35217.95	6594.002	125118.8	T-bar = 12.9175
pxpd	overall	0.000566	0.00308	0	0.0886829	N = 1465
	between		0.001883	8.66E-06	0.0151366	n = 96
	within		0.002592	0.0126944	0.0741119	T-bar = 15.2604
exval	overall	72.80178	499.7273	0	9650.43	N = 1441
	between		303.5828	0.0138462	2947.582	n = 97
	within		357.8445	-2571.761	6775.649	T-bar = 14.8557



The data descriptive shows there is a very large variance between products and over time for the variables gross value added (gvad), patent and pharma exports (exval). In case of variables export price (Px), patent, gross value added (gvad), price ratio (PxPd) and pharma exports (exval) the overtime variance is higher than between products variance. For these variables time varying factors might have more influence in explaining their variance. For rest of the variables time invariant factors like product characteristics seems to be more important in explaining their variance.

Past Studies

Our study is concerned with exploring the relationship between patenting of drugs and pharmaceuticals and pharmaceutical export along with some other variables. Since both grants of patents and export volume have increased significantly in the Indian pharmaceuticals industry after 1995, it would be reasonable to hypothesize that it is the patent grants made by Indian pharmaceutical firms that have caused improvement in their export competitiveness and hence led to increased exports.

Some earlier studies on the Indian pharmaceuticals industry have come up with empirical evidence that suggests a positive relationship between technology and export performance among Indian pharmaceuticals firms. For instance, a study found R&D to be a major determinant of exports among Indian pharmaceutical firms (Aggarwal, 2004). The product cycle and neo-technology theories of trading in the context of exports of generic pharmaceuticals from India studied over 131 pharmaceutical firms for the period 1989-2004. An econometric model was estimated explaining inter-firm and inter-temporal variations in exports. The results showed that technology proxied by the acquisition of foreign patents has a favourable effect on exports (Chadha, 2009).

The influence of TRIPS and Regional Trade Agreements (RTAs) along with GDP, tariff, health expenditure, distance, language and FDI on Indian pharmaceutical product exports has been examined by



using the Gravity Model (Loitongbam, 2016). TRIPS is found to have a negative impact on pharma exports whereas RTAs have a positive influence.

4. Results and discussion

The estimation of base specifications as mentioned in equations 1-3 and equations 1, 2.1 and 3 are presented in Appendix I Table 3. For the base model except for tariff all the variables have the correct sign and are statistically significant. The equation including patent as one of the variables keeps the results unaltered and causes the tariff variable to significantly impact export supply but positively. Patents is seen to have a significant positive impact on pharma exports. A number of studies highlighted earlier shows that patents in India have been significantly impacted by adoption of TRIPS. Hence the timing of adoption of TRIPS might have significantly impacted the filling of patents. In Table 4 (Annexure I) in column 2 the results of considering this relationship is presented. Interestingly the coefficient on the dummy regime (explained earlier) is significant negative. This shows that the buffer of 10 years that was granted to India after accession to WTO in 1995 had caused a number of companies to file for patents expecting a stricter regime post 2005. Looking at the fillings it seems that the major reason for increase was to protect application, formulation and devices rather than new molecules. The latter requires substantial capability and finances which may be the reason for decrease in patent filings (Gokhale and Kannan, 2017). Additionally, post-2008 Global Financial Crisis there is a significant decline in patents grant to companies in India (Figure 3). Thus the demand conditions might have also influenced the filling of patents. All other coefficients retain their sign and significance.

The coefficient on tariff still remains positive and statistically significant. Raju et al. (2016) had found an inverse relationship between average tariff and export price of products going from India. It was found that for products with lower price tariffs were high in the destination countries. Protecting domestic industries lower down the value chain may be one of the reasons to do so. The next empirical



specification includes this relationship between tariff and export price. Results in column (3) of Table 4 (Annexure I) confirms our conjecture with the coefficient of export price variable being significant negative. This also corrects the sign of the coefficient on tariff in the reduced form equation. The coefficient on patent though retains the correct sign is now non-significant. The final equation uses regime as an independent variable to explain export supply of pharma products. Given its importance in explaining the exports of these products from India. This formulation finally gives the correct signs and significance for all the independent variables. The diagnostics also shows that the variables as a whole explains the dependent variable appropriately. The specifications mentioned were also estimated by fixed and random effects models. There was no significant departure from the already obtained results.

5. Conclusion and Policy Implications

The world pharmaceutical market has changed immensely with progress of globalization. Developing countries are growing rapidly their developed counterparts are witnessing loss in market share. The remarkable growth of major developing countries particularly India and China is the main reason behind this erosion of market share for developed countries. In order to adopt themselves to the new product patent regime, the leading domestic firms have increased their exports of generic drugs to the regulated markets. R&D agreements and M&A activities have become order of the day. Looking at the future the Indian domestic firms must strengthen their industrial competences which will enable them to be more competitive and help them to capture a larger share of global pharmaceutical market. This market is influenced by the ability to obtain patents. Such activity involves huge investments in R&D and knowledge building. Hence it is of utmost importance to ascertain whether obtaining a patent enhance exports of pharma products which is a significant revenue generator.



The paper attempts to answer this question through a simultaneous equation approach. The results show that after controlling for the relevant variables impacting the export of pharma products, patents have a significant positive impact on pharma exports. Trends in pharma patents shows a significant downward trend especially post-2008. This is a worrying sign. Given the way the market is moving and given the results of this paper this may signal a slowing down of exports in the future (which has already happened). So the need of the hour is specific policy to boost R&D and patent filing for firms in this sector.

The Indian government have specific policies for the sector. Pharmaceutical clusters have been promoted with a number of incentives. Exemption from import duties for the products which are exported along with state-specific exemptions from taxes are extended to the sector. Tax related benefits amount to 14% reduction in taxes if produced in the cluster (WHO, 2017). Pharmexcil has been formed specifically to incentivise pharma exports. Problem lies in absence of specific policies to boost patent filing. If we consider the case of China a lot of incentives are available. Cash incentives for both domestic and international patent filing are provided for Chinese companies¹⁶. A company identified as high technology firm is given corporate tax breaks, subsidies on cost of R&D and investment, subsidised loans and reduction in other fees. Special funds have been earmarked for patent use.

The results obtained in the paper reinforces the importance of patents to enhance exportability of pharma products from India. Existing policies are not pin pointed towards incentivising patent filings. Chinese policies may guide the government on kind of policies required to boost patent filing. Especially, given their success in obtaining patents.

¹⁶ <https://www.managingip.com/Article/3538144/How-patent-subsidies-boost-R-D.html?ArticleId=3538144>



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Annexure I

Table 3: Results 2SLS

Dependent Variable	Base Model	Equation set2
Log(Export)	2SLS	2SLS
Independent Variables	Coefficients	Coefficients
	(z-values)	(z-values)
Log(Px/PD)	8.19**	7.17**
	(2.47)	(2.77)
Log(Tariff)	1.71	1.51*
	(1.57)	(1.7)
Log(WGDP)	2.79**	2.53**
	(3.41)	(3.98)
Log(Patent)		0.88*
		(1.9)
Constant	84.98**	69.57**
	(2.62)	(2.86)
Instrumented	Log(Px/PD)	Log(Px/PD)
Instrument	Log(GVAD)	Log(GVAD)
Observations	1123	1123
Wald Chi2(3)	82.92	113.05
Prob>Chi2	0.000	0.000

Table 4: Results Reg3 2SLS

Systems estimation	Reg3	Reg3	Reg3
	2SLS	2SLS	2SLS
Equation1			
Dependent Variable	Log(Export)		
Independent Variables	Coefficients	Coefficients	Coefficients
	(t-values)	(t-values)	(t-values)
Log(Px/PD)	6.82**	0.81**	0.87**
	(2.78)	(16.18)	(17.55)
Log(Tariff)	1.44*	-3.23**	-2.33**
	(1.75)	(-9.91)	(-8.18)
Log(WGDP)	2.44**	1.17**	1.13**
	(4.04)	(44.85)	(46.81)



Log(Patent)	1.18	0.29	2.52**
	(1.13)	(1.02)	(34.78)
Regime			1.71**
			(7.81)
Constant	64.3**	13.81**	Omitted
	(2.56)	(7.71)	
Equation 2			
Dependent Variable	Log(Px/PD)		
Independent Variables	Coefficients	Coefficients	Coefficients
	(t-values)	(t-values)	(t-values)
GVAD	0.22**	0.22**	0.22**
	(3.45)	(3.45)	(3.45)
Constant	-11.48**	-11.48**	-11.48**
	(-17.03)	(-17.03)	(-17.03)
Equation 3			
Dependent Variable	Log(Patent)		
Independent Variables	Coefficients	Coefficients	Coefficients
	(t-values)	(t-values)	(t-values)
Regime	-0.79**	-0.79**	-0.79**
	(-13.55)	(-13.55)	(-13.55)
Constant	6.05**	6.05**	6.05**
	(408.36)	(408.36)	(408.36)
Equation 4			
Dependent Variable	Log(Tariff)		
Independent Variables	Coefficients	Coefficients	Coefficients
	(t-values)	(t-values)	(t-values)
Log(Px)		-0.14**	-0.14**
		(-12.24)	(-12.24)
Constant		0.32**	0.32**
		(7.24)	(7.24)
Observations	1123	1123	1123
F-Stat			
Equation 1	31.50**	626.40**	644.51**
Equation 2	11.92**	11.92**	11.92**
Equation 3	183.51**	183.51**	183.51**
Equation 4		149.83**	149.83**

**List of Working Papers**

S. No	WP. No	Title	Author(s)
1	LD-10-01	A Multi Dimensional Approach to Management of Port Life Cycle: The Case of Major Ports in India	Deepankar Sinha
2	EC-10-02	Export Potential at the State-Level: A Case Study of Karnataka	Bibek Ray Chaudhuri, Debottam Chakraborty
3	EC-11-03	Comprehensive Economic Partnership Agreement between India and Sri Lanka: Where does it lead?	Biswajit Nag
4	LD-11-04	Container Yard Capacity Planning: A Causal Approach	Deepankar Sinha
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