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Harmonization of Intellectual Property Rights Across the Globe: Impact on India's Pharmaceutical Exports

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HARMONIZATION OF INTELLECTUAL PROPERTY RIGHTS ACROSS THE GLOBE: IMPACT ON INDIA'S PHARMACEUTICAL EXPORTS

Supriya Bhandarkar[1]

Abstract

Critics of the global intellectual property rights (IPR) regime have argued that the harmonization of IPRs across the globe would lead to a fall in exports from a developing country like India by restricting the production and export of patented products. Methodologically, in a gravity model framework using the pseudo passion maximum likelihood (ppml) estimator and detailed product level data from 1991 to 2018, this paper assesses the impact of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement on Indian pharmaceutical exports. The Ginarte and Park index serves to identify the impact. The results, contrary to assumption show that the strengthening of IPRs did not have a negative impact on the exports from India. Additionally, the results demonstrate that patent protection has not impacted Indian firms' exports, not due to innovation of new products but because of the adoption of other survival strategies such as the utilisation of the patent cliff and investing in incremental innovation.

Key Words: TRIPS, Exports, Pharmaceuticals, Intellectual Property Rights

Introduction

The period since the 1990s has seen widespread reforms in patent laws across the globe. The increasing desire to protect domestic innovation as well as the demand by technologically-developed innovator countries to ensure protection and maintenance of exclusive rights in their export markets (Maskus, 2012) has led to the harmonization of intellectual property rights across the globe. This was mainly facilitated by the signing of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement by the World Trade Organisation (WTO) members in 1995. TRIPS required all member-countries to enforce 'high minimum standards of intellectual property (IP) protection' and grant patents in all fields of technology, including pharmaceuticals, subject to their inventiveness and industrial application, for a period of 20 years. (Kapczynski,2009)

However, the emergence of this global intellectual property right (IPR) regime, that requires all WTO member-countries to bring their IPR laws into conformity with one another, has been the source of much debate (Lanjouw, 1998; Kumar, 2003). The weak patent regime and strong reverse engineering skills in developing countries was a hindrance to the exports of multinational firms due to the fear of misappropriation and imitation. The strengthening of IPR laws mandated by TRIPS serves to minimize this threat and incentivise firms to increase their exports to developing countries (Ivus, 2015). Therefore, it was assumed that strengthening patent rights was mainly beneficial to developed countries who are innovators rather than developing countries who are imitators. Empirical studies have supported this reasoning. (Maskus & Penubarti, 1995; Smith, 1999)

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However, the impact of TRIPS on exports of developing countries has received very little attention in the literature. This is possibly due to the widespread acceptance of the assumption that the global strengthening of the patent regime would have a negative impact on the exports from developing countries since they would lose their market share in those countries that did not previously provide strong patent protection (Pradhan, 2007). For instance, in the case of India, it was largely assumed that the implementation of TRIPS would result in a decline in pharmaceutical exports from the country since the ability of firms to produce and export generic drugs without infringing on pharmaceutical patents was curbed in 2005 due to the implementation of TRIPS (Reichman & Dreyfuss, 2006).

From 1970 to 1995 India was a major exporter of generic medicines to the developing countries. The Patents Act, 1970, which abolished pharmaceutical product patents and allowed for only process patent, meant that every drug could be legally copied for sale as long as a different process of manufacturing the drug was used. This resulted in a dramatic increase in the manufacturing and export of generic drugs, such as antiretroviral drugs (ARVs) from the country. Approximately 350,000 people worldwide suffering from HIV and AIDS, who were receiving ARV treatment, used ARVs produced in India (Carroll, 2010). However, generic exporters would have to cease operations since the implementation of TRIPS would mean that they would no longer be able to manufacture patented products. The harmonization of patent rights would also make it illegal for countries to import these drugs. Therefore, the objective of the present paper is to empirically examine to what extent the strengthening and harmonization of the patent regime globally would affect the export of pharmaceuticals from a developing country like India.

Given this background the rest of the paper is organised as follows: Section 2 provides a brief review of the literature. Section 3 outlines the methodology adopted for the study. The data sources are reported in Section 4. The main findings from the empirical analysis are presented in Section 5. A concluding Section follows thereafter.

A Brief Review of Literature

Empirical studies that have analysed the impact of TRIPS or product patents on the exports of pharmaceuticals in the context of developing countries have shown mixed results. The study conducted by Grace (2004) on the impact of product patents on India and China found that there was a decline in the profits of domestic firms due to the implementation of TRIPS. In order to compensate for this revenue loss India increased exports to regulated markets. This finding is confirmed by the EXIM bank study that stated that pharmaceutical firms have also been able to establish their foothold in the international market. Despite constraints faced due to TRIPS, the growth momentum has continued in this sector (EXIM Bank, 2007). Chadha (2009) studied the export performance of 131 Indian pharmaceutical firms for the post-liberalisation period 1989-2004. The results indicate that patent rights have a positive impact on exports. This suggests that developing countries, which are adept at process innovations, are capable of entering the international market at the later stages of the product cycle by using process patents, which acted as barriers to trade in the early stages of the product cycle. Thus, being adept at reverse-engineering of branded drugs, Indian pharmaceutical firms had an opportunity to enter the global generic market for off-patent drugs. In her study on the Indian pharmaceutical

industry Pradhan (2007) used an augmented gravity model of bilateral trade flows where IPRs were incorporated as one of the explanatory variables that affected India's exports. She found that the strength of patent protection in host countries was an important factor that affected India's exports. *Ceteris Paribus,* it was seen that in the absence of patent protection India would export, on an average, about $38,000 worth of pharmaceuticals whereas in the face of providing maximum patent protection globally, India's exports doubled to about $82,000.

Most of the studies conducted on the Indian industry focus on exports, and completely ignore the impact of TRIPS on the imports into the country. Joseph (2012) studied the trends in both exports and imports of India's pharmaceutical sector. His study shows that apprehensions that India would move away from domestic production and start importing drugs as a result of TRIPS has only partly come true. Exports of formulations have increased in the post-TRIPS period and there has been no rise in imports keeping the balance of trade positive, as far as this sector is concerned. Bulk drugs, on the other hand, have shown a rise in imports and a fall in domestic production. Chaudhuri et al (2019) used a simultaneous equations approach in order to analyse if patents have a significant effect on the exports of pharmaceuticals from India. Their study found that pharmaceutical companies in India increased their patent filings from 1995 to 2005, in anticipation of a stricter patent regime post-2005. The increase in patent filings have had a significant positive impact on pharma exports.

The other debate in terms of exports is centred around the question if the exports of India have shown a decline as a result of the country no longer being able to manufacture a low-cost copied version of drugs. Malhotra (2010) analysed export data of 249 drugs from India and found that in relative terms of dollar value, only around 1 per cent of India's pharmaceutical exports were jeopardised by the new regime. However, since India used to export low-cost drugs to many countries the absolute number of patients affected by the TRIPS regime was much higher. Additionally, future opportunities for firms to develop new processes and provide cheaper alternatives to expensive innovator drugs have been lost. In the long run, this will restrict access to medicines to the poor in India as well as in other developing countries. Loitongbam (2016) in his study used the gravity model to analyse how the implementation of TRIPS in partner countries along with the signing of Regional Trade Agreements (RTAs) have influenced the Indian pharmaceutical exports. The study found that the implementation of TRIPS had a significant negative impact on the exports of pharmaceuticals from the country. The study states that exports from India have reduced because of increasing costs incurred in order to comply with sanitary and pharmaceutical regulations in importing countries and reduction in the comparative advantage that India possessed in generic production. This has resulted in India shifting its export market from developed countries to developing and underdeveloped countries gradually.

Impact of Stronger Patent Regime on India's Pharmaceutical Exports

Framework for Analysis

The gravity model of trade is used to determine the impact of stronger patent protection in partner countries on the exports of pharmaceuticals from India. The gravity model has been extensively used in literature to explain the trade flows between countries. In the case of the pharmaceutical sector too,

scholars have used this model to understand the extent of international trade. Following the literature, we have also utilised this model for our paper. However, we have incorporated other important determinants in addition to what is generally prescribed in a classical gravity model framework. In its traditional form, the gravity model predicts bilateral trade flows between countries based on the economy's size and geographical distance. It suggests that trade flows increase with the size of the economies of the two countries and decrease with the distance between them. More generally it states that the proximity between two countries is expected to increase trade (Boring, 2015). In the basic form of the gravity equation, proximity generally refers to economic and geographic proximity with more recent studies including a measure of cultural proximity as well. In the present study, we also include a measure of legal proximity in order to determine the impact of TRIPS on the exports from India.

In its general formulation, the gravity equation has the following multiplicative form:

$$X_{ij} = GS_iM_jO_{ij}$$

where X_{ij} is the value of exports from country i to country j, M_j denotes all importer-specific factors, such as the importing country's GDP, and S_i comprises exporter-specific factors. G represents variables that do not depend on either country i or j such as the level of world liberalisation. O_{ij} represents the ease of access of exporter i to market j.

The gravity model is generally used to explain bilateral trade flows among a group of countries for several goods. However, since we are interested in the analysis of the impact of harmonization on the exports from India, we have attempted to analyse unidirectional export flows of pharmaceuticals from India to 104 other countries (See Appendix for the list of countries) from 1990-2018.

Selection of Appropriate Estimator

Quite a few studies that use gravity model use OLS technique. This is done by taking the logs of all variables that can be estimated by OLS regression. However, in recent years the usage of OLS method of estimation has been criticised for the handling of zero trade flows. Since India does not export to all countries in all years, there are 0 trade values present in our dataset.

Using OLS technique will therefore, result in zero trade flows being dropped as the log of zero is not defined. However, dropping the zero trade values may yield inconsistent results. Zero trade data may represent very small trade flows due to high transport costs, administrative difficulties, etc and dropping these values will result in a loss of useful information.

The second criticism of the OLS model is that when logs of the variables are used in the equation, the error term is in log too. If the error term is heteroskedastic, then the expected value of the error term depends on one or more of the explanatory variables because it includes the variance term. This violates the first assumption of OLS technique and suggests that the estimator may be biased and inconsistent.

The fixed effects estimator and the random effects estimator are also commonly used to estimate the gravity model. However, the fixed effects estimator fails to take into consideration the time invariant effects such as distance, common language, border, etc., which are important variables in our

model. The random effects estimator accommodates time invariant variables but if there is heteroscedasticity and autocorrelation present in the data the estimator becomes inefficient.

We therefore use the Poisson pseudo-maximum likelihood estimator (ppml) proposed by Silva & Tenreyro (2006). The ppml estimator includes observations for which the observed trade value is zero and is robust in the presence of heteroscedasticity. The ppml model is also consistent in the presence of fixed effects which can be entered as simple dummy variables. We have used the ppml estimator with clustered standard errors. The OLS estimator is therefore only used as a robustness test.

Data Sources

In the following estimations, the dependent variable is X_{jt}. It represents the Indian pharmaceutical exports to country j in time period t. Export data are collated from the WITS database. The data are expressed in constant 2010 US dollars by deflating the data using the export index for medicinal and pharmaceutical products obtained from the Directorate General of Commercial Intelligence and Statistics.

Basic Gravity variables

GDPPC – The gravity model predicts that the bilateral trade between two countries increases with the economic size between them. Gross Domestic Product (GDP) is generally taken as a proxy for economic size. However, since we are dealing with the exports from one country to the rest of the world, we take into consideration income level proxied by the partner countries' GDP per capita. ($GDPPC_{jt}$) Since GDPPC is a measure of welfare, the higher the GDPPC of an importing country, one would expect more pharmaceutical exports from India into that country. GDPPC data, in constant 2010 USD is taken from the World Bank database.

Distance – Geographical distance ($Dist_j$) is calculated as the physical distance between country j's main city and the main city in India (in terms of population), using data obtained from CEPII. Traditional gravity model took into consideration only geographical distance as a proxy for transportation costs. A negative relationship is expected between distance and exports since it is assumed that, other things being equal, India can gain from exporting to nearby countries rather than those far-off countries, due to lower transportation costs (Brun, Carrere, P, & Melo, 2005).

Population – Measures the trading partner's mid-year population, which refers to the population at 12 am local time on July 1st of a given year (Pop_{jt}). Population is used as a measure for the size of the foreign country's market. Higher the population of the partner country, greater are the expected exports to the country. Population data was collected from the International Data Base of the U.S. Census Bureau.

Variables of Interest-Legal Proximity

In order to measure the impact of harmonization on India's exports we take into consideration the implementation and enforcement of TRIPS by India's trading partners since all countries which have

implemented TRIPS have to comply with the minimum standards of protection of intellectual property, especially the provision of providing patents for a period of 20 years.

The closer in conformity the laws of the partner country with the domestic patent laws in India, we consider them in close legal proximity to one another. WTO members were given different deadlines to implement TRIPS based on their level of development. In order to measure to what extent the laws related to granting of patents are in conformity with its trading partners, we take into consideration two variables.

Implementation of TRIPS – The impact of the implementation of TRIPS is measured with the help of the dummy variable ($TRIPS_{jt}$) which equals 1 if the partner country has implemented minimum standards of protection as specified in the TRIPS agreement in the particular year. According to the TRIPS agreement, developed countries were given till 1996, developing countries till 2005 and the least developed countries till 2016 to implement the caveats of the agreement. Some countries have implemented TRIPS before the deadline. We use a dummy variable equal to 1 if the county has implemented TRIPS in time period t, or else 0. Data regarding the implementation of TRIPS were compiled from the WTO website and Kyle & McGahan(2009).

Ginarte and Park Index – However, since the implementation of the TRIPS agreement does not necessarily mean that they enforce the patent laws mentioned in the agreement, we also take into consideration the IPR index developed by Ginarte and Park ($GPIndex_{jt}$). The index is the unweighted sum of five separate scores for: coverage (inventions that are patentable); membership in international treaties; duration of protection; enforcement mechanisms; and restrictions (Park, 2008). The overall index value ranges from 0 to 5, with a value closer to 5 indicating a higher strength of patent protection. A value of India's index closer to that of its partner countries indicates the reduction of the legal distance between them. Ginarte and Park provide data for 122 countries from 1960 to 2005 at 5-year intervals. The main advantage of the TRIPS variable, as compared to the Ginarte and Park index, is that it provides data for every year of the study from 1990 to 2018 which considerably increases the number of observations available for panel data estimation compared to the Ginarte and Park index which is available only at 5-year intervals.

Control Variables

In addition to the basic gravity variable and the variables of interest we also take into account control variables that may have an impact on the Indian export of pharmaceuticals.

Trading Blocs – Membership of an importing country in a trading bloc can also be an important determinant of India's pharmaceutical exports. If India and the importing country are members of the same trading bloc, then their trade can be expected to expand, whereas trade between a member country and non-member country is likely to contract. Members of a trading bloc grant each other preferences in terms of reduced tariffs etc, which are not available to a non-member. To capture the effect of regional trading agreements on India's pharmaceutical exports, two of the most important

trading blocs dummies were included in the model. These trading blocs are: ASEAN India Free Trade Agreement ($AIFTA_{jt}$) and the South Asian Association for Regional Cooperation ($SAARC_{jt}$). A dummy variable equal to 1 was used if the partner country was a member of the trading bloc, and zero otherwise.

Openness – Economic openness is measured through the KOF Index of Economic Globalisation ($Global_{jt}$). It measures a country's degree of economic globalisation by taking into account its actual economic flows in terms of total trade (imports plus exports), FDI and foreign portfolio investment (FPI). The components taken into consideration are trade (as per cent of GDP) for 23%, FDI (as per cent of GDP) for 29%, FPI (as per cent of GDP) for 27%, and income payments to foreign nationals (as per cent of GDP) for 22%. Higher the index, higher is the expected trade flows. The data for the index were drawn from the KOF Swiss Economic Institute website.

Land-locked country – Trade with a land-locked country is expected to be lower due to lack of their own seaport which raises transportation cost. The trade of a land-locked country depends on ports of other countries, and transit economies further impose road tolls and fees that increase the cost. A dummy variable equal to 1 is used if the trade partner is a land-locked territory (LL_j) and zero otherwise. Data on land-locked countries were compiled from the CEPII database.

Common Border – A dummy variable equal to one ($Border_j$) is used if the country shares a common border with India. A common border can be expected to increase trade due to lower distance and hence lower transportation costs. However, this may not hold true in many cases where relations are not friendly due to political or security problems. Bangladesh, China, Pakistan, Nepal, Myanmar, Bhutan and Afghanistan share a common border with India.

Exchange Rate – Trade may also depend on the exchange rate between two countries. Two countries having stable exchange rates tend to trade more with each other. Exchange rate volatility is associated with risks and transaction costs that can hinder trade. In the present study, it is expected that depreciation of the currency of the importing countries would have a negative impact on India's pharmaceutical exports by making it costlier in the importing countries. Data on local currency per US$ in j^{th} importing country was obtained from International Financial Statistics of IMF. ($ExRate_{jt}$)

Empirical Estimation

Taking into account the above-mentioned variables, the following empirical model is specified for the present study:

$$Exp_{jt} = \alpha + \beta_1 \ln (GDPPC_{jt}) + \beta_2 \ln (Dist_{jt}) + \beta_3 \ln (Pop_{jt}) + \beta_4 TRIPS_j + \beta_5 \ln (Global_{jt}) + \beta_6 D\_LL_j + \beta_7 D\_BORDER_j + \beta_8 D\_SAARC_j + \beta_9 D\_AIFTA + \beta_{10} \ln (Exrate_{jt}) + u$$

Table 1 describes the summary statistics for each variable, for 104 countries, for the period from 1991 to 2018.

Table 1: Summary Statistics

Variable	Obs	Mean	Std. Dev.	Min	Max
lnglobal	3,796*	4.019871	0.294363	3.034693	4.512703
lnexrate	3,948	2.905252	2.997355	-18.8262	15.40475
lnpop	3,948	15.98621	1.697502	11.16761	21.04484
lndist	3,948	8.761689	0.605877	6.527036	9.737228
lngdppc	3,948	8.402781	1.575583	4.431055	11.62597
TRIPSImp	3,948	0.531662	0.49906	0	1
Landlocked~t	3,948	0.177558	0.382189	0	1
AIFTA	3,948	0.018237	0.133825	0	1
SAARC	3,948	0.034195	0.181752	0	1
Border	3,948	0.03926	0.194238	0	1

*Data on Globalisation index not available for 2018

Implementation of the TRIPS agreement is likely to have a negative impact on the exports from India since Indian pharmaceutical companies will no longer be able to reap the benefits of reverse engineering and cost competitiveness; hence, a strict patent regime will be against the export potential of the country. An increase in GDPPC and sharing a common language, population, currency and border is also likely to increase Indian exports. Being a part of a trading bloc with India is also likely to see an increase in exports to the members of the trading bloc. An increase in distance is likely to have a negative impact on exports, and India is likely to export less to countries not very open to trade or that are landlocked since having no access to the seaports tends to increase transportation costs.

Results of Estimation

Table 2 summarizes the results obtained from ppml estimation of the gravity model. This analysis includes the variable that measures the impact of the implementation of TRIPS with the help of the dummy variable ($TRIPS_{jt}$) the results for ppml regression, in which the Ginarte and Park index replaces the TRIPS dummy. The number of observations drops because the G-P Index includes only 3 years (1995, 2000 and 2005) and only 78 countries. Ginarte and Park index also shows that the impact of patent protection on Indian exports is statistically significant.

Table 2: Impact of Patent Protection on Indian Exports of Pharmaceuticals

Export	Coef.	Export	Coef.
	PPML with TRIPS Dummy		PPML with Ginarte and Park Index
Ln_GDPPC	0.121 (0.17)	Ln_GDPPC	0.114 (0.13)
Ln_ExRate	-0.044 (0.04)	Ln_ExRate	-0.338 (0.03)
Ln_Dist	-0.420 (0.26)	Ln_Dist	-0.033 (0.20)
Ln_Pop	1.010*** (0.16)	Ln_Pop	0.719*** (0.11)
Ln_Global	3.032** (1.21)	Ln_Global	1.273* (0.76)
D_TRIPS	0.391 (0.21)	GP_TRIPS	-0.126 (0.16)
D_AIFTA	0.363 (0.39)	D_LL	-0.008 (0.35)
D_SAARC	2.450*** (0.67)	D_SAARC	1.185*** (0.45)
D_Border	-2.066*** (0.73)	D_Border	-1.770*** (0.44)
D_LL	0.798** (0.40)	D_AIFTA	
_cons	-22.491** (7.58)	_cons	-5.567 (4.69)

Note: Robust Standard Errors are in parenthesis. * indicates significance at 10%, ** at 5%, *** 1%

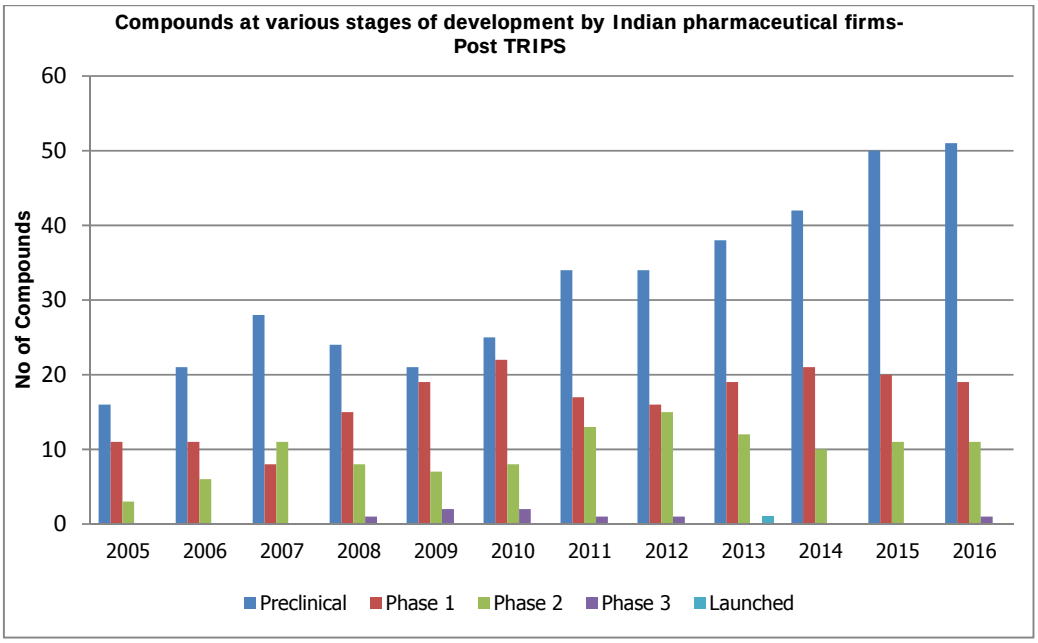
The above analysis shows that the common gravity variables of distance and economic size does not have a significant impact on pharmaceutical exports from India. The dummy for common border has a negative effect that is statistically different from zero. This negative sign of the variable may have been due to political tension, immigration issues and security concerns that India has had with her neighbouring countries for a long time. For instance, Pakistan had recently imposed a trade ban on pharmaceutical products from India due to security issues. Similarly, Afghanistan imports 75 percent of its medicinal needs from Belgium and 10 percent from Pakistan, while India has a negligible share. Indian pharmaceutical companies too consider Afghanistan a very small market and hence not a lucrative source of revenue. The population and globalisation coefficient and coefficient for the dummy for landlocked countries have a positive sign as predicted and is statistically significant. Indian pharmaceutical exports, thus, appear to be more for those countries that have a larger population, have seaports and are more open to trade. The exchange rate and AIFTA dummy are not significant while the dummy for SAARC is positive and significant. This is probably because India has been a founder-member of SAARC since 1985. The launching of the South Asian Preferential Trading Agreement (SAPTA) in 1995 gave a boost to the pharmaceutical exports from India, while AIFTA came into force only in 2010 and hasn't shown the full benefits of the agreement yet.

The performance of TRIPS variable is of primary interest here. The coefficient of the TRIPS variable is not significant, indicating that the strengthening of patent protection in partner countries has not affected the bilateral exports of pharmaceuticals. This implies that intellectual property considerations do not have an impact on the exports of pharma products from India. Possible reasons why TRIPS has not had a significant impact on Indian exports have been highlighted below.

TRIPS and the Indian Pharmaceutical Industry

While the signing of the TRIPS agreement played an important role in facilitating the increase in R&D expenditure of firms, it was seen that in the post-TRIPS period, the New Chemical Entity (NCE) research was only a minor component (around 25% of total R&D expenditure) of the entire expenditure. This is reflected in the fact that Zydus Cadila's Saroglitazar, launched in 2013 for the treatment of type II diabetes, remains so far, the only compound that was entirely discovered and developed by an Indian company. (See Figure 1)

Figure 1: Compounds at Various Stages of Development by Indian Pharmaceutical Firms



Source: Compiled using data from Differding (2017)

Therefore, the question arises as to how TRIPS has not had a negative impact on Indian pharmaceutical firms despite them no longer being able to export 'on-patent' generic drugs and not having domestically invented new drugs to make up for the loss of exports. This was the result of 'patent cliff", patent expiration of a large number of blockbuster drugs over the last ten years.

Patent Cliff

Many blockbuster drugs have gone off-patent in the last 10 years enabling firms to produce generic versions of those drugs. (See Table 3)

Table 3: Patents on Blockbuster Drugs Expiring between 2011 and 2017

Drug	Manufacturer	Disease	US $ Sales	Patent Expiry
Lipitor	Pfizer	Cardiovascular	$7.7 billion	2011
Plavix	Bristol-Myers Squibb/Sanofi Aventis	Cardiovascular	$6.8 billion	2012
Advair	GlaxoSmithKline	Asthma	$4.6 billion	2012
Cymbalta	Eli Lilly	Anti-depressant, antianxiety	$3.7 billion	2013
Nexium	AstraZeneca	Acid Reflux	$6.2 billion	2014
Abilify	Otsuka, Bristol-Myers Squibb	Anti-depressant	$5.2 billion	2014
Neulasta	Amgen	White Cell Booster	$3.93 billion	2015
Crestor	Shionogi, Astra Zeneca	Cardiovascular	$4.3billion	2016
Lyrica	Pfizer	Nerve and Muscle Pain	$3.46 billion	2018
Rituxan	Roche	Blood cancer	$7.9 billion	2018

Source: Khanna & Singh, 2015 and websites of various companies

A large number of blockbuster patented drugs that were the main source of pharma profits to the developed countries saw their patents expire between 2011 and 2018, a phenomenon known as the 'Patent Cliff.' 'Blockbuster drugs' are patented brand names that generate more than $1 billion in sales annually, with many generating revenues as high as over $5 billion in the US alone (Khanna & Singh, 2015). Loss of patents means that any firm could continue the manufacturing and export of the generic version of these drugs.

However, despite continuing to produce generics drugs, firms have adopted certain strategies to be able to survive in the market. There has been a territorial shift in the exports of firms post TRIPS. Pharmaceutical firms in the country are mainly exporting generics to developed countries rather than to low- and middle-income countries.

This was in response to the developed countries modifying their laws on generic medication as a result of rising health costs due to an aging population. Some key reforms such as endorsement of generics in programmes such as 'Obamacare', incentivising doctors to prescribe generics, removal of obligations to manufacture locally, etc. have resulted in an increase in exports to the regulated markets of America and Europe, where profits of firms would be more substantial. Therefore, today most Indian pharmaceutical firms obtain their revenue from exports rather than from local sales. (See Table 4)

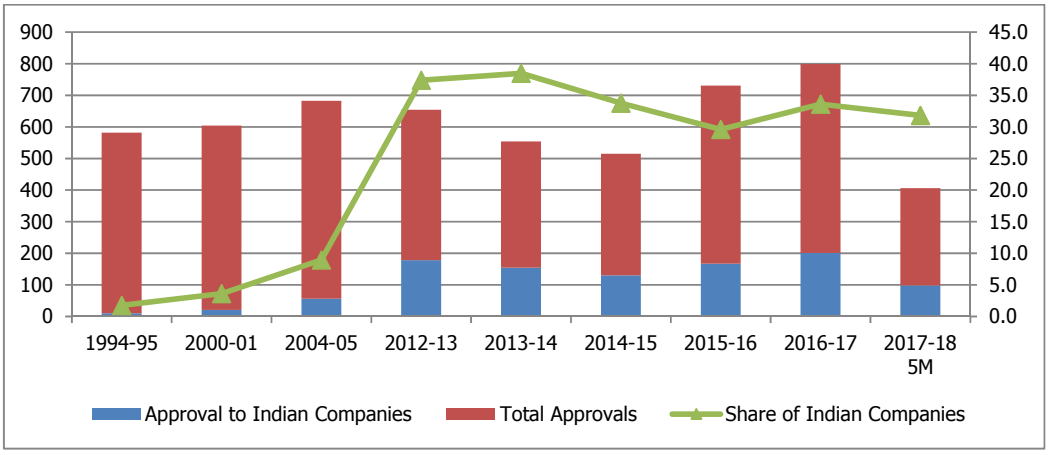
Table 4: Leading Export Destinations for Indian Drugs in 2016-17

Bulk Drugs			Formulations		
Country	**US$ Million**	**% of Exports**	**Country**	**US$ Million**	**% of Exports**
USA	207.58	11.17	USA	3327.55	37.23
China	72.06	3.88	South Africa	353.13	3.95
Brazil	68.04	3.66	United Kingdom	311.72	3.49
Turkey	61.43	3.30	Russian Federation	301.79	3.38
Indonesia	59.72	3.21	Nigeria	247.41	2.77
Bangladesh	59.15	3.18	Australia	160.12	1.79
Nigeria	58.63	3.15	United Rep. of Tanzania	142.37	1.59
Viet Nam	43.44	2.34	Brazil	141.01	1.58
Egypt	40.89	2.20	Nepal	136.24	1.52
Pakistan	38.84	2.09	Kenya	135.33	1.51

Source: UN COMTRADE

Consequently, Indian firms have started to seek opportunities in the US market by filing for Abbreviated New Drug Application (ANDA) approvals. Generic drug applications are termed 'abbreviated' because they are generally not required to include pre-clinical and clinical data to establish safety and efficacy. They are required only to demonstrate the bioequivalence of the product. When filing an ANDA, a company is required to certify that its product does not infringe on any patent rights. If it is the first to get approval for the generic version, it gets market exclusivity for 180 days. During this period, no other generic company is permitted to enter the market.

Figure 4: ANDA Filings by Indian Pharmaceutical Companies



Source: Compiled using data from USFDA

As Figure 4 shows, India has a substantial share in ANDA approvals. In 1997 the share of Indian companies in the total ANDA approvals granted was only 1.7 percent. In 2003 Indian pharmaceutical firms filed 73 ANDA applications with the US FDA constituting 20% of the total. At the end of 2017 Indian firms had a total of 201 ANDAs approved by the FDA, almost 33.6% of total submissions to USFDA.

The United States is now India's largest export partner, making up 11.17 percent of total bulk drug and 37.23 percent of total formulation exports. Further, in order to boost exports, the Government of India made it mandatory for all pharma firms to follow the Good Manufacturing Practices (GMP) developed by the World Health Organisation (WHO) from July 2005 (GOI 2007e). Further, in order to ensure easier access to the markets of developed countries, firms have obtained regulatory approval from the USFDA (United States), MHRA (UK), TGA (Australia) and ANVISA (Brazil) (Joseph, 2016).

Incremental Innovation

Apart from the export of generics, firms have started engaging in incremental innovation targeting their efforts on developing drugs for diseases prevalent in developed countries, rather than those specific to India. As Table 5 shows, most firms are engaging in the development of drugs for cardiovascular, cancer and other non-communicable diseases, which have a vast international market. Further, due to the presence of Section 3 (d) of the Indian Patent Act, pharmaceutical firms cannot apply for a patent in India for an incrementally modified drug for the fear of evergreening. However, since most developed countries such as the USA, Europe, etc., provide patents for incrementally modified drugs, the Indian firms are focusing on drugs suited to these markets.

Table 5: Status and Therapeutic Area of New Drug Development by Leading Firms

Compound	Therapeutic Area	Status
Sun Pharma		
Seciera	Ophthalmology	Phase III Confirmatory Clinical Trials
Tildrakizumab	Chronic Plaque Psoriasis	Awaiting Regulatory Approval
MM-II	Osteoarthritis	Ongoing Phase II, III
Glenmark		
GBR 1302	Oncology	Phase I ongoing
GBR 1342	Oncology	Pre-Clinical Trials
GBR 1372	Oncology	Preclinical Trials
GBR 830	Dermatology	Phase II ongoing
GRC 39815	Respiratory	Pre-Clinical Trials
Ryaltris™ (GSP 301)	Respiratory	Phase III ongoing
GSP 304	Respiratory	Phase II ongoing
GBR 310	Respiratory	Pre-Clinical Trials
Lupin		
Unnamed	Immunology	Phase II ongoing
Unnamed	Endocrine	Phase II ongoing
Unnamed	Oncology	Phase I completed
Wockhardt		
WCK 4086	Anti-Infectives	Pre-Clinical
WCK 2349	Anti-Infectives	Phase I ongoing
WCK 771	Anti-Infectives	Phase II ongoing

Source: Websites and Annual Reports of Respective Companies

Conclusion

The existing literature on the impact of patent regime on exports has been largely confined to the experiences of developed countries in the OECD and the USA. Their empirical results strongly support the hypothesis that weak patent system existing in the developing countries acts as a barrier to the exports of developed countries.

The present paper analyses the experience of an imitative country, such as India, to see how the strengthening of patent regime on a global scale is going to affect its export performance. The analysis has been conducted using the ppml gravity model of bilateral trade flows in which intellectual property rights, with the help of the Ginarte and Park Index and a dummy for TRIPS implementation, has been incorporated as another factor affecting India's exports to the host countries. The empirical results indicate that the strength of patent protection in the importing countries has not been an important factor affecting India's pharmaceutical exports. Both the implementation and enforcement of TRIPS in partner countries were found to be insignificant and did not impact export flows from India. This contrasts with the notion that an imitator country, like India, would lose market in the previously weak patent following low- and middle-income countries. However, it is seen that the exports of Indian pharmaceuticals have not had a negative impact due to the implementation of TRIPS, not because firms are innovating new drugs but because of other survival strategies adopted by them. It was seen that domestic firms have undergone a territorial shift in the direction of their export market. There are two aspects to this shift. First, countries are taking full advantage of the patent cliff and the opening of developed country markets to establish a foothold in those countries. This is reflected from the increasing number of ANDA applications granted to Indian firms in recent years. Second, investment in R&D for incremental innovation towards the development of drugs suited for the international market has resulted in firms mainly obtaining their revenue from export sales.

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Appendix: List of Countries

High Income	Low Income	Lower Middle Income	Upper Middle Income
Argentina	Afghanistan	Angola	Albania
Australia	Aguila	Bangladesh	Algeria
Austria	Benin	Bhutan	Armenia
Bahrain	Burkina Faso	Bolivia	Belarus
Barbados	Burundi	Cambodia	Belize
Belgium	Central African Republic	Cameroon	Bosnia and Herzegovina
Bermuda	Chad	Cape Verde	Botswana
Canada	Christmas Island	Egypt	Brazil
Chile	Eritrea	El Salvador	Bulgaria
Czech Republic	Ethiopia	Georgia	China
Denmark	Gambia, The	Ghana	Dominica
Estonia	Guinea	Honduras	Dominican Republic
Finland	Guinea-Bissau	Indonesia	Ecuador
France	Haiti	Kenya	Equatorial Guinea
Germany	Liberia	Kiribati	Fiji
Greece	Madagascar	Lesotho	Gabon
Greenland	Malawi	Mauritania	Grenada
Hong Kong, China	Mali	Myanmar	Guatemala
Hungary	Nepal	Pakistan	Guyana
Iceland	Rwanda	Papua New Guinea	Iran
Ireland	Senegal	Philippines	Iraq
Israel	Yemen	Sri Lanka	Jamaica
Italy	Zimbabwe	Swaziland	Jordan
Japan		Uzbekistan	Kazakhstan
Lithuania		Vanuatu	Lebanon
Luxembourg		Vietnam	Libya
Netherlands		Zambia	Macedonia, FYR
New Zealand			Malaysia
Palau			Maldives
Panama			Marshall Islands
Poland			Mauritius
Portugal			Mexico
Qatar			Namibia
Saudi Arabia			Nauru
Singapore			Paraguay
Spain			Peru
Sweden			Romania
Switzerland			Russian Federation
United Arab Emirates			South Africa
United Kingdom			Thailand
United States			Venezuela
Uruguay			

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