Impact of TRIPS and RTAs on the Indian Pharmaceutical Product Exports

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Abstract: Until India fully implemented TRIPS in 2005, the Indian pharmaceutical industry had maintained a comparative advantage of cheap and skilled workers among developing economies. However, recent changes in regulatory environment have made the situation challenging for the industry. India seems to be losing its position in the global arena in both the production of bulk drugs and formulations. This paper investigates how TRIPS (implemented by partner countries) and Regional Trade Agreements (RTAs) influence Indian pharmaceutical product exports, using the Gravity Model. This analysis finds that TRIPS has negative effect on Indian pharmaceutical products exports. And RTAs increase pharmaceutical products exports.

Keywords: TRIPS, RTA, Gravity Model, Indian Pharmaceutical Industry

1. Introduction:

The Indian pharmaceutical industry (IPI) is the leading supplier of cheap generic drugs in the world. The spectacular growth in this sector is mainly due to various legislative reforms of the Indian government to protect its domestic pharmaceutical industry and diminish foreign dominance, and other changes including reverse engineering of patented drug molecules, and the implementation of the Trade Related Intellectual Property Rights (TRIPS). Since India's implementation of TRIPS, in compliance with the World Trade Organization (WTO) accession, there has been significant change in the policy, growth and development of the IPI. Due to this new policy regime, India could not produce drugs patented by the foreign companies through reverse-engineering. Surprisingly, in spite of the very notion that a strong intellectual property rights would lead to higher drugs' prices and may hamper their domestic, infant, high technological industry like pharmaceutical industry in the less developed countries, India has witnessed a surge in production in the post TRIPS period. The increased number of product registrations in both regulated and emerging markets is the driving force of this growth. India is also converging and thereby reaping the advantages of its underdeveloped state. In general, after the Uruguay Round of trade negotiations under the General Agreement on Tariffs and Trade (GATT), implementation of TRIPS has been progressing and thereby countries are agreeing to enforce their domestic laws and regulations designed for the protection of intellectual property rights (IPRs). But IPRs are highly contentious in international relations. Developing economies believe that the stronger IPRs only benefit the developed countries at the expense of developing countries which strengthen the monopoly of big companies based in industrial countries. Still, implementation of TRIPS is very crucial in knowledge intensive industries like the pharmaceutical industry. Since the world pharmaceutical industry has had relatively significant growth during the last several decades, the role of developing countries in the pharmaceutical

global value chains (GVCs) is growing. According to IMS Health reports, medication use around the world will reach 4.5 trillion doses by 2020 with over half of the world's population taking one medicine a day, up from one third in 2005. Almost half of the projected growth will be contributed by just four major emerging economies which include India, China, Brazil and Indonesia. Access to healthcare in these countries has also increased significantly. With the increase in access to medicines worldwide, global spending on drugs is expected to rise by 30 percent to $1.4 trillion. Developed countries still contribute the lion's share of this spending growth on drugs. Even though the purchasing power of people in the emerging economies has increased, they can only buy low-cost medications. Sales of generic drugs account for 88 percent of total medications bought, whereas sales of newer, specialty medications that target chronic, rare or genetic disease like cancer, hepatitis C, and autoimmune diseases account for only 1% of the total in these countries[1].

The case of India is interesting because India has implemented TRIPS in compliance with the WTO accession in 1995. The Indian Patent Act 1970 has been amended three times; once in March 1999, again in June 2002, and the third having come in April 2005 (Jha, 2007). India has undertaken many industrial and trade reforms, such as lowering tariffs levels and eliminating or decreasing non-tariff barriers, etc. R&D expenditures, by the domestic and foreign pharmaceutical companies, merger and 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 and ease of access. The growth of exports has also increased dramatically. The main reason for this

[1]How India, the World's Pharmacy, Is Becoming More Medicated, http://blogs.wsj.com/indiarealtime/2015/11/19/how-india-the-worlds-pharmacy-is-becoming-more-medicated/

growth has to do with the generic markets, particularly within the regulated market which has shifted from the export of bulk drugs to formulations which implies that bulk drugs exports don't enjoy a comparative trade advantage any longer.

Pharmaceutical industry sector being a knowledge-based sector have been an important sector both in the developed and developing countries, including India. In amidst of the rapid globalization process, India shifted its pharmaceuticals trade pattern and faced a tough competition in the global pharmaceutical markets, particularly from developing countries. Thus, it is immensely important to analyze the issue of global competitiveness of India in the world pharmaceutical market. We would like to examine how India achieves such a rapid rise in pharmaceuticals exports in the world. To estimate the determinant of trade, we use the gravity model. It explains (the natural logarithm of) trade with (the logs of) the distance between countries and their joint income. We, then, try to investigate the effect of TRIPS implementation, Regional Trade Agreements (RTAs) and tariff (proxy for trade openness) on the Indian pharmaceutical exports. We extended the basic gravity equation with a number of extra conditioning variables such as common language, health expenditure and foreign direct investment (FDI). The study finds that the effect of partner countries' TRIPS implementation is negative and significant on the IPI. It implies that India is shifting its pharmaceutical exports from regulated markets to unregulated markets. TRIPS implementation has greater impact on formulations exports than that on bulk exports. The RTAs have increased the export performance of India. It benefits more on formulations exports than bulk exports.

This paper is arranged as follows. Section II gives literature review. Section III shows data and methodology for the study of impact of globalization on the IPI through WTO accession

and the integration of global value chains, and its patterns of trade. Finally, Section IV summarizes the results and concludes.

2. LITERATURE REVIEWS:

By protecting IPR, TRIPS allow technology transfer and diffusion, and relate to a set of administrative and market-organizing regulated rules. They enable agents to use or transfer resources among each other, and allow governments to achieve economic efficiency which is one goal observed in IPR regulations, or product liability and safety regulations. In the context of IPI, after the implementation of TRIPS, there is a major change in the IPI in terms of output, productivity, R&D, technological capabilities, etc. at industry level and at firm level. The implementation of TRIPS has increased the patenting activity and R&D investment of the Indian pharmaceutical companies (Chaudhuri, 2007; Chadha, 2009; Bedi, et al., 2013) and increased sales and export performances of the companies (Kiran and Mishra, 2009a). This finding is in line with that of Guennif & Ramani (2012), that the IPI had had more success in industrial capabilities than that of Brazil due to State policy after the IPR reform. Fink (2000) examined the effects of the introduction of product patent protection on the two therapeutic groups in the IPI. He found that the impact of patent protection on Indian pharmaceutical products depended on the values of the assumed elasticities. Possibility of increase in prices and welfare losses will be minimized if close and off-patent substitute drugs are available and vice versa. Watal (2000) also examined the effects of patent protection in 22 patentable pharmaceutical markets and found that prices and welfare losses are likely to increase in moving from current market structures to patent monopoly depending on the demand structure. TRIPS implementation raised drug's prices and decreased technological activities and exports in the IPI. Thus, stronger patent protection leads to higher drug prices and welfare losses in developing economies.

Examining the effects of product patent in India and China, Grace (2004) found that product patent limited profit earnings from the sales of drugs domestically and India increased its exports to regulated markets to compensate this revenue loss. This finding is confirmed by Jha, (2007). With the new patent policies, Indian pharmaceutical companies had shifted its business from domestic markets to regulated markets and had become net exporters of pharmaceuticals and import dependence on bulk drugs (Jha, 2007). It indicates that India focuses mainly on regulated markets. Besides TRIPS implementation has a significant effect on the firms' patenting activity in India. Patent applications by the Indian companies increased more than proportional to patents granted over time, suggesting technology transfer to India. This decrease of the granting ratio might be caused by strict regulations of the TRIPS. Kiran and Mishra (2009a) confirmed these findings that TRIPS implementation led to increase sales, exports, profits, R&D expenditures, patents filling and granting by the Indian pharmaceutical firms. But it reduced the availability of affordable drugs in developing countries (Hafner and Popp, 2011) as these countries could not do reverse-engineering of patented drugs. They also examined the role of India and China as suppliers of cheap medicines to other developing countries and the competitive effect of drug imports from these two countries on the price of drugs imported from high-income countries. They found that Latin America relies totally on intraregional trade and imports from the US, while Sub-Saharan Africa depends on India accounting for 45% of its imports. TRIPS implementation led Latin America to invoke compulsory licensing and negotiate cheaper drug prices. It also reduced drug imports and the availability of affordable drugs. For Sub-Saharan Africa, it might not have direct effects on drug prices as most countries have to implement TRIPS by 2016. They further showed that TRIPS implementation reduced the availability of affordable drugs both from India and high-income countries due to reduced competition.

Analyzing the effects of strengthening patent protection on income redistribution and deadweight loss between countries, McCalman (2001) found that developed countries especially the US significantly benefited from strengthening patent protection, while developing countries significantly lost from it. Accounting for the increase in dead weight loss from higher standards of patent protection undermined the aggregate benefits of the Uruguay Round package, with the increase in dead weight loss amounting to as much as one fifth of the efficiency gains from trade liberalization. As far as Indian consumer welfare is concerned, Chaudhuri, et al., (2006) found that the implementation of TRIPS results to some welfare loss, which includes the loss of product variety, price increase, etc. For example, they estimated the welfare loss for the quinolone sub-segment of the systematic anti-bacterial segment and found that the loss is between $144 million and $ 450 million per year, depending on the policies implemented. But they concluded that TRIPS would not have much detrimental effect on the IPI, as it increases domestic firms' profits. In an attempt to find out the impact of TRIPS on innovation and on export using export data, Bouet (2015) found that TRIPS helped the Indian pharmaceutical firms to improve productive capabilities, by increasing the export of high-value added products and it enabled this industry to enter new markets with new trade flows .i.e. innovation. However, the impact of TRIPS on the value of exports is found to be insignificant.

Most of these literatures about the IPI have been documented on the impact of the trade liberalization and the change in the Patent regime on the performance of the Indian pharmaceutical sector on industry performance. This issue involves a cross-country analysis of the growth, productivity, trade performance and technology with other countries in the global market. Our analysis is concordant to these recent contributions, and adds to the literature on the influence of TRIPS implementation on the IPI by testing the hypothesis that the significance of TRIPS and RTAs are related to the persistence and the intensity of India's total pharmaceutical

exports as well as both for bulk drugs and formulations exports. It is quite necessary to examine how TRIPs implemented by trading partners and RTAs affect Indian pharmaceutical product exports in the light of the rapid globalization process. Before going forward to empirically examine all these analyses, it is quite necessary to examine the basic characteristics and development of this industry.

3. Data and Measures

Trade factors such as transport costs and trade costs affect firms' strategic decision as well as the decision to enter a new market. Distance can affect Indian pharmaceutical exports' competitiveness as it involves transaction costs. To examine whether changes in trade costs favor proximate countries for Indian pharmaceutical exports, we look at changes in simple average tariffs and changes in transport costs. Indian exports of pharmaceutical products also depend on the foreign domestic demand for Indian pharmaceutical products which is represented by both the size and the characteristic of the demand to the industry's product. Partners' GDP and health expenditures are variables which represents foreign domestic demand for pharmaceutical products.

The dependent variable is export of pharmaceuticals from India (X_{ijkt}) to a country *'j'* for a product 'k' on a given year *'t'* ('*t'* years, '*t'*= 1993 to 2013; '*j'* destinations; '*j'*= 1 to 99 countries; '*k'* products = 1 to 45 – HS Combined 6 digits nomenclature. X_{ijkt} can be decomposed into total formulations exports and total bulk drugs exports from country '*i'* to partner country '*j'* in time '*t'* for a product *'k'*. The paper used export data from the UN COMTRADE for cross-country analysis and is based on HS 1992 for 1993 to 1998, HS 1996 for 1999 to 2002, HS 2002 for 2003 to 2008 and HS 2007 for 2009 to 2013. The pharmaceutical products are classified into bulk drugs and formulations and we use to classify it by using 6-

digits, combined HS concordances and BEC concordance. The survey covers 6-digit combined HS codes: 63 bulk drugs codes and 14 formulations codes. We restricted the sample to countries whose bilateral export values exceeds $1 million in 2013, except for countries that signed FTAs with India, which accounts for 99 country units. The largest destination is the US. The exports value is measured in US dollar. The regressions use panel data for the years 1993 to 2013.

The key independent variables in the paper are partner's compliance of TRIPS ($TRIPS_{jt}$), and RTAs between India and importing countries (RTA_{ijt}). The first one is central interest to our analysis for it will allow the analysis of export flow of Indian pharmaceuticals between regulated markets (TRIPS compliant) and unregulated markets. Thus it enables us to differentiate between the regulated markets and unregulated markets. TRIPS is a dummy variable which takes the 1 value if the importing country *'j'* implemented TRIPS for the year '*t*' and 0 if not. RTA_{ijt} represents the combination of free trade agreements (FTAs) and preferential trade agreements (PTAs) between the host country '*i'* and the destination country '*j'* in time '*t'*. India signs FTAs with 15 countries. This study includes 20 countries, out of these 14 FTAs countries (excluded Brunei as some of the basic indicators are not available for this country) and 6 PTAs countries. However, other factors may impact the export of Indian pharmaceuticals.

In order to get unbiased estimated coefficients of the key independent variables, it is necessary to control for other factors that could also affects the export of pharmaceuticals. The other corresponding independent variables are tariff, WTO membership, distance, destination GDP, language and health expenditure which is the total health expenditure. $Tariff_{jpt}$ applied by the importing countries '*j'* for product '*k'*on year '*t'* affects the export flow. Distance ($Dist_{ij}$) is the log geographical distance between country '*i'* and country '*j'* in kilometer. Distance may affect export for it impacts the products' transaction costs. The log GDP of the partner country '*j'*

for a given year *'t'* (Y_{jt})represents the demand conditions in the partner countries '*j'* on year '*t'*. The values are in $ millions of constant 2005 internationals USD. The health expenditure, $Health_{jt}$, of partner country '*j'* for a given year *'t'* indicates the demand conditions of the partner country '*j'* in time '*t'*. It is expressed as the total health expenditure (% GDP) of importing country '*j'* in time '*t'*. Language is a dummy variable which is 1 if both the country shares a common English language and zero otherwise. We include language as language barriers inhibit bilateral trade as it associate costs while communication.

The paper used data from WTO database to create an indicator of FTAs and Ministry of Commerce and Industry, Government of India for PTAs. The standard gravity variables of destination GDP which measures the size, health expenditure, come from the World Bank's World Development Indicators (WDI) database. However, since the Myanmar's GDP is not available at the WDI database, we use this country's GDP from IMF's World Economic Outlook Database. Distance between capital cities and linguistic, are taken from Rose's 2004 website. TRIPS compliance data comes from (Kyle and McGahan, 2012). Average tariffs are the (unweighted) average tariffs from World Integrated Trade System. FDI data is taken from the Annual Survey of Industries (ASI) database.

4.3.2. **Gravity Model**

To organize our empirical analysis of globalization and its impact on Indian pharmaceutical exports, we rely on the Gravity model. As the name suggests, the idea behind the model comes from the law of universal gravitation and is a widely used tool to understand bilateral trade flows in international economics. The most robust empirical result in international economics is that bilateral trade decreases with distance (Melitz, 2007; Disdier, et al., 2008).Trade flows are positively related to the size of the trading partners and inversely related

to the distance between them. It is used to explain bilateral trade flows, and dates back to (Tinbergen, 1962) and (Pöyhönen, 1963). Anderson, (1979) and Anderson and Wincoop, (2003) provide theoretical foundations for the gravity model. Anderson, (2011) examines the exporting country's average exporting capability in the industry. Lawless (2010) empirically examined that trade cost barriers work more through the extensive margin rather than the intensive margin (also; Hanson, et al., 2014). Rose, (2004) and Feenstra et al., (1998), empirically examined the effect of multilateral trade agreement on international trade using gravity model.

Since the study uses a panel data with a time dimension, we use '*t'* subscripts to signify variables that change over time. In a typical gravity equation, it is usual to have data on many different pairs of trading partners and include both exporter and importer income in the regression. But, since our data are for a single exporting country (i.e. India), exporter income is captured in the regression constant, and partners' income is included in the regression.

The exact specification of the gravity model will then be:

$$\mathrm{Ln}(X_{ijpt}) = \alpha + \beta_1 lnDist_{ij} + \beta_2 lnY_{jt} + \beta_3 TRIPS_{jt} + \beta_4 RTA_{ijt} + \beta_5 Tariff_{jpt} + \beta_6 Health_{jt} + \beta_7 FDI_{jt} + \beta_8 Lang_j + \delta_t + \mu_{ijt} \quad (1)$$

Where '*i'* and '*j'* denote India and its trading partners respectively '*t'* denotes time.

X_{ijpt} is the unit value of exports of each product '*p*' from country '*i'* to country '*j'* in time '*t'*; Dist_{ij} is the geographical distance between country '*i'* and country '*j'* in kilometer; and Y_{jt} is the country *j's* GDP in time '*t'*. TRIPS_{jpt} indicate the implementation of TRIPS by the importing country *'j'* on year *'t'*. RTA_{ijt} represents the regional trade agreement between the host country '*i'* and the destination country '*j'* in time '*t'*. We expect a positive sign for this coefficient. Tariff_{jpt} signifies the tariff imposed by the country '*j'* on the import product '*p'* from country '*i'*

in time 't'. $Health_{jt}$ and $Lang_{ij}$ indicate the health expenditure (expressed as percentage GDP of importing countries' health expenditure) of the partner country 'j' in time 't' and sharing a common English language between the country and the importing countries respectively. δ_t and μ_{ijt} are time dummy and an error term respectively. FDI_{jt} is inward foreign direct investment (FDI) in the IPI from the country *'j'* at time *'t'*.

We use ordinary least squares (OLS) to estimate the gravity model. Since the dependent and explanatory variables are in logarithms, the estimated coefficients correspond to elasticities. Distance effects are estimated as a parameter in the gravity equation. We define β_1 as the "distance effect," the negative of the elasticity of bilateral trade with respect to distance. There is time subscript for the dummy variables for RTAs. TRIPS and RTAs are the two explanatory variables of central interest.

4.3.3 **Empirical Results**

Table 1 reports the results. Column (1), (4) and (7) of Table 1 present the benchmark gravity model using distance and GDP as explanatory variables. As expected, the distance variable has an estimated coefficient whose sign is negative and highly significant. The distance coefficient on total export is -0.14. The estimated coefficient of distance suggests that 10% increase in distance lowers export of pharmaceuticals by about 1.4%. Splitting the total export into exports of formulations and exports of bulk drugs, most of the distance effect is negative and significant at 1 percent level. Its coefficient on the formulations export is -0.31 and that of bulk export is -0.19 which are slightly higher that of the total exports. The GDP effect has almost similar pattern across the exports of formulations and bulk drugs with the distance effect. The GDP effect is also higher in case of formulations exports: the GDP effect for total export, formulations and bulk drugs are 0.17, 0.26 and 0.25 respectively. The estimated coefficients for

GDPs are positive and highly significant at the 1 percent level. The coefficient of GDP suggests that 10% in increase in partners' GDP will increase a 1.7% in total exports. It suggests that trade is sharply decreasing with distance and increasing in destination GDP. Both the distance and GDP effect is higher in case of formulations exports than that of bulk drugs exports. Thus, India exports less to countries that are farther apart and increases its exports with economically larger countries.

Drawing all of the elements together, columns (2), (5) and (8) present results for an extended gravity model that includes a range of TRIPS, RTAs, tariff, health expenditure, language and year dummies, in addition to the standard elements of GDP and distance. The fit of this extended model is higher than that of the benchmark model that contained just GDP and distance. The R^2 for the total trade column has increased slightly from 0.02 to 0.03, for formulations export, it increases from 0.05 to 0.09, and for bulk drugs export, from 0.04 to 0.04. The coefficient of distance effect is now only significant on formulations export and insignificant for both total exports and bulk drug exports. The GDP coefficients are highly positive and significant for all the three variables.

The dummy variable for TRIPS as whether a trading partner implements TRIPS in time '*t*' or not is negative and has a highly significant effect on the total exports. The coefficient of TRIPS on the total exports is -0.55. It confirms our prediction that India has shifted its exports to unregulated markets from regulated markets. Bouet (2015) had also found the same negative effect of TRIPS on the Indian pharmaceutical exports. He propounded a possible reason that the compliance of TRIPS led to increase sanitary and pharmaceutical regulations in importing countries, which in turn increase costs to the detriment of foreign exporters. As India's comparative advantage lies on generic production and cost-based strategies, it reduces the

comparative advantage of India. Another possible reason could be rising US concerns over regulatory standards, quality parameters, etc. and increase global competition in regulated markets. For instance, according to Ind-Ra estimates, the impacts on Indian pharmaceutical exports due to import alert by US FDA over issues of data documentation, testing facilities and procedures at Indian facilities, banned facilities contributed around 7%-8% of the total exports to the US and around 2% of the overall 2013 pharmaceutical exports from India. In other words, estimated impact on the existing exports revenue would be around 7-8% of the total exports to the US, and around 2% of the overall 2013 pharmaceutical exports from India.

From column (5) and (8), the impact of TRIPS implementation on the formulations is higher than that on export of bulk drugs. The coefficient of TRIPS on the exports of formulations is -0.69 which is higher than that of bulk drugs (i.e. -0.38) by 0.31. A possible reason could be that though India exports most of its generic drugs in the regulated markets, India has started shifting its formulations exports from highly regulated market to unregulated markets. Its impact on bulk drugs exports is not quite surprising as India mainly exports bulk drugs to developing and underdeveloped countries. The coefficient of RTA has positive and highly significant effect on total exports. The RTA coefficient on the total exports is 0.23. Further, its impacts on exports of formulations and bulk drugs are 0.28 and 0.29 respectively. It indicates that the RTA has also contributed to the growing bulk drugs exports of India at a very significant rate. Here, it is worth mentioning that most of the India's RTA signed countries are developing and underdeveloped countries. Thus, TRIPS implementation adversely affects developing countries like India by lowering its comparative advantage and by reducing revenues due to stronger quality control measures imposed by USFDA. As a result of it, competition among developing economies increases in the regulated generic markets which directly affect India and in search of new markets, she has to shift its trade pattern from regulated markets to unregulated markets where

lesser patent protection prevails. Improving productivity, quality of its drugs and institutions becomes mandatory in order to sustain its dominant role in regulated generic market. In short, pharmaceutical industry in developing countries faces a difficult time as a result of TRIPS implementation. It again proves that RTAs is helpful in promoting bilateral trade between countries. It increases Indian pharmaceutical exports within partner countries.

Surprisingly, tariff has positive and significant effect on total exports. The coefficient of tariff on the total exports is 0.03. It is also positive and significant on both formulations exports and bulk drugs exports. The tariff coefficient is higher on the bulk drug exports (i.e. 0.02) than that of the formulations export (i.e. 0.01). This result is against the conventional theory. One possible explanation is that Most Favored Nation (MNF) tariffs are not the best measure of tariff restrictions and transaction costs that restricts Indian pharmaceutical exports. India, being a WTO member, apply MNF tariffs to other member countries, as well as, she can also apply preferential rates with a limited number of countries, which are lower than MNF tariffs (Bouet, 2015). We run OLS regression on Indian pharmaceutical exports to OECD countries (excluding Japan and Korea) to double check our arguments.

Table 2 gives the result. The tariff coefficient is negative and significant for total exports. It implies that 10% increase in tariff rates renders to 0.8% decrease of Indian pharmaceutical exports to OECD countries. However, the tariff coefficient for formulations is positive and significant, and negative and insignificant for bulk drugs exports. This positive effect for formulations exports might be due to the fact that, in the wake of developed countries' increasing dependence on Indian pharmaceutical exports, though developed countries applied higher tariff rates to formulations drugs, they could not resist importing Indian generic drugs due to cheap and quality drugs. In other words, the domestic demand for Indian made drugs is very high in the

host country. The same goes to the developing and underdeveloped countries. Most of these countries are imposing higher tariff rates on Indian pharmaceutical exports, on the one hand, and, on the other hand, they still import a large quantity of Indian pharmaceuticals, suggesting that they are trying to adopt import substitution policy for drugs and pharmaceuticals but had failed.

The coefficient of health care expenditure is negative and insignificant except for bulk drug exports. The healthcare expenditure effect on bulk drug exports is negative and significant at 1 percent level. It indicates that 10% increase in healthcare expenditure (expressed as % GDP of importing countries' health expenditure) of the importing countries will reduce 0.04% bulk drug exports from India. It is quite opposite to what was expected. One of the possible explanations of this result could be that as health expenditure increases, rich countries usually implement more restrictive sanitary and pharmaceutical regulations increasing transactions costs for exporters making them less competitive (Bouet, 2015). The FDI coefficient is positive and highly significant for all three variables. Its coefficient for formulations (0.24) is higher than that of total exports (0.1) and bulk drugs exports (0.1). The dummy variable for English as a common language is positive and has a highly significant effect on the total exports (0.39) and formulations (1.1). It suggests that countries sharing common language export more. But the coefficient of English dummy is positive but insignificant for bulk drug exports. Sharing English language in common once again favors more on formulations exports than on bulk drug exports.

Table 1: Impact of TRIPS and RTA on Indian Pharmaceutical Exports:
Regressing Log Exports/Log Formulations/Log Bulk Drugs on TRIPS, RTA and Other Variables Using Gravity Model.

	Log Export (Total)			Log Export (Formulations)			Log Export (Bulk Drugs)		
	OLS	**OLS**	**FE**	**OLS**	**OLS**	**FE**	**OLS**	**OLS**	**FE**
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**(8)**	**(9)**
$Distance_{ij}$	-0.137	-0.029	-	-0.308	-0.314	-	-0.187	-0.057	-
	(7.21)***	(0.96)	-	(10.27)***	(6.36)***	-	(8.54)***	(1.64)	-
GDP_{jt}	0.168	0.214	-0.016	0.257	0.324	0.283	0.250	0.302	-0.076
	(28.47)***	(18.66)***	(0.17)	(28.30)***	(18.43)***	(2.12)**	(35.07)***	(22.21)***	(0.72)
$TRIPS_{jt}$		-0.550	0.046		-0.692	-0.137		-0.376	-0.070
		(10.85)***	(0.45)		(9.19)***	(0.90)		(6.22)***	(0.57)
RTA_{ijt}		0.226	0.003		0.282	-0.338		0.288	0.124
		(3.60)***	(0.03)		(2.65)***	(2.52)**		(4.16)***	(1.34)
$Tariff_{jpt}$		0.031	0.029		0.011	0.019		0.017	-0.013
		(8.75)***	(6.44)***		(2.29)**	(2.41)**		(3.58)***	(2.32)**
Health Exp_{jt}		-0.006	0.031		-0.010	0.055		-0.037	0.005
		(0.76)	(1.18)		(0.84)	(1.50)		(4.29)***	(0.15)
Ln_FDI_{jt}		0.097	0.053		0.241	0.149		0.094	0.084
		(2.22)**	(1.19)		(3.80)***	(2.35)**		(1.79)*	(1.58)
$Language_{j}$		0.388	-		1.101	-		0.049	-
		(9.70)***	-		(17.81)***	-		(1.05)	-
Year Effects	NO	YES	YES	NO	YES	YES	NO	YES	YES
Constant	8.054	4.683	10.714	8.405	2.558	2.296	5.670	2.201	11.336
	(42.43)***	(4.72)***	(5.12)***	(27.75)***	(1.77)*	(0.77)	(25.86)***	(1.83)*	(4.57)***
N	45905	25357	25357	17319	8921	8921	28586	16436	16436
RMSE	2.5485	2.5795		2.4173	2.3783		2.3475	2.3876	2.3821
R^2	0.0174	0.0252	0.0058	0.0456	0.0879	0.0243	.0413	0.0381	0.0070
Adjusted R^2	0.0173	0.0243	0.0011	0.0455	0.0853	0.0112	0.0412	0.0367	-0.0001

NOTES: Robust standard errors are in parenthesis. * indicates significance at 10% level, ** at 5% level and *** at 1%

Table 2: Tariffs Effect of Develop Countries on Indian Pharmaceutical Exports: Regressing Log Exports/Log Formulations/Log Bulk Drugs on TRIPS, RTA and Other Variables Using Baseline Gravity Model.

	Log Export (Total)		Log Export (Formulations)		Log Export (Bulks Drugs)	
	OLS (1)	FE (2)	OLS (3)	FE (4)	OLS (5)	FE (6)
$Distance_{ij}$	-0.507	-	-1.063	-	-0.206	-
	(1.86)*	-	(2.31)**	-	(0.68)	-
GDP_{jt}	0.223	-0.854	0.486	-0.200	0.307	-0.969
	(8.21)***	(3.28)***	(11.57)***	(0.47)	(9.50)***	(3.28)***
$TRIPS_{jt}$	-1.406	-0.435	-0.186	-0.040	-0.691	0.408
	(2.32)**	(3.35)***	(0.22)	(0.05)	(0.82)	(0.48)
$Tariff_{jpt}$	-0.077	-0.106	0.144	0.030	-0.009	-0.021
	(2.44)**	(3.35)***	(2.02)**	(0.38)	(0.29)	(0.65)
Health Exp_{jt}	0.147	0.133	0.179	0.031	0.116	0.125
	(7.01)***	(2.22)**	(5.29)***	(0.31)	(4.85)***	(1.88)*
Ln_FDI_{jit}	-0.068	0.099	0.039	0.212	-0.027	0.137
	(1.11)	(1.26)	(0.42)	(1.71)*	(0.37)	(1.50)
$Language_{j}$	0.599	-	1.290	-	0.230	-
	(6.23)***	-	(8.47)***	-	(2.08)**	-
Year Effects	YES	YES	YES	YES	YES	YES
Constant	11.141	32.276	6.099	13.840	4.463	33.332
	(4.17)***	(5.22)***	(1.43)	(1.37)	(1.43)	(4.72)***
N	9356	9356	3100	3100	6256	6256
RMSE	2.6431	-	2.4796	-	2.4324	-
R^2	0.0565	0.0087	0.1662	0.0247	0.0658	0.0094
Adjusted R^2	0.0541	0.0040	0.1597	0.0107	0.0622	0.0025

NOTES: Robust standard errors are in parenthesis. * indicates significance at 10% level, ** at 5% level and *** at 1%

4. Conclusions

With the increase in globalization process, the world pharmaceutical industry has also changed. The role of developing countries in the pharmaceutical GVCs becomes more momentous due to this growing interconnectedness of production processes across countries. On the other hand, the developed countries have lost its market shares in the world pharmaceutical industry. One of the main reasons behind this losing of market share is due to the rapid growth of

the major developing countries in the world pharmaceutical sector, particularly China and India. The IPI has already been affected in its business by other developing countries such as China. A concern has been growing about the replacement of sales lost to TRIPS compliance. In order to make up this loss, the leading domestic firms have increased their exports of generic drugs to the regulated markets. R&D agreements and M&A activities have also been undertaken significantly. Indian domestic firms must strengthen their industrial capabilities over time. This will enable them to stay more competitive and able to capture a bigger pie of global pharmaceutical market share. This raises the question as to what extent India can move forward in the wake of globalization.

We investigate the determinants of trade in pharmaceutical products using standard gravity model. Both the distance and GDP effect is higher in case of formulations exports than that of bulk drugs exports, suggesting that India exports less to countries that are farther apart and increases its exports with economically larger countries. Interestingly, the coefficient of TRIPS is found to be negative. Some of the possible reasons are stated. First, due to TRIPS implementation by partner countries, India finds itself to be in a very difficult position to export to regulated market due to increase sanitary and pharmaceutical regulations in importing countries. Such regulations raise exporting costs thereby impeding pharmaceutical exports. As a result of it, India exports more in unregulated markets. It confirms that after implementation of TRIPS, India shifts its export market from developed countries to developing and underdeveloped countries gradually. Second, TRIPS implementation reduces the comparative advantage of India, i.e. generic production and cost-based strategies. The impact of TRIPS implementation on the formulations is higher than that on export of bulk drugs. It is believed that though India exports most of its generic drugs in the regulated markets, India has shifted its formulations exports from highly regulated market to unregulated markets. The coefficient of

RTA has positive and highly significant effect on total exports. It indicates that the RTA has also contributed to the growing bulk drugs exports of India at a very significant rate.

Surprisingly, tariff has positive and significant effect on total exports and also on both formulations exports and bulk drugs exports, which is against the conventional theory. One possible explanation is that Most Favored Nation (MNF) tariffs are not the best measure of tariff restrictions and transaction costs that restricts Indian pharmaceutical exports. India, being a WTO member, apply MNF tariffs to other member countries, as well as, she can also apply preferential rates to selected countries, which are lower than MNF tariffs (Bouet, 2015). To double check our arguments, we examine the impact of tariffs on Indian pharmaceutical exports to OECD countries (excluding Japan and Korea). The tariff coefficient turns out to be negative and significant for total exports and bulk drugs. It confirms the above argument have some merits. However, the tariff coefficient for formulations is positive and significant. One possible explanation is that even though developed countries applied higher tariff rates to Indian formulations drugs, they still import a large quantity of Indian generic drugs due to its cheap and high quality drugs. In other words, the domestic demand for Indian made drugs is very high in the host country. The same goes to the developing and underdeveloped countries. Most of these countries are trying to adopt import substitution policy for drugs and pharmaceuticals but had failed. The coefficient of health care expenditure is negative and insignificant except for bulk drug exports. Another unexpected result is the negative effect of health care expenditure on drugs exports. One of the possible explanation of this result could be, as health expenditure increases, rich countries usually implement more restrictive sanitary and pharmaceutical regulations increasing transactions costs for exporters making them less competitive (Bouet, 2014). The FDI coefficient is positive and highly significant for all three variables. The dummy variable for English as a common language is positive and has a highly significant effect on

pharmaceuticals exports, indicating that sharing English as a common language increases pharmaceutical exports. Thus, widespread regulatory actions by importing countries have affected Indian pharmaceutical exports. It indicates that after the success in acquiring a favorable share in the regulated markets, India is trying to bolster its market share in the unregulated markets.

With changing political and regulatory environment, TRIPS implementation has made developing countries like India shift its pattern of trade from regulated markets to unregulated markets, on the one hand, and, on the other hand, it adversely affects these countries by lowering its comparative advantage and by reducing revenues due to stronger quality control measures imposed by USFDA. It necessitates developing countries to improve productivity, efficiencies, institutions, etc. for their survival. RTAs promote bilateral trade between countries. It suggests that countries at different levels of industrial and technological development may be faced with varying economic costs and benefits from stronger IPRs.

Policy Implications and Recommendations:

Since developing economies don't have better technologies and components, they could not produce niche and high quality medications. Therefore, they should not protect their domestic industries, for international cooperation is necessary to build their industrial capabilities. Trade barriers may restrict them to participate in pharmaceuticals GVCs. Thus, a regulatory regime, adhering to global regulatory practices, to provide healthcare affordable and accessible is necessary in developing country like India. But it should not be at the cost of the industry, as stringent regulatory policy with its intended purposes may hinder product launch and lose focus in India. For instance, a strict price control measure for essential medicines may lead to unexpected fallout of several drugs due to less profitability. The government should find a

balancing path with viability and as such, policy measures like insurance and public private partnerships could be initiated.

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APPENDICES

A. List of Countries

1	Afghanistan	20	Colombia	37	Haiti
2	Algeria	21	Congo, Dem. Rep.	38	Hong Kong, China
3	Angola	22	Congo, Rep.	39	Hungary
4	Argentina	23	Costa Rica	40	Indonesia
5	Australia	24	Cote d'Ivoire	41	Iran, Islamic Rep.
6	Austria	25	Czech Republic	42	Ireland
7	Bangladesh	26	Denmark	43	Italy
8	Belarus	27	Dominican Republic	44	Jamaica
9	Belgium			45	Japan
10	Benin	28	Ecuador	46	Jordan
11	Bhutan	29	Egypt, Arab Rep.	47	Kazakhstan
12	Brazil	30	Ethiopia (excludes Eritrea)	48	Kenya
13	Burkina Faso	31	Finland	49	Korea, Rep.
14	Cambodia	32	France	50	Lao PDR
15	Cameroon	33	Germany	51	Libya
16	Canada	34	Ghana	52	Malawi
17	Chad	35	Guatemala	53	Malaysia
18	Chile	36	Guinea	54	Mali
19	China			55	Malta

56	Mauritius	71	Portugal	86	Turkey
57	Mexico	72	Romania	87	Turkmenistan
58	Morocco	73	Russian Federation	88	Uganda
59	Mozambique	74	Rwanda	89	Ukraine
60	Myanmar	75	Senegal	90	United Arab Emirates
61	Nepal	76	Singapore	91	United Kingdom
62	Netherlands	77	Slovenia	92	United States
63	New Zealand	78	South Africa	93	Uruguay
64	Niger	79	Spain	94	Uzbekistan
65	Nigeria	80	Sri Lanka	95	Venezuela
66	Pakistan	81	Sweden	96	Vietnam
67	Paraguay	82	Switzerland	97	Yemen
68	Peru	83	Tajikistan	98	Zambia
69	Philippines	84	Tanzania	99	Zimbabwe
70	Poland	85	Thailand		

B. **List of Free Trade Agreement Countries**

1	Bhutan
2	Cambodia
3	Indonesia
4	Japan
5	Korea, Rep.
6	Lao PDR
7	Malaysia
8	Myanmar
9	Nepal
10	Philippines
11	Singapore
12	Sri Lanka
13	Thailand
14	Vietnam

C. List of Preferential Trade Agreement Countries

1 Afghanistan

2 Argentina

3 Brazil

4 Chile

5 Paraguay

6 Uruguay