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DETERMINANTS OF FOREIGN DIRECT INVESTMENT IN THE INDIAN PHARMACEUTICAL INDUSTRY WITH SPECIAL REFERENCE TO INTELLECTUAL PROPERTY RIGHTS:
EVIDENCE FROM A TIME-SERIES ANALYSIS (1990-2019)

Supriya Bhandarkar[1] and Meenakshi Rajeev[2]

Abstract

The Indian pharmaceutical industry is playing an important role to combat the Covid-19 pandemic and other important illnesses. However, to have enough capital to carry out R&D and bring forth innovation, FDI is essential. The signing of the TRIPS agreement saw a global harmonization of intellectual property rights underpinned by the theory that stronger IPRs spur increased foreign direct investment inflows by reducing the threat of imitation. Following an ARDL approach and using time series data for India between 1990 and 2019, this study examines the impact of IPRs on FDI inflows into the Indian pharmaceutical industry. We consider two measures of IPR protection- implementation of TRIPS and strengthening of the IPR regime through the construction of a new pharmaceutical patent index for India. We also take into account the impact of industry characteristics and host-country conditions on FDI flows into the country. Furthermore, as governments in developing countries seek more FDI, they open their economies and adapt market-friendly policies that ensures a global process of competition. While such competition is indeed widespread, given that the Chinese pharmaceutical industry is India's biggest competitor, due to its cost-competitive manufacturing sector producing the largest number of active pharmaceutical ingredients, we take into consideration the competition offered by China through the FDI confidence index. Our results show that while the implementation of TRIPS in the country has increased the FDI inflow into the pharmaceutical sector, the enforcement of the IPR regime, as measured by the pharmaceutical patent index has led to the reduction of FDI inflow. We also find that institutional factors such as corruption and political instability in the economy along with the degree of trade openness are major determinants of investment decisions in India, while the competition from China does not play a significant role.

Introduction

The World Trade Organization (WTO) was established in 1995, the result of 8 years of multilateral trade negotiations, also known as the Uruguay Round of negotiations. This culminated into the signing of the Marrakesh agreement, the highlight of which was the formal inclusion of intellectual property rights (IPRs) into international trade rules. (Athreye *et al*, 2020) This was achieved through the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement which required all 123 signatories to enforce 'high minimum standards of 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) For countries like India this effectively raised the protection from 0 to 20 years in the country.

Despite being a member of the World Intellectual Property Organization (WIPO)since 1975 and signatories to many treaties dealing with patent rights such as the WIPO Convention (1975), Paris Convention (1998), Patent Cooperation Treaty (1998) etc, the inclusion of IPRs in the WTO framework was opposed by many developing nations, including India. While WIPO was established in order to ensure protection of IP rights of member states across the globe in collaboration with international organizations, it did not mandate the provision of product patents to pharmaceuticals for two reasons-in order to ensure equitable access of medicines and growth of pharmaceutical industry in developing countries since pharmaceutical inventions were owned mainly by developed countries. (He, 2019)

Therefore, the remarkable growth of the Indian pharmaceutical industry prior to 1995 was the result of the Patents Act, 1970, which abolished pharmaceutical product patents and allowed only process patents for seven years from the date of filing. This change meant that every drug henceforth could be legally copied for sale as long as a different process of manufacturing the drug was used. The eventual economic effect of the India Patents Act, 1970, was a dramatic increase in domestic generic drug manufacturing in the country making India almost self-sufficient in medicines. This unauthorised use of intellectual property was perceived to be a threat to the patented products of MNCs thereby disincentivising foreign investment into the country.

Despite the Indian pharmaceutical industry having a comparative advantage in various determinants such as abundant low-cost labour, low manufacturing and R&D costs as compared to developed counties and the largest number of US Food and Drug Administration (USFDA) approved manufacturing plants outside the US with over 1,300 manufacturing plants compliant with World Health Organisation (WHO) Good Manufacturing Practices. (ET Edit, 2020) the FDI flow into the Indian pharmaceutical industry was a mere 12.7 million USD in 1990. (GoI, 1991) This was probably because MNCs were hesitant to invest in the country due to its weak patent laws and India's reputation as an imitator rather than an innovator of drugs.

However, to have enough capital to carry out R&D and bring forth innovation, Foreign Direct Investment (FDI)from developed countries was needed to ease the domestic resource constraint. (Rai, 2008) Realising the importance of FDI and the possibility of being kept entirely outside framework of WTO India acceded to the TRIPS agreement with certain flexibilities. After the transition period of 10 years given to developing countries in 2005India re-established patent protection for pharmaceutical products to comply with the disciplines of the TRIPS agreement. Therefore, we need to examine if India's pharmaceutical sector is likely to attract more FDI as a result of the TRIPS compliance regime.

Theoretical literature and empirical studies have still produced mixed results regarding the relationship between intellectual property rights (IPR) and the inflow of FDI into host countries. On the one hand, since the primary motive of most pharmaceutical companies is profit making, a strong IPR regime decreases the probability of imitation, which makes a host country an attractive location for investment. On the other hand, strong IPRs are associated with a reliable legal framework, providing protection against duplication of the product and therefore progressive strengthening of IPRs may shift the preference of MNCs from FDI towards exports or licensing. (Javorcik, 2002)

Yet, the question of how important IPR protection is for foreign direct investment (FDI) is still unsettled. In the present paper, we hypothesize that the threat of an unauthorized use of intellectual-

property-related assets depends on industry characteristics as well as host-country conditions. Hence, we analyse the impact of IPR protection on FDI at sectoral level of disaggregation. In contrast to earlier studies, this paper considers both, the implementation of the TRIPS agreement as well its enforcement by constructing a Pharmaceutical Patent Index for India. Even when legal institutions are put in place to ensure protection against the theft of intellectual property, other institutional factors such as the level of corruption, political stability, etc. have a critical role to play in ensuring the effectiveness of these institutions. In addition to host country characteristics affecting FDI decisions we also take into consideration that the impact of IPRs on FDIs varies depending on sector specific variables such as profitability and R&D.

The remainder of the paper is organised as follows. Section 2 provides a brief review of literature. Section 3 details the data sources and section 4 presents the model specification and estimation technique. Section 5 presents the empirical results. Section 6 concludes.

Review of Literature

Foreign direct investment (FDI) is defined as "*a category of cross-border investment made by a resident in one economy (the direct investor or parent) with the objective of establishing a lasting interest in an enterprise (the direct investment enterprise or affiliate) that is resident in an economy other than that of the direct investor*" (OECD, 2008) There have been various studies that have analysed what factors determine MNCs choice of one country over another for their investment decisions. Most studies focus on the economic determinants of FDI such as market size and population (Scaperlanda and Mauer, 1969; Chakrabarti, 2001), labour force (Havlik, 2005a; Bevan *et al*, 2004; Bekes, 2005; Demekas *et al*, 2005), exchange rate (Aliber 1970; Xing, 2006; Alba *et al*, 2010; Tomlin, 2000) infrastructure development, trade openness (Edwards, 1990; Pistoresi, 2000; Biglaiser and deRouen, 2006; Seim, 2009) etc. More recently studies have also focused on the importance of institutional variables that may influence FDI flows. Studies have analysed the impact of various institutional factors such as bureaucratic red tape, political instability, corruption and the quality of the legal system etc (Wheeler and Mody, 1992; Kaufman *et al*,1999; Ghemawat, 2001; Bevan, Estrin, & Meyer, 2004; Buchanan *et al*, 2012; Bailey, 2018)

In recent years, while many empirical studies have examined the relationship between IPRs and FDI at a macro level (Ferrantino, 1993; Mansfield, 1993; Maskus and Konan, 1994; Correa, 2000; Mayer and Pfister, 2001; Fosfuri, 2004; Watkins and Taylor, 2010) there have been very few sectoral studies, especially within the pharmaceutical industry.

Intellectual Property Rights and FDI in the Pharmaceutical Sector

Studies that analysed the relationship between FDI and IPRs in developed countries pharmaceutical sectors mostly found a positive relationship between the strengthening of IPRs and the inflow of FDI. Park and Lippoldt (2003) using regression analysis studied the relationship between an index of patent rights to FDI and trade in the 1990s. The analysis revealed a positive relationship. For pharmaceuticals, a 1% increase in the index of patent rights was associated with a 0.24% increase in investment from the USA into the host country. Kyrkilis and Koboti (2015) too found a positive relation between FDI into

Greece and the IPR regime. Using ANOVA, they found that strengthening Greece's IPR regime was a prerequisite for FDI decisions to transfer technology.

In the case of developing countries, studies have shown mixed results. Analysing the pharmaceutical sectors in developing countries, Alavi and Azmi (2005) highlighted the relationship between patents, FDI, and technology transfer in the Malaysian pharmaceutical industry. Surveying the MNCs investing in Malaysia, the study found that the strength of the IPR regime was not a significant factor in investment decisions in Malaysia. This was reflected in the fact that despite Malaysia having strong patent laws comparable to international standards, the investment into the pharmaceutical industry had been negligible. On the other hand, the study by Rai (2008) on the Indian pharmaceutical to analyse if India's signing of the TRIPS agreement resulted in inward FDI flows showed contrasting results. The study conducted a survey to gauge the perception of the industry and conducted an empirical analysis to verify the results. The study highlighted that a strong IPR regime was a significant determinant of FDI flows, along with other macro-economic factors such as GDP growth, market size, etc. Shapiro and Mathur (2014) corroborated the positive relationship between IPR and FDI in India, in their study on the Indian pharmaceutical industry. The study by Pugatch and Chu (2011) analysed the impact of IPRs on FDI in clinical research in the biopharmaceutical field in developing countries. Using the Pharmaceutical IP Index they found that stronger the IPR regulations in a country greater the is the FDI inflow into clinical trials research by MNCs into the host country.

As can be seen by the reviewed literature limited studies that exist on the sector focus on the implementation of TRIPS as a measure for IPR protection or rely on surveys to gauge the perception of the industry. The enforcement aspect of IPRs which we deem critical is neglected by the existing literature on the sector. We also observe that most studies take into account macro determinants of FDI and fail to recognize the more important sector specific determinants. Our study attempts to bridge these gaps.

Methodology

Model Specification and Estimation Technique

To examine the long-run relationship between FDI inflows into the pharmaceutical sector and its determinants, we employ the autoregressive distributed lag (ARDL) method. We use the ARDL technique due to the numerous advantages it possesses over the Johansen cointegration technique. Since we have a small sample size of 30 years, the ARDL model will be a more statistically significant approach to determine the cointegration relation. Secondly, the ARDL method can be appliedirrespective of whether the regressors are I(1), I(0) or a combination of the two. Furthermore, with the ARDL method regressors can have different optimal numbers of lags, unlike the Johansen integration approach.

The following specification of the ARDL model is used in the study:

$$\Delta \quad = ⬚ + ⬚ \quad + ⬚ \quad + ⬚ \quad + ⬚ \quad + ⬚ \quad +$$
$$⬚ \quad + ⬚ \quad + ⬚ \quad + ⬚ \quad + ⬚ \quad + \sum \Delta \quad +$$
$$\sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad +$$
$$\sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad +$$
$$\sum \Delta \quad + \text{......}$$

We follow the two step procedure outlined by Pesaran and Pesaran (1997). We first check for the presence of any long-term relationship among the variables of interest using a Wald Test(F-statistic). The existence of a long-run relationship among theseis tested for the null hypothesis of no cointegration against its alternative hypothesis of a cointegrating relationship. The null and alternative hypotheses are as follows:

H_0: $\alpha_1 = \alpha_2 = \alpha_3 = \alpha_4 = \alpha_5 = \alpha_6 = \alpha_7 = \alpha_8 = \alpha_9 = \alpha_{10} = 0$(No long run relationship)

H_0 = $\alpha_1 \neq 0$, $\alpha_2 \neq 0$, $\alpha_3 \neq 0$, $\alpha_4 \neq 0$, $\alpha_5 \neq 0$, $\alpha_6 \neq 0$, $\alpha_7 \neq 0$, $\alpha_8 \neq 0$, $\alpha_9 \neq 0$, $\alpha_{10} \neq 0$(Long run relationship exists)

The second step of the analysis is to estimate the coefficients of the long-run relationship and determine their values.

Long run relationship

$$= ⬚ + \sum ⬚ \quad + \sum ⬚ \quad + \sum ⬚ \quad +$$
$$\sum ⬚ \quad + \sum ⬚ \quad + \sum ⬚ \quad + \sum ⬚ \quad +$$
$$\sum ⬚ \quad + \sum ⬚ \quad + \sum ⬚ \quad + \text{...... (1)}$$

Next, we estimate the short-run elasticity of the variables with the error correction representation of the ARDL model. By applying the ECM version of ARDL, the speed of adjustment to equilibrium will be determined.

ECM model

$$\Delta \quad = ⬚ + \sum \Delta \quad + \sum \Delta \quad _{} + \sum \Delta \quad +$$
$$\sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad +$$
$$\sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad + \sum \Delta \quad +$$
$$+ \text{...... (2)}$$

Where, α_0 is the constant, α_i,is the long run coefficient Δ is the first differenceoperator,γ_i is the short-run coefficient, ECMt-1 is one period lagged errorcorrection term,   is the speed of adjustment, εt is the errorterm of the estimated model.

Variable Description and Measurement

This section discusses the variables used in the study, their measurements and data sources.

Dependent Variable

The dependent variable in our study is foreign direct investment (FDI_t) flows into the Indian Drugs and Pharmaceutical industry from 1990-2018. In the present study, we define FDI in accordance to the definition presented by GoI (2017), according to which FDI refers to *"the investment made by a non-resident entity/person resident outside India in the capital of an Indian company".* The data for FDI inflows was collected from Department for Promotion of Industry and Internal Trade, GoI website. Nominal FDI inflow values are deflated using GDP deflator to arrive at real FDI inflows.

Independent Variables

To study what determines the flow of FDI into the Indian pharmaceutical industry we classify the variables into 3 categories- measures of IPR protection, country specific determinants and sector specific determinants.

Measures of IPR Protection

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 India has implemented minimum standards of protection as specified in the TRIPS agreement in the particular year. We use a dummy variable equal to 1 if the county has implemented TRIPS in time period t, or 0 otherwise. In our model since the treatment started in 2005 years before 2005 will have a value of 0 and 2005+ a 1. While MNC's look at the implementation of TRIPS while considering India as a host country for their investment, mere implementation is not sufficient for continual flow of capital. Firms also look at the enforcement of the agreement in the country in order to ensure a robust legal framework that can protect their patents and ensure monopoly profits for their products.

Strength of IPRs- Pharmaceutical Patent Index (PPI) - We construct a new pharmaceutical patent index for the period 1990-2019 that measures the strength of pharmaceutical patent protection in India. Statistically, the index measures 7 categories-Implementation, Administration, Membership in International Agreements, Operational Efficiency, Enforcement and Adjudication, Exemptions to IP Protection and Barriers to IP protection. Each category can score values between 0 and 1 and the cumulative score of the index ranges between 0 and 7.

Each category includes sub-categories assigned either the value of 0—if the particular subcategory does not exist in India—or 1—if the particular subcategory does exist. **(See Appendix for the details on construction of the index)**

Sector Specific Determinants

R&D expenditure - MNC's tend to invest in those countries that spend more on research and development, since this is an indicator that the host country's industry is technologically advanced and attract skilled R&D personnel. A host country with an innovative domestic industry attracts inwards investment by MNCs to set up their domestic R&D facility to shift their research intensive manufacturing into the host country and further gain from the local Science & Technology infrastructure. (Mrinalini *et al*, 2013) Data on R&D expenditure for the Indian pharmaceutical industry is compiled from the CMIE database.

Profitability - Industries earning higher profits retain larger surpluses for future investment, and offer scope to foreign firms to send back higher remittances to home countries. We therefore expect more FDI to flow with increasing profits. We take into consideration profit margin computed from the CMIE Prowess database as a measure of profitability.

Country Specific Determinants

Corruption Perception Index - There are two alternate views on the effect of corruption on economic activity. The grease the wheels hypothesis states that in countries with weak government institutions and inefficient implementation of policy, corruption can benefit economic activity by hastening the process of obtaining approvals, licenses etc through the payment of bribes. (Aidt 2009; Shleifer and Vishny 1993). On the other hand the 'sand the wheels hypothesis' states that corruption is harmful for growth and investment into the country, for instance in cases where corrupt officials intentionally cause delays in the anticipation of a bribe. (Myrdal, 1968) We use the Bayesian Corruption Index to measure the level of corruption in India. Corruption is defined as the *"abuse of power for private gain among governmental institutions and the integrity of people in a position of authority".* (Standaert, 2015) The BCI index values lie between 0 and 100, with an increase in the index corresponding to a rise in the level of corruption. The data for the BCI is from Ghent University compiled by Samuel Standaert.

Government Stability Index (Govt. Stab) - Internalization theory states that in countries that are considered 'high political risk', most MNCs tend to substitute FDI with exports or licensing. MNCs are discouraged from investing in local production and often switch to arms length servicing measures. To measure the political stability in the country we use the Government Stability Index which measures "*the government's ability to carry out its declared program(s), and its ability to stay in office*". The index is the sum of three subcomponents-Government Unity, Legislative Strength and Popular Support. The index ranges from0 to 4. A score of 4 indicates 'Very Low Risk' and a score of 0 indicates 'Very High Risk'. Data is taken from the International Country Risk Guide dataset.

Trade Openness Index (Trade Op) - Those MNCs that are market-seeking and want to capture foreign markets are not deterred by trade barriers in the host country. This is because this allows MNCs to avoid competition through the import of pharmaceuticals from other foreign firms. However, MNCs

that are resource- seeking are motivated by low manufacturing costs in host countries and aim to serve both the domestic and foreign markets will invest in those countries that are more open to trade. Since most firms import raw materials and intermediate goods to aid domestic production, trade barriers will act as a deterrent. Therefore, trade openness can have a positive or negative impact on FDI (Asiedu, 2002; Sahoo, 2006). Trade openness is proxied as the ratio of the export plus import divided by GDP.

FDI Confidence Index (FDICI) - Another factor that closely affects the Indian pharmaceutical sector is the Chinese pharmaceutical industry which is India's biggest competitor. To account for this the ratio transformation on the FDI Confidence Index of India and the FDI Confidence Index of China was used. The Kearney FDI Confidence Index is "*an annual survey of global business executives that ranks the markets likely to attract the most investment in the next three years. The Index is constructed using primary data from a proprietary survey of 500 senior executives of the world's leading corporations".* (Laudicina *et al*, 2019) Data for the FDI Confidence Index is from A.T Kearney.

Table 2: Variable description, Measurement and Sources

Variable	Description/Measurement	Data Source
LFDI	Natural log of FDI flows into Indian pharmaceutical industry	DIPP
D_TRIPS	Dummy variable measuring the implementation of TRIPS in the host country	WIPO
PPI	Pharmaceutical Patent Index constructed by the author	Various Sources (See Appendix for details)
LGDP	Natural log of GDP of the host country	EPWRF India Time Series
STAB	Degree of political stability of the host country	International Country Risk Guide, PRS Group
BCI	Corruption index by Standaert (2019)	Ghent University
TRADE	Trade Openness Index measured as a ratio of export plus import divided by GDP	MOSPI
LAB	Labour cost percentage (compensation to employees as a percentage of total revenue	CMIE Prowess
PROFIT	Profit Margin	CMIE Prowess
RD	R&D Intensity	CMIE Prowess
FDICI	FDI Confidence Index	AT Kearney

Note: DIPP - Department for Promotion of Industry and Internal Trade; WIPO- World Intellectual Property Organization; EPWRF- Economic and Political Weekly Research Foundation; MOSPI- Ministry of Statistics and Programme Implementation; CMIE- Centre for Monitoring Indian Economy

Empirical Results

Data for GDP and FDI is transformed in logarithmic form as to smooth the data and overcome the heteroskedasticity issue. (Ahmad and Du, 2017) All indices are rescaled from 0-1 to ensure better comparison of results. (See Appendix for sample statistics for the variables)

Unit Root Test

Before proceeding with the ARDL estimation we first check the stationarity of all the variables. ARDL methodology can be used with a combination of I(0) and I(1) variables. Therefore, we use the Augmented Dickey Fuller (ADF) test to make sure that none of the variables are I(2).

Table 3: Augmented Dicky Fuller Test Results

Variable	Augmented Dickey Fuller Test Statistic (At Level)	Augmented Dickey Fuller Test Statistic (At First Difference)
ln(FDI)	-4.334047 (0.0095)*	-8.486497 (0.0000)
Ln(PPI)	-1.726193 (0.7135)	-4.471953 (0.0077)*
Ln(GDP)	-3.006204 (0.1477)	-5.350652 (0.0009)*
GovtStab	-2.895388 (0.1784)	-6.315491 (0.0001)*
BCI	-6.256474 (0.0000)*	-3.305112 (0.0277)
TradeOp	-1.679795 (0.7343)	-3.538106 (0.0019)*
LabCost	-2.379239 (0.3818)	-5.922437 (0.0002)*
Profit	-2.697646 (0.2447)	-5.467435 (0.0007)*
RD	-0.696967 (0.9638)	-5.283951 (0.0019)*
FDICI	-2.419931 (0.1456)	-4.285081 (0.0023)*

*   Significant at 1% level of significance

Looking at the p values we can see that some variables are integrated of order one I(1) while ln(FDI) and the Baynesian Corruption Index are I(0). None of the variables are I(2).

Bounds Test

The ARDL bounds test is performed to test the long-run relationships among the selected variables. If the value of the computed F-statistic is below the lower bound we state that there is no cointegration. If the value of the F-statistic is higher than the upper bound, we conclude that there is cointegration. Finally, if the F-statistic falls between the upper and lower bound values, the test is inconclusive. Table 4 displays the results of the bounds test of the selected ARDL models.

Table 4: Results of the Bounds Test

Test Statistic	Value	k
F-statistic	**6.294339**	**9**
Critical Value Bounds		
Significance	**I0 Bound**	**I1Bound**
10%	1.63	2.75
5%	1.86	3.05
2.5%	2.08	3.33
1%	2.37	3.68

The computed value of F-statistics of 6.29 is higher than the upper bound critical value (3.68) at one percent significance level. Therefore, the null hypothesis of no co-integration is rejected and we

accept the alternative at one percent level of significance and state that there is cointegration among the variables.

Estimated Long-run and Short-run Coefficients using the ARDL Approach

After confirmation of the long-run relationship among these variables, equation (1) is estimated. The lag selections of these models are carried out using the Akaike information criterion (AIC). The results of both long-run and short-run estimations are shown below

Table 5: Long Run and Short Run Coefficients

Long Run Coefficients		Short Run Coefficients	
Variable	**Coeff**	**Variable**	**Coeff**
PPI	-2.198180 (0.0001)***	ΔPPI	-0.860783 (0.0265)**
D_TRIPS	0.964349 (0.0013)***	ΔD_TRIPS	0.964270 (0.0006)***
GovtStab	1.548751 (0.0026)***	ΔGovtStab	-0.749527 (0.0986)
BCI	-2.407930 (0.0238)**	ΔBCI	-1.453368 (0.0051)***
TradeOp	7.896737 (0.0007)***	ΔTradeOp	1.781136 (0.1891)
FDICI	0.426028 (0.4230)	ΔFDICI	-0.285476 (0.6470)
Profit	0.085742 (0.0075)***	ΔProfit	0.085735 (0.0023)***
RD	-0.842830 (0.0601)	ΔRD	0.510948 (0.0674)
LabCost	0.353966 (0.0091)***	ΔLabCost	-0.078722 (0.3256)
Ln(GDP)	0.187745 (0.3739)	ΔLn(GDP)	0.187729 (0.3519)
		ECM(-1)	-0.99 (0.0000)***
R^2	0.87	Adjusted R^2	0.71
Diagnostic Test			
Breusch Godfrey Serial Correlation LM Test	4.301115 (0.0649)		
Breusch-Pagan-Godfrey Heteroskedasticity Test	0.862957 (0.6235)		

***, ** and * denotes 1, 5 and 10 per cent levels of significance respectively. Coeff is the estimated coefficients. The figures in brackets are the respective p values.

Discussion

Table 5 shows that the dummy variable used to measure TRIPS implementation has a significant and positive effect in explaining the FDI inflows into the pharmaceutical sector in India. Implementing the TRIPS regime in India made it illegal for domestic firms to duplicate patented products developed by other firms through reverse engineering. Thus, strengthening IPR protection in India alleviated the fears of unauthorised use of intellectual property thereby increasing FDI into the sector.

However, the pharmaceutical patent index used as a measure of enforcement of IPRs within the country has a significant and negative impact. Table 5 shows that as the index value increases by 1,

the FDI decreases by 2.19 percent. It implies that in the long-run, while firms look at the implementation of IPRs for initial investment into the country, leading to an increase in FDI flows, the further strengthening of the IPR regime leads to a decrease in the FDI flows. Looking at the pharmaceutical patent index (PPI) constructed for India, we observe that the value of the index has increased from 0.73 in 1990 to 4.1 2005 when TRIPs was implemented to 5.13 in 2019. (See appendix for the PPI values) Trends in the FDI flows into the pharma sector reflect the IP related policy changes in India. Before India implemented the TRIPS agreement, from 1990 to 2004, FDI into the pharmaceutical sector constituted 2.1 percent of the total inward FDI flows to India. From 2005 to 2013, the sector contributed an average of 5 percent to total FDI flows. However, since 2013, there has been a substantial fall in the FDI into the country from USD 1279 million to USD 296 million in 2019. This is because as the IPR regime is strengthened, i.e. TRIPS agreement is enforced, firms would not need to rely as much on the direct form of FDI and may choose more licensing or joint venture agreements. When an MNC enters into a licensing agreement with a domestic firm in the host country they grant them the right to produce and sell the patented product. The domestic firm in turn pays compensation to the licensing firm. Under a joint venture agreement, the MNC and the domestic firm jointly set up a commercial enterprise, but otherwise retain their individual identities. (Simonet, 2002) In contrast to a situation where an MNC invests directly in a country and incurs the full cost of setting up and operating a manufacturing or R&D plant, in a licensing agreement the licensee undertakes the cost of production and marketing of the drug in return for technical expertise. Similarly in a joint venture, the costs are shared among the MNC and the domestic firm and tend to be lower than what would be incurred by setting up a new plant in the host country. (Dharmesh, 2018)

The Government of India has been focusing on strengthening the IPR measures in the country. During the 11th and 12th Five Year Plan the GoI launched the Modernisation and Strengthening of Intellectual Property Office scheme. (MSIPO). The objective of the scheme was to improve the working of the regional patent offices within the country enabling it to function at par with international offices, training human resources for improving quality of service etc. (DIPP, 2019) The National IPR policy too brought about various measures to improve legal infrastructure in the country.

Due to these initiatives taken by the government, MNCs have begun to license the manufacturing of their patented drugs and enter into joint ventures with Indian firms. Dr Reddy's, Zydus Cadila, Glenmark, Sun pharmaceuticals etc have licensing agreements with MNCs. MNCs such as Bayer AG and Merck have also startedjoint ventures with Zydus Pharma and Sun Pharma respectively to sell generic drugs in India as well as other emerging markets.

Looking into the sector specific variables we can see that while profitability also has a significant and positive impact on FDI inflows into the country, R&D of the industry has an insignificant effect. Interestingly, however, the coefficient of the FDI Confidence Index shows us that China does not have an impact on the FDI flows into India. This is probably because, despite India and China closely competing in similar areas for pharmaceutical FDI, each of the countries have their own distinct specialization. While China is the leading manufacturer of APIs across the globe, most APIs manufactured in China are for bacterial infections. On the other hand, the APIs for most chronic and tropical diseases are manufactured by Indian pharma companies who have greater R&D expertise.

(Zhang, 2012) Similarly, India's capability in vaccine manufacturing and complex formulations sets it apart from China.

However, the estimation of long-run coefficients by ARDL method (Table 5) reveals that only the presence of a patent regime is not sufficient to induce FDI inflows in the economy and institutional factors such as the presence of corruption, political stability, and trade openness as are significant determinants of FDI. The corruption perception index has a negative and significant impact on FDI inflows into the economy. Our results show that an increase in the host-country corruption has a negative effect on the likelihood of receiving FDI, as high value of corruption index means an increase in corruption. Our estimates show that a one-unit increase in the BCI index leads to a decrease of 2.4% in FDI inflows. Corruption within the country results in delays in applying for or obtaining patents or having to legally defend one's patents due to inept judicial systems, delays in application and grants process etc. Similarly, government instability in the country also may divert funds from issues such as infrastructure development, providing subsidies for R&D etc within the sector towards solving issues within the political framework. Government stability index has a significant and positive impact on FDI flows indicating that greater the perception of instability within the country, more unlikely are MNCs willing to set up operations in the host economy. Increase in the government stability index by 1 unit may lead to an increase of FDI flows by 1.54 percent. Lack of stability and frequent changes in the ruling party often leads to the implementation of opposing policies on subsidies, tax holidays, etc thereby creating uncertainty in pharmaceutical companies' operations.

Since pharmaceutical companies operate in India and establish manufacturing plants to not only serve the domestic market but also produce and export pharmaceuticals to foreign countries the trade openness index also has a significant and positive impact of FDI inflows into the sector. As manufacturing of pharmaceuticals in India requires the import of 53 critical active pharmaceutical ingredients (APIs), 70 percent of these from China (Dadhich, 2020) along with import of raw materials and almost 80 percent of its requirement of medical devices, firms will likely invest more in the pharmaceutical sector as trade barriers reduce. Table 5 shows that trade openness is the most dominant factor that has an impact on the FDI flows into the country.

The results of the short-run estimates show that the speed of adjustment term (-0.99) is highly significant at one per cent level. The magnitude of this coefficient implies that nearly 99% of any disequilibrium in FDI and is corrected within one year. In the short run, we see that the TRIPS dummy has a positive and significant effect, showing that the favourable impact of TRIPS implementation is immediately realised in India. Table 4 also highlights that the expectation of higher profits is an important decision for firms to invest in the country in the short run. Most pharmaceutical firms make profits from the innovation of new drugs. The development of these innovator drugs takes billions of dollars, not all of which even reach the market. Therefore, MNCs often look at their profit margins while taking investment decisions. These estimates also highlight the importance of reducing corruption in the country, since despite the presence of an IPR regime and the expectation of high profits in India, even in the short run corruption hinders investments into the country.

The robustness of the estimated model has been tested by several diagnostic checks such as Serial Correlation Test and Heteroscedasticity Test. The results of these tests (see table 5) show that

the selected models have no serial correlation and no heteroscedasticity. Hence, the results from these models are robust and reliable.

Stability Diagnostics

To check the stability of the model we use the CUSUM and CUSUM square tests. At the 5% level of significance, if the plot of the CUSUM statistics lies within the critical bounds we can accept the null hypothesis of stable coefficients in the ECM model. If the plot crosses either of the critical bounds, we can state that coefficients are not stable. Similarly, we also carry out the CUSUM squares test. Figure 1 and 2 shows a graphical representation of the CUSUM and CUSUMSQ test. As seen, both CUSUM and CUSUMSQ plots are within the critical bounds, indicating structural stability.

Figure 1: CUSUM Stability Test
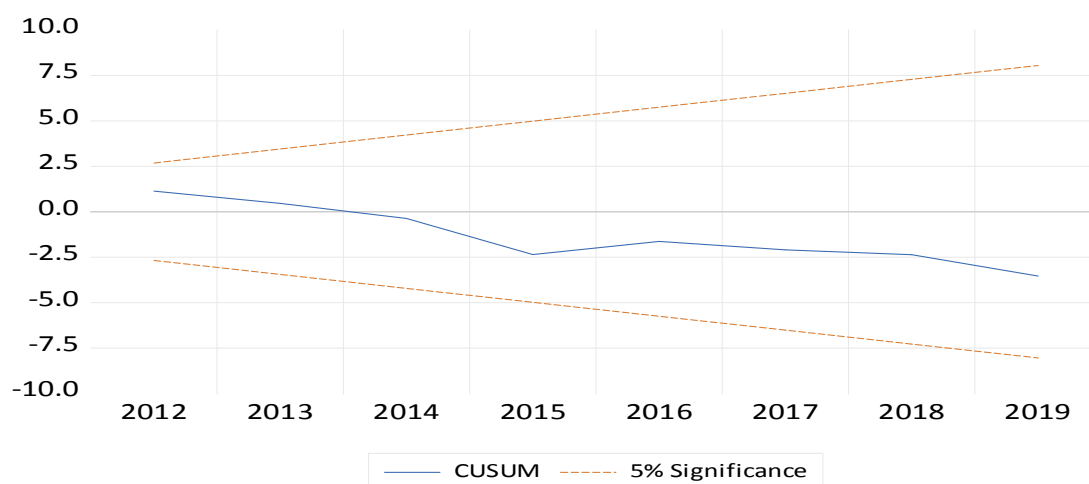
Figure 2: CUSUM of Squares Stability Test
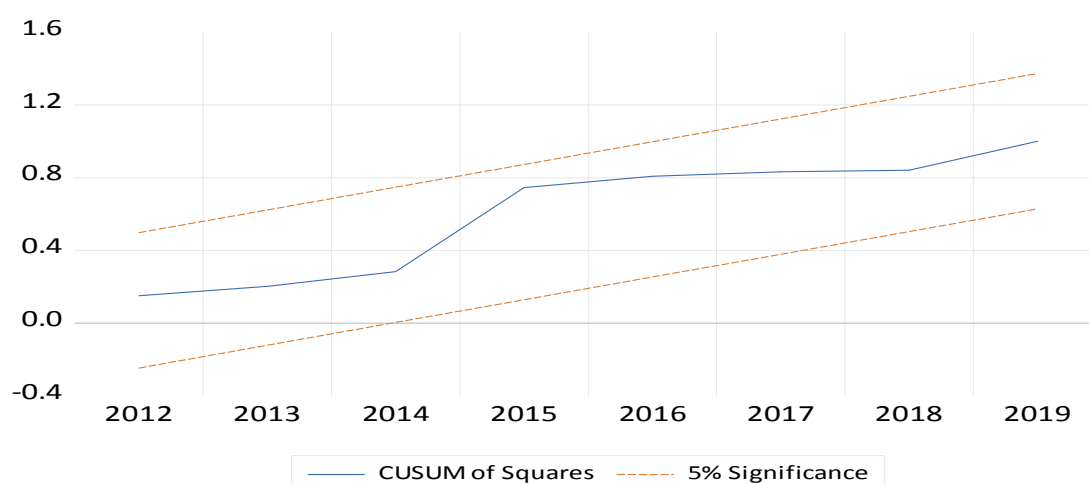
Conclusion

Foreign direct investment has traditionally been seen as an important factor contributing to the growth of the pharmaceutical sector. Due to the lack of capital in developing economies, inward FDI is seen to be highly desirable. Of the various factors that determine the flow of FDI, increasing importance has been given to IPR protection only in recent years. Given the steep increase in FDI inflows into developing economies in the recent past and the implementation of the TRIPS agreement, we undertake an ARDL analysis to analyse the impact of TRIPS on FDI flows. Our analysis shows that there is a statistically significant and positive impact of implementation of IPRs, and a statistically significant and negative impact of the strengthening of these IPR rights, on the FDI flows into the Indian pharmaceutical industry. The implementation of IPRs in the country is a significant factor that determines if the MNC will enter the host country. If an MNC can't rely on the country's IPR laws, it must rely on alternative means to minimize losses. By looking outside the IP legal framework for protection, companies have to indulge in masquing, which increases their costs. These added costs are increasingly being factored into the analysis MNCs make in deciding where to invest their resources. By focusing on establishing a strong IP rights regime, a country should attract more FDI relative to those countries that do not consider IP rights protection as important. However, as these rights are strengthened MNCs prefer licensing agreements or joint ventures with domestic firms. However, our analysis shows that competition from China does not have a significant impact on the FDI flows into the Indian pharmaceutical sector. Despite India and China being close competitors of pharmaceutical FDI from developed countries there are significant differences in the possible opportunities for MNC investment among the two countries. For instance, China specialises in preclinical trials whereas India is competent in late stage clinical trials. Similarly, India has stronger capabilities in small molecule R&D while China is stronger in biotech R&D and manufacturing. Therefore, India needs to strengthen its own sector level core competencies to attract more FDI.

While the global pharmaceutical industry is highly R&D intensive, with the R&D intensity of the research based pharmaceutical industry in Japan being 13.3 percent, 17.1 percent in the US and 13.3 percent in the European Union (IFPMA, 2017), investment in R&D in India has been a slightly new phenomenon and is still 5 percent. The government must encourage additional innovation by protecting incremental innovation. Section 3(d) was implemented to address the problem of 'evergreening', where patent holders would apply for additional patents on minor improvements of existing drugs to extend patent life and delaying the entry of lower price generic versions of the drug. Therefore, while the intent of the Indian government to ensure that the population can access low cost lifesaving drugs is laudable, this acts as a disincentive for pharma firms to further direct their R&D investment into incremental and consequently the innovation of new drugs. It also ensures lower profits for pharmaceutical companies, which acts as a major disincentive to invest in the sector.

However, our study shows that a strong legal framework must also be accompanied by a strong institutional framework concerning corruption and political stability to ensure inflow of FDI. Corruption and political instability often have distortionary effects. Resources that could have been more productively utilized are often diverted into having to pay bribes or having to incur extra operating

expenses to deal with changes in the political environment. Improvement in these variables therefore would be key to continue attracting foreign investment on a long term basis.

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Appendix

Table A.1: Descriptive Statistics

	FDI	GDP	BCI	GovtStab	LabCost	RD	Profit	TradeOp	D_TRIPS	PPI	FDICI
Mean	2231.41	6728828	49.51	7.26	10.186	2.82	9.91	35.84	0.50	3.18	1.08
Median	1043.58	5697497	49.61	7.81	9.59	3.35	9.80	38.83	0.50	4.00	1.10
Maximum	14605.03	14565951	54.27	10.08	14.50	5.88	16.50	55.79	1.00	5.13	1.44
Minimum	11.042	2514549	41.42	2.91	8.15	0.19	3.51	15.50	0.00	0.73	0.59
Std. Dev.	3136.46	3686948	2.55	1.65	1.77	1.91	4.12	13.47	0.50	1.59	0.22
Skewness	2.39	0.69	-1.35	-1.123	1.04	0.00	-0.13	0.03	0.00	-0.53	-0.41
Kurtosis	9.24	2.30	6.50	3.94	3.08	1.45	1.79	1.54	1.00	1.64	2.12
Jarque-Bera	77.37	3.05	24.57	7.41	5.50	2.99	1.90	2.65	5.00	3.73	1.79
Probability	0.00	0.21	0.00	0.02	0.06	0.22	0.38	0.26	0.08	0.15	0.40
Observation	30	30	30	30	30	30	30	30	30	30	30

Source: Compiled by the author

This appendix provides more information on the novel pharmaceutical patent index developed and used in this paper. Figure A.1 shows the most value of the index from 1990-2019. In Table A.2 we report the components and scoring methodology.

Figure A.1: Pharmaceutical Patent Index for India (1990-2019)
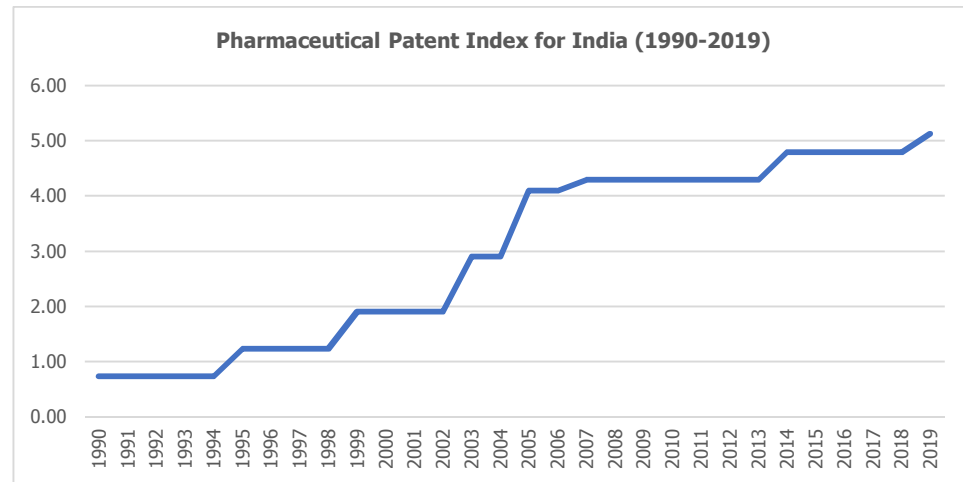
Source: Compiled by the Author

Components and Scoring Method of the Pharmaceutical Patent Index

The Pharmaceutical Patent Index for India is constructed for the years 1990 to 2019 and measures 7 components as highlighted in Table A.1. Each component can score values between 0 and 1 and the cumulative score of the index ranges between 0 and 7. Each component includes sub-components which take the value of 0—if the particular IP component does not exist in India—or 1—if the particular IP component does exist. Given that each category of the proposed index is essential to the existence of a robust pharmaceutical IP regime we assign equal weights to each sub component.

Table A.2: Components and Scoring Methodology

(1) **Implementation**	Available	Not Available
Patentability of pharmaceutical products	1	0
(2) **Administration**	Available	Not Available
Presence of webpage for Indian patent office	1	0
(3) **Membership in International Agreements**	Signatory	Not Signatory
PCT-Patent Cooperation Treaty	1/3	0
Paris Convention	1/3	0
PPH= Patent Prosecution Highway	1/3	0
(4) **Operational Efficiency**	Exists	Does not Exist
Stakeholder consultation during IP policy formation	½	0
IPR awareness-Outreach and promotion	½	0
(5) **Enforcement and Adjudication**	Available	Not Available
(5a) Border enforcement	1/5	0
(5b)Territorial enforcement		
Civil Remedies	1/5	0
Criminal Procedures	1/5	0
Burden of Proof	1/5	0
Preliminary Injunction	1/5	0
(6) **Exemptions to IP Protection**	Exists	Does not Exist
No provision of compulsory licensing	1/3	0
Ban on the parallel imports of patented medicines	1/3	0
No provision of Bolar exemptions	1/3	0
(7) **Barriers to IP protection**	Exists	Does not Exist
No price controls/ceilings imposed by the Government	1/3	0
Allowance for direct to consumer advertising of prescription drug	1/3	0
No provision for post grant opposition	1/3	0

A detailed description of each component-

(1) **Implementation of Product Patents**- The TRIPS Agreement requires all signatories to provide 20 years of product patents to innovator drugs. Compliance with the TRIPS Agreement requirements is an indication of the provision of product patents. 1999+ value of 1, 0 otherwise. The year 1999 was taken into consideration as the first Patent Act, 1970 was first amended in 1999, which was the first step towards the compliance of TRIPS.

(2) **Administration-** Based on Lesser (2002) we use presence of a webpage for the patent office as a proxy to measure the efficiency of the administration of a patent office- this is indicative of transparency and dispersion of information. Value 0 for the period 1990 to 2002, and 1 for the period 2003 onwards as the Indian Patent Office established its website after the passage of Patent (Amendment), Act 2002.

(3) **Membership in International Agreements**–Measures the extent to which India facilitates ease of obtaining global patents. The index equally weights each country's participation in the Paris Convention of 1883, the Patent Cooperation Treaty (PCT) of 1970, and Pharmaceutical Patent Highway (PPH) with atleast one country. Each sub component gets a value of 1/3 if they are a signatory or 0 otherwise.

India became a member of the PCT and Paris Convention in December 1998. Thus, PCT and Convention Membership was assigned a value of 0 for the period from 1990 to 1998and 1/3 for the period from 1999 to 2019.

PPH- In late 2018, Indian and Japanese authorities agreed to begin a PPH program in the first quarter of 2019. Allot a score of 1/3 for 2019, 0 otherwise

(4) **Operational Efficiency-** Two sub-components:
Stakeholder consultation during IP policy formation – Measures the extent to which the government consults all concerned parties while formulating patent policies. The Indian government released first draft of the National IPR policy in 2014. Consequently, in a press release dated 30th December, 2014, the DIPP for the first time called for comments and suggestions on the draft from all stakeholders. We therefore allot a score of ½ from 2014-2019, 0 otherwise.

IPR awareness-Outreach and promotion– This indicator measures the extent to which the government conducts training programmes for the judiciary, patent officers, police etc and includes awareness programmes regarding the importance of patent rights in educational institutions. The Patent Facilitation Center, set up in 1995 by the Department of Science & Technology has been in the forefront in creating awareness about intellectual property rights (IPR) in the country. The activities of the centre includes assisting educational institutions in protecting their inventive work, spreading IPR culture to the state level, evolving policies at the national level, providing technical input to the government on IPR related issues and interacting with other science departments. Allot a score of ½ from 1995-2019, 0 otherwise.

(5) **Enforcement**- Take into consideration both territorial and border enforcement.
Border enforcement- Measured by the extent to which suspected counterfeit goods can be seized at the border without restrictions from the patent rights-holder. The Government has issued Intellectual Property Rights (Imported goods) Enforcement Rules, 2007 which allows border guards the right to inspect and seize suspected illegal goods at the borders of India. We allot a score of 1/5 from 2007-2019 and 0 otherwise.

Territorial enforcement- Comprises of 4 sub categories:
Civil remedies- Measures the presence of a robust legal framework through the presence of civil remedies. A patent holder can file civil proceedings when seeking to enforce their rights. The provision of civil remedies was present since the Patent Act, 1970. Allot a score of 1/5 from 1990-2019.

Criminal remedies- Measures the presence of a robust legal framework through the presence of criminal remedies. Criminal proceedings for patent infringement cannot be instituted under the Patents Act,1970 and in the Patents Amendment Act, 2005. Allot a score of 0 from 1990-2019.

Burden of proof reversal- In cases of patent infringement the burden to prove that there is no infringement of the patent rests on the defendant. The provision of burden of proof was present since the Patent Act, 1970. Allot a score of 1/5 from 1990-2019.

Preliminary Injunction -In actions for patent infringement, the claimant can seek preliminary relief in the form of a preliminary injunction, which requires the defendant to stop producing and marketing of a drug, if certain conditions are satisfied, provision for which was introduced in the Patents Amendment Act, 2005. Allot a score of 1/5 from 2005-2019, 0 otherwise.

(6) Exemptions to IP Protection –Comprised of 3 sub-components:

No provision of compulsory licensing- Measures the ability of a government of a country to grant permissions to third parties to produce and sell a patented product without the patent holders consent. Under Indian Patent Act, 1970, the provision with regard to compulsory licensing is specifically given under Chapter XVI. Allot a score of 0 from 1990-2019.

Prohibiting parallel imports of patented medicines- Measures the allowance for parallel imports in the country. The import of a patented product by any person duly authorised under the law to produce and sell or distribute this product is not considered to be an infringement. India does not prohibit parallel imports. Allot a score of 0 from 1990-2019.

Prohibiting commercial testing during the patent term (Bolar exemption)- India recognises the concept of Bolar exemption. Under section 107A (a) of the Patents Act 1970 "the act of making, constructing, using, selling, or importing a patented invention solely for uses related to the development and submission of information required under any law in force in India will not amount to infringement". Allot a score of 0 from 1990-2019.

(7) Barriers to IP Protection- Comprises of 3 sub-components**:**

No price ceilings imposed by the Government- Measures the autonomy of firms to fix any price for a pharmaceutical product without a ceiling imposed by the Government. Not applicable to India since India imposes price controls on certain pharmaceuticals through Drug Price Control Orders (DPCO), 1970 and its subsequent revisions. We therefore allot a score of 0 from 1990-2019.

No provision of post-grant opposition- Measures the ability of an opponent to file an opposition once the patent has been granted. India allows for post grant opposition since the Patents Act 1970. Allot a score of 0 from 1990-2019.

Allowance for direct to consumer advertising of prescription drugs—(DTCA)- Measures the ability of pharmaceutical firms to directly advertise their product to citizens as patients rather than a health professional. Since DTCA is not allowed in India we allot a score of 0 from 1990-2019.

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